
Calyx RIM 6.2 Release Notes

CALYX™

Contents

Calyx RIM 6.2 Release Notes.....	1
New in Calyx RIM 6.2.....	1
List of Enhancements: Calyx RIM 6.2.....	21
Data Administration Tables: Calyx RIM 6.2.....	33
Entity Fields Added: Calyx RIM 6.2.....	51
Query Fields Added: Calyx RIM 6.2.....	57
Entity Fields Updated: Calyx RIM 6.2.....	61
Query Fields Updated: Calyx RIM 6.2.....	77
Database Columns Changed: Calyx RIM 6.2.....	97
Resolved Issues: Calyx RIM 6.2.....	97
Calyx RIM 6.2 CHF 1 Release Notes.....	123
Data Administration Tables: Calyx RIM 6.2 CHF 1.....	124
Entity Fields Updated: Calyx RIM 6.2 CHF 1.....	125
List of Enhancements: Calyx RIM 6.2 CHF 1.....	125
Resolved Issues: Calyx RIM 6.2 CHF 1.....	126
Calyx RIM 6.2 CHF 2 Release Notes.....	128
List of Enhancements: Calyx RIM 6.2 CHF 2.....	129
New Fields Added: Calyx RIM 6.2 CHF 2.....	133
Entity Fields Updated: Calyx RIM 6.2 CHF 2.....	134
Database Columns Changed: Calyx RIM 6.2 CHF 2.....	135
Resolved Issues: Calyx RIM 6.2 CHF 2.....	135
Calyx RIM 6.2 CHF 3 Release Notes.....	151
List of Enhancements: Calyx RIM 6.2 CHF 3.....	153
Entity Fields Added: Calyx RIM 6.2 CHF 3.....	156
Database Columns Changed: Calyx RIM 6.2 CHF 3.....	159
Resolved Issues: Calyx RIM 6.2 CHF 3.....	159
Calyx RIM 6.2 CHF 4 Release Notes.....	167
Data Administration Tables: Calyx RIM 6.2 CHF 4.....	171
New Fields Added: Calyx RIM 6.2 CHF 4.....	172

Database Columns Changed: Calyx RIM 6.2 CHF 4.....	172
List of Enhancements: Calyx RIM 6.2 CHF 4.....	173
Resolved Issues: Calyx RIM 6.2 CHF 4.....	178
Calyx RIM 6.2 CHF 5 Release Notes.....	188
Database Columns Added/Changed: Calyx RIM 6.2 CHF 5.....	190
New Fields Added: Calyx RIM 6.2 CHF 5.....	191
Data Administration Fields Updated: Calyx RIM 6.2 CHF 5.....	195
New Queries Added: Calyx RIM 6.2 CHF 5.....	198
List of Enhancements: Calyx RIM 6.2 CHF 5.....	199
Resolved Issues: Calyx RIM 6.2 CHF 5.....	203
Calyx RIM 6.2 CHF 6 Release Notes.....	210
New Fields Added: Calyx RIM 6.2 CHF 6.....	211
List of Enhancements: Calyx RIM 6.2 CHF 6.....	211
Resolved Issues: Calyx RIM 6.2 CHF 6.....	212
Calyx RIM 6.2 CHF 7 Release Notes.....	214
New Fields Added: Calyx RIM 6.2 CHF 7.....	215
List of Enhancements: Calyx RIM 6.2 CHF 7.....	215
Resolved Issues: Calyx RIM 6.2 CHF 7.....	217
Calyx RIM 6.2.8 Release Notes.....	222
Resolved Issues: Calyx RIM 6.2.8.....	222
Calyx RIM 6.2.9 Release Notes.....	224
Entity Fields Updated: Calyx RIM 6.2.9.....	224
Calyx RIM 6.2.10 Release Notes.....	225
Resolved Issues: Calyx RIM 6.2.10.....	225
Calyx RIM 6.2.11 Release Notes.....	226
Resolved Issues: Calyx RIM 6.2.11.....	226
Clarification of Behavior.....	227
Known Issues.....	229
Access the Customer Service Portal.....	231
Index.....	232

Calyx RIM 6.2 Release Notes

The Release Notes contain information about updated files, new functionality, resolved issues, and any open issues or workarounds in this release of Calyx RIM®.

The details in these Release Notes supersede all similar details that appear anywhere else in this release of the product or its other documentation.

New in Calyx RIM 6.2

Calyx RIM 6.2 includes enhancements and also addresses prioritized hotfixes and known issues from previous versions. The following enhancements, functional changes, and updates are included with this release.

Web Browsers

Calyx RIM 6.2 provides support for the following Web browsers:

- Microsoft Internet Explorer (IE) 11 (set Compatibility View Settings to Off)
- Microsoft Edge (supported on Windows 10 only)
- Google Chrome

Note: Please note that Calyx RIM for Analytics module is not compatible with the Microsoft Edge browser.

Single Sign On (SSO)

Calyx RIM single sign on (SSO) will enable authorized users who are authenticated by your enterprise's SSO the capability to access LIQUENT InSight without the need to login again.

Calyx RIM API

LIQUENT InSight 6.2 provides an application programming interface (API) for integration with external systems. The Calyx RIM API enables external systems to access data within LIQUENT InSight and to perform actions such as create, read, update, and delete. New platform components can integrate with the LIQUENT InSight API, and will observe authentication and authorisation rules.

New Assembly Tree

Calyx RIM 6.2 completes the transition to the new version of the assembly tree introduced in Calyx RIM 6.1 CHF 3. The legacy assembly tree option is no longer available.

This release also discontinues support of the drag-and-drop node assignments between assemblies opened in separate browser windows. The Import Assembly wizard should be used to copy content between different assemblies.

The new assembly tree enables the following functionality:

- Drag assembly elements to in-between nodes and filter the assembly tree elements using the new assembly tree search option.
- Set a limit to the number of assembly elements displayed on the new version of the assembly tree as a result of a search operation.
- Set a limit to the number of nodes that can be expanded in the new version of the assembly tree.
- Drag a TOC onto the icon corresponding to a volume.
- Calyx RIM 6.2 enhances the TOC tree to allow selecting multiple nodes and dragging them in between the other nodes when modifying a TOC.

Cross-site Scripting (XSS) Filtering

Calyx RIM 6.2 includes Cross-site Scripting (XSS) filtering that prevents users from adding malicious script codes in the form of user input in an attempt to access data.

Performance Improvements

Calyx RIM 6.2 provides performance improvements for the following:

- Manufacturer Report Analytics Predefined Report functionality.
- XEVMPD Audit Report functionality.
- DMS Synchronization functionality invoked from the **Publishing View** of the Assembly.
- Updating the Publishing Settings to add or remove a DTD.
- Expanding the nodes in the Assembly Tree and refreshing the expanded Assembly Tree.
- Queries related to getting Events under Application, actions with the XEVMPD change history, and DTD change for an Assembly have been optimized to reduce the possibility of database locks. As part of this optimization, a new index has been added to the XEVMPD change history.

OpenText Documentum D2 Integration

Calyx RIM 6.2 enhances the capability to harmonize data between Calyx RIM and OpenText Documentum D2:

- When a Product Family is created in Calyx RIM, both a Product Registration Form and a Project Registration Form will be created within Documentum D2.
- When an Application is created under a Product Family in Calyx RIM, a Regulatory Application Registration Form (RARF) will be created within Documentum D2.
- When a Sequence is created within a Product Family in Calyx RIM, a Submission Registration Form (SARF) will be created within Documentum D2.

Note: *The Product Registration Form, Project Registration Form, RARF, and SARF are created only if the Product Family type is one of the following:*

- *Pharmaceutical*
 - *Pharmaceutical-Medical Device*
 - *Any custom Product Family type that is mapped to the Pharmaceutical or Pharmaceutical-Medical Device internal type*
 - *Any Product Family type in **Data Administration** that is modified and mapped to any of the Pharmaceutical or Pharmaceutical-Medical Device internal type*
-

The created Product Registration Form, Project Registration Form, Regulatory Application Registration Form, and Submission Registration Form will then be updated according to the changes made to Product Family within Calyx RIM.

Updates to D2 forms (Product Registration Form, Project Registration Form, Regulatory Application Registration Form, and Submission Registration Form) may result in updates to the PDS status. Allowed PDS Status values include:

- Pending Add
- Approved
- Not Approved

The out-of-the-box configuration can be modified to match your need. To understand more about the available Documentum D2 mapping for Product Registration Forms, Project Registration Forms, Regulatory Application Registration Forms (RARF), Submission Registration Forms (SRF), please contact your Calyx RIM account representative.

D2 Data Dictionaries

Starting with Calyx RIM 6.2, the following D2 Data Dictionaries are supported:

- Application Status
- Application Type
- Geographic Regions
- Regulatory Submission Type
- Route of Administration List
- Submission Country
- Submission Status
- Dosage Levels
- Dosage Forms
- Health Authority

Regulatory Updates

Australia eCTD Module 1 Specification Version 3.1

Calyx RIM 6.2 supports Australia eCTD Module 1 Specification Version 3.1. The following structural updates are provided with this Specification Version:

- The following sections are added to the **1 Administration Information and Prescribing Information > 1.3 Medicine information and labeling** folder:
 - **1.3.1.3 Product information - approved**
 - **1.3.2.3 Consumer medicine information - approved**
- The following sections are updated in the **1 Administration Information and Prescribing Information > 1.3 Medicine information and labeling** folder:
 - **1.3.1.3 Package Insert** section now appears as **1.3.1.4 Package Insert**

- 1.3.3 Label mock-ups and specimens section is split to be 1.3.3.1 Label mock-ups and specimens - clean, 1.3.3.2 Label mock-ups and specimens - annotated, and 1.3.3.3 Label mock-ups and specimens approved
- 1.5.2 Orphan designation section now appears as 1.5.2 Designation applications - supporting documents

Calyx RIM 6.2 also supports the AU NeeS v2.0 specification. This new NeeS version TGA (Therapeutic Goods Administration) introduces Envelope Form to provide greater validation of NeeS Submissions and automation of the uploading processes. The envelope form is an XML file with information from Envelope. The NeeS format dossier must contain tables of contents (TOC) in PDF format. The XML file should be included in the 1001-cover folder of the NeeS application and it should be referenced by the `m1-toc.pdf`.

Please note that the previous specifications versions will be acceptable for use until 30 June 2018.

This specification introduces the following updates to Data Administration:

- New sequence types has been added to the **Sequence Maintenance > Filing Type Values** table:
 - Provisional Registration - TGA initiated variation
 - Notification
 - CN
 - Extension of Provisional Registration
 - Duplicate
- The following sequence type has been updated in the **Sequence Maintenance > Filing Type Values** table:
 - Withdrawal filing type has been updated to be Product Withdrawal.
- New Sequence Description value has been added to the **Submission Maintenance > Sequence Description Values** table:
 - Provisional approval - rolling data submission - {date: d}
- New Regulatory Activity Lead value has been added to the **Submission Maintenance > Regulatory Activity Lead Values** table:
 - Prescription meds-biological

European Union eCTD Module 1 Specification Version 3.0.3

Calyx RIM 6.2 supports EU eCTD Module 1 Specification Version 3.0.3.

The EU eCTD Module 1 Specification has been updated to reflect clarifications of the 3.0.1 version in the 3.0.3 version. Version 3.0.3 is in force immediately and is recommended to be used as soon possible. There are no changes to the DTD in this version (version 3.0.1 is still valid) and the validation criterion has not changed as a result of this update.

The following updates are introduced:

- For the Centralised (CP) template, in the **1.2 Application Form > 1.2 EMA** folder:
 - The **Application Form** leaf has been renamed to be **Application Form Annex** (the **Use Native File** parameter is set to **No**).
 - A new leaf has been added **Application Form eAF** (the **Use Native File** parameter is set to **Yes**).

- For the National (NP) and Mutual Recognition (MRP)/Decentralised (DCP) templates in the **1.2 Application Form > Country** folder:
 - The **Application Form** leaf has been renamed to be **Application Form Annex** (the **Use Native File** parameter is set to **No**).
 - A new leaf has been added **Application Form eAF** (the **Use Native File** parameter is set to **Yes**).

STF Stylesheet v2.3 Support

Calyx RIM 6.2 introduces support for the ICH STF Stylesheet v2.3.

Best Practices for Publishing

The following topics on best practices for publishing have been updated in the Online help:

- Complying with the Study Data Technical Conformance Guide v4.1
- Updating an AU Submission to Migrate to v3.1

Withdraw Country Updates

Calyx RIM 6.2 updates how withdrawn Application Countries are filtered in the **Country** fields of Mutual Recognition Procedure (MRP) and Decentralised Procedure (DCP) procedures. On application-related entities, withdrawn application countries that have a **Withdraw Date** value that equals today's date or earlier can no longer be selected for the following:

- **Event > Countries** field when adding an Event
- **Sequence > Concerned Member States** field when adding a Sequence
- **Registration > Country** field when adding a Registration
- **Product Detail Set > Label > Label Country** field when adding a Label Detail
- **Product Detail Set > Country > Country** field when adding a Country Detail
- **Product Detail Set > Indication/Intended Use > Countries** field when adding or modifying an Indication/Intended Use Detail (non-Veterinary Product Detail Sets)
- **Product Detail Set > Species Indication > Countries** field when adding or modifying an Indication Use Detail (for Veterinary Product Detail Sets)
- **Product Detail Set > Manufacturer > Countries** field when adding or modifying a Manufacturer for the following parent Product Detail Set Details:
 - Active Ingredient
 - Active Ingredient Manufacturing Process Function
 - Active Ingredient Manufacturing Process Step Function
 - Active Ingredient Manufacturing Process Step Material
 - Component Function
 - Component Manufacturing Process Function
 - Component Manufacturing Process Step Function
 - Component Manufacturing Process Step Material
 - Package Set Component Packaging
 - Package Set Function
 - Package Set Packaging
 - Product Detail Set Function

- Product Detail Set Manufacturing Process Function
- Product Detail Set Manufacturing Process Step Function
- Product Detail Set Manufacturing Process Step Material
- Substance
- Substance Manufacturing Process Function
- Substance Manufacturing Process Step Function
- Substance Manufacturing Process Step Material

The **Countries** tab on the **Application Attributes** page has been enhanced by adding a new column named **Withdraw Date**.

The logic of populating the **Withdraw Date** for an Application Country has changed. The following rules apply to the **Application Country > Withdraw Date** if this specific country is associated to the Country PDS Detail:

- If the **Country Status** field of the related Country PDS Detail is modified to **Approved**, the **Application Country > Withdraw Date** field is automatically updated to be equal to Today's Date.
- If the Event is closed as Approved, meaning it has the **Associations Closed As** field set to APPROVED, the **Application Country > Withdrawn Date** field is automatically updated to be equal to **Event Closed Date** value. As an additional rule, the withdrawn **Country PDS Detail > Country Status** field is automatically updated to Approved. See *If the Event Is Closed with the Status Approved*.

Note: *The Update Status and Update Event Country Status wizards, launched from the Event > Countries tab and Project > Event Country Dates tab, has been updated accordingly. The following new messages have been added:*

- *Confirmation page: The Withdraw Date will be set to <Event Closed As Date> for <Country that is being withdrawn>.*
- *Summary page: The Withdraw Date was set to <Event Closed As Date> for <Country that is being withdrawn>.*

This enhancement updates a variety of existing queries and adds a new Product Detail Management query named **List of Application Countries with PDS Country and Registration Details**. See the *Queries* section.

See *Entity Fields Updated: Calyx RIM 6.2* and *Entity Fields Added: Calyx RIM 6.2*.

Global Project Plan Wizard

Calyx RIM 6.2 enhances the **Global Project Plan** (GPP) wizard by adding new process flows:

- Add Manufacturing Process
- Add Manufacturing Process Step Function
- Add Material
- Add Substance
- Modify Active Ingredient
- Modify Manufacturing Process Step
- Modify Manufacturing Process Step Function

- Modify Material
- Modify Packaging for Package Set
- Modify Substance
- Withdraw Material
- Withdraw Substance
- Replace Manufacturing Process Step Function

To support the enhancement to display the Manufacturer Name value as a concatenation of `Manufacturer Name + Address Line 1 + Country Code` values, the following **Global Project Plan > Update Product Detail Sets** project flows have been updated:

- Add Active Ingredient Manufacturer
- Add Active Ingredient Manufacturing Process Function Manufacturer
- Add Substance Manufacturer flow
- Add Substance Manufacturing Process Function Manufacturer
- Add Component Function Manufacturer flow
- Add Component Manufacturing Process Function Manufacturer
- Add PDS Function Manufacturer flow
- Add PDS Manufacturing Process Function Manufacturer
- Add Package Set Function Manufacturer
- Add Package Set Packaging Manufacturer
- Add Package Set Component Packaging Manufacturer

Calyx RIM 6.2 enhances the Global Project Plan wizard by adding the multi-select field **Application Type** as an additional filter criterion for the following project types:

- **Create New Events Package Set Registration > Search by Product, Country and Application Status** page
- **Update Product Detail Sets > Input Query Filter Criteria** page, when searching by:
 - Active Ingredient
 - PDS Code/PDS Name
 - Product and Country
 - Substance
 - Trade Name
- **Create New Events Product Registration > Search Country and Application Status** page
- **Withdraw Product Package Set Registration > Search by Product, Country Application and PDS Statuses** page

Events

Calyx RIM 6.2 introduces new rules to enforce Event uniqueness within an Application. The Event Name and Event Code combination must be unique within an Application.

Calyx RIM 6.2 enhances the Event entity by renaming the **Event Closed As** field as **Associations Closed As** and the **Event Closed Date** field as **Closed Date**. The following has been updated accordingly:

- **View Event Attributes** page for the closed events.

- *Modify Event Attributes* page, if the **Closed** checkbox is selected.
- **Wizards > Update Status > Update Event Country Status** page, if the **Close Event?** drop-down field is set to **Yes**.
- **Project > Event Country Dates > Update Project Event Country Status** wizard, if the **Close Event?** drop-down field is set to **Yes**.

This enhancement also provides a variety of updates to existing queries. See *Queries* section.

See *Entity Fields Updated: Calyx RIM 6.2*

Projects

Calyx RIM 6.2 enables Sequences to be updated in bulk within a project. The *Project Attributes* page has been enhanced by adding the **Bulk Update Sequences** icon that launches the *Bulk Update Sequences* wizard.

With Calyx RIM 6.2, the **PLANNED** status has been added to the following fields:

- **Project Pivot Status** drop-down field on the *Create/Modify Project Attributes* page.
- **Enter Project Pivot Values > Project Pivot Status** drop-down field of the *Calculate Projected Dates* wizard (Global Project Plan wizard).

Product Detail Sets (PDS)

Calyx RIM 6.2 enhances the **Countries** field on the *Add Indication/Intended Use* detail page for Non-Veterinary Product Detail Set (PDS) and the *Add Indication* detail page for Veterinary Product Detail Set (PDS). By default, all countries of the associated Application appear in the **Selected** box of the **Countries** multi-select field. You can deselect countries, if needed.

To enforce PDS uniqueness within an application, a PDS name must now be unique.

To enforce PDS template uniqueness within a product, a Product name must now be unique.

The **Specialty Number** field has been renamed to be **Speciality Number**.

To ensure the **Excipient Role** field availability for all substance types in the Product Detail Set and Product Detail Set Template, Calyx RIM 6.2 renames the **Excipient Role** field for the Substance Detail as **Substance Role**. The **Substance Role** field appears on the *Add Substance* page regardless of the selected **Substance Type** value.

Starting with Calyx RIM 6.2, the Manufacturer Name value is displayed as a concatenation of **Manufacturer Name + Address Line 1 + Country Code** values in the **Manufacturer** field for each **Product Detail Set > Manufacturer Detail** instance. This update includes enhancements to the following Calyx RIM areas:

- **Data Administration > Product Detail Set Maintenance > Manufacturer Values** table
- **Product Detail Management, Registration Planning and Tracking, and Administration Queries**
- A variety of **Global Project Plan Wizard > Update Product Detail Sets** project flows
- **Comparator > Supplier** field

A new configured field named **Local Route of Administration** for tracking country Route of Administration at the PDS level has been added to the PDS Attributes page.

Note: This field is hidden by default and can be enabled via custom XML overrides.

See the corresponding sections in the *New in Calyx RIM 6.2*, *Entity Fields Updated: Calyx RIM 6.2*, and *Data Administration Tables: Calyx RIM 6.2*.

Products

Calyx RIM 6.2 enhances the following Product Strength-related fields to display a leading zero value for the decimal numbers that are less than 1 in the **Product Strength** field on the *View Product Attributes* page:

- Product Strength Measure 1
- Product Strength Measure 2

A new entity named Country Specific Detail has been introduced for the Products of Medical Device and Pharmaceutical Medical Device types.

See *Entity Fields Added: Calyx RIM 6.2*

Applications

Starting with Calyx RIM 6.2, the **Application Status** of an Application can be set to the Application Status mapped to the internal WITHDRAWN status only when all Registrations associated to this Application have a status mapped to the internal WITHDRAWN status.

The **Update Status** and **Update Event-Country Status** wizards mapped to the internal WITHDRAWN status reflect this enhancement. If you set **Associations Closed As** to WITHDRAWN, the Application Status will be set to WITHDRAWN only when all Registrations associated to this Application have a status mapped to the internal WITHDRAWN status. Otherwise, the warning message appears ! Associated Registration(s) must be Withdrawn prior to the Application.

See *Entity Fields Updated: Calyx RIM 6.2*

Registrations

In Calyx RIM 6.2, the logic of the *Copy Package Set Registration* wizard has been reworked for the MRP (Mutual Recognition Procedure) and DCP (Decentralised Procedure) Application types to provide the ability to select the country to copy the Package Set Registration. A new drop-down list named **Country** now appears on the following wizard pages for the MRP and DCP Application types:

- New Package Set specific Registration(s) > Select Product Detail Set page
- New Product specific Registration(s) > Copy License Code page

A new field named **Legal Basis** has been added to the Package Set Registration entity. The **Registration Attributes > Entity History Query** and **Querying > Administration > Entity Audit Trail** queries have been updated to display the correct values for the new **Legal Basis** field. This update includes enhancements to the following Calyx RIM areas:

- Data Administration > Application Maintenance and Data Administration > Other sections
- XEVMPD Submission Wizard data collection logic

See the corresponding sections in the topics: *New in Calyx RIM 6.2*, *Entity Fields Added: Calyx RIM 6.2*, and *Data Administration Tables: Calyx RIM 6.2*.

Full Product Presentations

With Calyx RIM 6.2, the **MPID** (Medicinal Product Identifier) field has been hidden on the Full Product Presentation View, Create, and Modify pages.

Calyx RIM 6.2 enhances the *Full Product Presentation Attributes* entity by adding the following new fields:

- Formulation Part
- Intended Use Part
- Target Population Part
- Container or Pack Part
- Device Part
- Time Period Part
- Flavour Part
- Countries

To enable the Previous EV Code value for the Full Product Presentation entity to be added manually, Calyx RIM 6.2 provides the following enhancements:

- The Authorised Product option has been hidden from the **Data Administration > Other > Previous EV Code Values > Code Type** drop-down list.
- The **Full Product Presentation > Previous EV Code** drop-down list has been reworked to be the *FPP Previous EV Codes* tab on the *Full Product Presentation Attributes* page. If there are several Previous EV Code values, this will result in several `<previousevcode>` tags being added to the XEVMPD XML file.

Calyx RIM 6.2 updates the uniqueness rule for the Full Product Presentation entity to have the concatenation of the following fields unique within the Registration: **Full Product Name**, **EEA Country**, **Language**, **Package Description**, **Authorisation Status**, **Authorisation/Renewal Date**, and **EV Code**.

See *Entity Fields Added: Calyx RIM 6.2*, and *Data Administration Tables: Calyx RIM 6.2*.

Registration FPP Attachments

With Calyx RIM 6.2, the **Attachment Name** field has been reworked to be a *Registration Attachment Selection* list on the *Create Registration FPP Attachment* page. Once selected, the search results page displays all **Active** Registration Attachments that are available in the system and are not associated to the current Full Product Presentation.

See *Entity Fields Updated: Calyx RIM 6.2*.

Registration Attachments

Using XML overrides, Calyx RIM 6.2 can be configured to disable the autopopulate function for one or more Registration Attachment fields, if the Attachment file is uploaded from a DMS Repository:

- Attachment Name
- File Name

- File Type
- Attachment Version

For details, please contact your Business Development Representative to consult with our Client Enablement team.

References

To enforce Reference uniqueness within its parent entity, a Reference name must be unique.

Tasks

To enforce Task uniqueness within its parent entity, a Task name must be unique.

To provide the ability to identify the association between the parent Task and its Sub-Task, Calyx RIM 6.2 enhances the Task entity by adding a new field named **Related Task Name**. When a Task has an associated Sub-Task entity, the **Related Task Name** field for the Sub-Task will be automatically populated with the parent Task Name value. This field will always be empty for the parent Task entity.

With Calyx RIM 6.2 release, the inactive or disabled users are omitted from the lists of available values (`username`; or `username (email address)` combination) for the following Task entity fields:

- **Assigner** drop-down list
- **Premier Assignee** drop-down list
- **Task Concerned Parties** popup window

See *Entity Fields Added: Calyx RIM 6.2* and *Query Fields Added: Calyx RIM 6.2*.

Workflows

Calyx RIM 6.2 includes the following enhancements in the optional Calyx RIM Workflow Integration module to provide support for the XEVMPD entities:

- This release provides the ability to configure a workflow XML file to create and update the following entities:
 - Active Ingredient
 - Component
 - FPP Previous EV Code
 - Full Product Presentation
 - PDS Details: Active Ingredient
 - PDS Details: Flu Strain
 - PDS Details: Indication
 - PDS Details: Indication/Intended Use
 - PDS Details: Package Set
 - PDS Details: Reference Strain
 - PDS Details: Substance
 - Pharmaceutical Product
 - Product
 - Product Family
 - Reference Active Ingredient

- Registration Attachment
- Registration FPP Attachment

— The following additional tabs are added to the Full Product Presentation Attributes page:

- Activities
- Workflows

With Calyx RIM 6.2, it is now possible to associate a Package Set to a Registration via workflow.

Find

The **Find > Activities** functionality, available on the Calyx RIM home page, has been enhanced with a new Workflow-related report and now enables you to find the activities associated with the XEVMPD-related entities. The **Entity Type** drop-down list available on the *View Activities List* page is updated with a new entity type named XEVMPD.

SPOR Integration

To support the integration with EMA OMS and RMS API, to enable adding the controlled vocabulary for organisations and referentials data from the external system, and to enable the authentication between Calyx RIM system and SPOR API client, Calyx RIM 6.2 provides the ability to enable and configure the SPOR services through the appropriate options in the `insightConfig.bat` or `insight.var` files:

— In the `insightConfig.bat` file, in the newly introduced SPOR API Settings section, values for the `Enable SPOR API for RMS`, `Enable SPOR API for OMS`, `Defined Interval (minutes)`, `User Name`, and `Password` options must be set.

OR

— In the `insight.var` file, in the newly introduced SPOR API SETTINGS section, values for the `spor.api.enable.rms`, `spor.api.enable.oms`, `spor.api.update.interval.minutes`, `spor.api.user`, and `spor.api.password` options must be set.

XEVMPD Submission Wizard

With Calyx RIM 6.2, the `mrpnumber` generated by the XEVMPD Submission wizard is displayed without a space between Procedure Identifier/Application Code and Speciality Number. For example: [Procedure Identifier/Application Code][Speciality Number1].

Calyx RIM 6.2 enhances the XEVMPD submission data collection features. Although the Package Set information is not included in the XEVMPD submission, the Package Set assigned to the Full Product Presentation will determine the Active Ingredient, Substance, Indication/Intended Use (non-Veterinary), or Species Indication (Veterinary) PDS Details to be included. Only those PDS Details, with Package Set from the parent PDS associated to the Full Product Presentation, are included in the XEVMPD submission.

Important: If any Package Set is associated to the Registration, but is not associated to the Full Product Presentation under the Registration, then the Active Ingredient, Substance, Indication/Intended Use (non-Veterinary), or Species Indication (Veterinary) Details of the parent Product Details Set are not included in the XEVMPD submission.

With Calyx RIM 6.2, the *Initial Report* option has been hidden in the *XEVMPD Submission* wizard:

- The **Run Initial Report?** drop-down has been hidden on the *Select Sender/Receiver Information* page.
- The *Initial Report Selection* and *Initial Report Selection Results* pages that appeared when the **Run Initial Report?** drop-down field was set to Yes, has been hidden in the wizard.

Calyx RIM 6.2 enhances the Package Set Registration entity by adding the new field named **Legal Basis**. The **Registration > Legal Basis** value is included in the XEVMPD Submission XML file instead of the **Application > Legal Basis** value, if:

- The field is populated with a value for both entities.
- The **Application > Legal Basis** field is not populated with a value.

Calyx RIM 6.2 provides an additional enhancement to the XEVMPD submission data collection features and now allows the Route of Administration value to be taken into an XEVMPD submission from the PDS level. A new configured field named **Local Route of Administration** for tracking country Route of Administration on the PDS level has been added to the PDS Attributes page. This field is hidden by default and can be enabled via the overrides.

A new validation has been added to the XEVMPD Submission wizard invoked for the Authorised Product flow. When the MFL (Master File Location) value is not selected for a Registration being submitted, a warning message appears indicating that the MFL is required for this operation type. To be able to proceed with the wizard and have the MFL tag included in the submission XML file, the MFL value on the Registration Attributes page must be defined.

Note: *The MFL value is mandatory for Insert, Update and Invalidate MA operation types.*

Calyx RIM 6.2 enhances the XEVMPD Submission wizard to take the prior approved PDS Detail from the previous Event into the XEVMPD Submission if the current PDS Detail has one of the following statuses:

- Pending Modify
- Pending Withdrawal

This enhancement is applicable to the following PDS Details:

- Active Ingredient (including the Reference Active Ingredient logic)
- Indication/Indented Use
- Indication (under Veterinary Product Family)
- Strain
- Reference Strain
- Substance (Excipient, Adjuvant, and Substance entities used as Active Ingredient)

The PDS Details with status set to Withdrawn are not:

- Included into XEVMPD Submission
- Displayed in the XEVMPD Audit Analytics report

See *Entity Fields Added: Calyx RIM 6.2*, *Entity Fields Updated: Calyx RIM 6.2* and *Data Administration Tables: Calyx RIM 6.2*

Create Submission Wizard

Calyx RIM 6.2 enhances the **Create Submission Wizard > Initial Application** flow. The **Event Type** field is now available for modifications on the *Complete Submission Properties (event/sequence)* page. The drop-down field displays all Active values from **Data Administration > Event Maintenance > Event Type Values**.

See *Entity Fields Updated: Calyx RIM 6.2*

Change Submittal Status Wizard

Calyx RIM 6.2 enhances the logic of determining the **Confirmed Sequence Code** value in the *Change Submittal Status* wizard. The **Confirmed Sequence Code** value is determined based on the number of sequences that have been submitted to this application lifecycle, and now considers all previously submitted sequences, even if the current **Sequence Status** is set to **Approved**.

See *Entity Fields Updated: Calyx RIM 6.2*

Submitted Views

Calyx RIM 6.2 provides the ability to edit the **Reference Leaf** elements in the **Unlocked Submitted View** of a **Sequence Assembly**, if the following rules are met:

- To modify a **Reference Leaf** element in the **unlocked submitted assembly plan view**, in **Security Administration** you must have the **Entity Security > Submission Plans** set to at least **WRITE** and **Entity Security > Sequence Assemblies** set to **ADMIN**.
- To modify a **Reference Leaf** element in the **unlocked submitted assembly view**, in **Security Administration** you must have the **Application Country Rights** set to at least **WRITE** and **Entity Security > Sequence Assemblies** set to **ADMIN**.

Assemblies

The following **Assembly** enhancements have been introduced in Calyx RIM 6.2:

- Search for the **folder and leaf assembly elements** by the values of the **extended attributes**.
- Search for **leafs** that are operated in **parallel sequences**.
- When filtering an **assembly tree**, you can now select a **node type** as a criterion to narrow the search results.
- Ability to select and delete **multiple assembly nodes** simultaneously.
- The **delete (Withdraw) lifecycle operation** is now available in the **right-click menu** for **multiple selected leafs**.

Volumes

Calyx RIM 6.2 provides the ability to delete the **first and the last elements** in a **Volume**:

- **Assembly tree elements** can be deleted from the **Locked Volume**
- **Assembly tree elements** can be deleted from the **Unlocked Volume**

After the element is deleted, the **volume structure** will be adjusted automatically to **start, finish, or continue** from the next or previous **assembly tree element** within the **volume range**.

Queries

Calyx RIM 6.2 provides the following enhancements to the **List of Applications with Products Registration Planning and Tracking** query:

- You can now search for all application types available in the system. All application types are displayed and available for selection in the **Application Type** multi-select list.
- The **Application Name** field has been renamed to be **Application Name/Study Number**. The **Application Name/Study Number** field is displayed on the List of Applications with Products Query search criteria selection page and appears as a column on the Search Results page.

Calyx RIM 6.2 enhances the **Entity Audit Trail Administration Query** for the Full Product Presentation entity to include the newly introduced fields:

- Formulation Part
- Intended Use Part
- Target Population Part
- Container or Pack Part
- Device Part
- Time Period Part
- Flavour Part

Calyx RIM 6.2 enhances the **Entity Audit Trail Administration Query** to add support for the **CT Shared Data**. The **CT Shared Data** option is added to the **Entity Type** multi-select list.

To reflect renaming of the **Excipient Role** field for the Substance Detail as **Substance Role** and the **Excipient Name** to a **Substance Name**, the following Administration and Product Details Management queries have been updated to display **Substance Role** and **Substance Name** column names:

- **Application History Query > Substance Details Changed?** subquery
- **Application QC Status History Report > Substance Details QC Passed?** subquery
- **Entity Audit Trial > Product Detail-Substances** entity type
- **List of Excipient Manufacturers**
- **List of Registrations with Excipients**

To support the enhancement to display the **Manufacturer Name** value as a concatenation of **Manufacturer Name + Address Line 1 + Country Code** values, the following queries have been updated:

- **Queries > Registration Planning and Tracking:**
 - **List of Manufacturers From Data Administration**
- **Queries > Product Detail Management:**
 - **Application History Query**
 - **Application QC Status History Report**
 - **List of Active Ingredient Manufacturers**
 - **List of Active Ingredient Function Manufacturers**
 - **List of Active Ingredient Material Manufacturers**
 - **List of Excipient Manufacturers**

- List of PDS Manufacturers
- List of Component Manufacturers
- List of Package Set Manufacturers

— Queries > Administration:

- Entity Audit Trail

To support the Withdraw Country enhancement, Calyx RIM 6.2 introduces a new Product Detail Management query named **List of Application Countries with PDS Country and Registration Details**. This is designed to query for countries based on the Application Country information as well as the related PDS Country information: Registration, Registration Package Set, and Registration Package Set Country information. The hyperlinked attributes on the report Search Results page will navigate you to the related entity attributes page. The following queries have been updated with a new drop-down list named **Applications with Withdrawn Country**:

- Registration Planning and Tracking > List of Application Countries with Registration Details
- Product Detail Management > List of Application Countries with Registration and Product Details
- Submission Planning and Tracking > List of Application Countries

The following reports have been updated to support the renaming of the **Event Closed As** field to **Associations Closed As** and the **Event Closed Date** field to **Closed Date** on the Event attributes page:

- Querying > Registration Planning and Tracking queries:
 - List of Products with Event and Product Registration Details
 - List of Events with Application Properties
 - List of Sequences with Application and Event Properties
- Querying > Product Detail Management queries:
 - Application History Query
 - Application QC Status History Report
 - List of Product Detail Sets
- Querying > Registered Document Analysis > Registered Document Query.
- Event Attributes > Entity History Query

To support the enhancement of providing the ability to identify the association between the parent Task and its Sub-Task, the following Registration Planning and Tracking queries have been updated with a new filter field named **Related Task Name (enter parent Task/Sub-Task name if any)**:

- List of Tasks
- List of Tasks - Rollup by Product Family
- List of Tasks - Rollup by Application
- List of Tasks - Rollup by Project

The following changes are also introduced to support this enhancement:

- The listed Registration Planning and Tracking queries have been updated to add a new column named **Related Task Name** to the *Search Results* page. The value in the column is hyperlinked. When selected, navigates you to the appropriate *Task Attributes* page.
- The **Related Task Name** column has been added to the **Querying > Administration > Entity Audit Trail > Query** table when querying for the Task entity. The value is not hyperlinked.

Calyx RIM 6.2 enhances the **Entity Audit Trail Administration Query** to add support for the **CT Shared Data**. The **CT Shared Data** option is added to the **Entity Type** multi-select list.

Search

The **SEARCH** function on the menu bar now includes the ability to search for sequences. You can search for sequences filtered by specific text found in the **Name**, **Code**, **Keywords**, or **Description** attributes.

To support the enhancement of providing the ability to identify the association between the parent Task and its Sub-Task, the **Related Task Name** column has been added to the **Search Results** page of the **SEARCH** function on the menu bar when invoked for the **Tasks/Sub-tasks** option. The value in the column is hyperlinked. When selected, navigates you to the appropriate Task Attributes page.

Analytics

The Analytics Schema (DM schema) has been updated:

- The DM schema includes views for reporting on audit data.
- All views affected by changes in this release are also updated in the DM Schema.
- The DM schema was updated with the view containing chronological representation of Sequences and References.

Analytics Predefined Reports

Calyx RIM 6.2 enhances the **XEVMPD Audit** Analytics Predefined Report to include an additional filter named **Message Sender**. An additional column named **Message Sender** has been added to the **XEVMPD Audit** Analytics Predefined Report *results page*.

The **XEVMPD Audit** Analytics Predefined Report logic for displaying the following list of entities has been updated to consider the Package Set-Full Product Presentation association instead of the Package Set-Registration:

XEVMPD Entity Type	InSight Entity Type
Authorised Product - Authorisation	PDS
Authorised Product - Product Indications	Indications/Intended Use
Pharmaceutical Product	Pharmaceutical Product
Pharmaceutical Product - Active Ingredient	Component Active Ingredient
Pharmaceutical Product - Active Ingredient	PDS Active Ingredient
Pharmaceutical Product - Active Ingredient	PDS Substance
Pharmaceutical Product - Active Ingredient	Reference Active Ingredient
Pharmaceutical Product - Adjuvant	Adjuvant
Pharmaceutical Product - Administration Route	Component
Pharmaceutical Product - Administration Route	Product
Pharmaceutical Product - Excipient	Excipient
Pharmaceutical Product - Medical Devices	Pharmaceutical Product

Job Requests

Calyx RIM 6.2 enhances the *Job Requests* functionality to work with the data exchange user and receive the results of actions performed by the user.

Data Exchange

Calyx RIM Data Exchange enables you to import the following types of records into the Calyx RIM database:

- Legal Status Values
- Registration Status Values
- Event Country
- Event Country Status
- Product Detail Set (PDS)

Note: To be able to import PDS data via Calyx RIM Data Exchange, the parent Event entity must have the Status of Open.

- PDS Substance Component Detail
- PDS Flu Strain Detail
- PDS Reference Strain Detail
- PDS Species Indication Detail
- Region Values

Calyx RIM 6.2 enhances Data Exchange by adding the User Authentication, Authorisation, and Auditing support.

Data Administration

Calyx RIM 6.2 provides a variety of updates to Data Administration section:

- The *Region Type Values* table in the Application Maintenance section has been updated with a new default region type named IDMP.
- The *Region Values* table in the Application Maintenance section has been updated with a new region named IDMP Integration.
- A new field named **Organisation Identifier** has been added to the following Data Administration tables:
 - Product Detail Set Maintenance > Manufacturer Values
 - Other > MAH/Development Sponsor/Organisation Values
 - Application Maintenance > Country Values > Health Authority
- The *Procedure Type Values* table in the Application Maintenance section has been updated by adding a new field named IDMP Internal Procedure Code.
- In the Registration Maintenance > Registration Status Values, the Internal System Status field has been updated with a new internal status named APPROVED.

To maintain the integration with Organisations management service (OMS) introduced by European Medicines Agency (EMA), Calyx RIM 6.2 provides the following enhancements:

- The Data Administration > Other Maintenance > MAH/Development Sponsor/Organisation Values table is updated by adding the following fields:
 - Location Identifier

- Location Status
- The following Data Administration Tables have been updated to include a new drop-down list named **RMS Term Name**:
 - Application Maintenance > Country Values
 - Application Maintenance > Procedure Type Values
 - Other > Concentration Measure Type Values
 - Other > Denominator Unit Values
 - Other > Language Values
 - Other > Legal Basis Values
 - Other > Numerator Unit Values
 - Other > Unit of Measure Prefix Values
 - Product Detail Set Maintenance > Compendial Designation/Source Values
 - Product Family Maintenance > ATC Values
 - Product Maintenance > Dosage/Pharmaceutical Form Values
 - Product Maintenance > Medical Device Values
 - Product Maintenance > Route of Administration Values
 - Registration Maintenance > EMA Authorisation Status Values
 - Registration Maintenance > Medicinal Product Type Values

To make the **Excipient Role** field available for all substance types in the Product Detail Set and Product Detail Set Template, the **Data Administration > Product Detail Set Maintenance > Excipient Role Values** table is renamed as **Substance Role Values**.

Calyx RIM 6.2 introduces the **SPOR Maintenance** section in Data Administration. This section is designed to maintain the European Medicines Agency (EMA) Substance, Product, Organisation and Referential (SPOR) service compliance. According to the roadmap designed by EMA the SPOR support starts with an introduction of OMS (Organisations management service) and RMS (Referentials management service) components.

To enable the **Manufacturer Name** value to be displayed as a concatenation of **Manufacturer Name + Address Line 1 + Country Code** values in the **Manufacturer** field for each **Product Detail Set > Manufacturer Detail** instance, Calyx RIM 6.2 introduces the following enhancements to the **Data Administration > Manufacturer Values > Manufacturer** value attributes page:

- The **Country** text field has been reworked to be a drop-down list with all active Country values from the **Data Administration > Country Values** table available for selection.
- The **Country Code** drop-down list is no longer presented on the **Create/Modify Manufacturer** attributes page.

To identify medical devices and also facilitate data exchange between manufacturers, regulators, and healthcare authorities, **Global Medical Device Nomenclature (GMDN) Code Values** has been introduced under **Data Administration > Product Maintenance** section.

To maintain the specific detail type value of the country attribute, the **Product Maintenance** section in **Data Administration** has been updated with the following new tables:

- **Country Specific Detail Type Values**

— Country Specific Detail Values

To maintain the applicable standard version, the **Applicable Standards Values** table has been updated to include the **Version of Standard** option.

To identify, process, retrieve, transfer, and communicate data about medical devices, the **UMDNS Code Values** option has been introduced under **Data Administration > Product Maintenance** section.

For the enhancement that adds a new field named **Legal Basis** to the Package Set Registration entity, the **Legal Basis Values** table has been removed from the **Data Administration > Application Maintenance** section and is now included in the **Data Administration > Other** section.

The following tables have been removed from the Calyx RIM 6.2 Data Administration section:

- Device Classification Values
- FDA Regulation Number Values

See *Data Administration Tables: Calyx RIM 6.2*

Additional Enhancements

With support for the Microsoft Edge and Google Chrome Enterprise Edition browsers, Calyx RIM 6.2 provides the ability to display all windows throughout the system with Kendo (HTML5 user interface framework).

***Note:** Calyx RIM 6.2 supports Microsoft Edge and Google Chrome Enterprise Edition browsers only when configured for Kendo. When not configured for Kendo, LIQUENT InSight 6.2 supports only Microsoft Internet Explorer 11.*

The Kendo-styled windows can be minimized, maximized, moved, and re-sized. When the settings are configured to support Kendo, using one of the following methods, then all windows will be displayed in the newly supported browsers:

- In the `insight.var` file, the `insight.window.type.kendo=true` setting must be added.
If the setting is `insight.window.type.kendo=false`, then all windows are displayed in standard style.

OR

- In the `insightConfig.bat` file, in the `Browser Independence Settings` section, the `Enable Kendo Window UI` option is set to `true`: `Enable Kendo Window UI=true`.
The default value is set to `true`. If the default value is preserved, then all windows are displayed in kendo style.



Attention: Please note that Calyx RIM for Analytics module is not compatible with the Microsoft Edge browser.

The **PLANNED** internal event status has been added. By default, the internal Event Status **PLANNED** is mapped to the **Planned** Event Status.

The maximum number of users that can access Calyx RIM for Analytics Reports has been increased from 1280 to 5000.

Calyx RIM 6.2 provides support for the following Ricoh Pro Printers:

- Ricoh Pro C5200s/C5210s
- Ricoh Pro C5200s/C5210s, US Punch*
- Ricoh Pro C5200s/C5210s, ISO Punch*

*Requires additional hardware.

The `AssemblyImport.xsd` file included in the Calyx RIM 6.2 release along with the corresponding *Assembly XML Specification* set topics located in the Calyx RIM Administration Guide have been provided to aid in the creation of the Assembly XML file from scratch using third-party tools, or leveraging it from an exported Assembly.

List of Enhancements: Calyx RIM 6.2

Requested new features and enhancements are included in each release. The items are listed in descending order by their tracking numbers. Customer case numbers that were recorded when the enhancements were requested are included in brackets [#####] following the tracking number.

Calyx RIM 6.2

Calyx RIM 6.2 includes the following enhancements.

Issue	Description
<p>25698; [00057639]</p>	<p>Calyx RIM 6.2 enhances the XEVMPD Submission wizard to take the prior approved PDS Detail from the previous Event into the XEVMPD Submission if the current PDS Detail has one of the following statuses:</p> <ul style="list-style-type: none"> – Pending Modify – Pending Withdrawal <p>This enhancement is applicable to the following PDS Details:</p> <ul style="list-style-type: none"> – Active Ingredient (including the Reference Active Ingredient logic) – Indication/Indented Use – Indication (under Veterinary Product Family) – Strain – Reference Strain – Substance (Excipient, Adjuvant, and Substance entities used as Active Ingredient) <p>The PDS Details with status set to Withdrawn are not:</p> <ul style="list-style-type: none"> – Included into XEVMPD Submission – Displayed in the XEVMPD Audit Analytics report
<p>25680; [00056846]</p>	<p>Calyx RIM 6.2 updates the uniqueness rule for the Full Product Presentation entity to have the concatenation of the following fields unique within the Registration:</p> <p>Full Product Name, EEA Country, Language, Package Description, Authorisation Status, Authorisation/Renewal Date, and EV Code.</p>
<p>25675; [00057202, 00057471, 00057946, 00058223]</p>	<p>Calyx RIM 6.2 introduces support of the ICH STF Stylesheet v2.3. The following updates have been applied:</p> <ul style="list-style-type: none"> – When you select the <code>stf-2-2</code> in the XML Definitions field, the published output will contain the new version of the Stylesheet file: <code>util\style\ich-stf-stylesheet-2-3.xml</code> – When you select the <code>stf-2-2-3-0</code> in the XML Definitions field, the published output will contain the new version of the Stylesheet file: <code>util\style\ich-stf-stylesheet-2-3.xml</code> <hr/> <p>Note: <i>The MD5 checksum of the STF stylesheet is:</i> <code>92BFEB4CB358A4AF786317A0DA2309C5</code></p> <hr/>
<p>25663</p>	<p>Calyx RIM 6.2 provides support for Australia eCTD Module 1 Specification Version 3.1 and AU Nees v2.0 specification.</p>

Issue	Description
25662; [00057090, 00057174]	<p>Calyx RIM 6.2 supports EU eCTD Module 1 Specification Version 3.0.3. The EU eCTD Module 1 Templates have been updated.</p> <hr/> <p>Note: See <i>Clarification of Behavior: Calyx RIM 6.2</i>.</p> <hr/>
25607; [00056665]	<p>With Calyx RIM 6.2, it is now possible to associate a Package Set to a Registration via workflow.</p>
25563	<p>With Calyx RIM 6.2, a new configured field named Local Route of Administration has been added to the PDS Attributes page for tracking country Route of Administration on PDS level. This field is hidden by default and can be enabled via the overrides.</p> <p>In addition, if configured to be available, the Local Route of Administration field is displayed in the XEVMPD Audit Report under the Pharmaceutical Product-Administration Route XEVMPD Entity.</p>
25575; [00056237]	<p>With Calyx RIM 6.2, a new validation has been added to the XEVMPD Submission wizard invoked for the Authorised Product flow. When the MFL (Master File Location) value is not selected for a Registration being submitted, a warning message appears indicating that the MFL is required for this operation type.</p> <hr/> <p>Note: <i>The MFL value is mandatory for Insert, Update and Invalidate MA operation types.</i></p> <hr/> <p>To be able to proceed with the wizard and have the MFL tag included to the submission XML file, the MFL value on the Registration Attributes page must be defined.</p>
25533	<p>The <code>AssemblyImport.xsd</code> file included in the Calyx RIM 6.2 release along with the corresponding <i>Assembly XML Specification</i> set topics located in the Calyx RIM Administration guide have been provided to aid in the creation of the Assembly XML file from scratch using third-party tools, or leveraging it from an exported Assembly.</p>

Issue	Description
25527	<p>With Calyx RIM 6.2, the following enhancements have been introduced to support the Legal Basis field to be available for the Package Set Registration entity and be included to the XEVMPD Submission XML file:</p> <ul style="list-style-type: none"> – A new drop-down list named Legal Basis has been added to the Registration of a Package Set type. – The Legal Basis Values table has been removed from the Data Administration > Application Maintenance section and is now included under the Data Administration > Other section. – The Registration Attributes > Entity History Query and Querying > Administration > Entity Audit Trail queries have been updated to display the correct values for the new Legal Basis field. – The Registration > Legal Basis value is included to the XEVMPD Submission XML file instead of the Application > Legal Basis value, if: <ul style="list-style-type: none"> • The field is populated with a value for both entities. • The Application > Legal Basis field is not populated with a value
25521; [00055762]	<p>This enhancement introduces the ability to have a workflow that allows for updating of Active Ingredient, Reference Active Ingredient, and Pharmaceutical Product entity specific data.</p>
25435	<p>With Calyx RIM 6.2, the <i>Initial Report</i> option has been hidden in the <i>XEVMPD Submission</i> wizard:</p> <ul style="list-style-type: none"> – The Run Initial Report? drop-down has been hidden on the <i>Select Sender/Receiver Information</i> page. – The <i>Initial Report Selection</i> and <i>Initial Report Selection Results</i> pages that appeared when the Run Initial Report? drop-down field was set to Yes, has been hidden in the wizard.
25430; [00054572]	<p>With Calyx RIM 6.2, the PLANNED status has been added to the:</p> <ul style="list-style-type: none"> – Project Pivot Status drop-down field on the <i>Create/Modify Project Attributes</i> page. – Enter Project Pivot Values > Project Pivot Status drop-down field of the <i>Calculate Projected Dates</i> wizard (Global Project Plan wizard). <p>In addition, the PLANNED internal event status has been added. By default, the internal Event Status PLANNED is mapped to the Planned Event Status.</p>

Issue	Description
25416	To make the Excipient Role field available for all substance types in the Product Detail Set and Product Detail Set Template, the Data Administration > Product Detail Set Maintenance > Excipient Role Values table is renamed as Substance Role Values , and the Excipient Role field for the Substance Detail is renamed as Substance Role . The Substance Role field appears on the <i>Add Substance</i> page regardless of the selected Substance Type value.
25407	Using XML overrides, Calyx RIM 6.2 can be configured to disable the autopopulate function for one or more Registration Attachment fields, if the Attachment file is uploaded from a DMS Repository: <ul style="list-style-type: none"> – Attachment Name – File Name – File Type – Attachment Version
25387; [00054264]	Calyx RIM 6.2 enhances the XEVMPD submission data collection features. Although the Package Set information is not included in the XEVMPD submission, the Package Set assigned to the Full Product Presentation will determine the Active Ingredient, Substance, Indication/Intended Use (non-Veterinary), or Species Indication (Veterinary) PDS Details to be included. Only those PDS Details, with Package Set from the parent PDS associated to the Full Product Presentation, are included in the XEVMPD submission.
25373; [00053960]	Starting with Calyx RIM 6.2, the Application Status of an Application can be set to Withdrawn only when all Registrations associated to the Application have a status mapped to internal WITHDRAWN status.
25372	With Calyx RIM 6.2, the Attachment Name field on the <i>Create Registration FPP Attachment</i> page has been reworked to be a Registration Attachment Selection list. The selected Registration Attachment is displayed in the Attachment Name > Selected box in the concatenation of four fields: Internal Name, Attachment Language, Attachment Name, Attachment Version.
25367	Calyx RIM 6.2 enhances the Entity Audit Trail Administration Query to add support for the CT Shared Data . The CT Shared Data option is added to the Entity Type multi-select list.
25341; [00053767]	Calyx RIM 6.2 provides updates to the Indication/Intended Use detail in the Non-Veterinary Product Details Set (PDS) and Species Indication detail in the Veterinary Product Detail Set (PDS). All countries of the associated Application by default appear in the Selected box of the Countries field on the <i>Add Indication/Intended Use</i> detail (Non-Veterinary PDS) and <i>Add Indication</i> detail (Veterinary PDS) pages. You can deselect countries, if needed.

Issue	Description
25340; [00053739]	<p>With Calyx RIM 6.2, the <code>mrpnumber</code> generated by the XEVMPD Submission wizard is displayed without a space between Procedure Identifier/Application Code and Speciality Number. For example: [Procedure Identifier/Application Code][Speciality Number1]. As an addition to this enhancement, the Specialty Number field has been renamed to be Speciality Number.</p>
25335; [00053740]	<p>To enable the Previous EV Code value for the Full Product Presentation entity to be added manually, Calyx RIM 6.2 provides the following enhancements:</p> <ul style="list-style-type: none"> – The Authorised Product option has been hidden from the Data Administration > Other > Previous EV Code Values > Code Type drop-down list. – The Full Product Presentation > Previous EV Code drop-down list has been reworked to be the <i>FPP Previous EV Codes</i> tab on the <i>Full Product Presentation Attributes</i> page. If there are several Previous EV Code values, in the <i>XEVMPD XML</i> file that results in several <code><previousevcode></code> tags.
25329, 24993; [00053680, 00049980]	<p>Calyx RIM 6.2 enhances Data Exchange by adding the User Authentication, Authorisation, and Auditing support.</p> <ul style="list-style-type: none"> – Data Exchange can be configured to enforce user authentication for each incoming request. – Data Exchange can be configured to enforce authorisation to specific user accounts. – Authentication and authorisation logging has been added in the following categories: <ul style="list-style-type: none"> • <code>com.liquent.insight.dataexchanger</code> • <code>com.liquent.insight.messaging.jms</code> <p>The Data Exchange XML schema contains the additional attributes named <code>user</code> and <code>password</code> on the root <code><dataexchange></code> tag. This is used to pass the credentials of the user to authenticate and use during the Data Exchange transaction.</p> <p>For example: <code><dataexchange user="de_user" password="de_password"></code></p> <p>Important: These attributes are only required if Data Exchange authentication is configured to be used.</p>

Issue	Description
25284;	Calyx RIM 6.2 provides support for the following Ricoh Pro Printers: <ul style="list-style-type: none"> – Ricoh Pro C5200s/C5210s – Ricoh Pro C5200s/C5210s, US Punch* – Ricoh Pro C5200s/C5210s, ISO Punch*
25280; [00052554; 00054120]	Calyx RIM 6.2 enhances the logic for determining the Confirmed Sequence Code value in the <i>Change Submittal Status</i> wizard. The Confirmed Sequence Code value is determined based on the number of sequences that have been submitted to this application lifecycle, and now considers all previously submitted sequences, even if the current Sequence Status is set to Approved.
25273; [00051853]	Calyx RIM 6.2 provides support for the following Web browsers: <ul style="list-style-type: none"> – Microsoft Internet Explorer (IE) 11 (set Compatibility View Settings to Off) – Microsoft Edge (supported on Windows 10 only) – Google Chrome <hr/> <p><i>Note: Please note that Calyx RIM for Analytics module is not compatible with the Microsoft Edge browser.</i></p> <hr/>
25242	Calyx RIM 6.2 enables you to copy a Registration entity using the <i>Copy Package Set Registration</i> wizard. The wizard can be invoked for a Package Set Registration only. Two flows are available for selection in the <i>Copy Package Set Registration</i> wizard: <ul style="list-style-type: none"> – New Package Set specific Registration(s). This flow also allows you to copy the Full Product Presentations and Registration FPP Attachments, if any are assigned to the Registration you selected to copy, and the minimum required security settings are met. – New Product specific Registration(s).
25239; [00055798]	Calyx RIM 6.2 enables you to copy a Full Product Presentation entity using the <i>Copy Full Product Presentation</i> wizard. Two flows are available for selection in the <i>Copy Full Product Presentation</i> wizard: <ul style="list-style-type: none"> – Full Product Presentation under different Registration(s) – Full Product Presentation under the same Registration

Issue	Description
25218; [00052214]	<p>Calyx RIM 6.2 provides the ability to edit the Reference Leaf elements in the Unlocked Submitted View of a Sequence Assembly, if the following rules are met:</p> <ul style="list-style-type: none"> – To modify a Reference Leaf element in the unlocked submitted assembly plan view, in Security Administration you must have the Entity Security > Submission Plans set to at least WRITE and Entity Security > Sequence Assemblies set to ADMIN. – To modify a Reference Leaf element in the unlocked submitted assembly view, in Security Administration you must have the Application Country Rights set to at least WRITE and Entity Security > Sequence Assemblies set to ADMIN.
25179	<p>Calyx RIM 6.2 enhances the XEVMPD Audit Analytics Predefined Report to include an additional filter named Message Sender. An additional column named Message Sender has been added to the XEVMPD Audit Analytics Predefined Report <i>results page</i>.</p>
25169; [00051802]	<p>Calyx RIM 6.2 enhances the Create Submission Wizard > Initial Application flow. The Event Type field on the <i>Complete Submission Properties (event/sequence)</i> page is now available for modifications. The drop-down field displays all Active values from Data Administration > Event Maintenance > Event Type Values.</p>
25163; [00047861]	<p>The maximum number of users that can access Calyx RIM for Analytics Reports has been increased from 1280 to 5000.</p>
25159; [00051747]	<p>Calyx RIM 6.2 enhances the List of Applications with Products query, in the Registrations Planning and Tracking section, to provide the ability to search for all application types available in the system. All application types are now displayed and available for selection in the Application Type multi-select list.</p>

Issue	Description
<p>25083; [00050940]</p>	<p>To provide the ability to identify the association between the parent Task and its Sub-Task, Calyx RIM 6.2 enhances the Task entity by adding a new field named Related Task Name. When a Task has an associated Sub-Task entity, the Related Task Name field for the Sub-Task will be populated automatically with the parent Task Name value. This field will always be empty for the parent Task entity.</p> <p>To support this enhancement, the following Registration Planning and Tracking reports have been updated with a new filter field named Related Task Name (enter parent Task/Sub-Task name if any):</p> <ul style="list-style-type: none"> – List of Tasks – List of Tasks - Rollup by Product Family – List of Tasks - Rollup by Application – List of Tasks - Rollup by Project <p>The following changes are introduced to support this enhancement:</p> <ul style="list-style-type: none"> – The listed Registration Planning and Tracking reports have been updated to add a new column named Related Task Name to the <i>Search Results</i> page. The value in the column is hyperlinked. When selected, this displays the appropriate <i>Task Attributes</i> page. – The Related Task Name column has been added to the Querying > Administration > Entity Audit Trail > Query table when querying for the Task entity. The value is not hyperlinked. – The Related Task Name column has been added to the <i>Search Results</i> page of the SEARCH functionality when invoked for the Tasks/Sub-tasks option. The value in the column is hyperlinked. When selected, this displays the appropriate Task Attributes page.
<p>25055</p>	<p>Calyx RIM Data Exchange now provides the ability to import Region Values records into the Calyx RIM database.</p>

Issue	Description
<p>24743; [00047073]</p>	<p>Calyx RIM 6.2 enhances the Global Project Plan wizard by adding the multi-select field Application Type as an additional filter criterion for the following project types:</p> <ul style="list-style-type: none"> — Create New Events Package Set Registration > Search by Product, Country and Application Status page — Update Product Detail Sets > Input Query Filter Criteria page, when searching by: <ul style="list-style-type: none"> • Active Ingredient • PDS Code/PDS Name • Product and Country • Substance • Trade Name — Create New Events Product Registration > Search Country and Application Status page — Withdraw Product Package Set Registration > Search by Product, Country Application and PDS Statuses page
<p>24742; [00047074]</p>	<p>Calyx RIM 6.2 enables a Sequence to be updated in bulk within a project. The <i>Project Attributes</i> page has been enhanced by adding the Bulk Update Sequences icon that launches the <i>Bulk Update Sequences</i> wizard.</p>

Issue	Description
<p>24711; [00046629]</p>	<p>To enable the Manufacturer Name value to be displayed as a concatenation of Manufacturer Name + Address Line 1 + Country Code values in the Manufacturer field for each Product Detail Set > Manufacturer Detail instance, Calyx RIM 6.2 introduces the following enhancements to the Data Administration > Product Detail Set Maintenance > Manufacturer Values > Manufacturer value attributes page:</p> <ul style="list-style-type: none"> — The Country text field has been reworked to be a drop-down list with all active Country values from the Data Administration > Country Values table available for selection. — The Country Code drop-down list is no longer presented on the <i>Create/Modify Manufacturer</i> attributes page. <p>In addition to all instances of Manufacturer Detail in the Product Detail Set, to support this enhancement the Manufacturer Name value concatenation is now displayed for the following areas:</p> <ul style="list-style-type: none"> — Queries > Product Detail Management: <ul style="list-style-type: none"> • Application History Query • Application QC Status History Report • List of Active Ingredient Manufacturers • List of Active Ingredient Function Manufacturers • List of Active Ingredient Material Manufacturers • List of Excipient Manufacturers • List of PDS Manufacturers • List of Component Manufacturers • List of Package Set Manufacturers — Queries > Administration: <ul style="list-style-type: none"> • Entity Audit Trail — Global Project Plan wizard: <ul style="list-style-type: none"> • Add Active Ingredient Manufacturer flow • Add Active Ingredient Manufacturing Process Function Manufacturer flow • Add Substance Manufacturer flow • Add Substance Manufacturing Process Function Manufacturer flow • Add Component Function Manufacturer flow • Add Component Manufacturing Process Function Manufacturer flow • Add PDS Function Manufacturer flow • Add PDS Manufacturing Process Function Manufacturer flow • Add Package Set Function Manufacturer flow • Add Package Set Packaging Manufacturer flow • Add Package Set Component Packaging Manufacturer flow — Comparator > Suppliers multi-select list

Issue	Description
23671; [00038325]	The Analytics schema has been updated to include the audit trail information stored within Calyx RIM, enabling users to create reports and metrics against the audit information, using Calyx RIM for Analytics.
23634; [00038044]	<p>With Calyx RIM 6.2 you are now able to:</p> <ul style="list-style-type: none"> – Select a bunch of different Assembly Tree nodes using the Ctrl or Shift keys, invoke the context menu and delete the selected items in a bulk; – Select several different Assembly Tree nodes the Ctrl or Shift keys and drag-and-drop them on the valid node.
23580; [00037237]	<p>Calyx RIM 6.2 enhances the following Product Strength-related fields to display a leading zero value for the decimal numbers that are less than 1 in the Product Strength field on the <i>View Product Attributes</i> page:</p> <ul style="list-style-type: none"> – Product Strength Measure 1 – Product Strength Measure 2 <p>Calyx RIM 6.2 enhances the business rules for the Product Strength Measure 1 and Product Strength Measure 2 fields. The entered value must not exceed 5 decimal numbers before the decimal point and 5 decimal numbers after the decimal point.</p> <hr/> <p>Note: <i>The value cannot be larger than 99999.99999.</i></p> <hr/>
23432, 22641, 20705; [00028353, 00029094]	When modifying a TOC tree, it is now possible to select multiple nodes and drag them in between the other nodes.
22788, 15649; [00029856, 75107FW, 115454FW]	With the New Version of the Assembly Tree introduced in Calyx RIM 6.2, it is now possible to select and delete multiple Assembly Tree nodes simultaneously using the Ctrl or Shift keys.
22207; [00209161, 00042932]	Delete (Withdraw) lifecycle operation is now available in the right-click menu for multiple selected leaves.
21791; [00038699]	Calyx RIM 6.2 enhances the Event entity by renaming the Event Closed As field as Associations Closed As and the Event Closed Date field as Closed Date .

Issue	Description
21788; [000175882]	The performance of the List of Sequences with Application and Event Properties query has been improved in Calyx RIM 6.2.
20557; [000139077]	With Calyx RIM 6.2 release, using the Assembly Tree Filter functionality you can now search for a specific study folder in Module 4 and Module 5 using the value of the Report Number attribute.
16620; [00076590FW, 00083511FW, 000133431FW, 000142150FW, 00039250]	With Calyx RIM 6.2, it is possible to delete the first and last elements in either locked or unlocked volumes. After the element is deleted from the volume range, the Volume structure will be adjusted automatically.
14129; [00036861]	With Calyx RIM 6.2 release, the inactive or disabled users are omitted from the lists of available values (<code>username</code> , or <code>username (email address)</code> combination) for the following Task entity fields: <ul style="list-style-type: none"> – Assigner drop-down list – Premier Assignee drop-down list – Task Concerned Parties popup window
10376	Using the Search function on the menu bar, it is now possible to find sequences quickly.

See *New in Calyx RIM 6.2*, *Entity Fields Added: Calyx RIM 6.2*, *Entity Fields Updated: Calyx RIM 6.2*, *Query Fields Added: Calyx RIM 6.2*, *Query Fields Updated: Calyx RIM 6.2*, and *Data Administration Tables: Calyx RIM 6.2*.

Data Administration Tables: Calyx RIM 6.2

The following Data Administration tables, sections, or fields were added with Calyx RIM 6.2.

Data Administration Section: Application Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Country Values > Health Authority	N/A	Organisation Identifier	<p>The Data Administration > Application Maintenance > Country Values > Health Authority attributes page has been enhanced by adding a new attribute named Organisation Identifier:</p> <ul style="list-style-type: none"> – Field Type: text, non-mandatory – Field Size: 250 characters – Database Field Size: VARCHAR2(500)

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Country Values > Region	N/A	N/A	<p>The IDMP Integration region of IDMP region type appears in the <i>Region</i> tab on the <i>Country value attributes</i> page for the following list of countries:</p> <ul style="list-style-type: none"> – Austria – Belgium – Bulgaria – Croatia – Cyprus – Czech Republic – Denmark – Estonia – European Union – Finland – France – Germany – Greece – Hungary – Iceland – Ireland – Italy – Latvia – Liechtenstein – Lithuania – Luxembourg – Malta – Netherlands – Norway – Poland – Portugal – Romania – Slovakia – Slovenia – Spain – Sweden – United Kingdom

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Country Values	N/A	RMS Term Name	To maintain the European Medicines Agency (EMA) Substance, Product, Organisation and Referential (SPOR) service, the Country Values table has been updated with a new drop-down list named RMS Term Name . The active values from SPOR Maintenance > Country RMS Values table are available for selection.
Procedure Type Values	N/A	IDMP Internal Procedure Code	The Data Administration > Application Maintenance > Procedure Type Values attributes page has been enhanced by adding a new field named IDMP Internal Procedure Code : <ul style="list-style-type: none"> — Field Type: drop-down list — Values available for selection: CP, DCP, MRP, NATIONAL
Procedure Type Values	N/A	RMS Term Name	To maintain the European Medicines Agency (EMA) Substance, Product, Organisation and Referential (SPOR) service, the Procedure Type Values table has been updated with a new drop-down list named RMS Term Name . The active values from SPOR Maintenance > Procedure Type RMS Values table are available for selection.

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Region Type Values	<ul style="list-style-type: none"> – Region Values – Country Values > Region – <i>Update Applications</i> wizard – <i>Create Application</i> wizard (the Region(s) read-only field) – <i>Global Project Plan</i> wizard: <ul style="list-style-type: none"> • <i>Create New Applications Package Set Registration</i> project • Clinical Trial project > Create New CTA and/or IND Application(s) flow • Clinical Trial project > Create New CTA Application(s) and Create New Event for Existing IND Application(s) flow • Clinical Trial project > Create New Event for Existing CTA and/or IND Application(s) flow – <i>Create Timeline/Event Plan</i> wizard 	N/A	<p>The IDMP region type has been added. The default value is set to <code>Active</code>. This value is not available for modifications and cannot be deactivated.</p> <hr/> <p>Note: You can update the list of countries that are associated to the region of an IDMP type, or create a new region of an IDMP type, using the Region Values section.</p> <ul style="list-style-type: none"> – In the <i>Timeline/Event Plan</i> wizard, the <i>Region Type</i> field has been updated to allow the selection an IDMP region type. – The <i>Update Applications</i> wizard has been enhanced to include an IDMP region type. – The <i>Global Project Plan</i> wizard has been enhanced to include an IDMP region type a search criteria. – The <i>Create Application</i> wizard, <i>Application Attributes</i> page, and <i>Modify Application Attributes</i> page have been updated to show the IDMP region type and a region of IDMP type in the <i>Region(s)</i> read-only field, if a country associated to such region has been selected as a <i>Reviewing Country</i>. <hr/>

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Region Values	Country Values > Region	N/A	<p>A new default region named IDMP Integration has been added. The default value is set to Inactive. The type of an IDMP Integration region is set to IDMP.</p> <p>By default, the following list of countries belong to the IDMP Integration region:</p> <ul style="list-style-type: none"> – Austria – Belgium – Bulgaria – Croatia – Cyprus – Czech Republic – Denmark – Estonia – European Union – Finland – France – Germany – Greece – Hungary – Iceland – Ireland – Italy – Latvia – Liechtenstein – Lithuania – Luxembourg – Malta – Netherlands – Norway – Poland – Portugal – Romania – Slovakia – Slovenia – Spain – Sweden – United Kingdom

Data Administration Section: Other

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Concentration Measure Type Values	N/A	RMS Term Name	To maintain the European Medicines Agency (EMA) Substance, Product, Organisation and Referential (SPOR) service, the Concentration Measure Type Values table has been updated with a new drop-down list named RMS Term Name . The active values from SPOR Maintenance > Concentration Measure Type RMS Values table are available for selection.
Denominator Unit Values	N/A	RMS Term Name	To maintain the European Medicines Agency (EMA) Substance, Product, Organisation and Referential (SPOR) service, the Denominator Unit Values table has been updated with a new drop-down list named RMS Term Name . The active values from SPOR Maintenance > Denominator Unit RMS Values table are available for selection.
Language Values	N/A	RMS Term Name	To maintain the European Medicines Agency (EMA) Substance, Product, Organisation and Referential (SPOR) service, the Language Values table has been updated with a new drop-down list named RMS Term Name . The active values from SPOR Maintenance > Language RMS Values table are available for selection.
Legal Basis Values	<ul style="list-style-type: none"> – Package Set Registration – Data Administration > Application Maintenance > Legal basis Values 	Package Set Registration > Legal Basis	The Legal Basis Values table has been removed from the Data Administration > Application Maintenance section and is now included under the Data Administration > Other section. The table name has not been changed.

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Legal Basis Values	N/A	RMS Term Name	To maintain the European Medicines Agency (EMA) Substance, Product, Organisation and Referential (SPOR) service, the Legal Basis Values table has been updated with a new drop-down list named RMS Term Name . The active values from SPOR Maintenance > Legal Basis RMS Values table are available for selection.
MAH/Development Sponsor/Organisation Values	N/A	Organisation Identifier	The Data Administration > Other > MAH/Development Sponsor/Organisation Values attributes page has been enhanced by adding a new attribute named Organisation Identifier : <ul style="list-style-type: none"> – Field Type: text, non-mandatory – Field Size: 250 characters – Database Field Size: VARCHAR2(500)
MAH/Development Sponsor/Organisation Values	N/A	Location Identifier	To maintain the integration with Organisations management service (OMS) introduced by European Medicines Agency (EMA), the Data Administration > Other > MAH/Development Sponsor/Organisation Values attributes page has been updated with a new field named Location Identifier : <ul style="list-style-type: none"> – Field Type: text, non-mandatory – Field Size: 200 characters – Database Field Size: VARCHAR2(1000)

Data Administration Table Name	Entity Affected	Field Name	Value List Description
MAH/Development Sponsor/Organisation Values	N/A	Location Status	<p>To maintain the integration with Organisations management service (OMS) introduced by European Medicines Agency (EMA), the Data Administration > Other > MAH/Development Sponsor/Organisation Values attributes page has been updated with a new field named Location Status:</p> <ul style="list-style-type: none"> Field Type: drop-down list, non-mandatory The values available for selection are [Select], Active, Inactive. [Select] is set by default.
Numerator Unit Values	N/A	RMS Term Name	<p>To maintain the European Medicines Agency (EMA) Substance, Product, Organisation and Referential (SPOR) service, the Numerator Unit Values table has been updated with a new drop-down list named RMS Term Name. The active values from SPOR Maintenance > Numerator Unit RMS Values table are available for selection.</p>

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Previous EV Code Values	Full Product Presentation > Previous EV Code	Code Type	<p>The Authorised Product option has been hidden from the Code Type drop-down list. The options available for selection are:</p> <ul style="list-style-type: none"> – Approved Substance – Pharmaceutical Form – Rout of Administration <p>The field is not available for modifications once the Previous EV Code value is created and saved in Data Administration.</p> <p>The Full Product Presentation > Previous EV Code field has been reworked to be the <i>FPP Previous EV Codes</i> tab on the <i>Full Product Presentation Attributes</i> page without using the values from the Data Administration > Other > Previous EV Code Values section.</p> <p>The following set of rules apply to the FPP Previous EV Code > Previous EV Code field:</p> <ul style="list-style-type: none"> – Field Type: text, required – Field Size: 60 characters – Database Field Size: VARCHAR2(100)
Unit of Measure Prefix Values	N/A	RMS Term Name	<p>To maintain the European Medicines Agency (EMA) Substance, Product, Organisation and Referential (SPOR) service, the Unit of Measure Prefix Values table has been updated with a new drop-down list named RMS Term Name. The active values from SPOR Maintenance > Unit of Measure Prefix RMS Values table are available for selection.</p>

Data Administration Section Name: Product Detail Set Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Compendial Designation/ Source Values	N/A	RMS Term Name	To maintain the European Medicines Agency (EMA) Substance, Product, Organisation and Referential (SPOR) service, the Compendial Designation/ Source Values table has been updated with a new drop-down list named RMS Term Name. The active values from SPOR Maintenance > Compendial Designation/Source RMS Values table are available for selection.
Excipient Role Values	Product Detail Set > Substance Detail	N/A	The Excipient Role Values table in the Data Administration > Product Detail Set Maintenance section has been renamed as Substance Role Values.

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Manufacturer Values	<ul style="list-style-type: none"> – PDS > Component > Active Ingredient > Manufacturer – PDS > Component > Active Ingredient > Manufacturing Process > Function > Manufacturer 	Country	The Country text field has been reworked to be a drop-down list with all active Country values from the Data Administration > Country Values table available for selection.
Manufacturer Values	<ul style="list-style-type: none"> – PDS > Component > Substance > Manufacturer – PDS > Component > Substance > Manufacturing Process > Function > Manufacturer – PDS > Component > Manufacturing Process > Function > Manufacturer – PDS > Component > Function > Manufacturer – PDS > Manufacturing Process > Function > Manufacturer – PDS > Package Set > Function > Manufacturer – PDS > Package Set > Packaging > Manufacturer – PDS > Package Set > Component > Packaging > Manufacturer – Queries > Registration Planning and Tracking: <ul style="list-style-type: none"> • List of Manufacturers From Data Administration – Queries > Product 	Manufacturer Name	The uniqueness rule has been changed. Concatenation of the following values must be unique within the system: Manufacturer Name + Address Line 1 + Country Code
© Calyx™ 2023. Calyx.ai	Detail Management: <ul style="list-style-type: none"> • Application History Query • Application OC 	44	Calyx RIM 6.2 Release Notes Data Administration Tables: Calyx RIM 6.2

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Manufacturer Values	N/A	Country Code	The Country Code drop-down list is no longer presented on the <i>Create/Modify Manufacturer</i> attributes page.
Manufacturer Values	N/A	Organisation Identifier	The Data Administration > Product Detail Set Maintenance > Manufacturer Values attributes page has been enhanced by adding a new attribute named Organisation Identifier : <ul style="list-style-type: none"> Field Type: text, non-mandatory Field Size: 250 characters Database Field Size: VARCHAR2(500)

Data Administration Section Name: Product Family Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
ATC Values	N/A	RMS Term Name	To maintain the European Medicines Agency (EMA) Substance, Product, Organisation and Referential (SPOR) service, the ATC Values table has been updated with a new drop-down list named RMS Term Name . The active values from <i>SPOR Maintenance > ATC RMS Values</i> table are available for selection.

Data Administration Section Name: Product Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Applicable Standards Values	N/A	Applicable Standard	To maintain the version of standard, the Applicable Standards Values table has been updated to include the Version of Standard option.

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Country Specific Detail Type Values	Product > Country Specific Detail	Product > Country Specific Detail > Country Specific Detail Type	To maintain the specific detail type value of the country attribute, the Country Specific Detail Type Values table has been introduced. The Field Value Control drop-down list includes the options Controlled - Single Value , Controlled - Multiple Values , and User Entered .
Country Specific Detail Values	Product > Country Specific Detail	N/A	<ul style="list-style-type: none"> Country Specific Detail Type - All active Country Specific Detail Types are displayed. Countries - A multi select field displaying all active countries. Country Specific Value - This value is defined for the detail type when Field Value Control is set to Controlled in the Country Specific Detail Type. The field is hidden when Field Value Control is set to User Entered. The Country Specific Detail Value must be unique within the Country Specific Detail Type.
Dosage/ Pharmaceutical Form Values	N/A	RMS Term Name	To maintain the European Medicines Agency (EMA) Substance, Product, Organisation and Referential (SPOR) service, the Dosage/Pharmaceutical Form Values table has been updated with a new drop-down list named RMS Term Name . The active values from SPOR Maintenance > Dosage/ Pharmaceutical Form RMS Values table are available for selection.
Device Classification Values	N/A	N/A	This table has been removed.
FDA Regulation Number Values	N/A	N/A	This table has been removed.

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Global Medical Device Nomenclature (GMDN) Code Values	N/A	GMDN Term Name	To identify medical devices, the Global Medical Device Nomenclature (GMDN) Code option has been introduced. The values for the GMDN Code and GMDN Term Name can be entered in their respective text fields.
Medical Device Values	N/A	RMS Term Name	To maintain the European Medicines Agency (EMA) Substance, Product, Organisation and Referential (SPOR) service, the Medical Device Values table has been updated with a new drop-down list named RMS Term Name . The active values from SPOR Maintenance > Medical Device RMS Values table are available for selection.
Route of Administration Values	N/A	RMS Term Name	To maintain the European Medicines Agency (EMA) Substance, Product, Organisation and Referential (SPOR) service, the Route of Administration Values table has been updated with a new drop-down list named RMS Term Name . The active values from SPOR Maintenance > Route of Administration RMS Values table are available for selection.
Universal Medical Device Nomenclature System (UMDNS) Code Values	N/A	UMDNS Code Values	To identify, process, retrieve, transfer, and communicate data about medical devices, the UMDNS Code Values table has been introduced. The values for the UMDNS Code and UMDNS Description can be entered in their respective fields.

Data Administration Section Name: Registration Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
EMA Authorisation Status Values	N/A	RMS Term Name	To maintain the European Medicines Agency (EMA) Substance, Product, Organisation and Referential (SPOR) service, the EMA Authorisation Status Values table has been updated with a new drop-down list named RMS Term Name . The active values from SPOR Maintenance > EMA Authorisation Status RMS Values table are available for selection.
Medicinal Product Type Values	N/A	RMS Term Name	To maintain the European Medicines Agency (EMA) Substance, Product, Organisation and Referential (SPOR) service, the Medicinal Product Type Values table has been updated with a new drop-down list named RMS Term Name . The active values from SPOR Maintenance > Medicinal Product Type RMS Values table are available for selection.
Registration Status Values	N/A	Internal System Status	On the Registration Maintenance > Registration Status Values attributes page in Data Administration, the Internal System Status field has been enhanced by adding a new internal status named APPROVED .

Data Administration Section Name: SPOR Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
<ul style="list-style-type: none"> – ATC RMS Values – Compendial Designation/ Source RMS Values – Concentration Measure Type RMS Values – Country RMS Values – Denominator/ Numerator Unit RMS Values – Dosage/ Pharmaceutical Form RMS Values – EMA Authorisation Status RMS Values – Language RMS Values – Legal Basis RMS Values – Medical Device RMS Values – Medicinal Product Type RMS Values – Procedure Type RMS Values – Route of Administration RMS Values – Unit of Measure Prefix RMS Values 	<p>N/A</p>	<p>N/A</p>	<p>Calyx RIM 6.2 introduces the <i>SPOR Maintenance</i> section in Data Administration. This section is designed to maintain the European Medicines Agency (EMA) Substance, Product, Organisation and Referential (SPOR) service. According to the roadmap designed by EMA the SPOR support starts with an introduction of OMS (Organisations management service) and RMS (Referentials management service) components. The active values from SPOR Maintenance sections can be successfully selected and deselected in the corresponding sections in Data Administration:</p> <ul style="list-style-type: none"> – Application Maintenance > Country Values – Application Maintenance > Procedure Type Values – Other > Concentration Measure Type Values – Other > Denominator Unit Values – Other > Language Values – Other > Legal Basis Values – Other > Numerator Unit Values – Other > Unit of Measure Prefix Values – Product Detail Set Maintenance > Compendial Designation/Source Values – Product Family Maintenance > ATC Values – Product Maintenance > Dosage/ Pharmaceutical Form Values – Product Maintenance > Medical Device Values – Product Maintenance > Route of Administration Values – Registration Maintenance > EMA Authorisation Status Values – Registration Maintenance > Medicinal Product Type Values
<p>© Calyx™ 2023. Calyx.ai</p>		<p>49</p>	<p>Calyx RIM 6.2 Release Notes Data Administration Tables: Calyx RIM 6.2</p>

Data Administration Section Name: Workflow Management

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Workflow Management	Full Product Presentation	Available Entities	If configured, the Full Product Presentation entity is available for selection in the Available Entities multi-select list when updating a workflow in the <i>Workflow Management</i> section.

Entity Fields Added: Calyx RIM 6.2

The following tables describe new fields that were added to Calyx RIM 6.2.

Entities

Entity Name	Field Name	Field Type	Description	Business Rules
Full Product Presentation	Container or Pack Part	Text	The Container or Pack Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for The value. The database size of the field is VARCHAR2(500). For example: DrugLV, collapsible aluminium tube	N/A
	Countries	Multi-select list	All Package Set Countries available for selection. The field appears after the package set is selected in the Package Sets field.	For the application of National, Mutual Recognition (MRP) and Decentralised (DCP) Procedure types, the country of the parent Registration appears as selected by default.
	Device Part	Text	The Device Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500). For example: DrugLV, solution for injection in pre-filled pen (device Tradename)	N/A
	Flavour Part	Text	The Flavour Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500). For example: DrugLV for Children Strawberry	N/A
	Formulation Part	Text	The Formulation Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500). For example: DrugLV, sugar	N/A

Entity Name	Field Name	Field Type	Description	Business Rules
Package Set Registration	Legal Basis	Drop-down list	The legal basis for an authorisation of the product. The Registration Attributes > Entity History Query and Querying > Administration > Entity Audit Trail queries have been updated to display the correct values for the new Legal Basis field.	<p>All active values from Data Administration > Other > Legal Basis Values table are available for selection. The field is displayed for the Registration of a Package Set type only.</p> <p>The Registration > Legal Basis value is included to the XEVMPD Submission XML file instead of the Application > Legal Basis value, if:</p> <ul style="list-style-type: none"> — The field is populated with a value for both entities. — The Application > Legal Basis field is not populated with a value

Entity Name	Field Name	Field Type	Description	Business Rules
Product Detail Set	Local Route of Administration	Multi-select list	<p>With Calyx RIM 6.2, a new configured field named Local Route of Administration has been added to the PDS Attributes page for tracking country Route of Administration on PDS level.</p> <p>The values available for selection in the Local Route of Administration multi-select list are the values from Product > Product Route of Administration and Component > Component Route of Administration fields, displayed as a concatenation of those values. If multiple components are presented, then each Component Route of Administration value is included in the concatenation.</p> <p>For more information on how the Route of Administration is tracked for XEVMPD, see <i>XEVMPD Submission Wizard Data Collection Features</i>.</p> <p>The field data is tracked in the XEVMPD Audit pre-defined Analytics report. The value is displayed under the Pharmaceutical Product-Administration Route XEVMPD Entity. The InSight Entity Type for the field is PDS.</p>	<p>The Local Route of Administration field is hidden by default and can be enabled via the overrides. If configured, the multi-select list is displayed as empty by default.</p> <p>This field is not displayed on the PDS Template attributes page.</p>

Entity Name	Field Name	Field Type	Description	Business Rules
Task	Related Task Name	Text (populated automatically, non-modifiable)	<p>To provide the ability to identify the association between the parent Task and its Sub-Task, Calyx RIM 6.2 enhances the Task entity by adding a new field named Related Task Name. When a Task has an associated Sub-Task entity, the Related Task Name field for the Sub-Task will be automatically populated with the parent Task Name value.</p> <p>To support this enhancements, the following updates have been introduced:</p> <ul style="list-style-type: none"> — Several Registration Planning and Tracking reports have been updated. See <i>Query Fields Added: Calyx RIM 6.2</i>. — The Related Task Name column has been added to the Querying > Administration > Entity Audit Trail > Query table when querying for the Task entity. The value is not hyperlinked. — The Related Task Name column has been added to the Search Results page of the SEARCH functionality when invoked for the Tasks/Sub-tasks option. 	<p>The Related Task Name field value is hyperlinked. When selected, navigates you to the appropriate Task Attributes page.</p> <p>The Related Task Name field will always be empty for the parent Task entity.</p>

Wizards

Wizard Name	Field Name	Field Type	Description	Business Rules
Copy Package Set Registration	Country	Drop-down list	<p>For MRP (Mutual Recognition Procedure) and DCP (Decentralised Procedure) Application types, the <i>Copy Package Set Registration</i> wizard now provides the ability to select the country to copy the Package Set Registration while proceeding with the wizard pages.</p> <p>The <i>Copy Package Set Registration</i> wizard is updated with a new drop-down list named Country that appears on the following wizard pages:</p> <ul style="list-style-type: none"> – New Package Set specific Registration(s) > Select Product Detail Set page – New Product specific Registration(s) > Copy License Code page <p>The Country drop-down list is a required field. All Countries associated to the Application are available for selection. The field is populated by default with the Country value from the source Registration.</p>	The Package Sets will be available only if the country selected in the Country drop-down list already has the assigned Registration.

Wizard Name	Field Name	Field Type	Description	Business Rules
Global Project Plan	Application Type	Multi-select list	<p>To enhance the Global Project Plan wizard, the Application Type multi-select field has been added as an additional filter criterion. The following Global Project Plan wizard pages have been updated by adding the Application Type column:</p> <ul style="list-style-type: none"> – Create New Events Package Set Registration > Search by Product, Country and Application Status page – Create New Events Product Registration > Search Country and Application Status page – Update Product Detail Sets > Input Query Filter Criteria page, when searching by: <ul style="list-style-type: none"> • Active Ingredient • PDS Code/PDS Name • Product and Country • Substance • Trade Name – Withdraw Product Package Set Registration > Search by Product, Country Application and PDS Statuses page 	The Application Type multi-select field depends on the selected countries and appears only after the selection is made in the Countries multi-select field.

Query Fields Added: Calyx RIM 6.2

The following table describes fields that were added with Calyx RIM 6.2.

Table 1: Administration Queries

Query Name	Field Name	Field Type	Description	Business Rules
Entity Audit Trail When querying for the Task entity.	Related Task Name	Text	The name of the parent Task, if applicable. The reports have also been updated to add a new column named Related Task Name to the <i>Search Results</i> page.	The value in the column is hyperlinked. When selected, navigates you to the appropriate <i>Task Attributes</i> page.

Table 2: Product Detail Management Queries

Query Name	Field Name	Field Type	Description	Business Rules
List of Application Countries with Registration and Product Details	Applications with Withdrawn Countries	Drop-down list	<p>A non-required drop-down list with the following values available for selection:</p> <ul style="list-style-type: none"> – [Select] – Yes – No <p>The [Select] value is set by default.</p> <p>The query results depend on the value selected in the Applications with Withdrawn Countries drop-down list, as well as all other selected search criteria.</p>	<p>The following rules apply:</p> <ul style="list-style-type: none"> – If you select Yes, all applications and all associated countries are displayed on the Query Results page if at least one of those countries has a Withdrawn Date value populated. – If you select No, all applications and all associated countries are displayed on the Query Results page if those countries are not withdrawn. – If you do not make a selection and leave the default [Select] value, all applications and all associated countries are displayed.

Table 3: Registration Planning and Tracking Queries

Query Name	Field Name	Field Type	Description	Business Rules
List of Application Countries	Applications with Withdrawn Countries	Drop-down list	<p>A non-required drop-down list with the following values available for selection:</p> <ul style="list-style-type: none"> – [Select] – Yes – No <p>The [Select] value is set by default.</p> <p>The query results depend on the value selected in the Applications with Withdrawn Countries drop-down list, as well as all other selected search criteria.</p>	<p>The following rules apply:</p> <ul style="list-style-type: none"> – If you select Yes, all applications and all associated countries are displayed on the <i>Query Results</i> page if at least one of those countries has a Withdrawn Date value populated. – If you select No, all applications and all associated countries are displayed on the <i>Query Results</i> page if those countries are not withdrawn. – If you do not make a selection and leave the default [Select] value, all applications and all associated countries are displayed.

Query Name	Field Name	Field Type	Description	Business Rules
List of Application Countries with Registration Details	Applications with Withdrawn Countries	Drop-down list	<p>A non-required drop-down list with the following values available for selection:</p> <ul style="list-style-type: none"> – [Select] – Yes – No <p>The [Select] value is set by default.</p> <p>The query results depend on the value selected in the Applications with Withdrawn Countries drop-down list, as well as all other selected search criteria.</p>	<p>The following rules apply:</p> <ul style="list-style-type: none"> – If you select Yes, all applications and all associated countries are displayed on the <i>Query Results</i> page if at least one of those countries has a Withdrawn Date value populated. – If you select No, all applications and all associated countries are displayed on the <i>Query Results</i> page if those countries are not withdrawn. – If you do not make a selection and leave the default [Select] value, all applications and all associated countries are displayed.
List of Tasks List of Tasks - Rollup by Application List of Tasks - Rollup by Product Family List of Tasks - Rollup by Project	Related Task Name (enter parent Task/ Sub-Task name if any)	Text	<p>The name of the parent Task, if applicable. The reports have also been updated to add a new column named Related Task Name to the <i>Search Results</i> page.</p>	<p>The value in the column is hyperlinked. When selected, navigates you to the appropriate <i>Task Attributes</i> page.</p>

Entity Fields Updated: Calyx RIM 6.2

The following table describes fields that were updated or removed with Calyx RIM 6.2.

Entities

Entity Name	Field Name	Field Type	Description	Business Rules
Application	Application Status	Drop-down list	Starting with Calyx RIM 6.2, the Application Status of an Application can be set to Withdrawn only when all Registrations associated to this Application have a status mapped to internal WITHDRAWN status.	<p>The following wizards have been updated to reflect this enhancement:</p> <ul style="list-style-type: none"> – Update Status – Update Event-Country Status <p>If you set Associations Closed As to <code>WITHDRAWN</code>, the Application Status will be set to Withdrawn only when all Registrations associated to this Application have a status mapped to internal WITHDRAWN status. Otherwise, the warning message appears !</p> <p>Associated Registration(s) must be Withdrawn prior to the Application.</p>

Entity Name	Field Name	Field Type	Description	Business Rules
Application Country	Withdraw Date	Date	<p>When an Event is closed as Approved and the PDS associated to this Event has a withdrawn Country Detail, displayed as Country (Pending Withdrawal), the parent Application Country > Withdraw Date field is automatically updated to be equal to Event > Closed Date field value. The following explains specific conditions that governs the Application Country > Withdraw Date field change:</p> <ul style="list-style-type: none"> – If Application Country does not have the Withdraw Date value and the Event is closed with today's date, -1 day (or more) before today's date, or +1 after today's date, then the Application Country > Withdraw Date inherits the Event > Event Closed Date value. – If Application Country has the Withdraw Date field set to today's date and the Event is closed with -1 day (or more) before today's date, or +1 day after today's date, then the Application Country > Withdraw Date inherits the Event > Event Closed Date value. – If Application Country has the Withdraw Date field set to a date greater than +2 days (or more) after today's date and the Event is closed with today's date, -1 day (or more) 	<p>The Application Country > Withdraw Date is not updated, if:</p> <ul style="list-style-type: none"> – The Application Country > Withdraw Date value precedes the Event > Event Closed Date value and both dates are in the past. – The Event > Event Closed Date value is equal to Event > Event Closed Date value. – The Event > Event Closed Date is set to today's date -1 day and the Event > Event Closed Date is set to today's date.
© Calyx™ 2023. Calyx.ai			82	Calyx RIM 6.2 Release Notes Entity Fields Updated: Calyx RIM 6.2

Entity Name	Field Name	Field Type	Description	Business Rules
Comparator	Suppliers	Multi-select list	The Manufacturer Name value is now displayed as a concatenation of Manufacturer Name + Address Line 1 + Country Code.	No updates to the business rules.
Full Product Presentation	Full Product Presentation Comments	Display	The field has been enhanced to be a display-only field that includes the previously added comments. Can be updated or deleted from the <i>View Full Product Presentation Attributes</i> page.	Available on the <i>View/Modify Full Product Presentation Attributes</i> pages. Includes all comments entered by users, including the date and time the comments were entered, and the user ID of the person who entered them.
	MPID	Text	The unique identifier allocated to a Medicinal Product supplementary to any existing authorization number as ascribed by a Medicines Regulatory Agency in a jurisdiction.	The MPID field has been hidden on the <i>Full Product Presentation View, Create and Modify</i> pages. Important: The MPID values are displayed in the Entity Audit Trial report for the Full Product Presentation entity.
	Previous EV Code	N/A	The Previous EV Code drop-down list has been reworked to be the <i>FPP Previous EV Codes</i> tab on the <i>Full Product Presentation Attributes</i> page. <ul style="list-style-type: none"> — Field Type: text, required — Field Size: 60 characters — Database Field Size: VARCHAR2(100) 	If there are several Previous EV Code values, in the XEVMPD XML file that results in several <previousevcode> tags.

Entity Name	Field Name	Field Type	Description	Business Rules
Event	Comment	Text	The field has been renamed to be Event Add Comment .	Only the field display name has been changed.
	Countries	Multi-select list	Business rules for the Countries field on the <i>Create Event</i> page have been changed.	Withdrawn application countries with the Withdraw Date value equal to today's date or earlier are not available for selection in the Countries multi-select field on the <i>Create Event</i> page. This is applicable only to applications of Mutual Recognition (MRP) or Decentralised Procedure (DCP) types.
	Event Closed As	Multi-select list	The field has been renamed as Associations Closed As .	Only the field name has changed. The following pages, tables, and tabs have also been updated to display Associations Closed As column name: <ul style="list-style-type: none"> – Home Page > Events table – Application > Events tab – Project > Event Change Details tab – <i>View Comparator</i> page – <i>View Clinical Trial Shared Data</i> page
	Event Closed Date	Date	The field has been renamed as Closed Date : <ul style="list-style-type: none"> – <i>View Event Attributes</i> page for the closed events. – <i>Modify Event Attributes</i> page, if the Closed checkbox is selected. 	Only the field name has changed. The following pages, tables, and tabs have also been updated to display Closed Date column name: <ul style="list-style-type: none"> – Home Page > Events table – Application > Events tab – Project > Event Change Details tab – <i>View Comparator</i> page – <i>View Clinical Trial Shared Data</i> page

Entity Name	Field Name	Field Type	Description	Business Rules
Pharmaceutical Product	Add Pharmaceutical Product Comment	Text	The field has been renamed to be Pharmaceutical Product Add Comment.	Only the field display name has been changed.

Entity Name	Field Name	Field Type	Description	Business Rules
Product	Add Product Comment	Text	The field has been renamed to be Product Add Comment .	Only the field display name has been changed.
	Product Strength Measure 1	Numeric	<p>Product Strength Measure 1 field has been enhanced to display a leading zero value for the decimal numbers that are less than 1 on the <i>View Product Attributes</i> page for the:</p> <ul style="list-style-type: none"> – Pharmaceutical Product Family – Flu Vaccine Product Family – Pharmaceutical-Medical Device Product Family – Veterinary Product Family <p>For example, if you are entering 0.1 value in the Product Strength Measure 1 field, it will be displayed in the Product Attributes > Product Strength field including the leading zero, and followed by the Product Strength Unit 1 value, if any:</p> <p>0.1 mg</p>	The business rules for the field have been enhanced. The entered value must not exceed 5 decimal numbers before the decimal point and 5 decimal numbers after the decimal point. Value cannot be larger than 99999.99999.
	Product Strength Measure 2	Numeric	<p>Product Strength Measure 2 field has been enhanced to display a leading zero value for the decimal numbers that are less than 1 on the <i>View Product Attributes</i> page for the:</p> <ul style="list-style-type: none"> – Pharmaceutical Product Family – Flu Vaccine Product Family – Pharmaceutical-Medical Device Product Family 	The business rules for the field have been enhanced. The entered value must not exceed 5 decimal numbers before the decimal point and 5 decimal numbers after the decimal point. Value cannot be larger than 99999.99999.
© Calyx™ 2023. Calyx.ai			<ul style="list-style-type: none"> – Pharmaceutical-Medical Device Product Family 	<p>Calyx RIM 6.2 Release Notes Entity Fields Updated: Calyx RIM 6.2</p>

Entity Name	Field Name	Field Type	Description	Business Rules
Product Detail Set	Specialty Number	Text	This value is a part of <code>mrpnumber</code> for XEVMPD. The field has been renamed to be Specialty Number .	The concatenation formula is: [Procedure Identifier/ Application Code] [Specialty Number1]'-'[Specialty Number2], if there are two PDSs associated to the Full Product Presentation and the Specialty Number2 value is different from Specialty Number1 value.
	Manufacturer	Drop-down list	<p>The Manufacturer Name value is now displayed as a concatenation of <code>Manufacturer Name + Address Line 1 + Country Code</code> in the Manufacturer drop-down list for each instance of the Manufacturer Detail in the Product Detail Set:</p> <ul style="list-style-type: none"> – Component > Active Ingredient > Manufacturer – Component > Active Ingredient > Manufacturing Process > Function > Manufacturer – Component > Substance > Manufacturer – Component > Substance > Manufacturing Process > Function > Manufacturer – Component > Manufacturing Process > Function > Manufacturer – Component > Function > Manufacturer – PDS > Manufacturing Process > Function > Manufacturer – Package Set > Function > Manufacturer – Package Set > 	All active values from the Data Administration > Product Detail Set Maintenance > Manufacturer Values table are available for selection.

Entity Name	Field Name	Field Type	Description	Business Rules
Project	Project Pivot Status	Drop-down list	<p>With Calyx RIM 6.2, the following are updated with a new PLANNED status available for selection:</p> <ul style="list-style-type: none"> – Project Pivot Status drop-down field on the <i>Create/Modify Project Attributes</i> page. – Enter Project Pivot Values > Project Pivot Status drop-down field of the <i>Calculate Projected Dates</i> wizard (Global Project Plan wizard). 	N/A
Registration	License Comments	Text	The field name has been renamed to be License Add Comment .	Only the field display name has been changed.
	Country	Drop-down list	<p>Business rules for the Country field on the <i>Create Registration</i> page have been changed for the:</p> <ul style="list-style-type: none"> – Package Set Registration – Product Registration 	Withdrawn application countries with the Withdraw Date value equal to today's date or earlier are not available for selection in the Country drop-down list on the <i>Create Registration</i> page. This is applicable only to applications of Mutual Recognition (MRP) or Decentralised Procedure (DCP) types.

Entity Name	Field Name	Field Type	Description	Business Rules
Registration Attachment	Attachment Name	Text	Using XML overrides, Calyx RIM 6.2 can be configured to disable the autopopulate function for the Attachment Name field.	Only applicable if the Attachment file is uploaded from the DMS Repository.
	Attachment Version	Text	Using XML overrides, Calyx RIM 6.2 can be configured to disable the autopopulate function for the Attachment Version field.	Only applicable if the Attachment file is uploaded from the Documentum DMS Repository.
	File Name	Text	Using XML overrides, Calyx RIM 6.2 can be configured to disable the autopopulate function for the File Name field.	Only applicable if the Attachment file is uploaded from the DMS Repository.
	File Type	Drop-down list	Using XML overrides, Calyx RIM 6.2 system can be configured to disable the autopopulate function for the File Type field.	Only applicable if the Attachment file is uploaded from the DMS Repository.

Entity Name	Field Name	Field Type	Description	Business Rules
Registration FPP Attachment	Attachment Comments	Text	The field has been renamed to be Registration FPP Attachment Comments .	Available for modifications on the <i>Create/Modify Registration FPP Attachment Attributes</i> pages.
	Attachment Concerned Parties	Text	The field has been renamed to be Registration FPP Attachment Concerned Parties .	Only the field display name has been changed.
	Attachment Name	Selection list	The field has been reworked to be a Selection list on the <i>Create Registration FPP Attachment Name</i> page. The system returns the results after clicking the Select icon next to the Attachment Name > Selected box. The selected Registration Attachment will be displayed in the Attachment Name > Selected box in the concatenation of four fields: Internal Name, Attachment Language, Attachment Name, Attachment Version.	Only one Registration Attachment can be selected. The <i>search results</i> page displays all <i>Active</i> Registration Attachments available in the system. Important: The registration attachments, already associated to the current Full Product Presentation, are not displayed.
	Application Procedure Type	Display		N/A (attribute is removed)
	Authorisation Status	Display	The status of the authorisation of a medicinal product.	N/A (attribute is removed)
	Authorised Pharmaceutical Form	Display	The pharmaceutical form of the product.	N/A (attribute is removed)
	Language	Display		N/A (attribute is removed)
	Product Form	Display	The physical form in which this product is produced and dispensed.	N/A (attribute is removed)
	Product Strength	Display	The value used to define the product strength.	N/A (attribute is removed)
	Withdrawn/Invalidated	Display	The date of expiry of the marketing authorisation.	N/A (attribute is removed)

Entity Name	Field Name	Field Type	Description	Business Rules
Sequence	Concerned Member States	Multi-select list	Business rules for the Concerned Member States field on the <i>Create Sequence</i> page have been changed.	Withdrawn application countries with the Withdraw Date value equal to today's date or earlier are not available for selection in the Concerned Member States multi-select field on the <i>Create Sequence</i> page.
	Sequence Comments	Text	The field has been renamed to be Sequence Add Comment .	Only the field display name has been changed.
Task (Sub-Task)	Assigner	Drop-down list	Person responsible for creating the task. The business rules have been changed.	Only active users are available for selection. The inactive or disabled users are omitted from the lists of available values.
	Premier Assignee	Drop-down list	Calyx RIM user that has been assigned to this task. The business rules have been changed.	
	Task Concerned Parties	Selection list	Contains email addresses and/or Calyx RIM User IDs for which Notifications can be sent. The business rules have been changed.	

Wizards

Wizard Name	Field Name	Field Type	Description	Business Rules
Change Submittal Status > Complete Submission Status Properties	Confirmed Sequence Code	Text	Calyx RIM 6.2 enhances the logic of determining the Confirmed Sequence Code value in the <i>Change Submittal Status</i> wizard. The Confirmed Sequence Code value is determined based on the number of sequences that have been submitted to this application lifecycle, and now considers all previously submitted sequences.	All previously submitted sequences are taken into account, even if the current Sequence Status is set to Approved.
Create Submission wizard > Initial Application > Complete Submission Properties (event/sequence)	Event Type	Drop-down list	The Event Type field is now available for modifications.	The drop-down list displays all Active values from Data Administration > Event Maintenance > Event Type Values . The New Application value is selected by default in the Event Type field.

Wizard Name	Field Name	Field Type	Description	Business Rules
Find > Activities > View Activities List	Entity Type	Drop-down list	The Find > Activities functionality, available on the Calyx RIM Home Page, has been enhanced and now provides an ability to find the activities associated with the XEVMPD-related entities. The Entity Type drop-down list available on the View Activities List page is updated with a new entity type named XEVMPD.	<p>When XEVMPD is selected in the Entity Type drop-down list, the following list of filters is displayed on the View Activities List page:</p> <ul style="list-style-type: none"> — Entity Type Specific Filters: <ul style="list-style-type: none"> • Product Family Type • Product Family Name • PSet Registration — Common Filters: <ul style="list-style-type: none"> • Assigned User (multi-select list) • Assigned User (text field) <p>The following columns are available on the Search Results page:</p> <ul style="list-style-type: none"> — Activity name — Assigned User — Related Workflow — Related Entity — Parent Entity (The Parent entity for all activities of XEVMPD type is the corresponding Full Product Presentation) — Due Date — Priority — Paused

Wizard Name	Field Name	Field Type	Description	Business Rules
Global Project Plan > Add Manufacturer: <ul style="list-style-type: none"> – Add Active Ingredient Manufacturer flow – Add Active Ingredient Manufacturing Process Function Manufacturer flow – Add Substance Manufacturer flow – Add Substance Manufacturing Process Function Manufacturer flow – Add Component Function Manufacturer flow – Add Component Manufacturing Process Function Manufacturer flow – Add PDS Function Manufacturer flow – Add PDS Manufacturing Process Function Manufacturer flow – Add Package Set Function Manufacturer flow – Add Package Set Packaging Manufacturer flow – Add Package Set Component Packaging Manufacturer flow 	Manufacturer	Drop-down list	The Manufacturer Name value is now displayed as a concatenation of Manufacturer Name + Address Line 1 + Country Code.	No updates to the business rules.

Wizard Name	Field Name	Field Type	Description	Business Rules
Project > Event Country Dates > Update Project Event Country Status, if the Close Event? drop-down field is set to Yes	Event Closed As	Multi-select list	The field has been renamed as Associations Closed As.	<p>Only the field name has changed.</p> <p>The following pages, tables, and tabs have also been updated to display Associations Closed As column name:</p> <ul style="list-style-type: none"> – Home Page > Events table – Application > Events tab – Project > Event Change Details tab – <i>View Comparator</i> page – <i>View Clinical Trial Shared Data</i> page
	Event Closed Date	Date	The field has been renamed as Closed Date.	<p>Only the field name has changed.</p> <p>The following pages, tables, and tabs have also been updated to display Closed Date column name:</p> <ul style="list-style-type: none"> – Home Page > Events table – Application > Events tab – Project > Event Change Details tab – <i>View Comparator</i> page – <i>View Clinical Trial Shared Data</i> page

Wizard Name	Field Name	Field Type	Description	Business Rules
Update Status > Update Event Country Status page, if the Close Event? drop-down field is set to Yes	Event Closed As	Multi-select list	The field has been renamed as Associations Closed As.	<p>Only the field name has changed.</p> <p>The following pages, tables, and tabs have also been updated to display Associations Closed As column name:</p> <ul style="list-style-type: none"> – Home Page > Events table – Application > Events tab – Project > Event Change Details tab – View Comparator page – View Clinical Trial Shared Data page
	Event Closed Date	Date	The field has been renamed as Closed Date.	<p>Only the field name has changed.</p> <p>The following pages, tables, and tabs have also been updated to display Closed Date column name:</p> <ul style="list-style-type: none"> – Home Page > Events table – Application > Events tab – Project > Event Change Details tab – View Comparator page – View Clinical Trial Shared Data page
XEVMPD Submission > Select Sender/Receiver Information page	Run Initial Report?	Drop-down list	The Initial Report option has been hidden in the XEVMPD Submission wizard. The Run Initial Report? drop-down has been hidden on the Select Sender/Receiver Information page.	The Initial Report Selection and Initial Report Selection Results pages that appeared when the Run Initial Report? drop-down field was set to Yes, has been hidden in the wizard.

Query Fields Updated: Calyx RIM 6.2

The following table describes fields that were updated or removed with Calyx RIM 6.2.

Table 4: Administration Queries

Query Name	Field Name	Field Type	Description	Business Rules
Entity Audit Trail	Manufacturer Name	N/A	The Manufacturer Name value is now displayed as a concatenation of <code>Manufacturer Name + Address Line 1 + Country Code</code> in the Search Results > Manufacturer Name column for the Manufacturer-related subqueries.	No updates to the business rules.

Table 5: Product Detail Management Queries

Query Name	Field Name	Field Type	Description	Business Rules
Application History Query	Event Closed As	Multi-select list	The field has been renamed as Associations Closed As .	<p>Only the field name has changed.</p> <p>The following pages, tables, and tabs have also been updated to display Associations Closed As column name:</p> <ul style="list-style-type: none"> – Home Page > Events table – Application > Events tab – Project > Event Change Details tab – <i>View Comparator</i> page – <i>View Clinical Trial Shared Data</i> page
	Event Closed Date	Date	The field has been renamed as Closed Date .	<p>Only the field name has changed.</p> <p>The following pages, tables, and tabs have also been updated to display Closed Date column name:</p> <ul style="list-style-type: none"> – Home Page > Events table – Application > Events tab – Project > Event Change Details tab – <i>View Comparator</i> page – <i>View Clinical Trial Shared Data</i> page
	Manufacturer Name	N/A	The Manufacturer Name value is now displayed as a concatenation of <code>Manufacturer Name + Address Line 1 + Country Code</code> in the Search Results > Manufacturer Name column for the Manufacturer-related subqueries.	No updates to the business rules.
© Calyx™ 2023. Calyx.ai	N/A	N/A	The following column names	N/A

Query Name	Field Name	Field Type	Description	Business Rules
Application QC Status History Report	Event Closed As	Multi-select list	The field has been renamed as Associations Closed As .	<p>Only the field name has changed.</p> <p>The following pages, tables, and tabs have also been updated to display Associations Closed As column name:</p> <ul style="list-style-type: none"> — Home Page > Events table — Application > Events tab — Project > Event Change Details tab — <i>View Comparator</i> page — <i>View Clinical Trial Shared Data</i> page
	Event Closed Date	Date	The field has been renamed as Closed Date .	<p>Only the field name has changed.</p> <p>The following pages, tables, and tabs have also been updated to display Closed Date column name:</p> <ul style="list-style-type: none"> — Home Page > Events table — Application > Events tab — Project > Event Change Details tab — <i>View Comparator</i> page — <i>View Clinical Trial Shared Data</i> page
	Manufacturer Name	N/A	The Manufacturer Name value is now displayed as a concatenation of <code>Manufacturer Name + Address Line 1 + Country Code</code> in the Search Results > Manufacturer Name column for the Manufacturer-related subqueries.	No updates to the business rules.

Query Name	Field Name	Field Type	Description	Business Rules
	N/A	N/A	The following column names have been changed in the <i>Substance Details QC Passed?</i> subquery: <ul style="list-style-type: none"> – Excipient Role is renamed to Substance Role – Excipient Name to Substance Name 	N/A
List of Active Ingredient Function Manufacturers	Manufacturer Name	Drop-down list	The Manufacturer Name value is now displayed as a concatenation of <code>Manufacturer Name + Address Line 1 + Country Code</code> in the Enter Search Criteria > Manufacturer Name multi-select list.	No updates to the business rules.
List of Active Ingredient Manufacturers	Manufacturer Name	Drop-down list	The Manufacturer Name value is now displayed as a concatenation of <code>Manufacturer Name + Address Line 1 + Country Code</code> in the Enter Search Criteria > Manufacturer Name multi-select list.	No updates to the business rules.
List of Active Ingredient Material Manufacturers	Manufacturer Name	Drop-down list	The Manufacturer Name value is now displayed as a concatenation of <code>Manufacturer Name + Address Line 1 + Country Code</code> in the Enter Search Criteria > Manufacturer Name multi-select list.	No updates to the business rules.

Query Name	Field Name	Field Type	Description	Business Rules
List of Component Manufacturers	Manufacturer Name	Drop-down list	The Manufacturer Name value is now displayed as a concatenation of <code>Manufacturer Name + Address Line 1 + Country Code</code> in the Enter Search Criteria > Manufacturer Name multi-select list.	No updates to the business rules.
List of Excipient Manufacturers	Manufacturer Name	Drop-down list	The Manufacturer Name value is now displayed as a concatenation of <code>Manufacturer Name + Address Line 1 + Country Code</code> in the Enter Search Criteria > Manufacturer Name multi-select list.	No updates to the business rules.
	Excipient Name	Selection list	The Excipient Name multi-select list has been renamed to be Substance Role . The following column names have been changed: <ul style="list-style-type: none"> – Excipient Role is renamed to Substance Role – Excipient Name to Substance Name 	N/A
List of Package Set Manufacturers	Manufacturer Name	Drop-down list	The Manufacturer Name value is now displayed as a concatenation of <code>Manufacturer Name + Address Line 1 + Country Code</code> in the Enter Search Criteria > Manufacturer Name multi-select list.	No updates to the business rules.

Query Name	Field Name	Field Type	Description	Business Rules
List of PDS Manufacturers	Manufacturer Name	Drop-down list	The Manufacturer Name value is now displayed as a concatenation of <code>Manufacturer Name + Address Line 1 + Country Code</code> in the Enter Search Criteria > Manufacturer Name multi-select list.	No updates to the business rules.

Query Name	Field Name	Field Type	Description	Business Rules
List of Product Detail Sets	Event Closed As	Multi-select list	The field has been renamed as Associations Closed As .	<p>Only the field name has changed.</p> <p>The following pages, tables, and tabs have also been updated to display Associations Closed As column name:</p> <ul style="list-style-type: none"> – Home Page > Events table – Application > Events tab – Project > Event Change Details tab – <i>View Comparator</i> page – <i>View Clinical Trial Shared Data</i> page
	Event Closed Date	Date	The field has been renamed as Closed Date .	<p>Only the field name has changed.</p> <p>The following pages, tables, and tabs have also been updated to display Closed Date column name:</p> <ul style="list-style-type: none"> – Home Page > Events table – Application > Events tab – Project > Event Change Details tab – <i>View Comparator</i> page – <i>View Clinical Trial Shared Data</i> page

Query Name	Field Name	Field Type	Description	Business Rules
List of Registrations with Excipients	Excipient Name	Selection list	The following field names and column names have been changed: <ul style="list-style-type: none"> – Excipient Role is renamed to Substance Role – Excipient Name to Substance Name 	N/A
	Excipient Role	Multi-select list		

Table 6: Registered Document Analysis Queries

Query Name	Field Name	Field Type	Description	Business Rules
Registered Document Query	Event Closed As	Multi-select list	The field has been renamed as Associations Closed As .	Only the field name has changed. The following pages, tables, and tabs have also been updated to display Associations Closed As column name: <ul style="list-style-type: none"> – Home Page > Events table – Application > Events tab – Project > Event Change Details tab – <i>View Comparator</i> page – <i>View Clinical Trial Shared Data</i> page
	Event Closed Date	Date	The field has been renamed as Closed Date .	Only the field name has changed. The following pages, tables, and tabs have also been updated to display Closed Date column name: <ul style="list-style-type: none"> – Home Page > Events table – Application > Events tab – Project > Event Change Details tab – <i>View Comparator</i> page – <i>View Clinical Trial Shared Data</i> page

Table 7: Registration Planning and Tracking Queries

Query Name	Field Name	Field Type	Description	Business Rules
List of Applications with Products	Application Name/Study Number	Text	Application Name field has been renamed as Application Name/Study Number.	The Application Name/Study Number field is displayed on the <i>List of Applications with the Products Query search criteria selection</i> page and appears as a column on the <i>Search Results</i> page.
	Applicable Standards	Multi-select list	The Applicable Standards value is now displayed as a concatenation of Applicable Standards Name - version in the Applicable Standards multi-select list. <i>Note: The hyphen is excluded when the version field is blank.</i>	No updates to the business rules.
	Application Type	Multi-select list	Business rules for the field have been changed.	All application types are now available for selection in the Application Type multi-select list.
	EU Class	Drop-down list	This field has been removed.	N/A
	EU Classification Rule	Drop-down list	This field has been removed.	N/A
	FDA Device Class	Drop-down list	This field has been removed.	N/A
	FDA Regulation Number	Drop-down list	This field has been removed.	N/A
	Global Medical Device Nomenclature (GMDN) Code	Multi-select list	The Global Medical Device Nomenclature (GMDN) Code value is now displayed as a concatenation of GMDN Code - GMDN Term Name in the Global Medical Device	No updates to the business rules.

Query Name	Field Name	Field Type	Description	Business Rules
List of Events with Application Properties	Event Closed As	Multi-select list	The field has been renamed as Associations Closed As.	<p>Only the field name has changed.</p> <p>The following pages, tables, and tabs have also been updated to display Associations Closed As column name:</p> <ul style="list-style-type: none"> – Home Page > Events table – Application > Events tab – Project > Event Change Details tab – <i>View Comparator</i> page – <i>View Clinical Trial Shared Data</i> page
	Event Closed Date	Date	The field has been renamed as Closed Date.	<p>Only the field name has changed.</p> <p>The following pages, tables, and tabs have also been updated to display Closed Date column name:</p> <ul style="list-style-type: none"> – Home Page > Events table – Application > Events tab – Project > Event Change Details tab – <i>View Comparator</i> page – <i>View Clinical Trial Shared Data</i> page

Query Name	Field Name	Field Type	Description	Business Rules
List of Manufacturers From Data Administration	Manufacturer Name	Text	The Manufacturer Name value is now displayed as a concatenation of <code>Manufacturer Name + Address Line 1 + Country Code</code> in the Search Results > Manufacturer Name column.	No updates to the business rules.

Query Name	Field Name	Field Type	Description	Business Rules
List of Medical Device Products	Applicable Standards	Multi-select list	The Applicable Standards value is now displayed as a concatenation of <code>Applicable Standards Name - version</code> in the Applicable Standards multi-select list. <i>Note: The hyphen is excluded when the version field is blank.</i>	No updates to the business rules.
	EU Class	Drop-down list	This field has been removed.	N/A
	EU Classification Rule	Drop-down list	This field has been removed.	N/A
	FDA Device Class	Drop-down list	This field has been removed.	N/A
	FDA Regulation Number	Drop-down list	This field has been removed.	N/A
	Global Medical Device Nomenclature (GMDN) Code	Multi-select list	The Global Medical Device Nomenclature (GMDN) Code value is now displayed as a concatenation of <code>GMDN Code - GMDN Term Name</code> in the Global Medical Device Nomenclature (GMDN) Code multi-select list. <i>Note: The hyphen is excluded when the GMDN Term Name field is blank.</i>	No updates to the business rules.
	Medical Device Link/Listing	Text	This field has been removed.	N/A
	UMDNS Code	Multi-select list	The UMDNS Code value is now displayed as a concatenation of <code>UMDNS Code - UMDNS Description</code> in the UMDNS Code multi-select list.	No updates to the business rules.

Query Name	Field Name	Field Type	Description	Business Rules
List of Medical Device Products and Components	Applicable Standards	Multi-select list	The Applicable Standards value is now displayed as a concatenation of <code>Applicable Standards Name - version</code> in the Applicable Standards multi-select list. <i>Note: The hyphen is excluded when the version field is blank.</i>	No updates to the business rules.
	EU Class	Drop-down list	This field has been removed.	N/A
	EU Classification Rule	Drop-down list	This field has been removed.	N/A
	FDA Device Class	Drop-down list	This field has been removed.	N/A
	FDA Regulation Number	Drop-down list	This field has been removed.	N/A
	Global Medical Device Nomenclature (GMDN) Code	Multi-select list	The Global Medical Device Nomenclature (GMDN) Code value is now displayed as a concatenation of <code>GMDN Code - GMDN Term Name</code> in the Global Medical Device Nomenclature (GMDN) Code multi-select list. <i>Note: The hyphen is excluded when the GMDN Term Name field is blank.</i>	No updates to the business rules.
	Medical Device Link/Listing	Text	This field has been removed.	N/A
	UMDNS Code	Multi-select list	The UMDNS Code value is now displayed as a concatenation of <code>UMDNS Code - UMDNS Description</code> in the UMDNS Code multi-select list	No updates to the business rules.

Query Name	Field Name	Field Type	Description	Business Rules
List of Pharmaceutical and Medical Device Products	Applicable Standards	Multi-select list	The Applicable Standards value is now displayed as a concatenation of <code>Applicable Standards Name - version</code> in the Applicable Standards multi-select list. <i>Note: The hyphen is excluded when the version field is blank.</i>	No updates to the business rules.
	EU Class	Drop-down list	This field has been removed.	N/A
	EU Classification Rule	Drop-down list	This field has been removed.	N/A
	FDA Device Class	Drop-down list	This field has been removed.	N/A
	FDA Regulation Number	Drop-down list	This field has been removed.	N/A
	Global Medical Device Nomenclature (GMDN) Code	Multi-select list	The Global Medical Device Nomenclature (GMDN) Code value is now displayed as a concatenation of <code>GMDN Code - GMDN Term Name</code> in the Global Medical Device Nomenclature (GMDN) Code multi-select list. <i>Note: The hyphen is excluded when the GMDN Term Name field is blank.</i>	No updates to the business rules.
	Medical Device Link/Listing	Text	This field has been removed.	N/A
	UMDNS Code	Multi-select list	The UMDNS Code value is now displayed as a concatenation of <code>UMDNS Code - UMDNS Description</code> in the UMDNS Code multi-select list	No updates to the business rules.

Query Name	Field Name	Field Type	Description	Business Rules
List of Pharmaceutical and Medical Device Products and Components	Applicable Standards	Multi-select list	The Applicable Standards value is now displayed as a concatenation of <code>Applicable Standards Name - version</code> in the Applicable Standards multi-select list. <i>Note: The hyphen is excluded when the version field is blank.</i>	No updates to the business rules.
	EU Class	Drop-down list	This field has been removed.	N/A
	EU Classification Rule	Drop-down list	This field has been removed.	N/A
	FDA Device Class	Drop-down list	This field has been removed.	N/A
	FDA Regulation Number	Drop-down list	This field has been removed.	N/A
	Global Medical Device Nomenclature (GMDN) Code	Multi-select list	The Global Medical Device Nomenclature (GMDN) Code value is now displayed as a concatenation of <code>GMDN Code - GMDN Term Name</code> in the Global Medical Device Nomenclature (GMDN) Code multi-select list. <i>Note: The hyphen is excluded when the GMDN Term Name field is blank.</i>	No updates to the business rules.
	Medical Device Link/Listing	Text	This field has been removed.	N/A
	UMDNS Code	Multi-select list	The UMDNS Code value is now displayed as a concatenation of <code>UMDNS Code - UMDNS Description</code> in the UMDNS Code multi-select list	No updates to the business rules.

Query Name	Field Name	Field Type	Description	Business Rules
List of Product Families	Product Family Name	Multi-select list	The Product Family Name field has been reworked to be a multi-select list instead of a text field in the List of Product Families query.	This change enables the active ingredients in the <i>Substance Selection</i> list to be filtered according to their association to the selected product families.

Query Name	Field Name	Field Type	Description	Business Rules
List of Products with Event and Product Registration Details	Event Closed As	Multi-select list	The field has been renamed as Associations Closed As.	<p>Only the field name has changed.</p> <p>The following pages, tables, and tabs have also been updated to display Associations Closed As column name:</p> <ul style="list-style-type: none"> – Home Page > Events table – Application > Events tab – Project > Event Change Details tab – <i>View Comparator</i> page – <i>View Clinical Trial Shared Data</i> page
	Event Closed Date	Date	The field has been renamed as Closed Date.	<p>Only the field name has changed.</p> <p>The following pages, tables, and tabs have also been updated to display Closed Date column name:</p> <ul style="list-style-type: none"> – Home Page > Events table – Application > Events tab – Project > Event Change Details tab – <i>View Comparator</i> page – <i>View Clinical Trial Shared Data</i> page

Query Name	Field Name	Field Type	Description	Business Rules
List of Sequences with Application and Event Properties	Event Closed As	Multi-select list	The field has been renamed as Associations Closed As.	<p>Only the field name has changed.</p> <p>The following pages, tables, and tabs have also been updated to display Associations Closed As column name:</p> <ul style="list-style-type: none"> – Home Page > Events table – Application > Events tab – Project > Event Change Details tab – <i>View Comparator</i> page – <i>View Clinical Trial Shared Data</i> page
	Event Closed Date	Date	The field has been renamed as Closed Date.	<p>Only the field name has changed.</p> <p>The following pages, tables, and tabs have also been updated to display Closed Date column name:</p> <ul style="list-style-type: none"> – Home Page > Events table – Application > Events tab – Project > Event Change Details tab – <i>View Comparator</i> page – <i>View Clinical Trial Shared Data</i> page

Table 8: Entity History Queries

Entity Name	Field Name	Field Type	Description	Business Rules
Event	Event Closed As	Multi-select list	<p>The field has been renamed as Associations Closed As:</p> <ul style="list-style-type: none"> – <i>View Event Attributes</i> page for the closed events. – <i>Modify Event Attributes</i> page, if the Closed checkbox is selected. 	<p>Only the field name has changed.</p> <p>The following pages, tables, and tabs have also been updated to display Associations Closed As column name:</p> <ul style="list-style-type: none"> – Home Page > Events table – Application > Events tab – Project > Event Change Details tab – <i>View Comparator</i> page – <i>View Clinical Trial Shared Data</i> page
	Event Closed Date	Date	<p>The field has been renamed as Closed Date.</p>	<p>Only the field name has changed.</p> <p>The following pages, tables, and tabs have also been updated to display Closed Date column name:</p> <ul style="list-style-type: none"> – Home Page > Events table – Application > Events tab – Project > Event Change Details tab – <i>View Comparator</i> page – <i>View Clinical Trial Shared Data</i> page

Entity Name	Field Name	Field Type	Description	Business Rules
Product	Applicable Standards	Multi-select list	The Applicable Standards value is now displayed as a concatenation of <code>Applicable Standards Name - version</code> in the Applicable Standards multi-select list. <i>Note: The hyphen is excluded when the version field is blank.</i>	No updates to the business rules.
	EU Class	Drop-down list	This field has been removed.	N/A
	EU Classification Rule	Drop-down list	This field has been removed.	N/A
	FDA Device Class	Drop-down list	This field has been removed.	N/A
	FDA Regulation Number	Drop-down list	This field has been removed.	N/A
	Global Medical Device Nomenclature (GMDN) Code	Multi-select list	The Global Medical Device Nomenclature (GMDN) Code value is now displayed as a concatenation of <code>GMDN Code - GMDN Term Name</code> in the Global Medical Device Nomenclature (GMDN) Code multi-select list. <i>Note: The hyphen is excluded when the GMDN Term Name field is blank.</i>	No updates to the business rules.
	Medical Device Link/Listing	Text	This field has been removed.	N/A
	UMDNS Code	Multi-select list	The UMDNS Code value is now displayed as a concatenation of <code>UMDNS Code - UMDNS Description</code> in the UMDNS Code multi-select list.	No updates to the business rules.

Database Columns Changed: Calyx RIM 6.2

The following database columns were added or changed in Calyx RIM 6.2.

Field Name	Field Size	Database Column Name	Database Column Size	Database Table Name
N/A	N/A	ABSOLUTE_SEQ_NO	NUMBER(10) has been changed to NUMBER	<ul style="list-style-type: none"> – ODS.TOC_ENTRY – AUD.TOC_ENTRY
N/A	N/A	ASSIGNEE_LDAP_IDENTIFIER	VARCHAR2(100) has been changed to VARCHAR2(500)	WF_LOG

Resolved Issues: Calyx RIM 6.2

The following issues that were reported to Technical Support have been resolved.

Issues are listed in descending order by their internal tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets [#####] following the internal tracking number.

Calyx RIM 6.2 resolves the following issues.

Issue	Build	Hotfix Build	Description
25738	6.2.0.0.0296	N/A	Some internal Calyx RIM processes may have caused issues that resulted in the Status 500 error pages appearing in the user interface. However, those issues were recorded as a <code>SQLException: Protocol violation</code> message in the <code>server.log</code> file. This issue is resolved by upgrading the Oracle JDBC driver to be fully compatible with the Oracle 12.2.0.1 version.

Issue	Build	Hotfix Build	Description
25726	6.2.0.0.0296	N/A	<p>For MRP (Mutual Recognition Procedure) and DCP (Decentralised Procedure) Application types, the <i>Copy Package Set Registrations</i> wizard did not provide the ability to select the country to copy the Package Set Registration while proceeding with the wizard pages. This issue is resolved. The <i>Copy Package Set Registrations</i> wizard has been updated with a new drop-down list named Country that appears on the following wizard pages for the MRP and DCP Application types:</p> <ul style="list-style-type: none"> – New Package Set specific Registration(s) > Select Package Set(s) page – New Product specific Registration(s) > Copy License Code page
25667, 25352, 24982; [00057163, 00053947, 00049818, 00052494]	6.2.0.0.0296	N/A	<p>When you selected an Applicant Contact for the 1 Administrative Information folder in US eCTD Module 1 assembly template (v3.3), the Search and Sort functions did not work in the <i>Select Applicant Contact</i> list. This issue is resolved. The mechanism for data sorting and filtering has been improved. The correct results are now displayed when the Search, Sort, or Filter options are applied.</p>
25622; [00056776]	6.2.0.0.0296	N/A	<p>When you had one Registration with several Product Detail Sets assigned to it, and one assigned Full Product Presentation where Active Ingredient and Substance are identical, after the <i>XEVMPD Submission</i> wizard was completed you received an XML file with one tag for the same Active Ingredient and one tag for the same Substance without duplicating data. However, for the same Indication/Intended Use and Indication value the generated XML file contained duplicate tags. This issue is resolved. One Indication/Intended Use value is present in the generated XML file when the same Indication/Intended Use Detail (non-Veterinary Product Detail Sets), or Indication Detail (Veterinary Product Detail Sets) is associated to several Product Detail Sets that are associated to one Full Product Presentation via Package Sets.</p>

Issue	Build	Hotfix Build	Description
25605 [00056656]	6.2.0.0.0296	N/A	After an event was updated from a workflow, the list of products was not displayed in the Products tab under that Event. This issue is resolved. All associated products are displayed in the Products tab.
25561, 25535 [00056173, 00055825]	6.2.0.0.0296	<ul style="list-style-type: none"> – 25561 - 6.1.0.3.0115 – 25535 - 6.1.0.3.0111 	When a multi-select extra field had more than one value and was included in a workflow, not all values were displayed for the field on the Activity page. This issue is resolved. The mechanism of processing the custom multi-select fields is improved to handle fields that contain multiple values.
25557; [00056104]	6.2.0.0.0296	6.1.0.3.0115	When attempting to save changes to a Product Family through a workflow, the error message <code>Cannot modify active ingredients on a Product Family that has associated Products</code> was generated. This issue is resolved. The appropriate validation process is improved and the Product Family can now be updated through a workflow.
25554; [00055924]	6.2.0.0.0296	N/A	When creating and associating a PDS using a Product Detail Set template, clicking the Save button more than once resulted in the PDS appearing to be associated with an Event multiple times. This issue is resolved.
25551, 25381; [00056031; 00054223]	6.2.0.0.0296	6.1.0.3.0120	<p>When assigning an Activity or a Task to a user with a User Name containing a comma (,) character, the following appeared:</p> <ul style="list-style-type: none"> – The assigned Activity was not displayed in the My Activities tab invoked from GO TO > Activities or Navigation Pane > Activities. – The Task Alert was not displayed in the Alert Center on the Calyx RIM Home Page. <p>The system could not correctly interact with a database because the comma character was not included in the list of allowed special characters that can be processed during the execution of certain operations. This issue is resolved. The system has been updated to add the comma character to the list of allowed special characters that can be processed by the system.</p>

Issue	Build	Hotfix Build	Description
25546; [00055951]	6.2.0.0.0296	6.1.0.3.0117	Due to the Internet Explorer one hour time out, the XEVMPD Audit Report was not returning data and was not responding in an acceptable time limit. This issue is resolved. The Calyx RIM 6.2 release improves performance of the XEVMPD Audit Report functionality.
25542; [00055861]	6.2.0.0.0296	N/A	When modifying a closed event, setting the Event Closed As field to [Select] and trying to save changes caused an invalid reference exception to appear and the event itself to become unavailable through any navigation paths. This issue is resolved. A new warning message is displayed stating that Event Closed As is a required field and must be specified prior to saving the changes.
25541; [00055826]	6.2.0.0.0296	6.1.0.3.0111	When completing an activity that required selecting a user field where the distinguished name was greater than 100 characters, the following error message was generated: " <code>! Exception while executing event-listener</code> ". This issue is resolved by allowing for distinguished name values up to 255 characters long.
25539; [00055840]	6.2.0.0.0296	N/A	When statuses are deleted from the Event-Country Attributes > Status Dates tab, the system should update both Actual Date and Projected Date attributes to have the Null value in the database. However only the ACTUAL_DATE (Actual Date) database value was updated correctly and the SCHED_DATE (Projected Date) value stayed unchanged. This issue is resolved. When the status is deleted, the ACTUAL_DATE and SCHED_DATE values are updated to have Null value in the event_country_status_schedule database table.
25538, 25495; [00052193, 00058004, 00056979, 00055469]	6.2.0.0.0296	N/A	There were performance issues observed when expanding the Assembly Tree nodes. The performance of expanding the nodes in the assembly tree and refreshing the expanded assembly tree has been improved. For more information on the new version of the assembly tree see <i>Working with New Assembly Tree..</i>

Issue	Build	Hotfix Build	Description
25536; [00055812]	6.2.0.0.0296	6.1.0.3.0116	<p>A deadlock occurred in Calyx RIM when several workflow actions were performed when a long-running transaction (for example, lifecycle event) was in progress. When the workflow Activiti engine inserts a new row in a table in the Activiti schema, it uses an internal <code>DbIdGenerator</code> to generate the next ID value. The <code>DbIdGenerator</code> has a setting for <code>idBlockSize</code> that determines how many IDs to distribute before going back to the database for the next block.</p> <p>When a long-running transaction requested a new ID block, and then another transaction requested a new ID block before the first long-running transaction was committed, a deadlock occurred. This release reduces the possibility of a deadlock by increasing the default block size from 2,500 to 50,000. Also, this release enables the default block size value to be configurable by adding the following setting in the <code>insight.var</code> file specifying the appropriate block size:</p> <pre>— activiti.blockSize=50000</pre> <hr/> <p>Note: 50000 is a default size.</p> <hr/>
25526; [00055788]	6.2.0.0.0296	N/A	<p>The <code>Yes</code> value set in the Publishing Settings Library > Default Values for the Use Native File attribute was not inherited by the leaf elements created automatically by associating documents with the folders. This issue is resolved. When the leaf is automatically created, the value set for the Use Native File attribute in the Publishing Settings Library is preserved.</p>
25516; [00055405]	6.2.0.0.0296	6.1.0.3.0117	<p>Updating the Publishing Settings to add or remove a DTD sometimes took much longer in Calyx RIM 6.2 compared to previous versions. This release improves the performance by causing Oracle to choose a better execution plan when updating Publishing Settings to add or remove a DTD.</p>

Issue	Build	Hotfix Build	Description
25511; [00055024]	6.2.0.0.0296	N/A	<p>In the <i>Global Project Plan</i> wizard, the manufacturers available for selection in the Manufacturer drop-down list were displayed in a random order for the following Update Product Detail Set Project > Add Manufacturer flows:</p> <ul style="list-style-type: none"> – Add Active Ingredient Manufacturer – Add Active Ingredient Manufacturing Process Function Manufacturer – Add Substance Manufacturer – Add PDS Function Manufacturer <p>This issue is resolved. The sorting mechanism has been added to display the Manufacturer values in the Manufacturer drop-down list in alphabetical order.</p>
25510; [00055531, 00057192]	6.2.0.0.0296	N/A	<p>For the following listed queries, the <i>Substance Selection</i> list (Search Criteria > Active Ingredient Name > Select) displayed all Active Ingredients from the Data Administration > Product Family Maintenance > Substance Values table:</p> <ul style="list-style-type: none"> – Product Detail Management > List of Active Ingredient Manufacturers – Product Detail Management > List of Active Ingredient Function Manufacturers – Product Detail Management > List of Active Ingredient Material Manufacturers – Product Detail Management > List of Registrations with Active Ingredients – Registration Planning and Tracking > List of Product Families <p>In Calyx RIM 6.2, the <i>Substance Selection</i> list was reworked to display only Active Ingredients associated to the product families selected in the Product Family/ Product Family Name multi-select list.</p>
25508; [00055608]	6.2.0.0.0296	6.1.0.3.0111	<p>In Calyx RIM for Analytics, the XEVMPD Audit Report returned duplicated results when a product was associated with more than one application. This issue is resolved.</p>

Issue	Build	Hotfix Build	Description
25501, 25464; [00054523, 00054500, 00055108, 00054523]	6.2.0.0.0296	N/A	Performance issues were observed when the <i>Ready for Submission wizard</i> retargeted Reference Leafs for the entire Working View after the Assembly Plan was merged. This could cause the job to fail and the Source leaf cannot be a reference leaf error message to appear in the Job Details. The performance issue is resolved. The retargeting reference leafs system function is improved. The job is successfully completed and no error messages are displayed in the Job Details when the <i>Ready for Submission wizard</i> is finished.
25484; [00055433]	6.2.0.0.0296	6.1.0.3.0115	Volumes were created with blank names if the Assembly was volumized out of order. This issue is resolved. The mechanism of identifying the sibling volumes during the Bulk Volumization by Sheets operation has been improved.
25483; [00055072]	6.2.0.0.0296	6.1.0.3.0100	When in the Working View with Try New Version of an assembly tree option selected, using drag and drop to replace a document in a leaf with NEW status resulted in the leaf status not being automatically updated to REPLACE. This issue is resolved. The assign DMS nodes function is improved to refresh the assembly tree when the assign action is completed.
25481; [00055174]	6.2.0.0.0296	N/A	When requesting a DMS Synchronization from the Publishing View, all nodes from previous sequences were processed and that could take an extended period of time to complete. This issue is resolved. The performance of DMS Synchronization invoked from the Publishing View has been improved.
25475; [00054686]	6.2.0.0.0296	6.1.0.4.0041	Attempting to generate a volume TOC resulted in a Failed to resolve TocEntry Name error in the Job Requests window. The error ORA-01438: value larger than specified precision allowed for this column was also seen in the server.log.file. This issue is resolved. The precision constraint in the ods.toc_entry.absolute_seq_no column has been removed.
25469	6.2.0.0.0296		Attempting to delete a Dose Schedule PDS Detail resulted in an error. This issue is resolved.

Issue	Build	Hotfix Build	Description
25465	6.2.0.0.0296	6.1.0.3.0100	In Calyx RIM 6.1, an update trigger on the content table was modified to not create entries if the update was due to a renumbering event. The trigger, however, denoted updates to the content table as inserts instead of updates. The database script included with this release corrects the trigger and repairs affected data.
25461; [00055117]	6.2.0.0.0296	N/A	For the Canadian eCTD Module 1 v2.2, entering invalid numeric-only value for the Sequence Description field caused an <code>UndeclaredThrowableException</code> error message to appear in the publish Job Details. This issue is resolved. The revised message explains that numeric-only values are not supported for the Sequence Description field, and is displayed when you try to save the metadata.
25460; [00055109]	6.2.0.0.0296	N/A	When creating a New (Empty) Standalone Assembly, or a Standalone Assembly from an Assembly File using the New > Standalone Assembly option, the following fields were displayed as non-required: <ul style="list-style-type: none"> – Publishing Settings Library – Use Source Assembly Publishing Settings Library Saving those Standalone Assemblies without making any selections in the listed fields caused warning messages to appear. <p>This issue is resolved. The fields are followed by an asterisk (*) indicating that they are required.</p>
25457; [00055111, 00054917]	6.2.0.0.0296	N/A	In the unlocked Submitted View of an assembly you were unable to remove empty folders using the Delete icon on the <i>Folder Attributes</i> , if the Try New Version of an assembly tree option was selected. This issue is resolved. Now you can delete empty folders in the new version of an assembly tree.
25440; [00055119]	6.2.0.0.0296	6.1.0.4.0041	When creating a Working Assembly using the Create eCTD wizard, the error <code>ORA-00932: inconsistent datatypes: expected NUMBER got BINARY</code> occurred if the checkbox Update the sub-folder structure for was selected. This issue is resolved. The Create eCTD wizard can be finished successfully without displaying any errors.

Issue	Build	Hotfix Build	Description
25434; [00054636]	6.2.0.0.0296	N/A	When you selected the Create Missing Renditions and Extractions option for a PDF document with PDF Exists value set to <i>Yes</i> and Extractions Exist value set to <i>No</i> , the job was completed. However, the following message was displayed in the <i>Job Requests</i> details page: <i>No document to render</i> . This issue is resolved. An additional verification has been added for the <i>Prepare to Publish</i> . The system checks the Extractions Exist flag of a source document and the functionality now works as designed.

Issue	Build	Hotfix Build	Description
25422	6.2.0.0.0296	N/A	<p>The following columns that display data related to Substance PDS Detail child entities were missing from the Product Detail Management > Application History and Product Detail Management > Application QC Status History queries:</p> <ul style="list-style-type: none"> — Application History Query: <ul style="list-style-type: none"> • Substance Manufacturing Process Details Changed? • Substance Manufacturing Process Function Details Changed? • Substance Manufacturing Process Function Manufacturer Details Changed? • Substance Manufacturing Process Step Details Changed? • Substance Manufacturing Process Step Function Details Changed? • Substance Manufacturing Process Step Function Manufacturer Details Changed? • Substance Material Details Changed? • Substance Material Manufacturer Details Changed? — Application QC Status History Report: <ul style="list-style-type: none"> • Substance Manufacturing Process Details QC Passed? • Substance Manufacturing Process Function Details QC Passed? • Substance Manufacturing Process Function Manufacturer Details QC Passed? • Substance Manufacturing Process Step Details QC Passed? • Substance Manufacturing Process Step Function Details QC Passed? • Substance Manufacturing Process Step Function Manufacturer Details QC Passed? • Substance Material Details QC Passed? • Substance Material Manufacturer Details QC Passed? <p>This issue is resolved. The appropriate values are now available for selection in the Display Columns multi-select field on the Application History Query > Enter Search Criteria and Application QC Status History Report > Enter Search Criteria pages. The appropriate columns appear on the Search Results page of both queries for the Substance PDS Detail related entities, when those columns are selected. The value presented in each of the columns is a hyperlink to the specific subreport.</p>

Issue	Build	Hotfix Build	Description
25414; [00054605]	6.2.0.0.0296	6.1.0.4.0041	The <code>FLASHBACK_TIME=SYSTIMESTAMP</code> parameter was added to the <code>expdp</code> commands in the <code>dpexportinsight.sql</code> to keep all exported tables synchronised to the same point of time.
25410; [00055170, 00054235]	6.2.0.0.0296	6.1.0.3.0099	For US grouped submissions, the order of M1 metadata unintentionally affected whether or not the primary application was listed first in the published <code>us-regional.xml</code> . This issue is resolved. The primary application is always listed first in the <code>regional.xml</code> .
25405; [00054019]	6.2.0.0.0296	6.1.0.3.0093	For US eCTD v2.01 submissions: When using the <i>Import eCTD to Application</i> wizard (Import from eCTD icon on the Application attributes page) to import several sequences having 1.14.1.X subfolders introduced non-sequentially in different sequences, the nodes were not ordered numerically in the submitted view created by the import process. This issue is resolved.
25401; [00053089]	6.2.0.0.0296	6.1.0.3.0100	When the Rendition Identifier for an assembly document without a custom rendition was set to a non-standard value and the Use Standard Rendition option was selected for Missing Rendition Identifier Handling in Publishing Settings , Linking plug-in (PDF) was allowing you to create links in the standard rendition of the document instead of displaying an error as expected. This issue is resolved.
25395; [00054382]	6.2.0.0.0296	6.1.0.3.0092	When Calyx RIM attempted to create a <code>DataExchangeExport</code> file with the exact same timestamp-inclusive file name as an already existing export file, the duplicate name file would not be created. This issue is resolved by adding milliseconds to the timestamp portion of the filename to avoid duplicates.
25391; [00054454, 00054327, 00053609]	6.2.0.0.0296	DB_hotfix6_1_0_chf3_0136.zip	ORA-01789 and ORA-00942 errors occurred during the Calyx RIM6.2 CHF 3 migration when the AUD table had an obsolete column that did not exist in the corresponding table in the ODS/MGR/SEC schema. This issue is resolved and is no longer presented when migrating to Calyx RIM 6.2 from the previous Calyx RIM versions. Also, the <code>RULE</code> hint is added to improve the migration performance.

Issue	Build	Hotfix Build	Description
25379; [00054093]	6.2.0.0.0296	6.1.0.3.0092	When a Document with a Rendition Identifier that had been assigned to a document by default was later updated in the Working View of the Assembly to have any other Rendition Identifier value from Data Administration > DMS Integration > Rendition Identifier Values table, the change was not displayed in the Publishing View of the Assembly. However, in the published output the rendition was set correctly. This issue is resolved. During the document create or update actions, the list of specific attributes are copied from the Working View of an Assembly to the Publishing View. To have the Rendition Identifier value in the list that is copied to the Publishing View of an Assembly, the missing RenditionModifierTypeId value has been added to the system Copy function.
25376; [00054015, 00053356]	6.2.0.0.0296	N/A	Performance issues were observed when the system processed leafs in a sequence assembly within one application, for example converting a standard leaf to be a reference leaf. To fix the performance issue, the query has been optimized.
25370; [00053016]	6.2.0.0.0296	6.1.0.3.0100	When the <code>jp-regional-index.xml</code> file was replaced in Sequence 0001 and again in Sequence 0002, the <code>index.xml</code> file for Sequence 0002 referenced the 0000 regional xml file as the modified file instead of the 0001 version. This issue is resolved. For Japanese submissions, the method of searching for the sequence with the latest updated content is improved.
25361; [00054034]	6.2.0.0.0296	6.0.0.6.0027	If a Product Detail Set (PDS) had multiple approved Package Set details with approved Packaging details, the Product Detail Management > List of Registrations with Packaging query displayed each package set on the <i>Search Results</i> page, however only one Package Set was assigned to the Registration. This issue is resolved. The query <i>Search Results</i> page now displays only Package Set details associated to the Registration.

Issue	Build	Hotfix Build	Description
25358; [00053900]	6.2.0.0.0296	N/A	<p>The Applicant Contact table for the US Module 1 eCTD v2.3 specification (DTD v3.3) Assembly > 1 Administrative Information folder displayed the Telephone and Email values as dimmed and unavailable, if:</p> <ul style="list-style-type: none"> There were several Contact Telephone Number values with different telephone number types, but identical telephone numbers, assigned and one of them had been deactivated later on the Data Administration > Submission Maintenance > Applicant Contact Values > Applicant Contact Telephone Number tab. There were several Contact Email values assigned and one of them had been deactivated later on the Data Administration > Submission Maintenance > Applicant Contact Values > Applicant Contact Email tab. <p>The issue is resolved:</p> <ul style="list-style-type: none"> For Contact Email, only the deactivated value is displayed as dimmed and unavailable. For the Contact Telephone Number, the system checks the unique combination of the Telephone Number Type and Telephone Number values and indicates only the deactivated value to be displayed as dimmed and unavailable.
25348; [00054367]	6.2.0.0.0296	6.1.0.3.0117	<p>In Calyx RIM 6.2, the queries related to the following areas have been optimized to reduce the possibility of database locks:</p> <ul style="list-style-type: none"> Getting Events under Application Actions with the XEVMPD change history DTD change for an Assembly <p>As part of this optimization, a new index has been added to the XEVMPD change history.</p>
25345; [00053849]	6.2.0.0.0296	DB_hotfix6_1_0_chf3_0137.zip	<p>The performance of the upgrade script that was used to migrate to Calyx RIM 6.1 CHF 3 has been improved. The DB_hotfix6_1_0_chf3_0137.zip upgrade script supercedes the DB_hotfix6_1_0_chf3_0136.zip upgrade script and must be used to migrate to Calyx RIM 6.1 CHF 3.</p>

Issue	Build	Hotfix Build	Description
25333	6.2.0.0.0296	N/A	When setting up a notification for Registration FPP Attachment and selecting the When a value changes option to display the notification in the <i>Alert Center</i> , the notification was triggered. However, the entity URL on the <i>Notification Attributes</i> page displayed incorrectly concatenated data: Internal Name, Country, Attachment Name, and Attachment Version. This issue is resolved. The URL is displayed as a concatenation of Internal Name, Language, Attachment Name, and Attachment Version.
25324	6.2.0.0.0296	N/A	It was not possible to re-target a link that was already targeted to a bookmark. This issue is resolved.
25322	6.2.0.0.0296	N/A	When creating a new assembly using either the <i>Existing Template, Assembly, or View</i> option, the OK button on the <i>Search Assembly Wizard</i> remained unavailable after selecting the matching assembly. This issue is resolved. The OK button becomes active after you select the matching assembly and then click on <i>Next</i> .
25312; [00058254]	6.2.0.0.0296	6.1.0.4.0047	Attempting to delete a link from the Link Inspector results failed with an error. This issue is resolved. No error message is displayed when you delete a link from the Link Inspector results.
25309; [00054064; 00053322]	6.2.0.0.0296	6.1.0.3.0092	Calyx RIM 6.2 introduces a fix for Calyx RIM for Analytics to decrease the amount of time needed to load the Manufacturer Report page with the selection criteria. To improve the report performance, the PDS Name filter criterion has been removed from the Manufacturer Report filter criteria selection page. The PDS Name column on the report <i>Search Results</i> page is preserved.
25308; [00053352]	6.2.0.0.0296	N/A	In the Calyx RIM 6.1 CHF 1 and Calyx RIM 6.1 CHF 2 upgrade scripts, passwords from the <code>define.migration</code> file were stored and displayed in the resulting <code>master.sql</code> log file. The Calyx RIM 6.2 upgrade script resolves this issue.

Issue	Build	Hotfix Build	Description
25299; [00053287]	6.2.0.0.0296	6.1.0.3.0093	When assigning Withdrawal Time Unit values to the Species > Route of Administration > Withdrawal Times PDS Detail during the creation of a PDS Template, the Withdrawal Time Unit drop-down list displayed values that had been deactivated in <i>Data Administration</i> . This issue is resolved. The system has been enhanced to add a filtering option to the Species > Route of Administration > Withdrawal Times > Withdrawal Time Unit field that excludes the inactive values from the list.
25272; [00052896]	6.2.0.0.0296	N/A	After applying the upgrade script, importing the assembly template into Calyx RIM for the first time caused the following error message to be displayed: <code>The object you are acting on has been deleted or modified by another user. Refresh your object to view the current information.</code> This issue is resolved.
25268; [00052092]	6.2.0.0.0296	6.1.0.3.0089	Running the <i>Update Status</i> wizard from a <i>Product Family Attributes</i> page resulted in the unintentional changing of the Reviewing Country value for an application, when there was more than one country assigned. This issue is resolved. The reviewing country stays unchanged after the <i>Update Status</i> wizard is finished.
25266; [00052934]	6.2.0.0.0296	6.1.0.3.0089	Using the <i>eCTD Import</i> wizard to import an assembly that had a node-extension folder with hundreds of child leaf nodes took many hours to complete. This issue is resolved by separating one large import transaction into multiple smaller import transactions.
25264; [00052928]	6.2.0.0.0296	N/A	The M1 folder disappeared completely from the Assembly Tree during expand attempt if there were any nodes that contained a hyphen (-) in the node name. This issue is resolved. This symbol is ignored in the New Assembly Tree. In addition, a specific script <code>replace_soft-hyphen_with_minus.zip</code> that is aimed to replace each instance of the hyphen across the Assembly Tree has been introduced. Please contact Technical Support for more information.

Issue	Build	Hotfix Build	Description
25246 [00052728]	6.2.0.0.0296	6.1.0.3.0092	<p>Values in drop-down lists on the following Add PDS Detail pages were being sorted in a case-sensitive manner.</p> <ul style="list-style-type: none"> — Add Active Ingredient > Active Ingredient drop-down list — Add Function > Function drop-down list — Add Manufacturer > Manufacturer drop-down list <p>This issue is resolved. The case of values is ignored during the sorting process.</p>
25245; [00052399]	6.2.0.0.0296	N/A	<p>Using the <i>Update Status</i> wizard for an Event with an associated Sequence caused an extra APPROVED Sequence status to appear in the <i>Status Dates</i> tab, when the Event was closed as WITHDRAWN or NOT APPROVED. This issue is resolved. The correct statuses are now displayed in the Sequence > Status Dates tab, when the <i>Update Status</i> wizard is passed.</p>
25221; [00052338]	6.2.0.0.0296	6.1.0.3.0093	<p>Running the <i>Bulk Update Events</i> wizard (launched from the <i>Project Attributes</i> page) when nothing was selected in the non-required Secondary Event Type field resulted in the Secondary Event Type values being cleared unintentionally for all applicable events. This issue is resolved. The Secondary Event Type values are preserved when the wizard is finished if this field has not been selected for modifications on the <i>Select Attributes to update</i> page of the wizard.</p>
25215; [00052305]	6.2.0.0.0296	N/A	<p>There was a performance issue in displaying a large quantity of users in Calyx RIM Security Administration. This issue is resolved:</p> <ul style="list-style-type: none"> — ISM.DV_USER view has been updated — ISM.R_SEC package has been updated — lv_rc line has been increased from VARCHAR2(4000) to VARCHAR2(32767)

Issue	Build	Hotfix Build	Description
25210; [00052191]	6.2.0.0.0296	N/A	<p>There was a performance issue when logging on to Calyx RIM for Analytics. This issue is resolved. The following has been updated:</p> <ul style="list-style-type: none"> – An index <code>X2USR</code> has been added to the <code>USR</code> table, <code>NAME</code> field – The <code>ISM.DV_USER_ACCESS_LEVEL</code> view has been updated
25209; [00053438, 00052279, 00052147, 00052137]	6.2.0.0.0296	hotfix6_1_0_chf1_0115.zip	<p>The following error occurred during the Calyx RIM 6.1 CHF 1 migration: <code>ORA-01555: snapshot too old</code></p> <p>This issue is resolved in the <code>DB_hotfix6_1_0_chf4_0024.zip</code> migration script that is used to migrate to Calyx RIM 6.1 CHF 4 from the previous Calyx RIM 6.1 CHFs. After performing the migration to Calyx RIM 6.1 CHF 4 and proceeding with the migration to Calyx RIM 6.2 using the appropriate migration script, no migration errors appear.</p>
25206; [00051373, 00052844]	6.2.0.0.0296	N/A	<p>If an assembly had been created from the existing Submitted View with the Retarget Copied Reference Leaf option selected, the following issues occurred:</p> <ul style="list-style-type: none"> – The Find Reference Leaf Elements option invoked on the Leaf element of the created assembly displayed the reference leaf elements of the copied submitted view. – The created assembly could not be deleted. <p>These issues are resolved:</p> <ul style="list-style-type: none"> – The Find Reference Leaf Elements option now displays the reference leaf elements of the current assembly. – The created assembly can be deleted.

Issue	Build	Hotfix Build	Description
25197; [00052103]	6.2.0.0.0296	<ul style="list-style-type: none"> – master.zip – hotfix6_1_0_chf1_0115.zip 	<p>Data copied from a field in the <code>MGR.Application.Term_Withdraw_Reason</code> table to a field in the new <code>MGR.Term_with_reason_type</code> table that was too small resulted in the following errors:</p> <ul style="list-style-type: none"> – <code>ORA12899: value too large for column</code> – <code>ORA-00001: unique constraint</code> <p>This issue is resolved in the <code>DB_hotfix6_1_0_chf4_0024.zip</code> migration script that is used to migrate to Calyx RIM 6.1 CHF 4 from the previous Calyx RIM 6.1 CHFs. After performing the migration to Calyx RIM 6.1 CHF 4 and proceeding with the migration to Calyx RIM 6.2 using the appropriate migration script, no migration errors appear.</p>
25182; [00051882]	6.2.0.0.0296	N/A	<p>The Apache Commons Collections library was vulnerable to insecure deserialisation of data, which could result in arbitrary code execution. To fix this issue, the Apache Commons Collections version 3.2.2 has been applied to the Calyx RIM 6.2 Application Server. The Apache Commons Collections library version 3.2.2 mitigates the vulnerability by disabling the insecure functionality.</p>
25158; [00051744]	6.2.0.0.0296	<ul style="list-style-type: none"> – InsightForAnalytics.zip 6.1.0.3.0013 (InsightForAnalytics-6.1-chf3-hf1.zip) – WFConfig.zip 6.1.0.3.0009 (WFConfig-6.1-chf3-hf1.zip) 	<p>The log on to the Calyx RIM for Analytics failed if the Display Name contained the ampersand (&) character. This issue is resolved by escaping the ampersand characters for Display Name value in the <code>wfsqlusers.fex</code> and <code>user_name.fex</code> files.</p>

Issue	Build	Hotfix Build	Description
25156	6.2.0.0.0296	6.1.0.2.0017	The error <code>ORA-02292: integrity constraint (ODS.R_789) violated - child record found</code> occurred when attempting to delete an application having a lifecycled assembly with a reference leaf. This issue is resolved.
25141; [00051550]	6.2.0.0.0296	6.1.0.3.0099	Attempting to import a Japanese submission having a <code>DELETE</code> operation in module 1 failed. This issue is resolved by updating the <code>xlink:href</code> attribute processing for the Leaf that has a <code>DELETE</code> status.
25140; [00051261]	6.2.0.0.0296	N/A	It was possible to delete a sequence with a working assembly that was created by another user, or in another tab. The Delete button on the <i>Sequence Attributes</i> page was enabled until the page was refreshed. This issue is resolved by adding an additional check to identify the presence of working assembly in the verifiable sequence. If the working assembly exists, the warning message is displayed.
25134; [00052137, 00051492, 00051212]	6.2.0.0.0296	hotfix6_1_0_chf1_0115.zip	<p>During the migration from Calyx RIM 5.1 to Calyx RIM 6.1 CHF 1 the issue of an empty GUID column for leaves and folders was observed. This issue resulted in the following errors:</p> <ul style="list-style-type: none"> — Error adding new not null constraint on FOLDER.GUID ORA-02296: cannot enable (ODS.) - null values found — Error adding new not null constraint on LEAF.GUID ORA-02296: cannot enable (ODS.) - null values found <p>This issue is resolved in the <code>DB_hotfix6_1_0_chf4_0024.zip</code> migration script that is used to migrate to Calyx RIM 6.1 CHF 4 from the previous Calyx RIM 6.1 CHFs. After performing the migration to Calyx RIM 6.1 CHF 4 and proceeding with the migration to Calyx RIM 6.2 using the appropriate migration script, no migration errors appear.</p>

Issue	Build	Hotfix Build	Description
25110, 25001; [00048772, 00049481, 00049976, 00050201, 00050749, 00051273, 00051803]	6.2.0.0.0296	<ul style="list-style-type: none"> – 25110 - 6.0.0.5.0004, 6.1.0.2.0017 – 25001 - 6.0.0.5.0004, 6.1.0.2.0017 	<p>In Calyx RIM 6.1, if the default styles were not overridden, all native links were processed with the style obtained from the default link settings profile. This resulted in performance degradation of the publishing process. This issue is resolved with Calyx RIM 6.2, the functionality is modified by not altering native links unless the target page of the link is no longer in the same file due to a the file being split, or if the profile is not the default profile.</p>
25091; [00049218]	6.2.0.0.0296	N/A	<p>When Prepare to Publish, or Publish, was executed for a submission with any assigned documents that contained Xref links, you could experience an <code>UndeclaredThrowableException</code> error. This error was caused by Xrefs that are no longer supported by Calyx RIM. This issue is resolved:</p> <ul style="list-style-type: none"> – Xrefs are ignored and the link annotations are not created in the PDF rendition. – All CDCXrefs in an in-process rendition, or PDF document, or rendition to be published, are always deleted. – CDCXrefs no longer cause the publish request to fail.
25085; [00051005]	6.2.0.0.0296	N/A	<p>When you created the Publishing Settings Library Template using the New > Publishing Settings Library Template option, one of the following issues occurred:</p> <ul style="list-style-type: none"> – Clicking Save after the session timeout, displayed the warning message: <code>You have already sent this request to the server. Please try again.</code> Clicking Save for the second time saved the entity. – Navigating to the New > Publishing Settings Library Template option after the session timeout opened the <i>Create Publishing Settings Library</i> page, with the Publishing Library Owner field set to guest. Filling the attributes and clicking Save saved the entity. <p>This issue is resolved. The system now does not allow you to save the Publishing Settings Library Template after the session timeout.</p>

Issue	Build	Hotfix Build	Description
25075; [00050986]	6.2.0.0.0296	N/A	Navigating to Calyx RIM for Analytics while logged on to the Calyx RIM system caused the wrong user name value to be sent to the Calyx RIM for Analytics server. This issue is resolved. The system now uses the correct user name value for the SSO (Single Sign On) to the Calyx RIM for Analytics system.
25070; [00052810, 00051949, 00051259, 00050874]	6.2.0.0.0296	6.1.0.3.0093	When a user session expired, a guest account with no privileges was assigned to the session. Any subsequent action resulted in the login page being displayed. However, if the user was still idle when the guest session expired, errors were generated and logged in the <code>server.log</code> file. This issue is resolved. Calyx RIM no longer attempts to save settings for the guest user when the guest user session expires.
25058; [00050726]	6.2.0.0.0296	6.1.0.2.0015	Inactive functions were available for selection when executing the <i>Add Active Ingredient Manufacturing Process Function Manufacturer</i> step in the Global Project Plan Wizard > Update a Product Detail Set Project flow. This issue is resolved. Only Active functions are available for selection.
25054; [00050668]	6.2.0.0.0296	N/A	In email notifications, the old application logo was displayed and the Calyx RIM Manager notification system was indicated as the sender. This issue is resolved. The sender name is updated and is displayed as Calyx RIM notification system. The application logo is replaced with the most current one.
25045; [00050172, 00052819]	6.2.0.0.0296	N/A	The system allowed you to disassociate the approved Product Detail Set (PDS) with a withdrawn Shelf Life/ Storage Condition detail from the Event, but the <code>ORA-02292: integrity constraint (MGR.R_732B) violated - child record found</code> error occurred. This issue is resolved. The system now does not allow the disassociation if there are data dependencies.

Issue	Build	Hotfix Build	Description
25014; [00050210]	6.2.0.0.0296	N/A	For sequence assemblies only, you could convert a leaf to be a reference leaf referencing itself, which violated the business rule that a leaf cannot reference itself. This issue is resolved. Now, if a user attempts to create a leaf referencing itself, the following error message is displayed: <code>A leaf cannot reference itself.</code>
25013; [00050091]	6.2.0.0.0296	N/A	When using the Recalculate Checksums option, the backbone files in the electronic output location were not updated if the electronic output location contained a normalized Application Code. Instead, new backbone files were published to the location which was 2 folders above the correct one, in case if during the normalization process the Application Code value was changed. This issue is resolved.
25002; [00050016]	6.2.0.0.0296	N/A	When creating a new assembly using <i>Creating Assembly from a Template, Assembly, or View option or Import Assembly Wizard</i> , data under the Sequence Assemblies tab was not appearing in a reasonable amount of time. This issue is resolved.
24959; [0004923, 00050581, 00051103]	6.2.0.0.0296	— 6.0.0.5.00 08 — 6.1.0.2.00 17	Long publishing time issues could occur due to Oracle choosing an inefficient execution plan for a particular query. This issue is resolved. The problematic query is rewritten to prohibit Oracle from choosing the inefficient execution plan.
24958; [00049474]	6.2.0.0.0296	N/A	When you opened the Assembly tab, a "Loading" message appeared but the operation was not completed in a reasonable amount of time for the <i>Assembly Attributes</i> page. However, the assembly tree and assembly tree elements were fully loaded and accessible. This issue is resolved.
24956; [00049263]	6.2.0.0.0296	N/A	When the <i>Bulk Update Events</i> wizard was invoked from the <i>Project Attributes</i> page, you could update the events with countries to which you had Read access. This issue is resolved. The <i>Select Events to Update</i> page now lists only events with countries, to which your access is set to at least Write .

Issue	Build	Hotfix Build	Description
24923; [00049174, 00049530]	6.2.0.0.0296	N/A	The 1.A.5 Comparison Table section in Thailand Module 1 Specification v1.0 had incorrect leaf output file name <code>comparison.pdf</code> . This issue is resolved. The leaf output file name is now appearing as <code>comparison-table.pdf</code> .
24896; [00048871, 00049238, 00024896, 00050205]	6.2.0.0.0296	N/A	When trying to extract a document with a bookmark that contained a non-Unicode character, the extract job was displayed as Completed . However, the Job Details contained an error with an exception, and the Assembly > Document Attributes had the Extract Exists field set to No. The issue with the job statuses is resolved. The correct status, Failed , is now displayed when a document is not extracted.
24891; [00047906]	6.2.0.0.0296	6.0.0.3.0037	Leafs and documents with names beginning with <code>stf-</code> were omitted during the eCTD Import process because the code interpreted all files located in study folders beginning with <code>stf-</code> as STF XML files. This issue is resolved.
24876; [00048681]	6.2.0.0.0296	6.0.0.3.0037	Attempting to remove a sequence from a lifecycle was not completing in a reasonable amount of time even after increasing the timeout value. The delay occurred due to the unnecessary calls to two queries. This issue is resolved.
24860; [00048499, 00054314]	6.2.0.0.0296	N/A	When using the eCTD Import process to import an assembly containing reference leafs that target leafs further down in the assembly tree, the reference leafs and target leafs were switched in the imported assembly. This issue is resolved for the region specific Module 1, and also Module 2, Module 3, Module 4, and Module 5 that are common for all regions.
24832; [00047932]	6.2.0.0.0296	<ul style="list-style-type: none"> – 5.1.0.5.0013 – 6.0.0.3.0034 	Using the <i>Import Assembly Wizard</i> to import an assembly with the option to retarget selected reference leafs sometimes resulted in an invalid reference error. This issue is resolved.
24800; [00047397]	6.2.0.0.0296	6.1.0.3.0092	For null values on sequence <code>ACTUAL_DATE</code> fields from <code>01-JAN-1901</code> to <code>01-JAN-1900</code> the default date is set to avoid issues with incorrect event statuses appearing after migrations that set the values to dates between those two values.

Issue	Build	Hotfix Build	Description
24704	6.2.0.0.0296	N/A	<p>The issue of incorrect display names for the Full Product Presentation and Registration FPP Attachment comment fields has been resolved:</p> <ul style="list-style-type: none"> – The Full Product Presentation Comments field has been reworked to be a display-only field on the <i>View Full Product Presentation Attributes</i> page. – The Full Product Presentation Add Comment field has been added to the <i>Create/Modify Full Product Presentation Attributes</i> pages. – The Attachment Comments field has been renamed to be Registration FPP Attachment Comments. <p>See <i>Fields Added: Calyx RIM 6.2</i> and <i>Fields Updated: Calyx RIM 6.2</i>.</p>
24703	6.2.0.0.0296	N/A	<p>The discussion thread related fields had the incorrect display names for the Product, Pharmaceutical Product, Event, Registration, and Sequence entities. This issue is resolved. To support the naming convention across the Calyx RIM system, the display names had been reworked to be:</p> <ul style="list-style-type: none"> – Product > Product Add Comment – Pharmaceutical Product > Pharmaceutical Product Add Comment – Event > Event Add Comment – Registration > Registration Add Comment – Sequence > Sequence Add Comment <p>See <i>Fields Updated: Calyx RIM 6.2</i>.</p>
24641	6.2.0.0.0296		<p>When trying to delete a Product Details Set (PDS) with the child details added under the Substance node, the Delete button appeared dimmed after those details with Approved or Not Approved status had been deleted. This meant that the PDS could not be deleted due to data dependencies. This issue is resolved. The Delete button is now available and the PDS can be deleted.</p>

Issue	Build	Hotfix Build	Description
24561	6.2.0.0.0296	N/A	The <i>Next Renewal Date</i> column on the <i>Registrations</i> tab was displayed incorrectly as <i>First Renewal Date</i> when you were navigating to it from the <i>Product Family Attributes</i> and <i>Product Attributes</i> pages. This issue is resolved. The column name is now displayed correctly for <i>Product Family Attributes</i> , <i>Product Attributes</i> , and <i>Application Attributes</i> pages.
24474; [00044014]	6.2.0.0.0296	N/A	A client reported a performance issue that appeared when changing the status to APPROVED for Event entities that were created as part of a migration. This issue has been resolved and is no longer reproducible on the latest Calyx RIM versions.
24422	6.2.0.0.0296	N/A	When using the Veeva DMS, an error occurred while attempting to bind a document to any label other than CURRENT. This issue is resolved. When the selected label is other than CURRENT, a warning message informs you that the document must be bound to a CURRENT label only.
24408; [00032393]	6.2.0.0.0296	N/A	The sorting for Manufacturer Details in the PDS tree was performed by the Manufacturer Status Date attribute. This issue is resolved. The Manufacturer Details are now sorted alphabetically.
22781; [00029737, 00044188]	6.2.0.0.0296	N/A	You were not able to modify the Active Ingredients field on the <i>Modify Product Family</i> page after the associated Product, that contained a Component, was deleted. This issue is resolved. Once the related Product along with its Component is deleted, the Active Ingredients field is displayed as a selection list and is available for modifications on the <i>Modify Product Family</i> page.
23690; [00051715, 00048203, 00047314]	6.2.0.0.0296	6.1.0.3.0084	Closing an event as Approved did not set the Application Status to Approved if the current Application Status value was Submitted. This issue is resolved.

Issue	Build	Hotfix Build	Description
22697; [00027525]	6.2.0.0.0296	N/A	When an Event was closed with a status of Withdrawn, all related Sequence Status Dates were changed to the withdrawn date. This issue is resolved. When an event is now closed, the Sequence will keep its status as well as the date for any sequence with a status of Approved, Not Approved, Submitted, or Withdrawn. If the Sequence status is Planned, it will be changed to Withdrawn.
22028; [198009FW]	6.2.0.0.0296	N/A	When changing the value in Product Family Type multiple selection field, refreshing of the <i>List of Product Families</i> page took several minutes. This issue occurred on all multiple selection fields across the system. This issue is resolved for Internet Explorer 11 and Google Chrome browsers.
20703; [144950FW, 00043370]	6.2.0.0.0296	N/A	You were not able to select multiple documents using the Shift and Ctrl keys and drag them within the assembly. This issue is resolved with the New Version of the Assembly Tree introduced in Calyx RIM 6.2.
18655	6.2.0.0.0296	N/A	Create eCTD wizard failed if many sets of metadata were applied. This issue has been resolved and is no longer reproducible on the latest Calyx RIM versions.

Calyx RIM 6.2 CHF 1 Release Notes

This document describes a certified hotfix (CHF) provided to improve Calyx RIM 6.2. In addition to enhanced features and functionality, Calyx RIM 6.2 CHF 1 resolves issues that were reported to Technical Support. Our hotfixes are cumulative packages applied to a named version of our software.

As a certified hotfix, these updates have undergone Quality Control regression testing, certifying the system works as expected. These changes will not create a new code branch, but will be identified by the updated build number on the existing codeline of each version affected, not a new release number.

Prerequisites

Calyx RIM 6.2 CHF 1 requires overrides updates. Please allow 6 to 8 weeks for XML overrides review and updates. For details, please contact your Business Development Representative to consult with our Client Enablement team.

To enable the drag-and-drop from Veeva DMS functionality, the appropriate configurations need to be done in the Internet Explorer browser. Please review the procedures in the LIQUENT InSight 6.2 CHF 1 Installation Guide topic *Internet Explorer: Enabling the Drag-and-Drop from Veeva DMS* and make sure that the necessary configurations are applied. If you experience any difficulties in configuring the Internet Explorer browser to enable the drag-and-drop functionality, please contact Technical Support.

The following conditions must exist for D2 Forms when created via Calyx RIM 6.2 CHF 1:

- All forms (Product Registration Form, Project Registration Form, Regulatory Application Registration Form, and Submission Registration Form) have `external_system_attribute` in the properties list.
- The flag for `external_system_attribute` is always set to **True**.
- The value for the `external_system_attribute` cannot be empty.
- All forms (Product Registration Form, Project Registration Form, Regulatory Application Registration Form, and Submission Registration Form) are currently created in **Active** status in D2 as the required fields in D2 SDK are either equal or subset of the required fields in Calyx RIM 6.2 for that entity.

Open Text Documentum D2 Integration

This release provides the ability to differentiate between procedure types on the forms in an OpenText Documentum D2 application.

Users will be able to uniquely identify the description fields on forms in OpenText Documentum D2 application.

The following D2 Data Dictionaries are no longer automatically synchronized with Data Administration entities, but can be synchronized via configuration files as needed:

- Application Procedure Type
- GMP Drug Product Manufacturer
- GMP Drug Substance Manufacturer

Data Administration

The **IDMP Internal Procedure Code** field has been renamed to **External System Procedure Type Code** in the **Data Administration > Application Maintenance > Procedure Type Values** attributes page. Calyx RIM 6.2 CHF 1 requires **External System Procedure Type Code** to be configured to be a required field via overrides, such as the `meta.overrides.xml` file.

See *Entity Fields Updated: Calyx RIM 6.2 CHF 1*.

Veeva DMS Support Enhancements

Calyx RIM 6.2 CHF 1 enables you to drag-and-drop documents directly from the Veeva Vault window to the assembly.

This release significantly reduces the number of API calls that Calyx RIM performs to get data from Veeva DMS. This may avoid errors occurring due to the number of calls exceeding the Veeva Burst API Count limit.

Veeva Objects Cache

When you use the Veeva DMS, the number of requests accepted by Veeva Vault from Calyx RIM and other integrated systems is limited by the Burst API Count value specific for each Veeva Vault. Calyx RIM 6.2 CHF 1 leverages the Veeva Bulk API calls with an internal cache. This will decrease the chance of encountering 5-minute API burst restrictions imposed by Veeva Vault. This enhancement reduces the chance of exceeding the number of API calls allowed within a Veeva Vault. The optimal cache lifetime depends on the following factors:

- Burst API Count value for the Veeva Vault (the higher the Veeva objects cache timeout value, the fewer API calls are made by Calyx RIM to Veeva)
- Keeping the data up-to date

You can change the default Veeva cache timeout that is set to 3 minutes to be any other integer value. See *Configuring the Veeva Cache Timeout Setting*.

The behavior of the following Document attributes has been changed to provide better Veeva calls consumption:

- Has Relations
- Owner

See *Entity Fields Updated: Calyx RIM 6.2 CHF 1*.

Calyx RIM for Analytics

There are no revisions or enhancements, and no new installation or upgrade instructions, for Calyx RIM for Analytics with this certified hotfix for Calyx RIM 6.2. If you are upgrading from a version earlier than Calyx RIM 6.2, please follow the instructions within the appropriate Calyx RIM version.

Data Administration Tables: Calyx RIM 6.2 CHF 1

The following Data Administration tables field was modified with Calyx RIM 6.2 CHF 1.

Data Administration Section: Application Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Procedure Type Values	N/A	External System Procedure Type Code	<p>The IDMP Internal Procedure Code field has been renamed to External System Procedure Type Code in the Data Administration > Application Maintenance > Procedure Type Values attributes page:</p> <ul style="list-style-type: none"> Field Type: drop-down list Values available for selection: CP, DCP, MRP, NATIONAL

Entity Fields Updated: Calyx RIM 6.2 CHF 1

The following table describes fields that were updated or removed with Calyx RIM 6.2 CHF 1.

Entity Name	Field Name	Field Type	Field/Update Description	Business Rules
Document	Owner	Text	The business rules for the field have been changed according to the Veeva Enhancements introduced with Calyx RIM 6.2 CHF 1 release.	The value for the Owner text field derives from the Veeva file. Instead of <code>owner__v</code> attribute, this value is now taken from the <code>created_by__v</code> attribute.
	Has Relations	Read-only		The Has Relations property is calculated according to the presence of associated Relation object(s) in the Documentum Docbase. For Veeva Document the Has Relations property set to Yes by default regardless of actual association.

List of Enhancements: Calyx RIM 6.2 CHF 1

Requested new features and enhancements are included in each release. The items are listed in descending order by their tracking numbers. Customer case numbers that were recorded when the enhancements were requested are included in brackets [#####] following the tracking number.

Calyx RIM 6.2 CHF 1 includes the following enhancements.

Issue	Build	Hotfix Build	Description
25746; [00058184]	6.2.0.1.0004	N/A	<p>When you use the Veeva Vault, the number of requests sent to Veeva by Calyx RIM is limited by the number that is defined by the Veeva System. Calyx RIM 6.2 CHF 1 leverages the Veeva Bulk API calls with an internal cache. This will decrease the chance of encountering 5-minute API burst restrictions imposed by Veeva Vault. The optimal cache lifetime depends on one of the following factors:</p> <ul style="list-style-type: none"> – Optimizing the number of Veeva requests (the higher the Veeva objects cache timeout value, the fewer InSight API calls to Veeva) – Keeping the data up-to date <p>Keep in mind that setting the Veeva cache timeout to a higher value will reduce the number of Veeva requests. However, this can also lead to a risk of getting data that is not relevant.</p>

Resolved Issues: Calyx RIM 6.2 CHF 1

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their internal tracking numbers.

Customer incident numbers that were recorded when the issues were reported are included in brackets [#####] following the internal tracking number.

Calyx RIM 6.2 CHF 1 resolves the following issues.

Issue	Build	Hotfix Build	Description
25744; [00058035]	6.2.0.1.0004	6.1.0.4.0057	When the Default Rendition Identifier was set to "Viewable Rendition" in the Publishing Setting Library, users were unable to assign a document from a non-Veeva DMS. This issue is resolved.

Issue	Build	Hotfix Build	Description
25728 [00058029]	6.2.0.1.0004	N/A	<p>Veeva documents with hyperlinks would cause the publish to fail, and the message "Not supported yet" was displayed. This issue is resolved. Veeva documents with hyperlinks now publish successfully.</p> <p>Note: Authoring hyperlinks in Veeva is not supported by LIQUENT SmartLink for PDF and LIQUENT SmartLink for Word.</p>

Calyx RIM 6.2 CHF 2 Release Notes

This document describes a certified hotfix (CHF) provided to improve Calyx RIM 6.2. In addition to enhanced features and functionality, Calyx RIM 6.2 CHF 2 resolves issues that were reported to Technical Support. Our hotfixes are cumulative packages applied to a named version of our software.

As a certified hotfix, these updates have undergone Quality Control regression testing, certifying the system works as expected. These changes will not create a new code branch, but will be identified by the updated build number on the existing codeline of each version affected, not a new release number.

Prerequisites

Calyx RIM 6.2 CHF 2 requires overrides updates. Please allow 6 to 8 weeks for XML overrides review and updates. For details, please contact your Business Development Representative to consult with our Client Enablement team.

Cross-site Scripting Protection

Calyx RIM 6.2 CHF 2 enhances security protection against most cross-site scripting vulnerabilities, helping to prevent against hacker access and the theft or manipulation of customer sessions or cookies information.

Extended Support for Identity Providers

Calyx RIM 6.2 CHF 2 extends support for Identity Providers, including PingOne and Okta in addition to Microsoft Azure Active Directory.

For more details, follow the topic [Security Administration > Log on to Identity Provider](#)

OpenText Documentum D2 Integration

Calyx RIM 6.2 CHF 2 provides the following updates in D2 systems:

- Allows synchronization of all the statuses of Calyx RIM PDS nodes with OpenText Documentum D2.
- Enhances Regulatory Application Registration Form and Submission Registration Form with the new Concerned Member State table columns, to populate with Application Code and Health Authority values.
- Enhances the Submission Registration Form with the following fields:
 - Sequence Name
 - Event Name
 - Event Code
 - Event Type
- If a field on an integrated Calyx RIM 6.2 entity is updated, and it does not correspond to a column in the grid in D2, the existing Form is updated.
- If a field on an integrated Calyx RIM 6.2 entity is updated, and it corresponds to a column in the grid in D2, a new row is created keeping the old record in the D2 grid.

Regulatory Updates

Calyx RIM 6.2 CHF 2 supports CH eCTD Module 1 Version 1.4.

Calyx RIM 6.2 CHF 2 introduces support of Valid Values 5.0 for STF 2.2.

Optimization

Processing of the following functions has been optimized in Calyx RIM 6.2 CHF 2:

- Adding an assembly to a lifecycle
- Creating a working assembly
- Using the Ready for Submission wizard
- Moving folders in an assembly
- Variables resolution performance

Multiple Documentum Rendition Formats

Calyx RIM enables you to include additional PDF rendition formats for documents in Documentum.

For more details, see the topic [LIQUENT InSight Configuration for 6.2 CHF 2: Step 8](#)

New Sorting Logic in Create eCTD Wizard

Calyx RIM 6.2 CHF 2 provides new sorting logic in the Create eCTD wizard, enabling the display of all additional sections or folders in an assembly in the correct order.

For more details, see the topic [Creating an eCTD Submission: Steps 6 & 7](#)

Assign Document

Enhancements have been made to the *Assign Document* window and the *DMS Search Results* pane for better usability. This includes: retention of changes made to the size and position of the *Assign Document* window, and retention of changes made to the size, position, and sorting of columns in the *DMS Search Results* pane, including after re-login.

Parallel Planned Submissions

Calyx RIM 6.2 CHF 2 enables you to:

- Identify conflicting lifecycle operations in parallel working assemblies.
- Synchronize a working assembly with the latest changes in the submitted view and resolve conflicting lifecycle operations between a working assembly and a submitted view.

For more details, see: [Calyx RIM Publisher > Lifecycle > Parallel Submissions](#)

List of Enhancements: Calyx RIM 6.2 CHF 2

Requested new features and enhancements are included in each release. The items are listed in descending order by their tracking numbers. Customer case numbers that were recorded when the enhancements were requested are included in brackets [#####] following the tracking number.

Calyx RIM 6.2 CHF 2 includes the following enhancements.

Issue	Build	Hotfix Build	Description
25879; [00059428]	6.2.0.2.0069	N/A	With Calyx RIM 6.2 CHF 2, the size of the EU Grouping/ Worksharing Number field on the Event entity has been increased to 100 characters.
25768; [00058351, 00059919]	6.2.0.2.0069	N/A	Calyx RIM 6.2 CHF 2 introduces support in the Data Exchange export process for the Event Country Status data and the Event Change Detail entities.
25763; [00058350]	6.2.0.2.0069	N/A	When the option Use as Active Ingredient for XEVMPD is set to Yes , the substance with any type will now be taken as an Active Ingredient for submission XML, even if the PDS Active Ingredient is already present in the XML.
25703;	6.2.0.2.0069	N/A	Using the new Include Concentrations to XEVMPD? option that is included to the PDS Substance Details page for Excipient type, it is now possible to restrict concentrations from being included in the XEVMPD submission XML file.
25702; [00057443]	6.2.0.2.0069	N/A	It is now possible to add additional attributes exposed for the Package Set Detail in PDS on the Select Package Set(s) grid in the Copy Package Set Registration wizard for New Package Set specific Registration(s) flow.
25684; [00057296, 00057471, 00057541, 00059407]	6.2.0.2.0069	N/A	Calyx RIM 6.2 CHF 2 introduces support of Valid Values 5.0 for STF 2.2.
25490; [00054468]	6.2.0.2.0069	N/A	It is now possible to keep the original Module 1 leaf ID for the imported JP submissions.
25359; [00053549]	6.2.0.2.0069	N/A	With Calyx RIM 6.2 CHF 2, the Bookmark length limit has been increased to 4000 characters.

Issue	Build	Hotfix Build	Description
25304, 23861; [00050291, 00039668, 00040435, 00043936, 00039631, 00057333, 00060463]	6.2.0.2.0069	N/A	It is now possible to add additional PDF rendition formats for document in Documentum. List of formats can be defined in the insight.var file during Calyx RIM configuration.
25131; [00051433]	6.2.0.2.0069	N/A	With the new Synchronize with the Submitted View feature, it is now possible to update the Working View with the latest changes in the Submitted View.
24308, 24129; [00043483, 00043482, 00045217, 00041903, 00042379]	6.2.0.2.0069	N/A	The following enhancements have been made to the <i>Assign Document</i> window: <ul style="list-style-type: none"> – a horizontal scroll bar appears in the right frame (DMS Search Results) – the vertical separator line is moved to the left and persists (if changed) for the user after re-login – the full column names appear in the DMS Search Results frame – the size and the position of the <i>Assign Document</i> window persists (if changed) for the user after re-login – the size, position, and sorting of columns in the DMS Search Results frame persists (if changed) for the user after re-login
24041; [00040709, 00059360]	6.2.0.2.0069	N/A	Calyx RIM 6.2 CHF 2 enhances Application security protection to overcome the Cross-Site Scripting vulnerability.

Issue	Build	Hotfix Build	Description
22465; [00024678, 00042911, 00054968, 00055823, 00055848]	6.2.0.2.0069	N/A	<p>Calyx RIM 6.2 CHF 2 enhances the eCTD Wizard to copy the envelope information for the DCP and MRP Sequences. If the field is modified for the first Country on the Select Attribute tab of the Create eCTD Wizard, the modified value will be copied to the other Country field on proceeding ahead for the other Countries in the same tab. The modified value will be copied only for the creation of Working Assemblies.</p> <p>Following are the fields from which value can be copied for other Countries in the Create eCTD Wizard:</p> <ul style="list-style-type: none"> – UUID – Submission Type – Submission Mode – Submission Unit Type – High-level/Worksharing Submission Number – Application Tracking Number – Procedure Type – INN – Sequence – Related Sequence – Submission Description <hr/> <p>Note: <i>This behavior (Modified value of one country copied to other country) works only, when creating a Working Assembly and not when updating it.</i></p> <hr/>

Issue	Build	Hotfix Build	Description
20159; [000132847, 00028774, 00057075, 00057239, 00057214]	6.2.0.2.0069	N/A	<p>When working on a submitted entity in different working assemblies, it is now possible to update the latest changes using the Synchronize with the Submitted View feature.</p> <p>Example: Consider a leaf in the sequence 0000 submitted as new. Sequences 0001 and 0002 are created with Working View. Replacing that leaf in sequences 0001 and 0002 by different users replaces the leaf in 0000 twice. Now, if the leaf is replaced in 0001 and 0001 is added to lifecycle, the change to the leaf is indicated to the user working on 0002. On using the Synchronize with the Submitted View feature, the leaf in 0002 refers to the leaf in 0001 instead of 0000.</p> <p>For information on synchronization, see the topic <i>Synchronizing Current Working View with Latest Submitted View</i>.</p>
17153	6.2.0.2.0069	N/A	<p>When there are two or more Working assemblies, and if a folder or a leaf is added to one of them and then one of the Working assembly is lifecycled, you can use the Synchronize with the Submitted View feature to update the Working View with the latest changes in the Submitted View.</p>

New Fields Added: Calyx RIM 6.2 CHF 2

The following table describes fields that were added with Calyx RIM 6.2 CHF 2.

Field Name	Field Type	Entity Name	Description	Business Rules
Lifecycle Order	Text; Read-only	Assembly Plans under Submission Plans	The order of Assembly Plans in a lifecycle.	Index number added to Lifecycle Assembly/Assembly Plan and equals to Lifecycle Order value from the Sequence Attributes page. An empty value or a zero indicates that a Sequence/Assembly Plan has not been added to a Lifecycle.

Field Name	Field Type	Entity Name	Description	Business Rules
Updated Submitted Available	Text; Read-only	Working and Sequence view of Assembly/ Assembly Plan Attributes page	Indicates if updates are made to the Submitted view since the creation of the Working Assembly.	For newly created Working Assembly, the status is No by default. The status changes to Yes when the Submitted view is updated. When the synchronize with the Submitted view operation is performed, the status changes from Yes to No .
Include Concentrations to XEVMPD?	Drop-down list	PDS Substance Detail page	With Calyx RIM 6.2 CHF 2, the field Include Concentrations to XEVMPD? has been added to the PDS Substance Detail page for Excipient type to restrict concentrations from being included in the XEVMPD submission XML file.	The Include Concentrations to XEVMPD? field appears only with the substance type Excipient. The default value of Include Concentrations to XEVMPD? is No by default.

Entity Fields Updated: Calyx RIM 6.2 CHF 2

The following table describes fields that were updated or removed with Calyx RIM 6.2 CHF 2.

Entities

Entity Name	Field Name	Field Type	Description	Business Rules
Events	EU Grouping/ Worksharing Number	Text	With Calyx RIM 6.2 CHF 2, the GUI Field size has been changed from 30 to 100.	GUI Field Size: 100

Entity Name	Field Name	Field Type	Description	Business Rules
Sequence	Lifecycle Order	Numeric; Read-only	The Lifecycle Order column has been enabled in this release. The Lifecycle Order column displays the order of a sequence in a lifecycle. This column is available on the Sequence tab of an Application.	Index number added to Lifecycle Assembly/ Assembly Plan and equal to Lifecycle Order value from the Sequence Attributes page. An empty value or a zero indicates that a Sequence has not been added to a Lifecycle.

Database Columns Changed: Calyx RIM 6.2 CHF 2

The following database columns were added or changed in Calyx RIM 6.2 CHF 2.

Field Name	Field Size	Database Column Name	Database Column Size	Database Table Name
Use Native File	N/A	USE_NATIVE_FILE_FLAG	VARCHAR2(1 BYTE)	ODS.DEFAULT_PUB_VALUES
Include Concentrations to XEVMPD?	N/A	XEVMPD_CONCENTRATIONS_FLAG	VARCHAR2(1 BYTE)	MGR.PDS_SUBSTANCE_CHANGE
N/A	N/A	EU_GROUPING_NUMBER	VARCHAR2(30) has been changed to VARCHAR2(500)	MGR.EVENT
N/A	N/A	NAME	VARCHAR2(1000) has been changed to VARCHAR2(4000)	ODS.EXTRACT
N/A	N/A	TARGET_BOOKMARK	VARCHAR2(1000) has been changed to VARCHAR2(4000)	ODS.DOC_LINK_INSPECTOR_RESULT

Resolved Issues: Calyx RIM 6.2 CHF 2

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their internal tracking numbers.

Customer incident numbers that were recorded when the issues were reported are included in brackets [#####] following the internal tracking number.

Calyx RIM 6.2 CHF 2 resolves the following issues.

Issue	Build	Hotfix Build	Description
26048	6.2.0.2.0069	N/A	XEVMPD Audit Analytics: Legal Basis from the Registration entity was not audited. This issue is resolved. Legal Basis will appear in the XEVMPD Audit Analytics report.
26013, 25936; [00060710, 00060234]	6.2.0.2.0069	– 26013 - 6.1.0.4.0078 – 25936 - 6.1.0.4.0064	When sending an ADD/UPDATE/INSERT data exchange message for a ChangeDetail, if the <code>changeId</code> value included a tilde (~), plus (+), hash (#), or a dash (-), then the value was not converted and the Change Detail was not added. This issue is resolved.
25985	6.2.0.2.0069	N/A	When trying to reassociate a user that has been deleted from the Azure Active Directory, from within Calyx RIM, a 404 Not Found error was displayed. This message has been modified to display: User does not exist in the third party IdP system. To add the user to the group, user needs to be re-added in the IdP system.
25984	6.2.0.2.0069	N/A	When creating or identifying a notification while logged on as an Azure user, the Created By column does not display the full email address of the user. This issue has been resolved.
25983	6.2.0.2.0069	N/A	When attempting to get a full list of Azure users within Calyx RIM using the Add User/Group Wizard , a 400 Bad Request error would be displayed. This issue is resolved.

Issue	Build	Hotfix Build	Description
25968; [00060639]	6.2.0.2.0069	6.1.0.4.0077	Expanding a working assembly of more than 10,000 nodes folder by folder and switching from Working to Publishing/Submitted view and back caused the folders or the assembly to disappear. This issue is resolved. Assembly tree will be collapsed automatically if the amount of expanded nodes exceeds the limit. This limit is configurable and there is a default system value of '1000'. If the 'assembly.tree.expand.range.limit' parameter is not specified in insight.var file, the default system value is applied.
25949; [00059797, 00054015, 00057268]	6.2.0.2.0069	6.1.0.4.0077	Importing a large assembly into a working assembly via the Import Assembly Wizard could take an excessive amount of time to complete, or would not complete. This issue is resolved.
25942; [00060255]	6.2.0.2.0069	N/A	A deserialization vulnerability that allowed an attacker to execute arbitrary code was found. This issue is resolved.
25940; [00060256]	6.2.0.2.0069	6.1.0.4.0064	The JBoss RichFaces project is a UI component framework for integrating Ajax capabilities into business applications using JavaServer Faces . Because the RichFaces project has reached end-of-life status and there will be no further updates to the functionality, and it has been flagged as a security vulnerability. This issue is resolved. JBoss RichFaces has been removed from Calyx RIM.
25923; [00059341]	6.2.0.2.0069	6.1.0.4.0079	When there were 50 or more rows in the Recently Viewed details and no entity from this list was selected before logging out, the Recently Viewed details was not available when re-logging on to Calyx RIM. This issue is resolved.

Issue	Build	Hotfix Build	Description
25922; [00060089]	6.2.0.2.0069	N/A	It was not possible to export the following grids to Excel. This issue is resolved. <ul style="list-style-type: none"> – Reports in Querying – Jobs – Job Details – Links Inspector Report – Document List
25906; [00059680]	6.2.0.2.0069	6.1.0.4.0079	When working with a historical data an XEVMPPD Audit report showed incorrect data in the output. This issue is resolved.
25895	6.2.0.2.0069	N/A	Attempting to modify and save the TOC content in a Assembly resulted in the following errors: <ul style="list-style-type: none"> – On saving the edits, a blank pop-up appeared and the TOC tree displayed no changes. – When closing/cancelling the pop-up window, the Edit TOC Entry dialog box did not close. <p>This issue is resolved.</p>
25890	6.2.0.2.0069	N/A	When creating an Application using the Create Application Wizard, the Application Concerned Parties field and the Event Concerned Parties field were missing from the Create Application and Create Event page. This issue is resolved.
25889; [00059223]	6.2.0.2.0069	6.1.0.4.0068	This release includes a performance enhancement to reduce the number of Display Activity, Claim Activity, Unclaim Activity and Save Activity (after edit) calls to the database during workflow operations.
25886; [00059462]	6.2.0.2.0069	6.1.0.4.0068	When selecting Country Tree on the Navigation pane and expanding the country for the second time, performance issues were experienced and no information was displayed. This was due to a known bug in Oracle 12.1. It is resolved in Oracle 12.2 for Calyx RIM 6.2 CHF 2.

Issue	Build	Hotfix Build	Description
25880; [00059361]	6.2.0.2.0069	N/A	Identified deficiencies in the Application Security controls lead to a Session Fixation vulnerability (Cross-Site Scripting, Stored Cross-Site scripting) that could allow a hacker to access confidential information and tamper with the server. This issue is resolved. Application security protection has been enhanced.
25876; [00059363]	6.2.0.2.0069	N/A	Calyx RIM now uses the HttpOnly flag when generating a cookie to help mitigate the risk of a client-side script accessing the protected cookie. It instructs the browser that the cookie can only be accessed by the server and not by client-side scripts.
25875; [00059364]	6.2.0.2.0069	N/A	Server headers revealed the underlying server technologies and software versions in use, and was flagged as a server headers vulnerability. This issue is resolved.
25874; [00059375]	6.2.0.2.0069	6.1.0.4.0079	In Calyx RIM6.2 CHF1, appended leaves were duplicating IDs after the Convert to Reference Leaf > Revert operation. The Revert option was available for such leaves, but caused a data break. This issue is resolved. The Revert option has been removed to make it consistent with default leaves.
25870	6.2.0.2.0069	N/A	When trying to delete a PDS with Reference Flu Strain details, the following error message was generated: <code>Error calling stored procedure: ORA-02292: integrity constraint (MGR.T_1634) violated - child record found.</code> This issue is resolved. The PDS with Reference Flu Strain details is deleted and the Event Attribute page appears.
25868; [00059008; 00062766]	6.2.0.2.0069	6.1.0.4.0077	When multiple users were working in separate modules within the same complex Assembly , in some cases the database was locked and the following error message appeared: <code>java.sql.SQLException: ORA-00060: deadlock detected while waiting for resource.</code> This issue is resolved.

Issue	Build	Hotfix Build	Description
25866; [00059229]	6.2.0.2.0069	6.1.0.4.0064	On a system with applied overrides, after using the Build Query option to search for a document in the DMS Search window, clicking the Reset button did not clear all of the search criteria fields. When this happened, attempting to perform a search by specifying a Document Number value returned no results. This issue is resolved.
25864; [00059036, 00058799, 00059198, 00060075]	6.2.0.2.0069	N/A	The assigned document appeared as a placeholder icon in the assembly tree, despite the 'BOUND' value in Assignment Status and 'Yes' value displayed in both the PDF Exists and the Extraction Exists fields. This issue is resolved. The assembly tree is refreshed automatically and the placeholder icon is changed to the document icon when the document is assigned.
25863; [00059133; 00059005]	6.2.0.2.0069	6.1.0.4.0077	When a document with a bookmark name of more than 500 characters was assigned to an assembly that had a link targeted to the long bookmark, the Link Inspector results were empty after running Prepare to Publishing . The <code>ORA-12899</code> error was observed in <code>server.log</code> . This issue is resolved.
25858; [00059223]	6.2.0.2.0069	6.1.0.4.0058	Slow performance issues were observed in the Alert Center window for the list of activities assigned to the users. This issue is resolved. Calyx RIM 6.2 CHF 2 adds a database index to improve performance. It decreases the amount of time needed to display activities in the Alert Center .
25828; [00058914, 00058896]	6.2.0.2.0069	6.1.0.4.0079	When using the XEVMPD Submission wizard to take the prior approved Package Set PDS Details from the previous Event with the statuses Pending Modify or Pending Withdrawal, an error message regarding no active ingredients specified was displayed. This issue is resolved. Additional logic for Withdrawn status has been added for Not Valid status in EMA Authorisation Status field on Full Product Presentation entity.

Issue	Build	Hotfix Build	Description
25825; [00058868]	6.2.0.2.0069	6.1.0.4.0053	Results of the View Document List report could not be exported to an Excel spreadsheet. This issue is resolved.
25815; [00058064, 00060154]	6.2.0.2.0069	N/A	Attempting to disassociate a Package Set Detail from a Registration when it was associated to a different Registration resulted in an error. This Issue is resolved. A Package Set Detail can be deleted from a Registration when it is associated to a different Registration.
25797; [00058103]	6.2.0.2.0069	6.1.0.4.0057	When creating a Full Product Presentation for an Authorised Product with more than one active ingredient and one having a reference active ingredient, selecting the option to "Use Reference Ingredient for XEVMPD" resulted in the reference active ingredient being added to the XML, but not the active ingredients without a reference active ingredient. This issue was also valid for Reference Strain extraction for Flu Vaccine Component and Product Family Type. This issue is resolved.
25782; [00058380]	6.2.0.2.0069	N/A	Using the Create Submission Wizard, creating a Submission with a large number of products assigned to a Product Family took longer than expected and resulted in Windows Explorer being locked for a period of time. This issue is resolved. The performance has been improved by replacing Associated Products multi-select field type with the Selection Widget.
25776; [00058405]	6.2.0.2.0069	6.1.0.4.0053	Attempting to create a Linked System with a display name containing apostrophe resulted in a blank white screen. This issue is resolved.

Issue	Build	Hotfix Build	Description
25774	6.2.0.2.0069	N/A	<p>When an Event was closed with the values as below, an invalid reference message was displayed instead of displaying the reason for closing the Event.</p> <ul style="list-style-type: none"> — Closed: ON — Associations Closed As: NOT APPROVED — Reason for Termination/Withdrawal: Reason for closing event <p>This issue is resolved.</p>
25773, 25621, 25562 ; [00058380, 00056770, 00058337, 00055768, 00056182, 00058515]	6.2.0.2.0069	6.1.0.4.0044, CUSTOM6_1_0_25621_0004.zip, medtronic_chf3_25621_25724_25773_0007.zip	<p>Issues were found in the selection pop-up window with the larger number of items assigned. Below are some of the issues described here:</p> <ul style="list-style-type: none"> — Populating the products and Search functionality on the product selection pop-up window took long time to execute with large number of products assigned — Blank white screen appeared, when attempted to: <ul style="list-style-type: none"> • Associate/Disassociate Products with a Registration that has 3,900 or more Products assigned • Edit an Application that has 3,900 or more Products assigned • Associate Products with an Application <p>These issues are resolved. Selection pop-up window works smoothly with large number of items assigned.</p>

Issue	Build	Hotfix Build	Description
25759; [00058286]	6.2.0.2.0069	6.1.0.4.0061	<p>The Create Notification wizard displayed the wrong field name when viewing an existing notification configured on a custom extra field for the Application Types.</p> <p>This issue is resolved. The Create Notification wizard displays the correct field name and sends the Notifications for the Specifications correctly. Following are some examples of IND and CTA application type:</p> <ul style="list-style-type: none"> — Display correct field name when custom extra field settings have similar names for IND and CTA — Display correct values for IND and CTA Application Types — Display correct value when modifying extra field name — Display correct extra field values for IND and CTA even when modifying a Notification Specification
25756; [00058222]	6.2.0.2.0069	N/A	<p>The Use Native File value under Default Values conflicted with the key in <code>insight.var</code> file. This is resolved by adding the new Use Default value to the Use Native File option. When specified, the new leafs will get the value from Use Native File value according to the <code>dms.nativeLeafExtension</code> key only.</p>
25725; [00057843, 00055920]	6.2.0.2.0069	6.1.0.4.0061	<p>ABBR variable was not resolved for some cases even when Abbreviated Name for the specific element was present and specified.</p> <p>This issue is resolved. ABBR resolves to Abbreviated Name value when it is available and also resolves to blank for the elements that do not contain any value.</p>

Issue	Build	Hotfix Build	Description
25724; [00057878]	6.2.0.2.0069	6.1.0.4.0044, CUSTOM6_1_0_25621_0004.zip, medtronic_chf3_25621_25724_25773_0007.zip	Using the quick search feature to search for a product was taking a long time to execute. This issue is resolved.
25722; [00057807]	6.2.0.2.0069	N/A	<p>When Calyx RIM Publisher sent a Paper Publish or Electronic Publish request (IpFusion, IpLinksetter, PDFFile), some of the sub-jobs (such as All Leaf Elements or Selected Leaf Elements) used the on-fail parameter "continue" instead of "end".</p> <p>This issue is resolved. The on-fail attribute is set to the correct parameter for the following leaf elements of Paper Publish and Electronic Publish:</p> <ul style="list-style-type: none"> – Publish to a Single File – "end" – All Leaf Elements – "end" – Selected Leaf Elements – "end" – All Leaf Elements and XML – "continue" – Selected Leaf Elements and XML – "continue" – All Volumes – "end" – Volumes in Selected Range – "end"
25706; [00057170]	6.2.0.2.0069	N/A	When creating a PDS Template from an existing PDS with Withdrawn status, Withdrawn PDS Details were copied to the new PDS Template. This issue is resolved, and the Withdrawn PDS Details are not copied to the new PDS Template.
25690; [00057543]	6.2.0.2.0069	6.1.0.4.0043	<p>When exporting a report to an Excel spreadsheet, the application consumed a large amount of memory and it took longer than expected to export the results.</p> <p>This issue is resolved. This release reduces memory consumption when exporting a report to Excel by keeping only a configurable number of rows in memory at any given time. This number can be configured by defining a numerical value for Excel. The default value is 100.</p>

Issue	Build	Hotfix Build	Description
25681, 25677; [00057308]	6.2.0.2.0069	6.1.0.4.0045	Clicking the Export to Excel button multiple times consecutively could cause LIQUENT InSight to shut down. This issue is resolved. The Export to Excel button becomes inactive (dimmed) after one click. Also, when the number of results to export exceeds 1000, a warning message indicates that the operation could take a long time to complete.
25672; [00057246]	6.2.0.2.0069	N/A	A <i>JavaRMI</i> vulnerability was found on the Insight Publisher server, in all <i>IP</i> environments. This issue is resolved.
25659; [00056994, 00055703, 00059714]	6.2.0.2.0069	N/A	After running the Create eCTD Wizard for an Assembly and adding Leafs with Documents in sections 1.15 and 1.16, Leafs under these sections appeared out of order in the structure. This issue is resolved. Leafs in sections 1.15 and 1.16 appear in the correct order.
25625; [00056802]	6.2.0.2.0069	6.1.0.4.0044	On the Transfer Activities page, names in the "Assign to User" list were not sorted case-insensitive. This issue is resolved. Names now appear in the correct alphabetical order, with upper-case names included immediately after lower-case names. Example: <ul style="list-style-type: none"> – Aa1 – AA2
25623; [00056605]	6.2.0.2.0069	N/A	The legends in the Registration Status Summary by Country report were not displayed correctly. This issue is resolved.
25619; [00056296]	6.2.0.2.0069	6.1.0.4.0068	For US 3.3 submissions, IDs of '0000' were accepted by Calyx RIM, although US 3.3 only permits IDs of '0001' through '9999'. This issue is resolved for Set Application Metadata in the Create eCTD wizard and for the Add/Edit Metadata page invoked from the assembly or m1 folder. If an ID of '0000' is added, the message "Submission ID must be four digits between 0001 and 9999" appears and the system prevents you from proceeding.

Issue	Build	Hotfix Build	Description
25615, 25568; [00056158, 00056737]	6.2.0.2.0069	6.1.0.4.0043	Some workflow activities were taking a long time to open due to a lag in resolving entity attributes with many objects linked to each other, causing an extra load on the server. This issue is resolved, and performance has been improved.
25598; [00055911]	6.2.0.2.0069	N/A	<p>Due to the larger file size, user received an error while publishing the files into PDF. This issue is resolved. The publishing limit has been increased for the following regions:</p> <ul style="list-style-type: none"> – Size limit for CA M1: up to 200MB – Size limit for EU M1: up to 200MB – Size Limit for US M1: up to 400MB – Size Limit for M2-5 for US: up to 400MB – Size Limit for M2-5 for other regions: up to 400MB <p>If the publishing size limit exceeds the maxsize limit, the following warning message will appear:</p> <pre> FileSizeRule: invalid file size(actual file size MB)of leaf content "" path and name of leaf that contains this file "[XPath: ""/ href path @xlink:href""]/ </pre>
25596; [00056032]	6.2.0.2.0069	6.1.0.4.0043	When exporting a List of Application Countries with Registration and Product Details report results from Calyx RIM to an Excel file, entries containing a large number of Package Sets resulted in the addition of extra rows with Package Set Name information in two different columns. This issue is resolved. No extra rows are added when exporting a large amount of data to an Excel spreadsheet.

Issue	Build	Hotfix Build	Description
25595, 25590; [00055290, 00056757, 00056281, 00056320, 00056666, 00055362]	6.2.0.2.0069	6.1.0.4.0044	Due to an Activity framework defect, some workflow actions failed. Following errors found: <ul style="list-style-type: none"> — ORA-02292: integrity constraint (ACTIVITI.ACT_FK_VAR_EXE) violated - child record found. — org.apache.ibatis.exceptions TooManyResultsException: Expected one result (or null) to be returned by selectOne(), but found two results.
25593; [00056472]	6.2.0.2.0069	N/A	The messages in the following wizards for the Withdrawal operation have been revised to notify the result of the action more accurately. <ul style="list-style-type: none"> — Update Status — Update Event-Country Status — Update Project Event-Country Status
25585; [00056427]	6.2.0.2.0069	6.1.0.4.0047	This release introduces a performance improvement to decrease the amount of time it takes to display the bookmarks for a document when selecting the Edit Document Bookmarks option.
25580; [00053883]	6.2.0.2.0069	6.1.0.4.0052	Attempting to publish a tab using a "Canon imageRUNNER with imagePASS U2" printer resulted in an error. This issue is resolved.
25567; [00056152]	6.2.0.2.0069	6.1.0.4.0044	When performing an event bulk update for an existing Project, an error was encountered when trying to update the Event Type without selecting the Secondary Event Type when the Secondary Event Type field was configured in the overrides to be a required field. This issue is resolved.
25564; [00055331]	6.2.0.2.0069	6.1.0.4.0043	After assigning an email value in the Concerned Parties field for a sequence and then creating a working assembly for that sequence, the email value was missing from the Concerned Parties field when returning to the sequence page. This issue is resolved.

Issue	Build	Hotfix Build	Description
25558; [00056133]	6.2.0.2.0069	6.1.0.4.0044	When creating or editing a DTD/Schema type value using the Assembly DTD/Schema Types page in Calyx RIM Data Administration, the list of associated countries was not populated when a region was selected. This issue is resolved.
25547; [00055851]	6.2.0.2.0069	6.1.0.4.0057	In-process Lifecycle links to Native Leaf in a previous Sequence did not work in the previous output when published. This issue is resolved.
25493; [00055237, 00056897]	6.2.0.2.0069	N/A	When the Supporting Sequence Assemblies updated via Create eCTD wizard and attempted to delete, resulted in an error. This issue is resolved. Supporting Sequence Assemblies can be deleted successfully.
25437; [00054727, 00060709, 00062618, 00062617, 00057337]	6.2.0.2.0069	N/A	<i>FREAK (Factoring Attack on RSA-EXPORT Keys CVE-2015-0204)</i> is a weakness in some implementations of SSL/TLS that enables an attacker to decrypt secure communications between vulnerable clients and servers. Some SSL ciphers allowed SSL communication without authentication. This issue is resolved.
25375; [00052193, 00055172, 00055703, 00057012, 00058833, 00059176]	6.2.0.2.0069	N/A	Publishing failed: Application Number became invalid and displayed as blank field in 1.1.2 Form Folder. This issue is resolved. If the issue persists after publishing again, it will be handled as if Application Number is empty, prompting a warning to Job Request Details and replacing it with the default Application Number.
25261 [00054015, 00057268]	6.2.0.2.0069	N/A	Assigning 500 documents to a working assembly could take a long amount of time to complete or would not complete. This issue is resolved and performance has been improved.
25207; [00052121, 00054830, 00059055, 00059474]	6.2.0.2.0069	N/A	After running the Create eCTD Wizard to add new folders (3.2.P.4.4 and 3.2.P.4.1) to section 3.2.P in an Assembly, the added folders appeared out of order in the structure. This issue is resolved. All folders appear in the correct order.

Issue	Build	Hotfix Build	Description
25084; [00051037, 00052759, 00056925, 00058862]	6.2.0.2.0069	N/A	Deleting large applications or removing multiple sequences from a lifecycle took much longer than expected to produce results. The performance of these operations has been improved in this release.
24141; [00042142, 00052191, 00052706, 00056907, 00057078]	6.2.0.2.0069	N/A	When creating a new assembly using the JP eCTD Module 1 v1.0 and JP eCTD Module 2-5 v3.2 templates, the wrong information was displayed with missing details in these templates. The issue is resolved. JP eCTD Module 1 v1.0 and JP eCTD Module 2-5 v3.2 templates display correct information with all the details.
24051; [00041841, 00053298]	6.2.0.2.0069	N/A	Publishing requests were taking an unreasonably long time to reach the Calyx RIM Rendering server. Publishing even a single leaf took longer time than expected. This was due to resolving assembly repository variables for each leaf/document. This issue is resolved and performance has been improved.
23917; [00040709]	6.2.0.2.0069	N/A	The following issues were found in Calyx RIM: <ul style="list-style-type: none"> — Cross-Site Scripting — JBoss Java Management Extension Console Authentication Bypass — JBoss Web Management Console Authentication Bypass — Stored Cross-Site Scripting All of these issues have been fixed by providing enhanced Application security protection in this release.
22982; [00033229]	6.2.0.2.0069	N/A	It was possible to create more than one working assembly on a single sequence. This issue is resolved.
21599; [00047499, 00050725, 00052214]	6.2.0.2.0069	N/A	When a published submission with an updated reference leaf Title was imported from the eCTD into the application, the Reference Leaf Title value was not saved. The Leaf Name value was assigned to it. This issue is resolved.

Issue	Build	Hotfix Build	Description
17629	6.2.0.2.0069	N/A	After adding a lifecycle to an assembly, the Assembly Name field was blank in the List of Sequences with Application and Event Properties report. This issue is resolved.

Calyx RIM 6.2 CHF 3 Release Notes

This document describes a certified hotfix (CHF) provided to improve Calyx RIM 6.2. In addition to enhanced features and functionality, Calyx RIM 6.2 CHF 3 resolves issues that were reported to Technical Support. Our hotfixes are cumulative packages applied to a named version of our software.

As a certified hotfix, these updates have undergone Quality Control regression testing, certifying the system works as expected. These changes will not create a new code branch, but will be identified by the updated build number on the existing codeline of each version affected, not a new release number.

Overrides Updates

Calyx RIM 6.2 CHF 3 requires overrides updates. Please allow 6 to 8 weeks for XML overrides review and updates. For details, please contact your Business Development Representative to consult with our Client Enablement team.

Security Administration

With Calyx RIM 6.2 CHF 3, the field **Identity Provider Name** has been added to the **Security Administration > Users and Groups > Add User/Group Wizard**.

Java Support

Calyx RIM 6.2 CHF 3 includes support for Java AdoptOpenJDK as a direct replacement of Oracle Java. See *Liquent InSight Application Server Specifications* for the details .

Documentum connector

Calyx RIM 6.2 CHF 3 provides an ability to change DFC library used to connect to Documentum. The default DFC is 16.4. Please see *Liquent InSight 6.2 System Support Document (SSD)* for more information on supported versions of DFC.

D2/LSRD Drag-and-Drop Functionality

Calyx RIM 6.2 CHF 3 enables you to drag-and-drop documents directly from the D2/LSRD window to the assembly. Drag-and-drop is supported if the D2 window is opened in Java mode only. Make sure that you are aware of the product-specific notes that may apply to the requirements for OpenText Documentum D2 16.4.

To enable the drag-and-drop from D2/LSRD functionality, the appropriate configurations need to be done in the Internet Explorer browser. Please review the procedures in the Calyx RIM 6.2 CHF 3 Installation Guide topic *Internet Explorer: Enabling Drag-and-Drop from D2 /LSRD* and make sure that the necessary configurations are applied. If you experience any difficulties in configuring the Internet Explorer browser to enable the drag-and-drop functionality, please contact Technical Support.

Regulatory Updates

Calyx RIM 6.2 CHF 3 supports the Jordan (JO) eCTD Module 1 Version 1.0.2.

Workflows

Calyx RIM 6.2 CHF 3 provides the ability to:

- Create and update tasks, sub-tasks, and references within a workflow.

— Create and update tasks, sub-tasks, and references via a workflow API.

Calyx RIM 6.2 CHF 3 provides the ability to use the combination of Link Type and Link field within a single Activity for the following entities in a workflow:

- Create/Update Registration Attachment
- Create/Update References

Calyx RIM 6.2 CHF 3 provides the ability to configure a workflow XML file to send e-mail notifications when creating, updating, or associating entities. The workflow XML file can also be configured to send e-mail notifications or the workflows/activities to be run at a specified time.

Data Exchange

With Calyx RIM 6.2 CHF 3, it is possible to create and update references via upsert for Data Exchange.

Default Country Value - Global Project Plan

When creating **Indication/Intended Use** or **Species Indications** using *Global Project Plan*, the **Country** field now populates by default the value defined for **Country** from Application level.

XEVMPD - Authorised Product Selection

Additional filters - **Product Family Name**, **Product Name**, **Application Name**, **License Code**, and **EV Code** have been added to the *Authorised Product Selection* page. Selecting a **Product Name** or **Product Family Name** values in combination with the **Product** values, displays only the relevant values of other entities in their respective fields.

With the additions above, the list of **Authorised Product** columns has been updated as follows: **Operation Type**, **Product Family Name**, **Product Name**, **Application Name**, **Procedure Type**, **License Code**, **Country**, **Full Product Name**, **EV Code**, **Authorisation Status**, **Authorisation/Renewal Date**, **MAH/Organisation**, **Information Date**, **Withdrawn/Invalidated Date**, **Package Description**, **Last Updated Date**, **Date Submitted to EMA**.

In the *XEVMPD Submission Wizard*, the new **Package Set Registration** and **Full Product Presentation** fields (overrides) can be configured as additional filters and columns in the report layout.

Global Project Plan

Calyx RIM 6.2 CHF 3 includes the **Sequence Name** option in the *Global Project Plan* wizard in the *Select values for the new sequence you want to create* page. This new option helps include the sequence name when creating events using the *Create New Events Package Set Registration* project.

Parallel Submissions

Calyx RIM 6.2 CHF 3 enables you to handle multiple initial assemblies using the **Synchronize with the Submitted View** feature.

In-Process Links and Link Applicability

Calyx RIM enables you to create in-process links to documents or document bookmarks from a previous sequence.

When creating a link, it is now possible to specify the **Link Applicability**. Links created with **Application** applicability will not have a global copy of the link.

Additional Calyx RIM 6.2 CHF3 Enhancements

- Performance improvements for electronic and paper publish.
- Performance improvements for the document assignment function.
- Support for Xerox Color C60/C70 (XPIF) and Xerox Color C60/C70 Postscript (XPIF) printers. Support is provided for the FreeFlow controller.

List of Enhancements: Calyx RIM 6.2 CHF 3

Requested new features and enhancements are included in each release. The items are listed in descending order by their tracking numbers. Customer case numbers that were recorded when the enhancements were requested are included in brackets [#####] following the tracking number.

Calyx RIM 6.2 CHF 3 includes the following enhancements.

Issue	Build	Hotfix Build	Description
26164	6.2.0.3.0062	N/A	In Workflows, it is now possible to use the combination of Link Type and Link field within a single Activity for the following entities: <ul style="list-style-type: none"> — Create/Update Registration Attachment — Create/Update References
26155	6.2.0.3.0062	N/A	The country name Macedonia, The Former Yugoslav Republic of is replaced with North Macedonia . Note: The country name Macedonia, The Former Yugoslav Republic of must be updated manually to North Macedonia under Data Administration. For instructions to manually update the existing country name, see the topic Maintaining an Application Value .
26153	6.2.0.3.0062	N/A	Calyx RIM wizards now supports e-signature configuration of single entity or sub- set of entities.
26045; [00060995]	6.2.0.3.0062	N/A	Calyx RIM 6.2 CHF 3 now supports Xerox Color C60/C70 (XPIF) or Xerox Color C60/C70 Postscript (XPIF) printers.

Issue	Build	Hotfix Build	Description
26025	6.2.0.3.0062	N/A	When creating Indication/Intended Use or Species Indications using <i>Global Project Plan</i> , the Country field now populates by default the value defined for Country from the Application level.
26014; [00062531]	6.2.0.3.0062	N/A	When creating events using the <i>Create New Events Package Set Registration</i> project, it was not possible to include the sequence name. To fulfill this requirement, there is now the option Sequence Name in the <i>Global Project Plan</i> wizard in the <i>Select values for the new sequence you want to create</i> page. The Sequence Name field is specifically added for <i>Create New Events Package Set Registration</i> flow only.
25932; [00060177]	6.2.0.3.0062	N/A	<p>The <i>Authorised Product Selection</i> page now includes the following new filters:</p> <ul style="list-style-type: none"> — Product Family Name — Product Name — Application Name — License Code — EV Code <p>Report layout columns have been updated to accommodate the additional search results. Also, it is now possible to configure extra fields for Package Set Registration and Full Product Presentation as additional filters and/or columns in the report output.</p> <hr/> <p>Note: <i>The Product Name field shows only the products that are associated with the corresponding Full Product Presentation via Package Set. If no products are associated, the Product Name column will be blank.</i></p> <hr/>

Issue	Build	Hotfix Build	Description
25236, 21859; [00052583, 00054879, 00054873, 00054872, 00054784, 00054871, 00040316, 00052813, 00058011]	6.2.0.3.0062	N/A	It is now possible to create in-process links to documents or document bookmarks from a previous sequence.
22643; [00060811]	6.2.0.3.0062	N/A	With multiple initial sequence assemblies in an application, if one of the assemblies was added to a lifecycle it was not possible to add a second sequence to lifecycle. This caused the need to recreate an assembly from the beginning. There is now the option Synchronize with the Submitted View to synchronize initial assembly with the latest changes in the submitted view. Using the Synchronize with the Submitted View option results in the following: <ul style="list-style-type: none"> – Initial assembly converted to <i>Working</i> assembly along with other views. – All elements present in initial assembly are added as a new element in the <i>Working</i> view. – Resulting folder nodes include a merged list of child nodes from both the <i>Submitted</i> view and initial assemblies.
19678; [000121448F W, 00056051, 00058456]	6.2.0.3.0062	N/A	When creating a link, it is now possible to specify the Link Applicability to indicate whether the changes made to a link are Global or limited to the Application only.

Entity Fields Added: Calyx RIM 6.2 CHF 3

The following table describes fields that were added with Calyx RIM 6.2 CHF 3.

Identity Provider

Entity Name	Field Name	Field Type	Description	Business Rules
Security Administration > Identity Providers	Provider Type	Drop-down list	With LIQUENT InSight6.2 CHF 3, the field Provider Type has been added to the Identity Providers page.	When SSO is enabled and Calyx RIM is configured for multiple Identity Providers (IdPs), the Provider Types (Okta, Azure AD, and PingOne) are displayed in the drop-down list. The Provider Type field is editable only in the create mode of IdP. In the edit mode, this field is a read-only value.
	Provider Name	Text	With LIQUENT InSight6.2 CHF 3, the field Provider Name has been added to the Identity Providers page.	This is the name assigned by the Security Administration user to the Identity Provider. This field provides the uniqueness of an Identity Provider.
	Active Flag	Text	With LIQUENT InSight6.2 CHF 3, the field Active Flag has been added to the Identity Providers page.	While creating an Identity Provider, this field is set to "Y" by default. In the create mode this field is read-only. Upon deactivation, the flag is automatically set to "N". Only one active Identity Provider can exist at a given time.
	Activate/Deactivate	Button	With LIQUENT InSight6.2 CHF 3, the Activate/Deactivate button has been added to the Identity Providers page.	This field is hidden in the create mode and is displayed only in the edit mode on the Identity Providers page. The first time an Identity Provider is edited, the Deactivate button appears. Active=the value is still used. Inactive=the value is not active. When the IdP is deactivated, the active flag is set to "N", and when the IdP is activated, the active flag is set to "Y".

Identity Provider (IdP) type is Azure AD

Entity Name	Field Name	Field Type	Description	Business Rules
Security Administration > Identity Providers	Application Logout URI	Text	azure.appLogoutUri	Fields appear only if the Provider Type is Azure AD.
	Access Token URI	Text	azure.accessTokenUri	
	Client ID	Text	azure.clientId	
	Client Secret	Text	azure.clientSecret	
	Key Discovery URI	Text	azure.keyDiscoveryUri	
	User Authorization URI	Text	azure.userAuthorizationUri	
	Issuer Base URI	Text	azure.issuerBaseUri	
	Tenant ID	Text	azure.tenantId	
	SSO Trusted Applications	Text	sso.trusted.applications	
	Graph API URI	Text	azure.graphUri	
	Graph API Version	Text	azure.graphApiVersion	

Identity Provider (IdP) type is Okta

Entity Name	Field Name	Field Type	Description	Business Rules
Security Administration > Identity Providers	Application Logout URI	Text	azure.appLogoutUri	Fields appear only if the Provider Type is Okta.
	Access Token URI	Text	azure.accessTokenUri	
	Client ID	Text	azure.clientId	
	Client Secret	Text	azure.clientSecret	
	Key Discovery URI	Text	azure.keyDiscoveryUri	
	User Authorization URI	Text	azure.userAuthorizationUri	
	Issuer Base URI	Text	azure.issuerBase.uri	
	Base API URL	Text	sso.baseApiUrl	
	Authorization API Token	Text	sso.authApiToken	

Identity Provider (IdP) type is PingOne

Entity Name	Field Name	Field Type	Description	Business Rules
Security Administration > Identity Providers	Application Logout URI	Text	azure.appLogoutUri	Fields appear only if the Provider Type is PingOne.
	Base API URL	Text	sso.baseApiUrl	
	Authorization API Token	Text	sso.authApiToken	
	SAML Metadata	Text	sso.saml.metadata.file	
	SAML Entity ID		sso.saml.entityId	
	SAML Keystore File Name	Text	sso.cryptographic.store.file	
	SAML Keystore Password	Text	sso.cryptographic.store.password	
	SAML Key Name	Text	sso.cryptographic.key.name	
	SAML Key Password	Text	sso.cryptographic.key.password	

User/Group Wizard

Entity Name	Field Name	Field Type	Description	Business Rules
Security Administration > Users and Groups	Identity Provider Name	Drop-down list	The field Identity Provider Name has been added to the Security Administration > Users and Groups > Add User/Group Wizard to filter search results based on the selected IdP.	This field appears only when SSO is enabled and Calyx RIM is configured for multiple Identity Providers (IdPs). Only active IdPs are displayed in the drop-down list.

Database Columns Changed: Calyx RIM 6.2 CHF 3

The following database columns were added or changed in Calyx RIM 6.2 CHF 3.

Field Name	Field Size	Database Column Name	Database Column Size	Database Table Name
N/A	N/A	IDP_ID	NUMBER	SEC.GRP

Resolved Issues: Calyx RIM 6.2 CHF 3

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their internal tracking numbers.

Customer incident numbers that were recorded when the issues were reported are included in brackets [#####] following the internal tracking number.

Calyx RIM 6.2 CHF 3 resolves the following issues.

Issue	Build	Hotfix Build	Description
26225; [00064748]	6.2.0.3.0062	N/A	The validation rules described for issue 25619 in the Calyx RIM 6.2 CHF 2 Release Notes have been changed for US 3.3 submissions. Now, it is possible to change Submission ID to 0000 with no errors.
26220; [00064684]	6.2.0.3.0062	6.2.0.2.0080	Unicode characters were not displayed correctly in <code>assembly/leaf/folder/document</code> names when SSO was enabled. This issue is resolved

Issue	Build	Hotfix Build	Description
26207	6.2.0.3.0062	N/A	After migrating from Calyx RIM 6.2 CHF 1 to Calyx RIM 6.2 CHF 2, the association between the Filing Type values and the Filing Type eCTD Codes for legacy specification versions was lost. This issue is resolved.
26205; [00064416]	6.2.0.3.0062	N/A	An assembly created using the Swiss CH eCTD Module 1 v1.4 assembly template included a hyphen in the output file name field for the sections 1.2.3.4 and 1.2.3.5 leafs. This issue is resolved by removing the hyphens in the sections 1.2.3.4 and 1.2.3.5 in the Swiss CH eCTD Module 1 v1.4 assembly template.
26157	6.2.0.3.0062	N/A	Using the <i>Global Project Plan</i> wizard, it was possible to create a project using the event name and code details that were already used within an application. Though an event was not created, a project was still created. This issue is resolved. Now, a project will not be created if the event name and code are not unique within an application.
26156; [00063963]	6.2.0.3.0062	N/A	When a submission using the AU Nees and ICH XML definition file was published, the folder structure in the resultant output was incorrect. This issue is resolved.
26143; [00063832]	6.2.0.3.0062	N/A	The XEVMPD Audit report performance has been improved in this release. <hr/> Note: Due to the complexity of the data that includes entity joins and volume of the data, we recommend XEVMPD Audit report to be run as materialized views until the underlying issue is fixed. <hr/>

Issue	Build	Hotfix Build	Description
26121; [00063458]	6.2.0.3.0062	N/A	When an assembly with leafs with different statuses was published, some files were missing in the output. This was because the leaf statuses were not selected even though they were listed in the Include Leafs with Status option. Leafs were published only when the statuses were highlighted on Publish screen. This issue is resolved. Now, all leafs with statuses present in selected list go to published output.
26107; [00063264]	6.2.0.3.0062	N/A	When a new Change with at least two change details was associated to an Event, and extra field values were used for Event-Change details , the event appeared in duplicate on the Related Events tab. This issue is resolved, and the event appears correctly on the Related Events tab.
26096	6.2.0.3.0062	N/A	Synchronizing a current Working view with a Submitted View that included a leaf with operation Append with changed location caused no message to appear in the Job Requests. This issue is resolved, and the following message appears in Job Requests when such an operation cannot be processed: "Leaf <Name> with Leaf <ID> with operation New was not synchronized with the Submitted View."
26083, 26174; [00063266, 00064161]	6.2.0.3.0062	N/A	In Veeva, when a document with a name containing the following symbols was assigned to Calyx RIM, the symbols appeared as question marks in Calyx RIM. <ul style="list-style-type: none"> – em dash (—) – en dash (-) – ¶Ãö®§©£€?!"() <p>This issue is resolved.</p>
26069; [00062757]	6.2.0.3.0062	N/A	When attempting to publish a paper submission, the TOC generation failed if the TOC Title contained a slash. This issue is resolved. Now, slashes in a TOC Title are replaced with dashes. The symbols in the TOC Title that are replaced by dashes are \:*\?"<> .

Issue	Build	Hotfix Build	Description
26060; [00063046]	6.2.0.3.0062	N/A	When a PDF from Veeva was dragged on to an assembly and its Rendition Identifier was set to a Viewable Rendition from Standard Rendition and published as a Native File , the Rendition Identifier of the output file was still Viewable Rendition instead of Standard Rendition . This issue is resolved.
26043; [00062812]	6.2.0.3.0062	N/A	When a Binder from Veeva was dragged on to an Assembly and its Default Rendition Identifier in the <i>Publishing Settings Library</i> set to Viewable Rendition , the Rendition Identifier of the documents under the Binder was set to Standard Rendition instead of inheriting the Default Rendition Identifier value from the assembly's <i>Publishing Setting Library</i> . This issue is resolved.
26033; [00062765]	6.2.0.3.0062	N/A	The performance of the <i>Prepare to Publish</i> process when the option Remove Empty Leafs or Remove Empty Folders is selected has been improved in this release. Also, the <i>Prepare to Publish</i> process failed when the nodes from which the <i>Prepare to Publish</i> was invoked were deleted during the deletion process. This issue is resolved.
26024; [00060098]	6.2.0.3.0062	N/A	An incorrect value appeared for the Currently Marketed column in the following query reports: <ul style="list-style-type: none"> – List of Application Countries with Registration Details – List of Application Countries with Registration and Product Details This issue is resolved. To prevent confusion in the report results, the corresponding column has been hidden by default.

Issue	Build	Hotfix Build	Description
26018; [00062534]	6.2.0.3.0062	N/A	Authenticating API users to Calyx RIM using secure LDAP resulted in an error. This was due to the incorrect port routing in the configuration file. This issue is resolved with the addition of the configuration options for LDAP Port, Use Secure LDAP, and Secure LDAP Port in the insightConfig.bat configuration tool, in the Identity Provider Settings tab in Data Administration. See the <i>Calyx RIM 6.2 CHF 3 Installation Guide</i> for more information.
26015; [00060789]	6.2.0.3.0062	N/A	When setting the Event-Country date to the status which already had a date error regarding violating the business rules appeared. This issue has been fixed. It is now possible to set the same date to the status when progression is enabled.
26011; [00060969]	6.2.0.3.0062	N/A	XEVMPD Submission Wizard: In a Registration Attachment, despite the Attachment EV Code missing, the validity declaration flag was assigned to the Full Product Presentation (FPP) Registration Attachment and no error message was displayed. This issue is resolved. Now, when Validity Declaration is selected manually on a Registration FPP attachment entity and there is no EV Code to the attachment, the XEVMPD Submission Wizard will display a user-friendly message.
26002; [00060879]	6.2.0.3.0062	N/A	Some users experienced general performance issues after their upgrade from Calyx RIM 5.1 to Calyx RIM 6.2. This issue is resolved for Calyx RIM 6.2 CHF 3. The performance has been improved.
25970; [00058630, 00063658, 00056697]	6.2.0.3.0062	6.1.0.5.0027	When using drag-and-drop to move a document from a leaf to a folder in the Working view of the same assembly, the document did not appear in the Publishing view . This issue is resolved.

Issue	Build	Hotfix Build	Description
25948; [00060098]	6.2.0.3.0062	N/A	<p>An incorrect value appeared for the Currently Marketed column in the following query reports:</p> <ul style="list-style-type: none"> – List of Package Set Registration with Application and Product Detail Properties Query – List of Registrations with Application Properties Query <p>This issue is resolved. To prevent confusion in the report results, the corresponding column has been hidden by default.</p>
25921; [00055531]	6.2.0.3.0062	N/A	<p>For the following queries, the Active Ingredients widget showed Active and Inactive values instead of showing only the Active values from Data Administration. This issue is resolved. The Active Ingredients selection widget now shows only Active values for these queries.</p> <ul style="list-style-type: none"> – Applications Sent, Submitted, or Approved - Searched by INN or Active Ingredient – Applications Submitted and/or Approved and/or Terminated within a Date Range – List of Registrations with Excipient – List of Excipient Manufacturers
25912; [00059183]	6.2.0.3.0062	6.1.0.4.0082	<p>When two different sequence assemblies were added to a lifecycle under the same Event, and with the same leaf replaced twice, the Approved View window displayed leafs incorrectly. Two leafs from the parallel working assemblies appeared instead of one. This issue is resolved. Now, the last lifecycled leaf is displayed.</p>
25908; [00059723]	6.2.0.3.0062	N/A	<p>For an EU MRP Application with Concerned Member and Reference Members assigned to it, running a query using DM table resulted in the Concerned Member information missing in the query output. This issue is resolved.</p>

Issue	Build	Hotfix Build	Description
25907; [00058005]	6.2.0.3.0062	N/A	For a document that was added to a sequence that was not an initial sequence, changing its version in Documentum updated the new version in the sequence in the working view when the DMS synchronization was performed. However, the change in the document version was not discernible. This issue is resolved. Now, an icon is displayed in the Sequence to indicate the change of the document version.
25905; [00059142]	6.2.0.3.0062	N/A	After running the following query, the EEA and Switzerland country details were not displayed in the query report. <ul style="list-style-type: none"> — List of Registrations with Local Country Details This issue is resolved.
25887; [00059477]	6.2.0.3.0062	N/A	Entering multiple lines in a text field for a workflow resulted in an error. This issue is resolved.
25697; [00057606, 00059002, 00059026]	6.2.0.3.0062	N/A	The error <code>Invalid Reference or ORA-00957: duplicate column name</code> appeared when attempting to create or update a sequence, and the InSightManager service had to be restarted to eliminate the issue. This issue is resolved.
25565; [00054092]	6.2.0.3.0062	N/A	Updating a sequence while the submission was being removed from a lifecycle resulted in an error. This issue is resolved. Now, a message will be displayed to indicate that a sequence cannot be updated while a submission is being removed from a lifecycle.
25389; [00054324]	6.2.0.3.0062	N/A	Migration failure due to the column size constraints in the database has been fixed in this release.
25384; [00053999]	6.2.0.3.0062	N/A	Importing large applications (submission with large number of leafs under a folder) using the eCTD Import option could fail. This issue is resolved.

Issue	Build	Hotfix Build	Description
25364; [00053273]	6.2.0.3.0062	N/A	When target leafs were updated for output location, the output location information was not reflected in the reference leaf attributes. This issue is resolved when both the reference and target leafs are in the same assembly. If the target leaf belongs to another assembly, the reference leaf will not be updated and this is to prevent possible performance issues in Calyx RIM.

Calyx RIM 6.2 CHF 4 Release Notes

This document describes a certified hotfix (CHF) provided to improve Calyx RIM 6.2. In addition to enhanced features and functionality, Calyx RIM 6.2 CHF 4 resolves issues that were reported to Technical Support. Our hotfixes are cumulative packages applied to a named version of our software.

As a certified hotfix, these updates have undergone Quality Control regression testing, certifying the system works as expected. These changes will not create a new code branch, but will be identified by the updated build number on the existing codeline of each version affected, not a new release number.

Upgrade Guidelines

The new Calyx RIM 6.2 CHF 4 Upgrade Guidelines describes the upgrade process and provides links to necessary documents for performing your upgrade installation. See: *Calyx RIM 6.2 CHF 4 Upgrade Guidelines* in the Calyx RIM online help.

Overrides Updates

Calyx RIM 6.2 CHF 4 requires overrides updates. Please allow 6 to 8 weeks for XML overrides review and updates. For details, please contact your Business Development Representative to consult with our Client Enablement team.

Regulatory Updates

Calyx RIM 6.2 CHF 4 includes functionality related to the following regulatory updates for **preview and preparation purposes**:

- China (CN) eCTD Module 1 version 1.0 (draft, dated 17 September 2019)
- Eurasian Economic Union (EAEU) electronic submission format version 1.0. The following features are included as part of this support:
 - EAEU template
 - Create eCTD wizard
 - Lifecycle operations
 - Publishing of the output with the resulting xml being separate from the content files
- eCTD import of EAEU submissions is not part of the scope

***Note:** Providing regulatory updates for **preview and preparation purposes** means that some features that are part of the standard regulatory update support scope are not complete (EAEU eCTD import is not part of the release) or implementation is based on the draft specification from the health authorities (China eCTD specification). These regulatory updates are made available to provide for early access and feedback. The functionality is subject to the same level of quality control as the rest of the release.*

Non-eCTD Assembly Templates

Calyx RIM 6.2 CHF 4 provides new and updated non-eCTD assembly templates:

- Traditional and Abbreviated 510(k)s

- Original Pre-Market Application
- MD - IMDRF (HC) IVD Template
- MD - IMDRF nIVD Template

Data Administration

To maintain the submission product types of China region, the *Submission Product Type Values* table has been introduced.

Data Administration Table Enhancements

Due to enhancements related to the **RMS Term Name** field, it is now displayed as a column in the grid view for the following *Data Administration* tables:

- ATC Values
- Compendial Designation/Source Values
- Concentration Measure Type Values
- Country Values
- Denominator Unit Values
- Numerator Unit Values
- Dosage/Pharmaceutical Form Values
- EMA Authorisation Status Values
- Language Values
- Legal Basis Values
- Medical Device Values
- Medicinal Product Type Values
- Procedure Type Values
- Route of Administration Values
- Unit of Measure Prefix Values

DMS Support Enhancements

Calyx RIM 6.2 CHF 4 enables you to configure a field of comma-separated values to be used as search criteria in **DMS Search**, for Documentum only. Such configuration may be applied to most of the text-like document attributes in for Documentum. Please contact your Business Development Representative to consult with our Client Enablement team.

Veeva Integration Improvements

- API calls consumption has been significantly reduced for the following operations:
 - Browsing Veeva repository from DMS Browse
 - Searching documents in Veeva repository using DMS Search
 - Assignment of a Veeva section from Veeva native UI or DMS Browse/Search
- Two timeout values have been added to *insight.var* for connections to the Veeva DMS.
- Support for Veeva users configured for SSO authentication has been added.
- Renditions processing has been enhanced.

Show/Hide Product Family

It is now possible to hide specific product families from being displayed in the **Product Family** navigation tree. To show or hide product families, use the new option **Show in Tree** on the *Modify Product Family* page.

Workflows

Calyx RIM6.2 CHF 4 provides the following enhancements to the **Workflows** functionality:

- A link to a specific Activity is sent in e-mail.
- A link to a specific Workflow is sent in e-mail.
- Emails and scheduling are set via the Calyx RIM configuration file.
- A chain of Activities, which covers the XEVMPD XML creation flow for particular Full Product Presentation.
See: *Configure Workflows to Create an XEVMPD XML File* in the Calyx RIM Workflows online help.
- Options for Workflow Activities to update XEVMPD related fields on selected entities assigned under the same application, in bulk. See: *Configure Workflows to XEVMPD Bulk Update* in the Calyx RIM Workflows online help.

XEVMPD

The performance of the XEVMPD Submission Wizard has been improved in this release.

In the XEVMPD Submission Wizard, the Authorised Product section error messages have been revised for better understanding of the errors. The wording for some messages has been updated and one new topic for Authorized Product section has been added: *XEVMPD Error Messages for Authorised Product*

Queries

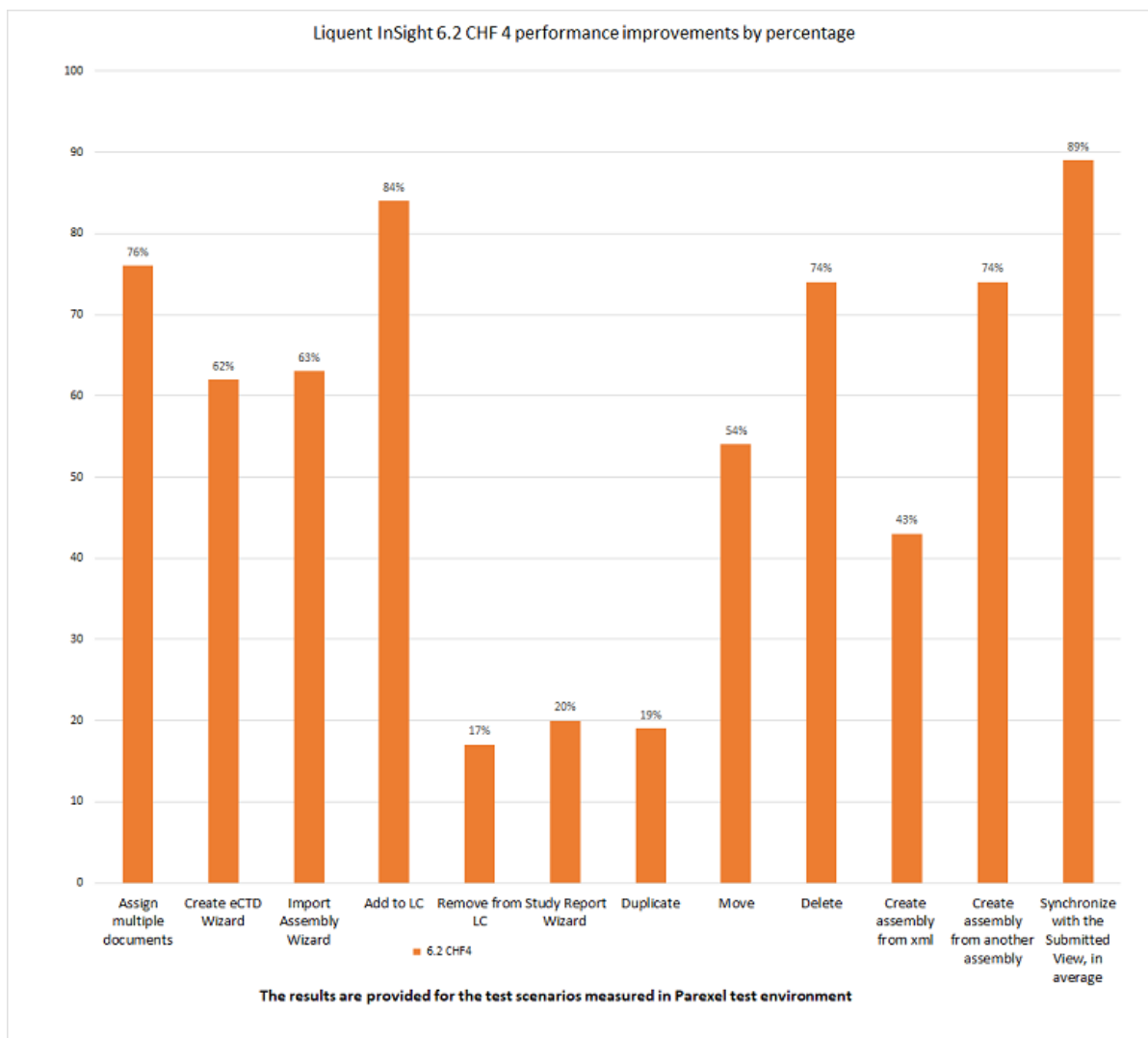
On the **Entity Audit Trail** of the Administration tab, it is now possible to query the following entities:

- Change
- Change Details
- Event Change Details

Assembly Enhancements

Due to a new way of storing assembly tree hierarchy, performance has been significantly improved for the following operations:

- Assign multiple documents
- Create eCTD wizard
- Import assembly using Import Assembly wizard
- Add to lifecycle/remove from lifecycle
- Study Report wizard
- Duplicate
- Move
- Delete
- Create assembly from xml
- Create assembly from another assembly
- Synchronize with the Submitted view



Link Inspector

Calyx RIM 6.2 CHF 4 increases speed for the following types of links when refreshing the Link Inspector:

- External links in documents when source and target are within the same tree
- Internal links in documents
- In-Process links in documents

Mass Update Properties

Calyx RIM6.2 CHF 4 provides the ability to set extensions or extension attributes for folders and leafs using the Mass Update Properties feature.

Leaf Attributes Mapping

Calyx RIM6.2 CHF 4 provides the ability to configure mapping of leaf attributes to document attributes for the auto-created leafs. This configuration needs to be done in `propertyMappings.xml` file. By default, this release

has the same configuration as previous releases. If you wish to change the default mapping, please consult with our Client Enablement team.

Usability Enhancements

The following usability enhancements introduced with this release improve your user experience:

- Ability to list comma-separated values in DMS Search for Documentum
- Warning message with hyperlinks in a new working assembly being created under an application with unlife-cycled working assemblies
- XML Definitions field added on the Publish Request window
- Improved formatting of Job Requests messages

See: *List of Enhancements: Calyx RIM 6.2 CHF 4* in the Calyx RIM6.2 CHF 4 Release Notes.

User Session Limits

Calyx RIM 6.2 enables a user with administrative permissions to set up the user session limit in the *insightConfig.bat* file. By default, this ability prohibits the same user from logging on from multiple locations at the same time. See: *Authentication for Identity Providers (IdP)* in the Calyx RIM Administration online help.

Data Administration Tables: Calyx RIM 6.2 CHF 4

Calyx RIM 6.2 CHF 4 provides the following modifications to Data Administration tables.

Data Administration Section: Submission Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
ods.DMF_SECTION_TYPE	<ul style="list-style-type: none"> — EAEU Leaf — Drug Registration File Documents Section 	<ul style="list-style-type: none"> — Section Code — Section Name 	To maintain the drug registration file documents section of the EAEU region, the <i>Drug Registration File Documents Section Values</i> table is introduced. The values for Section Code and Section Name can be entered in their respective fields.
ods.DMF_DOCUMENT_TYPE	<ul style="list-style-type: none"> — EAEU Leaf — Drug Registration File Document Values 	<ul style="list-style-type: none"> — Section — Document Code — Name 	To maintain the drug registration file documents of the EAEU region, the <i>Drug Registration File Document Values</i> table is introduced. The values for Section , Document Code and Name can be entered or selected in their respective fields.

Data Administration Table Name	Entity Affected	Field Name	Value List Description
mgr.SUBMISSION_PRODUCT_TYPE	<ul style="list-style-type: none"> – CN 1.0 Folder – Submission Product Type Values 	<ul style="list-style-type: none"> – Region – eCTD Code – Product Type – Applicable DTD/Schema 	To maintain the submission product types of the China region, the <i>Submission Product Type Values</i> table is introduced. The values for Region , eCTD Code , Product Type and Applicable DTD/Schema can be entered or selected in their respective fields.

New Fields Added: Calyx RIM 6.2 CHF 4

The following table describes fields that were added with Calyx RIM 6.2 CHF 4.

Field Name	Field Type	Entity Name	Description	Business Rules
Show in Tree	Drop-down list	<i>Modify Product Family</i> and <i>Product Family Attributes</i> pages.	With Calyx RIM 6.2 CHF 4, the option Show in Tree has been added to hide product families from being displayed when using the Tree Filter functionality.	You can use the Show in Tree to show or hide the product families on the <i>Modify Product Family</i> page. By default, this option is set to Yes .

Database Columns Changed: Calyx RIM 6.2 CHF 4

The following table describes database columns that were added or changed in Calyx RIM 6.2 CHF 4.

Field Name	Field Size	Database Column Name	Database Column Size	Database Table Name
Show in Tree	N/A	SHOW_IN_TREE_FLAG	VARCHAR2(1 BYTE)	MGR.PRODUCT_FAMILY
N/A	N/A	AS_CLIENT_ID	VARCHAR2(200)	ODS.DMS_REPOSITORY
N/A	N/A	AS_CLIENT_SECRET	VARCHAR2(200)	ODS.DMS_REPOSITORY
N/A	N/A	ABSOLUTE_ORDER has been deleted, HID has been added	RAW(2000)	ODS.PUB_READINESS_REPOR

Field Name	Field Size	Database Column Name	Database Column Size	Database Table Name
N/A	N/A	CHNG_REASON_CMNT	VARCHAR2 (1) has been changed to VARCHAR2(4000)	MGR.CHNG_MGMT_IN CIDENT
N/A	N/A	CHNG_REASON_CMNT	VARCHAR2 (1) has been changed to VARCHAR2(4000)	MGR.CHNG_MGMT_IN CIDENT_DETAIL
N/A	N/A	CHNG_REASON_CMNT	VARCHAR2 (1) has been changed to VARCHAR2(4000)	MGR.EVENT_CHNG_IN CIDENT_DETAIL
N/A	N/A	HID	RAW(2000)	ODS.CONTENT
N/A	N/A	HPATH	VARCHAR2(500)	ODS.CONTENT
N/A	N/A	HLEVEL	INTEGER	ODS.CONTENT
N/A	N/A	ABSOLUTE_SEQ_NO has been deleted	NUMBER	ODS.CONTENT
N/A	N/A	NAME_	VARCHAR2 (255) has been changed to VARCHAR2(1000)	ACTIVITI.ACT_RU_TAS K
N/A	N/A	NAME_	VARCHAR2 (255) has been changed to VARCHAR2(1000)	ACTIVITI.ACT_HI_TAS KINST

List of Enhancements: Calyx RIM 6.2 CHF 4

Requested new features and enhancements are included in each release. The items are listed in descending order by their tracking numbers. Customer case numbers that were recorded when the enhancements were requested are included in brackets following the tracking number.

Issue	Build	Hotfix Build	Description
26437	6.2.0.4.0079	6.2.0.3.0088	<p>To prevent instances when Calyx RIM could freeze due to an unstable connection to the Veeva DMS, the following timeout values have been added to the <i>insight.var</i> file for connections to the Veeva DMS:</p> <ul style="list-style-type: none"> – veeva.api.connect.timeout - The maximum number of milliseconds the application will wait when attempting to establish a connection to a Veeva vault. – veeva.api.read.timeout - The maximum number of milliseconds the application will wait for a response from Veeva after already having established a connection to a Veeva vault. <p>If these parameter values are missing, the respective timeouts will be equal to 30 seconds (veeva.api.connect.timeout) and 60 seconds (veeva.api.read.timeout).</p>
26421	6.2.0.4.0079	N/A	510k Template and PMA assembly templates have been updated.
26380	6.2.0.4.0079	N/A	<p>The following enhancements have been performed for the Job Request messages:</p> <ul style="list-style-type: none"> – Job Message text is formatted with line breaks. – Errors displayed in the Job Message column are presented in bold text. – For Calyx RIM Rendering errors, with long error text, the description of the error is presented in bold text. – Backbone Generator text that starts with <code>ERROR:</code> is presented in bold text starting from <code>ERROR:</code> up to the line break.
26360	6.2.0.4.0079	N/A	On the home page, it is now possible to hide specific product families from being displayed in the Product Family navigation tree.
26355	6.2.0.4.0079		<p>On the Entity Audit Trail of the Administration tab, Calyx RIM now provides you to ability to query the following entities:</p> <ul style="list-style-type: none"> – Change – Change Details – Event Change Details

Issue	Build	Hotfix Build	Description
26353	6.2.0.4.0079	N/A	The Event-Change Detail associations logic has been changed. Now, the logic is based on the individual Event-Change Detail Status . If there are multiple Change Details associated with one Event and one of the Change Details has a status of Not Approved or Withdrawn , it will be available for selection even if the overall Event is closed as Approved .
26348	6.2.0.4.0079	N/A	The number of Veeva API calls has been significantly reduced for Expand Tree , Assign Binder , and Assign Document actions in DMS Browse/Search .
26345; [INC0014459]	6.2.0.4.0079	N/A	The performance of the XEVMPD Submission Wizard has been improved in this release.
26315, 24020, 22557; [00063191, 00041781, 00053012]	6.2.0.4.0079	N/A	When assigning documents from DMS , the leaf name and the output file name used for documents required revisions. It is now possible to define customized leaf and document attributes in the <code>propertyMappings.xml</code> file and use them when documents are assigned from DMS or File Share .
26289; [INC0012144]	6.2.0.4.0079	N/A	Assigning Veeva sections caused the API burst limit to be exceeded. The number of Veeva API calls for assigning the Veeva document sections has been significantly reduced.

Issue	Build	Hotfix Build	Description
26200; [00064469]	6.2.0.4.0079	N/A	The RMS Term Name field will now appear as a column in the grid view for the following <i>Data Administration</i> tables: <ul style="list-style-type: none"> – ATC Values – Compendial Designation/Source Values – Concentration Measure Type Values – Country Values – Denominator Unit Values – Numerator Unit Values – Dosage/Pharmaceutical Form Values – EMA Authorisation Status Values – Language Values – Legal Basis Values – Medical Device Values – Medicinal Product Type Values – Procedure Type Values – Route of Administration Values – Unit of Measure Prefix Values
26181; [00063727]	6.2.0.4.0079	N/A	Calyx RIM 6.2 CHF 4 enables you to configure a field of comma-separated values for use as search criteria in DMS Search , for Documentum only. Such configuration may be applied to most of the text-like document attributes in for Documentum. Please contact your Business Development Representative to consult with our Client Enablement team.
26158; [00064073]	6.2.0.4.0079	6.2.0.3.0068	The Calyx RIM API authentication process has been enhanced to incorporate the LDAP configuration parameters defined in the <code>insight.var</code> file.
26099; [00063341]	6.2.0.4.0079	N/A	When a new working assembly is created under an application that includes unlifecycled assemblies, the warning message: "An unlifecycled working Assembly already exists for this Application under the following sequences:" displays the sequence codes for the working assemblies, with hyperlinks.
26081; [00063116]	6.2.0.4.0079	N/A	Calyx RIM6.2 CHF 4 now supports the International Medical Device Regulators Forum (IMDRF) assembly templates for Health Canada.

Issue	Build	Hotfix Build	Description
25954; [00060145]	6.2.0.4.0079	N/A	In the XEVMPD Submission Wizard, the Authorised Product section error messages have been revised for clarity. See: <i>XEVMPD Error Messages for Authorised Product</i> in the Lipient InSight for XEVMPD online help.
25991, 24795, 23817; [00060791, 00060643, 00047556, 00039935]	6.2.0.4.0079	N/A	When working with Study Tagging Files (STF), generic updates to extensions and extension attributes had to be made individually for each STF. It is now possible to update extensions or extension attributes for STFs in bulk using the Mass Update Properties feature.
25795; [00058695]	6.2.0.4.0079	N/A	To improve the user experience, the XML Definitions field, where the appropriate values are displayed, has been added to the Publish Request window.
23946, 23842; [00039378, 00039725]	6.2.0.4.0079	N/A	When modifying the metadata (for example, 2.3.S, 2.3.P, Node Extension) in an assembly, each node had to be individually revised and updated. It is now possible to revise and update the metadata revisions in bulk using the Mass Update Properties feature.
22824; [00030514, 00043876, INC0013821]	6.2.0.4.0079	N/A	When assigning multiple documents from DMS or a File Share, leafs were created with the name of the file along with the file extensions. It is now possible to define leaf and document attributes without extensions in the <code>propertyMappings.xml</code> file and use them when documents are assigned from DMS or a File Share.
22581; [00026219]	6.2.0.4.0079	N/A	When assigning documents, if the leaf title field was blank, the value for it was not retrieved from a DMS. It is now possible to define a leaf title value that is taken from a source document in the <code>propertyMappings.xml</code> file.

Issue	Build	Hotfix Build	Description
22108; [000197828FW]	6.2.0.4.0079	N/A	<p>It is now possible to control a user's access from multiple locations and set up a user session limit through the <i>insightConfig.bat</i> file with the help of the following parameters:</p> <ul style="list-style-type: none"> – Enable License Enforcement Functionality – Device Limit Per Named User – Enable User Session Limits functionality – Number of Sessions Allowed Per Named User <p>See: <i>Authentication for Identity Providers (IdP)</i> in the Lipient InSight Administration online help for more information.</p>

Resolved Issues: Calyx RIM 6.2 CHF 4

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their internal tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets following the internal tracking number.

Calyx RIM 6.2 CHF 4 resolves the following issues.

Issue	Build	Hotfix Build	Description
26452; [INC0015705]	6.2.0.4.0079	N/A	<p>The Concerned Parties values were getting deleted when the Create eCTD Wizard was used from the Sequence page of an application containing multiple sequences as well as from an application with a single sequence. This issue is resolved. The information of the Sequence Concerned Parties is displayed properly.</p>
26383; [INC0015705]			
26447	6.2.0.4.0079	N/A	<p>On the <i>Product Family Attributes</i> page, the following attributes were incorrectly listed after the Development Sponsor attribute. This issue was specific to the Pharmaceutical, Veterinary and Flu Vaccine product family types. This issue is resolved. Now, these attributes are listed after the Approved Trade Names attribute.</p> <ul style="list-style-type: none"> – Product Family Concerned Parties – Product Family Keywords – Product Family Description – Product Family Comments

Issue	Build	Hotfix Build	Description
26438; [INC0020386]	6.2.0.4.0079	N/A	The <i><sequence></i> value in published .xml output was not the same as the value defined for Sequence on the regional or envelope Folder Attributes page. This issue is resolved. The value defined under Folder Attributes is displayed in the <i><sequence></i> tag for the versions of EU 3.0.1/3.0.3, JO-1.0 and GCC-1.5.
26422; [INC0019310]	6.2.0.4.0079	N/A	Links with "Application" applicability were mixing (appeared where not necessary and disappeared where necessary) after DMS synchronization if the new minor version of the same document had been created in Documentum. This issue is resolved.
26419; [INC0019054]	6.2.0.4.0079	N/A	When a Package Set was associated with a Registration instead of with a Full Product Presentation (FPP), the information from the PDS Active Ingredients of the Package Set was included in the submission XML. This issue is resolved.
26417; [INC0018864]	6.2.0.4.0079	N/A	An Application was not updated with the Withdrawn status despite the Registration License Status value being internally mapped to Withdrawn . This issue is resolved.
26409; [INC0018167]	6.2.0.4.0079	N/A	The search functionality did not work in the Approved Views of an assembly. This issue is resolved.
26404; [INC0018012]	6.2.0.4.0079	N/A	When a link was created to a bookmark in a document from a previous sequence, the link created targeted to the first page of the document, instead of the bookmark. This issue is resolved. Now the links target to the correct page.
26398; [INC0017367]	6.2.0.4.0079	N/A	When using the Copy Registration Wizard, trying to copy a registration in a multiple country application such as an MRP or DCP resulted in an error. The error was due to the constraint on the Medicinal Regulatory Agency field. This issue is resolved. After using the Copy Registration Wizard, the field Medicinal Regulatory Agency becomes blank and the value must be updated manually.

Issue	Build	Hotfix Build	Description
26395; [INC0016670]	6.2.0.4.0079	6.2.0.3.0084	Folders in the approved view were out of order. This issue is resolved.
26388; [INC0016307]	6.2.0.4.0079	N/A	In the Create Submission wizard Sequence Code field, despite entering a code of four digits as recommended, the following error was displayed: <code>If this is an eCTD submission it is recommended you enter a four digit sequence code.</code> This issue is resolved. There are no warning messages if the four digits are entered.
26386; [INC0016091]	6.2.0.4.0079	N/A	A first request to create the <code>parexel__c</code> rendition for a PDF document from Veeva failed. This issue is resolved. The source document is retrieved instead of the <code>parexel__c</code> rendition if Standard Rendition is selected for a Veeva PDF file. For another Rendition Identifier value and non-PDF documents, the corresponding rendition is used. Now, in some cases two calls instead of three are sent to Veeva.
26371; [INC0015303]	6.2.0.4.0079	N/A	Gaps in the out-of-the-box (OOTB) Calyx RIM Reporting Schema for Analytics were identified during custom report development. This issue is resolved.
26367	6.2.0.4.0079	6.2.0.2.0091	Calyx RIM retrieved only the first 999 groups when authenticating a user in Azure. As a result, users not in one of the first 999 groups were unable to log on. This issue is resolved.
26361; [INC0014994]	6.2.0.4.0079	6.2.0.3.0073	Leaf attributes were missing from a leaf in the Approved View when that leaf was replaced in a previously lifecycled sequence. This issue is resolved.
26344; [INC0014379]	6.2.0.4.0079	N/A	On the Add or Edit Page Marker menu, changing the Page Number to more than 3 characters caused the error message: <code>Page Number cannot exceed 3 characters.</code> This issue is resolved. Now, it is possible to enter 5 characters in the Page Number field.

Issue	Build	Hotfix Build	Description
26339; [INC0014292]	6.2.0.4.0079	N/A	<p>Calyx RIM failed to update the following via the API:</p> <ul style="list-style-type: none"> Historical or future dates in the Event Country Status Schedule. Projected and actual dates in the Sequence Status Schedule. <p>The issues are resolved.</p>
26336; [INC0014237]	6.2.0.4.0079	N/A	<p>The XEVMPD Submission Wizard worked incorrectly for the Invalidate MA operation type on an Authorised Product when there was more than one Event for PDS prompting the error message: <code>No Active Ingredient was specified</code>. This issue is resolved.</p>
26328; [INC0014090]	6.2.0.4.0079	6.2.0.3.0070	<p>When the lifecycle operation on the same leaf across different sequences was performed and those events were added to the Approved View, using the Change Status Wizard resulted in an error. This issue is resolved.</p>
26323; [INC0013607]	6.2.0.4.0079	N/A	<p>Manually adding an event to the Approved view resulted in the error: <code>The object you are acting on has been deleted or modified by another user. Refresh your object to view the current information if the assembly had been created from another assembly and this source assembly was removed from the system.</code> In the Update Status Wizard, trying to add an event to the Approved view resulted in Calyx RIM freezing and the same error registering in the log file. These issues are resolved.</p>
26320; [CS0042776]	6.2.0.4.0079	6.2.0.2.0087, 6.2.0.3.0071	<p>Calyx RIM users authenticating with Azure AD were unable to access Veeva using Single Sign-On when Veeva was configured to authenticate using ADFS. This issue is resolved.</p>

Issue	Build	Hotfix Build	Description
26316; [INC0012933]	6.2.0.4.0079	N/A	Starting from Calyx RIM 6.1 CHF 4, the migration to Calyx RIM 6.2 and CHF4 failed with an ORA error in logs for some customers. This issue is resolved by removing the <code>select * from dv_user_workflow_secure</code> query from the migration package.
26307; [CS0027071]	6.2.0.4.0079	6.2.0.2.0091, 6.2.0.3.0074	When Calyx RIM was configured to use Single Sign-On via Microsoft Azure, a user disassociated from an Azure group added to Calyx RIM was unable to be re-associated back to that group. This issue is resolved.
26306; [INC0012619, INC0013266]	6.2.0.4.0079	N/A	Calyx RIM failed to populate the user name of the last logged on user on the Login page. This issue is resolved.
26300; [00063883]	6.2.0.4.0079	N/A	After an EU MRP assembly with an updated folder structure different from the template order was lifecycled, the Sequence view displayed empty folders in the next Working assembly after Create eCTD was launched. This issue is resolved. Now, the Sequence view does not include any empty folders.
26291, 26410; [INC0012181, INC0018227]	6.2.0.4.0079	N/A	In a Working assembly, the Replace action on a reference leaf resulted in infinite loading of the assembly tree. This issue is resolved.
26287; [00012133]	6.2.0.4.0079	N/A	The New menu on the Calyx RIM home page displayed the following options only when access was enabled to more than one of the options in Security Administration . When access was enabled to only one of the following options, that option failed to appear under the New menu: <ul style="list-style-type: none"> — System Alert — Publishing Settings Library Template — Change — Registration Attachment <p>These issues are resolved.</p>

Issue	Build	Hotfix Build	Description
26286; [INC0012051]	6.2.0.4.0079	N/A	Retrieving a list of assembly templates via Calyx RIM API requests failed. This issue is resolved.
26283	6.2.0.4.0079	N/A	When retrieving a full list of PingOne users using the Add User/Group Wizard , the search result displayed only 10 users. This issues is resolved.
26278	6.2.0.4.0079	N/A	When e-signature was enabled for Azure AD and Okta users, the system accepted any user credentials for e-signature instead of the logged in user credentials. As a result, anyone (including Read-only users) could sign in and save changes. This issue is resolved.
26255; [00065020]	6.2.0.4.0079	6.1.0.6.0016	Creating a standalone assembly using the JO 1.0 assembly template and then executing the Create Study Report Wizard failed with a <code>cannot determine region based on dtds</code> error. This issue is resolved.
26247, 26405; [00064107, 00016162, INC0018046]	6.2.0.4.0079	N/A	When a document from a Veeva repository was assigned, the rendition information was recognized incorrectly by Calyx RIM. This resulted in an unnecessary extract request: if a TOC had Calyx RIM bookmarks that were edited, the edit changes did not appear in the generated TOC. Also, an extraction request was sent with each rendition, even when the rendition parameters were not changed. These issues are resolved. When documents are assigned from a Veeva repository, the rendition information is recognized correctly and edits appear correctly in the generated TOC. If rendition parameters are not changed, no extraction request is sent.
26245; [00065009]	6.2.0.4.0079	6.2.0.3.0068	Calyx RIM authentication via API failed when an application server was configured with multiple domains. This issue is resolved.
26240; [00064944]	6.2.0.4.0079	6.2.0.3.0070	When replacing a leaf in a subsequent sequence associated with a new event, closing the event and creating an approved view, both the new leaf and the replaced leaf were displayed in the approved view. This issue is resolved. Only replaced leaf is displayed in approved view.

Issue	Build	Hotfix Build	Description
26236; [00064804]	6.2.0.4.0079	N/A	When the Procedure Identifier field was populated during migration by the system user, the User and Updated Date column values that were recorded in the XEVMPD Audit Report were incorrect. This issue is resolved.
26227; [00064595]	6.2.0.4.0079	N/A	If the time of the Approved status was set to a time that was earlier than that of the Submitted status, the status in the <i>Event</i> attributes in the Countries tab changed to Submitted . This issue is resolved.
26210, 25081; [00064119, 00064088, 00063968, 00050671]	6.2.0.4.0079	6.2.0.2.0081, 6.2.0.3.0065	Support for Veeva users configured for SSO authentication has been added to Calyx RIM.
26201;	6.2.0.4.0079	N/A	When e-signature is enabled for PingOne users, the system accepted any user credentials for e-signature instead of the logged in user credentials. As a result, anyone (including Read-only users) could sign in and save changes. This issue is resolved.
26199; [00064147]	6.2.0.4.0079	N/A	Extractions were generated for each assembly element containing a special sheet, if it pointed to the same template, and there was more than one settings profile with the same template file. It happened after the template update and the next Render Generated TOCs and Special Sheet Templates . This issue is resolved. Now extraction request is sent once per special sheet template.
26195; [00064087]	6.2.0.4.0079	N/A	When an activity name was longer than 255 characters, trying to complete that activity resulted in an error. This issue is resolved.
26193; [00064402]	6.2.0.4.0079	N/A	When selecting a file with an uppercase extension (For example - .DOC or .PDF) in the Registration Attachment page, the Attachment Name and the File Name fields were not populated. This issue is resolved.

Issue	Build	Hotfix Build	Description
26163; [00063867]	6.2.0.4.0079	N/A	Folder structure of study reports created when importing an eCTD application was incorrect. This issue is resolved.
26142; [00063604]	6.2.0.4.0079	N/A	When using the Volumize feature on an assembly that contained a volume with a TOC attached to it, there was an error. This issue is resolved.
26139; [00063733]	6.2.0.4.0079	N/A	Creating a new assembly, or importing using an existing assembly, took longer than expected. This issue is resolved.
26137; [00062685]	6.2.0.4.0079	N/A	An invalid reference error occurred when changing the XML definition file in the publishing settings from U.S. 2.0.1 to U.S 3.3 if more than one application type with the same us-3-3 Application DTD/Schema and eCTD code existed. This issue is resolved.
26127; [00063568]	6.2.0.4.0079	N/A	The URL in the e-mail that was sent to concerned users when an Event-Country Status was changed, failed to resolve to the expected target. This issue is resolved. Now, clicking the URL navigates to the event country where the status was created or updated.
26122; [00063208]	6.2.0.4.0079	6.2.0.3.0070	A role was not accessible on the Security Administration page if the role had all License Modules settings set to None/Select . This issue is resolved.
26120; [00063566]	6.2.0.4.0079	N/A	When an assembly section was selected in the Import Assembly Wizard or when creating an assembly from assembly, the corresponding assembly tree sections at the bottom half of the page were not displayed. Also, the full length of the scroll bar was not displayed, even on a maximized browser window. These issue are resolved.
26063; [00062715]	6.2.0.4.0079	N/A	The query for the List of Product Registrations with Application and Product Detail Properties report failed to display the result on the screen. This issue is resolved.

Issue	Build	Hotfix Build	Description
26057; [00063029]	6.2.0.4.0079	N/A	The Reset TOC Content button was not enabled in assemblies unless the Standalone Assemblies value for Home Page access under Security Administration was set to Yes . This issue is resolved.
26046; [00062700]	6.2.0.4.0079	N/A	The performance of refreshing the Link Inspector took several hours. This issue is resolved. The performance has been improved in sequence assemblies with: <ul style="list-style-type: none"> — External links in documents when source and target are within the same tree — Internal links in documents — In-Process links in documents
25996; [00060206]	6.2.0.4.0079	N/A	In the Global Project Planning (GPP) wizard, selecting multiple events that exceeded the query limit, resulted in the disappearance of the Update Project Event Country Status field in some cases. The SQL query limit has been increased. This issue is resolved.
25990; [00060779]	6.2.0.4.0079	N/A	When trying to create an Event-Country Status under a closed Event that was created via a workflow, there was an error. This issue is resolved.
25941; [00060258]	6.2.0.4.0079	N/A	Unauthorized remote users were able to access Red Hat JBoss <code>EJBInvokerServlet</code> . This issue is resolved by commenting the JBoss <code>EJBInvokerServlet</code> code block in the <code>web.xml</code> file. For more information, see Disabling Unauthorized Users from Accessing Red Hat JBoss EJBInvokerServlet .
25979; [00060743]	6.2.0.4.0079	N/A	When the screen resolution was set lower than [X]x1050 format, users were not able to send a publish request because the OK and Cancel buttons on the Publish Request and Job Details windows were not visible. This issue is resolved.

Issue	Build	Hotfix Build	Description
25862	6.2.0.4.0079	N/A	In an assembly tree, after running Prepare to Publish, deleting a leaf containing a source document linked to a target document resulted in a warning: "ORA-02292: integrity constraint (ODS.R_339) violated - child record found." This issue is resolved.
25566; [00054314]	6.2.0.4.0079	N/A	When using the eCTD Import process to import an assembly containing reference leafs and assigned documents down in the assembly tree, the reference leafs and the documents were switched in the imported assembly. This issue is resolved.
24253; [00042959]	6.2.0.4.0079	N/A	Performance was decreased when updating an assembly structure and when using the Prepare to Publish functionality to remove empty leafs and folders. The decrease in performance sometimes resulted in failures because of concurrent activities in progress. These issues are now minimized improved performance from Assembly enhancements. See: <i>Liquent InSight 6.2 CHF 4 Release Notes</i>

Calyx RIM 6.2 CHF 5 Release Notes

This document describes a certified hotfix (CHF) provided to improve Calyx RIM 6.2.

In addition to enhanced features and functionality, Calyx RIM 6.2 CHF 5 resolves issues that were reported to Technical Support. Our hotfixes are cumulative packages applied to a named version of our software.

As a certified hotfix, these updates have undergone Quality Control regression testing, certifying the system works as expected. These changes will not create a new code branch, but will be identified by the updated build number on the existing codeline of each version affected, not a new release number.

Overrides Updates

Calyx RIM 6.2 CHF 5 requires overrides updates. Please allow 6 to 8 weeks for XML overrides review and updates. For details, please contact your Business Development Representative to consult with our Client Enablement team.

Browser Support Update

Calyx RIM 6.2 CHF 5 adds support of Microsoft Edge based on Chromium. See *Calyx RIM 6.2 System Support Document (SSD)* for more details.

Database Server Specification Update

Calyx RIM 6.2 CHF 5 requires one of these Oracle versions:

- Oracle 19c (12.2.0.3) - 12.2.0.3.0 Standard Edition 2
- Oracle 19c (12.2.0.3) - 12.2.0.3.0 Enterprise Edition

Regulatory Updates

Calyx RIM 6.2 CHF 5 introduces functionality related to the following regulatory updates:

- CH eCTD Module 1 Version 1.5
- EAEU 1.0:
 - Embed PDF content into submission XML
 - eCTD import for submissions with embedded PDF content and submissions with PDF file references from the submission XML
 - Solvent metadata for the submission XML
 - Create separate folders based on the Substance and Solvent metadata
 - Auto-populate the **Output Folder** with the metadata values from Solvent and Drug Substance extensions
 - Bulk eCTD Import is not supported
 - Create Study Reports Wizard is not supported

Data Administration

Calyx RIM 6.2 CHF 5 provides:

- The ability to identify – and then export the results to `.xls` - historical audit trail data for any value in **Data Administration**, including when and by whom values were added. For **SPOR Maintenance** values, the audit trail will reflect in addition whether the values were updated from the EMA or manually by a Data Administration user.

- The ability to use filter functionality for Data Administration Values. See: *Filters for Data Administration Values*
- The ability to see the full field value when you create or modify the pick list.
- The ability to simultaneously update a MedDRA Version for multiple indications/intended use values.
- The new **System Process Default Flag** supports the ability to assign several display statuses to the same **Internal System Status** in Data Administration for:
 - Application Status Values
 - Event-Change Detail Status Values
 - Product Status Values
 - Product Detail Set Status Values
 - Sequence Status Values

When the status of an Application, Product, Product Detail Set, Event-Change Detail, and Sequence is updated as a result of running a status wizard or manually closing an event, the status set as the **System Process Default** is used. Prior to this update, the system would randomly pick a display status to show as the status when multiple display statuses were set to the same internal system status.

Global Project Plan Wizard

Extra fields can be updated in bulk on the **Event Change Detail** when the Details are associated to the **Event** via the **Project > Associate Change Detail(s) to Events** wizard. For details, please contact your Business Development Representative to consult with our Client Enablement team.

XEVMPD Acknowledgement Wizard

Calyx RIM 6.2 CHF 5 enables you to automate the inactivation of registration attachments when the corresponding acknowledgment is received via the **XEVMPD Acknowledgement** wizard. This option can be configured through application setup. By default, this option is disabled. These updates do not appear in the **XEVMPD Audit Report**.

XEVMPD Audit Report

To make the XEVMPD Audit Report more concise and efficient, the following inconsequential results are removed from the report:

- Automated updates when an EV Code or the Validity Declaration is assigned
- MedDRA Code and MedDRA Version when changes are made to them
- Rows added for each country when an indication is added or modified for EU CP
- Updates performed by SYSMAINT user

CT Shared Data

In prior versions of Calyx RIM for Registrations, on the **Product Family > CT Shared** window, the **Protocol Number** and **EudraCT Number** field had to be a unique combination. In Calyx RIM 6.2 CHF 5, the uniqueness rule is modified and only the **Protocol Number** must be unique within the **Product Family**.

Full Product Presentation

In Calyx RIM for Registrations, the **Full Product Presentation** (FPP) window displays a new field, **XEVMPD Submission Required?**, which enables you to categorize the FPPs ready for XEVMPD submission. You can trigger a system notification when the value of the new field changes.

Queries

The new **List of Events with Change Details** query enables you to view events that are associated with change, change details, and event change details.

Assemblies

In an assembly, you can now update the Folder or Leaf extension value from the **Change Type > Extension** without switching to Default value.

eCTD Import

Calyx RIM now retains the site folders in M5 after importing the study reports as node extensions.

Mass Update Properties

Clients with **Electronic Lifecycle Publishing (ELP)** licenses can use **Mass Update Properties** functionality.

Job Requests

In the Calyx RIM Publisher, new job statuses are introduced in the **Job Request** screen:

- Completed with Errors
- Completed with Warnings

Font Optimization in Paper Output

The new option **Optimize Fonts in Paper Output** minimizes font compatibility issues and provides stability to the process of printing paper output.

Optimized Memory Usage

Memory usage is optimized when publishing very large submissions in Calyx RIM 6.2 CHF 5.

Performance Improvements

Performance is improved for:

- Add Submission to Lifecycle and Remove Submission from Lifecycle functionality.
- Prepare to Publish with the options Remove Empty Assembly Folders and Remove Empty Assembly Leafs.
- Updating Folder or Leaf extended attributes using **Mass Update Properties** functionality.

Database Columns Added/Changed: Calyx RIM 6.2 CHF 5

The following table describes database columns that were added or changed in Calyx RIM 6.2 CHF 5.

Field Name	Field Size	Database Column Name	Database Column Size	Database Table Name
Optimize Font in Paper Output	N/A	OPTIMIZE_FONTS_FLAG	VARCHAR2(1)	ODS.PUB_SETTINGS

Field Name	Field Size	Database Column Name	Database Column Size	Database Table Name
System Process Default Flag	N/A	SYSTEM_PROCESS_DEFAULT_FLAG	VARCHAR2(1)	MGR.VALID_ENT_INT_STATUS
XEVMPD Submission Required?	N/A	XEVMPD_SUBMISSION_REQUIRED_FLAG	VARCHAR2(1)	MGR.FULL_PRODUCT_PRESENTATION

New Fields Added: Calyx RIM 6.2 CHF 5

The following table describes fields that were added with Calyx RIM 6.2 CHF 5.

Field Name	Field Type	Entity Name	Description	Business Rules
Created By	Username	All the SPOR Maintenance values in <i>Data Administration</i>	Created By has been added to ensure the visibility of who added the values.	You can use the Created By field to define by whom a SPOR Maintenance value was created, either via automated updates from the EMA or manually by Data Administration users. By default, this option is read-only. It is populated automatically when updates are made to the table.
Created Date	dd-mmm-yyyy	All the SPOR Maintenance values in <i>Data Administration</i>	The field Created Date has been added to ensure visibility of when the values are added.	You can use the Created Date field to define when a SPOR Maintenance value was created. By default, this option is read-only. It is populated automatically when updates are made to the table.

Field Name	Field Type	Entity Name	Description	Business Rules
DMS Versioning Scheme	Radio button	Import from eCTD option, on the Application page.	DMS Versioning Scheme has been added to provide functionality related to EAEU regulatory updates.	You can use DMS Versioning Scheme to import EAEU submissions. See: <i>Calyx RIM Best Practice: EAEU Submissions.</i>
EAEU XML with embedded PDFs	Drop-down list	Import from eCTD option, on the Application page.	EAEU XML with embedded PDFs has been added to provide the functionality related to EAEU regulatory updates.	You can use EAEU XML with embedded PDFs to import EAEU submissions. See: <i>Calyx RIM Best Practice: EAEU Submissions.</i>
EAEU XML Location	Browse button	Import from eCTD option, on the Application page.	EAEU XML Location has been added to provide the functionality related to EAEU regulatory updates.	You can use EAEU XML Location to import EAEU submissions. See: <i>Calyx RIM Best Practice: EAEU Submissions.</i>
Embed PDFs into EAEU XML?	Check box	Embed PDFs into EAEU XML? option, on the Export Published Output page.	Embed PDFs into EAEU XML? has been added to provide functionality related to EAEU regulatory updates.	You can use Embed PDFs into EAEU XML? to export EAEU submissions. See: <i>Calyx RIM Best Practice: EAEU Submissions.</i>
Last User Updated	Username	All the entities and grids in <i>Data Administration</i> .	Last User Updated has been added to identify historical audit trails.	You can use the Last User Updated field to define by whom the Data Administration value was created/ updated. By default, this option is read-only. It is populated automatically when updates were made to the table.

Field Name	Field Type	Entity Name	Description	Business Rules
Last Changed Date	dd-mmm-yyyy	All the entities and grids in <i>Data Administration</i> .	Last Changed Date has been added to identify a historical audit trail within user interface.	You can use the Last Changed Date field to define when a Data Administration value was created/ updated. By default, this option is read-only. It is populated automatically when updates were made to the table.
Mass Update	Action button	Indications/Intended Use	Mass Update enables you to update a MedDRA version for multiple indications/intended entities simultaneously.	You can use Mass Update to enter a MedDRA version. You can then use the option Update and Overwrite to update the new version for all selected Indications or use Update and Preserve to update the new version for only those selected Indications which have no values.
Optimize Font in Paper Output	Drop-down list	Publishing Settings Library	Optimize Font in Paper Output has been added to Publishing Settings Library .	Minimize font compatibility issues and provide stability to the process of printing the paper output. By default, the value is No. All assemblies migrated from a previous Calyx RIM version will have Optimize Fonts in Paper Output set to No.

Field Name	Field Type	Entity Name	Description	Business Rules
Output Document Type	Drop-down list	Import from eCTD option, on the Application page.	Output Document Type has been added to provide the functionality related to EAEU regulatory updates.	You can use Output Document Type to import EAEU submissions. See: <i>Calyx RIM Best Practice: EAEU Submissions</i>
System Process Default Flag	Drop-down list	The following entities in <i>Data Administration</i> <ul style="list-style-type: none"> – Application > Application Status Values – Event > Event-Change Detail Status Values – Product > Product Status Values – Product > Product Detail Set Status Values – Sequence > Sequence Status Values 	If you assign several display statuses to the same Internal System Status in Data Administration, the System Process Default Flag enables you to select the display status to show for Application, Product, Event-Change Detail, or Sequence after the Event is closed manually or via the wizard.	You can use System Process Default Flag to define the display status in the Name field which will be displayed after the Event is closed manually or via the wizard, provided that the appropriate Internal System Status is mapped to that display status.
XEVMPD Submission Required?	Drop-down list	Full Product Presentations	XEVMPD Submission Required? enables you to categorize the Full Product Presentations that are ready to be submitted to XEVMPD.	When creating or copying Full Product Presentations, the value of this field is automatically set to Yes. This indicates that the XEVMPD data is ready to be submitted.

Data Administration Fields Updated: Calyx RIM 6.2 CHF 5

This table describes fields that were updated or removed with Calyx RIM 6.2 CHF 5.

Pick List Name	Field Name	Field Type 6.2 CHF 5	Field Size Calyx RIM 6.2 CHF 4	Field Size Calyx RIM 6.2 CHF 5
Applicant Contact Values	Applicant Contact Name	Text box		
Applicant Contact Type Values	Applicant Contact Type	Text box		
Applicant ID Values	Applicant Name	Text box		
Application Form Type Values	Application Form Type	Text box		
Assembly Repository Variables	Variable Value	Text box		
ATC Values	ATC Description	Text box		
Concentration Measure Type Values	Concentration Measure Type Name	Text box		
Custom List Names	List Name	Text box		
Custom List Values	List Value	Text box		
Device Allergenicity Values	Code Name	Text box		
Device Nomenclature Values	Code Name	Text box		
Device Sterility Indicator Values	Code Name	Text box		
Device Type Values	Code Name	Text box		
Device Usage Values	Code Name	Text box		
Dosage/Pharmaceutical Form Values	Dosage Form (Long Name)	Text box		
	Dosage Form (Short Name)	Text box		
	Description	Text box		
Drug Registration File Documents Values	Name	Text box	50	500
Drug Registration File Documents Section Values	Name	Text box	50	500
Homepage Display Properties	Comments	Text box		
Indications/Intended Use Values	Indications/Intended Use	Text box		
Language Values	Language Name	Text box		

Pick List Name	Field Name	Field Type 6.2 CHF 5	Field Size Calyx RIM 6.2 CHF 4	Field Size Calyx RIM 6.2 CHF 5
Legal Basis Values	Legal Basis Name	Text box		
MAH/Development Sponsor/ Organisation Values	MAH/Development Sponsor/Organisation Name	Text box		
	Organisation Identifier	Text box		
	Address	Text box		
	Comments	Text box		
Manufacturer Values	Manufacturer Name	Text box		
	Organisation Identifier	Text box		
	Address Line 1	Text box		
	Comments	Text box		
	Keywords	Text box		
	Description	Text box		
Medical Device Values	Medical Device Name	Text box		
Medicinal Product Type Values	Medicinal Product Type Name	Text box		
Packaging Type Values	Name	Text box		
Procedure Type Values	Procedure Type Abbreviation		50	100
	Procedure Type Name	Text box	50	500
Product Characteristics Values	Code Name	Text box		
Product Family Values	Family Name	Text box		
Product Material Values	Code Name	Text box		
Promotional Material Doc Type Values	Promotional Material Doc Type	Text box		
Promotional Material Type Values	Promotional Material Type	Text box		
Promotional Material Audience Type Values	Promotional Material Audience Type	Text box		

Pick List Name	Field Name	Field Type 6.2 CHF 5	Field Size Calyx RIM 6.2 CHF 4	Field Size Calyx RIM 6.2 CHF 5
Qualified Person Responsible for Pharmacovigilance (QPPV) Values	QPPV Name	Text box		
Quantity Unit Of Measure Values	Code Name	Text box		
Reasons for Termination/Withdrawal List Values	Reasons for Termination/Withdrawal	Text box		
Region Values	Region Abbreviation		50	100
	Region Name	Text box	300	200
Region Type Values	Region Type Name	Text box		
Regulatory Activity Lead Values	Regulatory Activity Lead	Text box		
Route of Administration Values	Route of Administration (Long Name)	Text box		
RMS Values, for SPOR Maintenance section	Term Name	Text box		
	Short Name	Text box		
Secondary Event Type Values	Name	Text box		
Sequence Description Values	Sequence Description	Text box		
Shelf Life Type Values	Code Name	Text box		
Special Measure Values	Code Name	Text box		
Sterilization Requirement Values	Code Name	Text box		
Storage Condition Values	Storage Condition	Text box		
Sub Filing Type Values	Sub Filing Type	Text box		
Submission Product Type Values	Product Type	Text box		
Substances Values	Substance Name	Text box		
	Molecular Formula	Text box		
	CBD	Text box		
	Description	Text box		
	Comments	Text box		

Pick List Name	Field Name	Field Type 6.2 CHF 5	Field Size Calyx RIM 6.2 CHF 4	Field Size Calyx RIM 6.2 CHF 5
Substance Attachment Values	Attachment Name	Text box		
	File Name	Text box		
	Internal Name	Text box		
Substance Class Values	Substance Class Name	Text box		
Supplement Effective Date Type Values	Supplement Effective Date Type Name	Text box		
Trade Name Values	Trade Name Values	Text box		
Unit Of Presentation Values	Code Name	Text box		
Volume Unit Of Measure Values	Code Name	Text box		

New Queries Added: Calyx RIM 6.2 CHF 5

This table lists the filters available for the new **List of Events with Change Details** query that is included on the **Registration Planning and Tracking** tab.

Filter	Field Type	Business Rule
Product Family Type	Drop-down	Exact match on any selected value.
Product Family Name	Multi-select list	Exact match on any selected value.
Product Name	Product Name	Exact match on any selected value.
Application Name	Free text	Containing the matching text.
Application Country	Multi-select list	Exact match on any selected value.
Application Status	Multi-select list	Exact match on any selected value.
Application Type	Multi-select list	Exact match on any selected value.
Application Procedure Type	Multi-select list	Exact match on any selected value.
Event Country	Multi-select list	Exact match on any selected value.
Event Validation Number	Free text	Containing the matching text.
Event Name	Free text	Containing the matching text.
Event Type	Multi-select list	Exact match on any selected value.
Event Secondary Event Type	Free text	Containing the matching text.

Filter	Field Type	Business Rule
Event Action Type	Multi-select list	Exact match on any selected value.
Event Country Current Status	Multi-select list	Exact match on any selected value.
Event-Country Current Status Date	Date range	Containing the matching date.
Event-Country Projected Submittal Date	Date range	Containing the matching date.
Event-Country Actual Submittal Date	Date range	Containing the matching date.
Event-Country Projected Approval Date	Date range	Containing the matching date.
Event-Country Actual Approval Date	Date range	Containing the matching date.
Event-Country Actual Not Approval Date	Date range	Containing the matching date.
Event Open Flag	Flag	Match based on Yes/No selection.
Event Closed Date	Date range	Containing the matching date.
Event Associations Closed as	Multi-select list	Exact match on any selected value.
Change Type	Multi-select list	Exact match on any selected value.
Change Internal Number	Multi-select list	Exact match on any selected value.
Change External Number	Multi-select list	Exact match on any selected value.
Change Short Description	Free text	Containing the matching text.
Change Responsible Person	Free text	Containing the matching text.
Change Detail Number	Multi-select list	Exact match on any selected value.
Change Detail Short Description	Free text	Containing the matching text.
Change Detail Responsible Person	Free text	Containing the matching text.
Event Change Detail Status	Multi-select list	Exact match on any selected value.

The extra fields included in the following entities are included in the query list.

- Application
- Event
- Change
- Change Detail
- Event Change Detail

List of Enhancements: Calyx RIM 6.2 CHF 5

Requested new features and enhancements are included in each release. The items are listed in descending order by their tracking numbers. Customer case numbers that were recorded when the enhancements were requested are included in brackets [#####] following the tracking number.

Issue	Build	Hotfix Build	Description
26549, 25730; [00058042, 00063209]	6.2.0.5.0055	6.2.0.4.0104	Added functionality required to embed PDF content into submission XML according to the EAEU HA requirements.
26542	6.2.0.5.0055	6.2.0.4.0104	Added functionality to auto-populate the Output Folder with metadata values from Solvent and Drug Substance extensions for EAEU submissions.
26541	6.2.0.5.0055	6.2.0.4.0104	Added the ability to provide Solvent metadata for EAEU submission XML. Details of the new guidance can be found at: https://www.regmed.ru/download/eaeu/ToEaeuApplicants_DossierUpd_20200323_1.pdf
26519; [PRB004053 0]	6.2.0.5.0055	N/A	When diagnosing issues that required a restart, the data_exchanger.log and server.log files were cleared out after the restart. The configuration has been modified to prevent the log files from being cleared out after restart, and messages are continually added to the existing log files.
26512	6.2.0.5.0055	6.2.0.4.0104	Mass Update Properties was available for Calyx RIM with the SPT license, but not with the ELP license. This issue is resolved. Mass Update Properties functionality is now available for clients with Electronic Lifecycle Publishing (ELP) licenses.
26508	6.2.0.5.0055	6.2.0.4.0104	The eCTD Import wizard now supports the import of EAEU submissions with embedded PDF content and submissions with PDF file references from the submission XML.
26496; [INC0025048]	6.2.0.5.0055	N/A	When creating a new working assembly using the Create eCTD wizard in an EU MRP application, the country metadata for the subsequent countries is copied as the default country metadata from the first country page except for the Agency name, Applicant, and Invented Name values even if a new country was added to the application.
26480; [INC0023770]	6.2.0.5.0055	N/A	The new Mass Update feature enables you to update a MedDRA Version for multiple indications/intended use data administration values entities simultaneously.

Issue	Build	Hotfix Build	Description
26450; [CS0092205]	6.2.0.5.0055	N/A	Memory usage is optimized when publishing very large submissions in Calyx RIM 6.2 CHF 5.
26416	6.2.0.5.0055	N/A	The new List of Events with Change Details query enables you to view events that are associated with change, change details, and event change details.
26387	6.2.0.5.0055	N/A	The uniqueness constraint for the EudraCT Number on a protocol has been removed in this release. A study or the clinical trial shared data can now include a redundant EudraCT Number.
26359	6.2.0.5.0055	N/A	You can automate the inactivation of registration attachments once the corresponding acknowledgment is received via the XEVMPD Acknowledgement wizard. This option can be configured through application setup. By default, the option is disabled. These updates will not appear in the XEVMPD Audit Report .
26358	6.2.0.5.0055	N/A	To make the XEVMPD Audit Report more concise and efficient, the following inconsequential results have been removed from the report: <ul style="list-style-type: none"> – Automated updates when an EV Code or the Validity Declaration is assigned – MedDRA Code and MedDRA Version when changes are made to them – Rows added for each country when an indication is added or modified for EU CP – Updates performed by SYSMAINT user.
26357	6.2.0.5.0055	N/A	You can categorize the Full Product Presentations that are ready to be submitted to XEVMPD with the help of the new XEVMPD Submission Required? option.
26356	6.2.0.5.0055	N/A	Extra fields can be updated in bulk on the Event Change Detail when the Details are associated to the Event via the Project > Associate Change Detail(s) to Events wizard. For details, please contact your Business Development Representative to consult with our Client Enablement team.

Issue	Build	Hotfix Build	Description
26354	6.2.0.5.0055	N/A	The new System Process Default Flag provides the ability to assign several display statuses to the same Internal System Status in <i>Data Administration</i> for Application, Event-Change Detail, Product, Product Detail Set, and Sequence. You can see the assigned status after running the wizard or when the Event is closed manually. Before, the system randomly selected the first status that was mapped to the Internal System Status and you could not define which statuses would show after the updates.
26321; [INC0013546]	6.2.0.5.0055	N/A	It is now possible to create a folder or a leaf with an extension other than Default and extended attributes populated using a single API call.
26265	6.2.0.5.0055	N/A	You can identify when any SPOR Maintenance value was created and by whom. These fields are added: <ul style="list-style-type: none"> — Created By — Created Date
26264	6.2.0.5.0055	N/A	You can identify when any Data Administration value was created/last modified and by whom. These fields are added: <ul style="list-style-type: none"> — Last User Updated — Last Changed Date
26204; [00064468]	6.2.0.5.0055	N/A	The full field value can be viewed in Data Administration when you create or modify the pick list.
26095; [00063365]	6.2.0.5.0055	N/A	Calyx RIM 6.2 CHF 5 requires one of these Oracle versions: <ul style="list-style-type: none"> — Oracle 19c (12.2.0.3) - 12.2.0.3.0 Standard Edition 2 — Oracle 19c (12.2.0.3) - 12.2.0.3.0 Enterprise Edition
24325	6.2.0.5.0055	N/A	Calyx RIM now retains the site folders in M5 after importing the study reports as node extensions.

Issue	Build	Hotfix Build	Description
24532, 20873; [00044627, 00037898]	6.2.0.5.0055	N/A	New job statuses are introduced for Job Requests: <ul style="list-style-type: none"> – Completed with Errors – Completed with Warnings
23803 [00039687]	6.2.0.5.0055	N/A	In an assembly, you can update the Folder or Leaf extension value from the Change Type > Extension without switching to the Default value.

Resolved Issues: Calyx RIM 6.2 CHF 5

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their internal tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets following the internal tracking number.

Calyx RIM 6.2 CHF 5 resolves the following issues.

Issue	Build	Hotfix Build	Description
26608; [INC0038408]	6.2.0.5.0055	N/A	After migrating to Calyx RIM 6.2 CHF 4, clicking the Concerned Parties icon resulted in an error. This occurred if the domain of a user was changed and there was a NULL value for that user in the Domain column in the SEC.USR table. This issue is resolved.
26606; [INC0038763]	6.2.0.5.0055	N/A	The Submission Readiness report took a longer time to generate than usual and in some instances the report failed to generate. This issue is resolved. Now, the Submission Readiness report generates successfully and with less time.
26597	6.2.0.5.0055	6.2.0.4.0.0111	When EAEU submissions were published after performing a Delete operation on one or more leafs, incorrect leaf attributes and DocID values were included in the output XML. This issue is resolved.
26592	6.2.0.5.0055	6.2.0.4.0.0110	The Export Published Output process did not support Cyrillic symbols in filenames when choosing to embed PDF files into the EAEU XML file. This issue is resolved.

Issue	Build	Hotfix Build	Description
26588	6.2.0.5.0055	6.2.0.4.0.0110	The Export Published Output process failed intermittently when choosing to embed PDF files into the EAEU XML file when the processed file path included spaces. This issue is resolved.
26583; [INC0023438]	6.2.0.5.0055	6.2.0.4.0.0110	If a workflow was associated to the assembly root, a folder, or a document in an initial sequence assembly, and the Synchronize with the Submitted View option was applied, the workflow was lost. This issue is resolved. Associated workflows are kept for each node after the option is applied.
26582	6.2.0.5.0055	6.2.0.4.0.0110	The <code>mediaTypeCode</code> attribute was missing from the embedded PDF nodes of the EAEU XML output file. Although this attribute is not required per the schema, the agency validator requires it. This issue is resolved. The <code>mediaTypeCode</code> attribute is now included in the EAEU XML file for embedded PDF nodes.
26574	6.2.0.5.0055	6.2.0.4.0104	When an EAEU submission was published, the name of the XML index file generated was incorrect. This issue is resolved. Now, the XML index file includes the correct name: <code>index-r-022.xml</code>
26571	6.2.0.5.0055	6.2.0.4.0104	The incorrect <code>codeListId</code> value was generated in the <code>UnifiedCountryCode</code> of an EAEU assembly published XML. This issue is resolved.
26565; [INC0033560]	6.2.0.5.0055	6.2.0.4.0106	Calyx RIM did not recognize some users as members of their assigned Active Directory (AD) groups. This issue is resolved.
26556; [INC0033264]	6.2.0.5.0055		At times, the Synchronize with the Submitted View option took more time than usual. This issue is resolved.
26537; [INC0030024, INC0033088]	6.2.0.5.0055	N/A	If an assembly root was not selected during publishing, variables failed to be resolved in the submission output for all the leafs. This issue is resolved.
26533; [INC0029832]	6.2.0.5.0055	6.2.0.4.0104	Errors were found when the Publishing Readiness Query was run for the China eCTD. This issue is resolved.

Issue	Build	Hotfix Build	Description
26530; [INC0029543]	6.2.0.5.0055	6.2.0.4.0104	The Document Creation Date displayed the current date, even though no value was specified for that field in the modify mode. This issue is resolved. Now, Document Creation Date displays a date only when the field is populated.
26528; [INC0029467]	6.2.0.5.0055	6.2.0.4.0104	When creating and publishing an assembly with the new EAEU Assembly Template including section 2.7.3, the following message appeared: "WARN : The characters: ? were removed from the path". This issue is resolved.
26527, 26226, 25965; [INC0029460, 00064445]	6.2.0.5.0055	N/A	The options For this Element and Document were not available on the <i>Update Overlay Settings</i> page invoked from the Document . This issue is resolved.
26507	6.2.0.5.0055	6.2.0.4.0104	The EAEU 1.0 assembly template is updated and now eCTD is used as the assembly type.
26504	6.2.0.5.0055	6.2.0.4.0093	A Vertical Privilege Escalation (Systemic) vulnerability was reported as a result of penetration testing. This issue is resolved.
26502; [INC0025226]	6.2.0.5.0055	N/A	Applying the eCTD Import to an AU-3-0 assembly where the Sequence Description attribute had a code values different from those provided by the agency caused the import to fail. This issue is resolved. Now the import ignores the mismatches and takes the code value.
26491	6.2.0.5.0055	6.2.0.4.0096	When using Mass Update Properties with the Update and Preserve option selected to set the extension value for leafs in a folder, the extended attributes were erased for child folders or leafs within the selected range. This issue is resolved.
26487; [INC0024292]	6.2.0.5.0055	N/A	After importing published GCC submissions, some folders were renamed or missing. This issue is resolved. Now, the imported assembly keeps the original structure.

Issue	Build	Hotfix Build	Description
26486; [INC0024081]	6.2.0.5.0055	N/A	If an application had an <code>Active</code> or <code>Not Approved</code> or <code>Withdrawn</code> status, and the application had a registration with a status other than <code>Withdrawn</code> , it was not possible to update an event with <code>Withdrawn</code> status. This issue is resolved.
26469; [INC0023438]	6.2.0.5.0055	N/A	If a <code>Workflow</code> was associated to a leaf in an initial sequence assembly and the <code>Synchronize with the Submitted View</code> option was applied, the <code>Workflow</code> was lost. This issue is resolved. Associated <code>Workflows</code> are kept for each leaf after the option is applied.
26458; [INC0022479]	6.2.0.5.0055	6.2.0.4.0106	Publishing failed for the <code>2.3.S</code> , <code>2.3.P</code> , and <code>2.7.3</code> folders of <code>ICH Module 2-5 v3.2</code> when the metadata field contained a single quote character. This issue is resolved.
26455; [INC0022252]	6.2.0.5.0055	N/A	Variables with spaces in the <code>Variable Name</code> field did not resolve in the published output. This issue is resolved.
26449	6.2.0.5.0055	N/A	An InSight API request to retrieve a list of assemblies for assembly types other than templates did not work. This issue is resolved.
26446	6.2.0.5.0055	N/A	When using the <code>Mass Update Properties</code> functionality, the time taken for updating the extended attributes was longer than the time taken for the common attributes. This issue is resolved.
26444; [INC0021105]	6.2.0.5.0055	N/A	Incorrect Folder/Leaf names were observed in sections <code>1.08</code> , <code>1.09</code> , and <code>1.12</code> in <code>JP eCTD Module 1 v1.0</code> assembly template. This issue is resolved. The <code>JP eCTD Module 1 v1.0</code> assembly template is updated.

Issue	Build	Hotfix Build	Description
26439; [INC0020399]	6.2.0.5.0055	N/A	For an eCTD Import , the “Waiting for InSight” status appeared without updates in Job Status . There was no indication that the import failed when the imported submission had a sequence that failed to lifecycle due to mismatched Folder Types. This issue is resolved. "Completed" appears in the Job Status column, and the sequence is indicated. When the <code>m1-us-form</code> type folder is imported into submission with the Submitted view and <code>m1-us-admin-form</code> type folder is imported into submission with the Sequence view, the <code>Node type</code> mismatch is found: a node with <code>m1-us-admin-form</code> type replaced a node with <code>m1-us-form</code> type in the Submitted View. message appears.
26434; [INC0020054]	6.2.0.5.0055	N/A	In Internet Explorer, when using the Delete (Withdraw) option on multiple leafs from subfolders of a Working assembly, the process ran would spin for a long time with no result. This issue is resolved. The method used to communicate with the server is changed and now you can select any number of leafs to withdraw.
26432; [INC0019888]	6.2.0.5.0055	N/A	If it was associated to a Product and Project , an Event could not be updated using the API . This issue is resolved.
26425; [INC0376737]	6.2.0.5.0055	N/A	In a Working assembly with documents assigned from Documentum, the links created to bookmarks in other documents using Calyx RIM Linking plug-in (PDF) resolved to incorrect pages after publishing. This issue is resolved.
26402; [INC0017878]	6.2.0.5.0055	N/A	When an event was closed with a reason using the Specify Reason for Termination/Withdrawal option, the same reason was applied to the parent application. This issue is resolved.
26401; [INC0017630]	6.2.0.5.0055	N/A	When deleting leafs in bulk using Delete (Withdraw) lifecycle operation in the Working assembly, the assembly tree refreshed and the deletion symbol (crossed leaf) appeared only on one of the leafs instead of all of them. This issue is resolved.

Issue	Build	Hotfix Build	Description
26397, 24517; [INC0017263, 00044443]	6.2.0.5.0055	N/A	When deleting an assembly, there was no indicator of the deletion in progress. This issue is resolved. A progress indicator shows that the deletion is in progress.
26370; [INC0015274]	6.2.0.5.0055	N/A	<p>The pagination formulas using Reverse and Bates types did not resolve properly for paper publishing. Example: $\\$Bates (\\$Reverse (\\$Calculate (\\${ATP} - \\${ARP} + 1), "-1"), 5)$.</p> <p>This issue is resolved. The formula works when an intermediate variable is used as the first one in alphabetical order according to Variable Code. Example:</p> <ul style="list-style-type: none"> Variable Name = <i>someTestName</i>, Variable code = <i>calcRevPage</i>, Variable Value = $\\$Reverse (\\$Calculate (\\${ATP} - \\${ARP} + 1), "-1")$ Variable Name = <i>someTestName</i>, Variable code = <i>revBates</i>, Variable Value = $\\$Bates (\\$calcRevPage, 5)$ <p>To experience better performance, we recommend to minimize the formulas usage and set up them in Publishing Settings Library, not in Data Administration.</p>
26346; [INC0014465]	6.2.0.5.0055	N/A	Notifications were not sent even when the <code>mail-service.xml</code> file included a valid SMTP server name and port number. This issue is resolved.
26340; [INC0014300]	6.2.0.5.0055	N/A	After reordering leafs in a Working Assembly using Reorder Child Leafs option, users observed empty folders in Publishing and Sequence views. This issue is resolved in Calyx RIM 6.2 CHF 4 as a result of other fixes.
26310, 19440; [INC0012460]	6.2.0.5.0055	N/A	After performing a DMS Synchronization on an assembly with an assigned document that was versioned, the document attributes and assembly tree were not automatically refreshed by Calyx RIM. This issue is resolved. Now, the icon 'Newer version available' is displayed without having to manually refresh the assembly tree.

Issue	Build	Hotfix Build	Description
26276; [INC0011104]	6.2.0.5.0055	N/A	The Assembly templates for CH 1.3 and CH 1.4 contained errors that lead to validation issues. This issue is resolved.
26221; [00064631]	6.2.0.5.0055	N/A	In EU Submissions with MAA in Submission Type and with the initial value in Submission Unit Type, the users were able to save the empty INN in EMA Envelope Information. This issue is resolved. Now, the users are required to populate it when needed.
25831	6.2.0.5.0055	N/A	When using the Calyx RIM API to convert a leaf to reference, it could not be targeted to a leaf from a Sequence view. This issue is resolved.
25487; [00055381]	6.2.0.5.0055	N/A	The Find and Replace option did not function as expected in the Publishing view of an assembly and was not available for the folders with new or lifecycle-operated nodes in the current sequence in the Working view. This issue is resolved. Now, in the Publishing view, the Find and Replace option covers the leafs and documents and is available for folders with new or lifecycle-operated nodes in the current sequence in the Working view.
25325; [00053635, 00055122, 00059463, 00062975,INC001 6253, INC0016254, INC0017802]	6.2.0.5.0055	N/A	A GCC valid submission with the language missing failed to import from eCTD. This issue is resolved. Now, the eCTD import is completed with no errors in the Job Requests even if there is no information about the language. The system uses English as the default language, and the language folder name is the same as in the GCC template.
25263; [00052834]	6.2.0.5.0055	N/A	GCC submissions containing multiple Cover Letters could not be imported to Calyx RIM. This issue is resolved.
23864; [00039884, 00054020, 00055522, INC0016252]	6.2.0.5.0055	N/A	Using the Change Submittal Status wizard after changing a folder extension in a later sequence caused a reference error. This issue is resolved.

Calyx RIM 6.2 CHF 6 Release Notes

This document describes a certified hotfix (CHF) provided to improve Calyx RIM 6.2.

In addition to enhanced features and functionality, Calyx RIM 6.2 CHF 6 resolves issues that were reported to Technical Support. Our hotfixes are cumulative packages applied to a named version of our software.

As a certified hotfix, these updates have undergone Quality Control regression testing, certifying the system works as expected. These changes will not create a new code branch, but will be identified by the updated build number on the existing codeline of each version affected, not a new release number.

Overrides Updates

Calyx RIM 6.2 CHF 6 requires overrides updates. Please allow 6 to 8 weeks for XML overrides review and updates. For details, please contact your Business Development Representative to consult with our Client Enablement team.

Regulatory Updates

Calyx RIM 6.2 CHF 6 provides the following regulatory updates:

- Support for JO eCTD Module 1 Version 1.1
- EAEU 1.0
 - Formatted EAEU submission XML with embedded PDFs
 - Output folder values and output file names are updated for the EAEU v 1.0 assembly template

Data Administration

Calyx RIM 6.2 CHF 6 provides the updated **System Process Default Flag** functionality with the ability to assign several display statuses to the same **Internal System Status** in *Data Administration* for **Registration Status Values**. When the status of a Registration is updated as a result of running a wizard, the status set as the **System Process Default Flag** is used.

Withdraw Country Updates

It is now possible to withdraw a country from Centralized Procedure (CP) applications via the **Product Details Set**.

New Fields Added: Calyx RIM 6.2 CHF 6

The following table describes fields that were added with Calyx RIM 6.2 CHF 6.

Field Name	Field Type	Entity Name	Description	Business Rules
System Process Default Flag	Drop-down list	Data Administration > Registration > Registration Status Values	If you assign several display statuses to the same Internal System Status in Registration Status Values in Data Administration, the System Process Default Flag enables you to select the display status to show for Registration when the Global Project Plan > Withdraw Package Set Registration is run.	You can use the System Process Default Flag to define the display status in the Name field. This status shows after the Event is closed, provided that the appropriate Internal System Status is mapped to that display status.

List of Enhancements: Calyx RIM 6.2 CHF 6

Requested new features and enhancements are included in each release. The items are listed in descending order by their tracking numbers. Customer case numbers that were recorded when the enhancements were requested are included in brackets [#####] following the tracking number.

Issue	Build	Hotfix Build	Description
26644	6.2.0.6.0007	N/A	It is now possible to withdraw a country from Centralized Procedure (CP) applications via the Product Details Set. The withdrawn country is not available to associate with a subsequent Event (Countries list) created for the same Application.
26640; [INC0044227]	6.2.0.6.0007	6.2.0.5.0063	An EAEU submission XML with embedded PDFs could fail validation in the Russian agency validation service due to the absence of XML formatting. Now, Calyx RIM Publisher produces formatted EAEU submission XML with embedded PDFs.

Resolved Issues: Calyx RIM 6.2 CHF 6

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their internal tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets following the internal tracking number.

Calyx RIM 6.2 CHF 6 resolves the following issues.

Issue	Build	Hotfix Build	Description
26628; [INC0042144]	6.2.0.6.0007	6.2.0.5.0060	The feature to define a leaf title value, configured in the <code>propertyMappings.xml</code> file, worked for the Working view but not for the Publishing view. This issue is resolved.
26625	6.2.0.6.0007	N/A	In the EAEU v 1.0 assembly template, some output folder values were missing and some output file names were incorrect. This issue is resolved. Now, output folder values and output file names are updated as required.
26624	6.2.0.6.0007	N/A	After paper publishing an assembly, the View File option did not work for the selected volume. This issue is resolved.
26619	6.2.0.6.0007	N/A	The System Process Default Flag was not available for Registrations > License Status . A workaround required you to use only one display status (not multiple) mapped to one Internal System Status value. This issue is resolved. See <i>New Fields Added: Calyx RIM 6.2 CHF 6</i> .
26501; [INC0025308]	6.2.0.6.0007	N/A	When publishing JP submissions, the Delete operation with default Folder Attributes: Study Organization in XML: Leaf elements only - no differentiation between studies did not show in the <code>index.xml</code> file. This issue is resolved.
26476; [INC0029689]	6.2.0.6.0007	N/A	After the Product Family information and metadata were moved from Calyx RIM to D2 LSRD, making changes to Product Family Indications/Intended Use in Calyx RIM resulted in the deletion of the Submission Country value from D2 LSRD. In Calyx RIM, the application continued to display the Reviewing Country . This issue is resolved and the D2 LSRD shows all of the necessary information.

Issue	Build	Hotfix Build	Description
26424; [INC0019435]	6.2.0.6.0007	N/A	When an MRP or DCP Application country had more than one associated product, and only one product strength was being removed from that country, the system withdrew the country from the Application, leaving behind actively marketed products/product detail sets for that country. This withdrawal made the country unavailable for selection on new Events. This issue is resolved so that the countries with active products remain active in the Application and available for new Events.

Calyx RIM 6.2 CHF 7 Release Notes

This document describes a certified hotfix (CHF) provided to improve Calyx RIM 6.2.

In addition to enhanced features and functionality, Calyx RIM 6.2 CHF 7 resolves issues that were reported to Technical Support. Our hotfixes are cumulative packages applied to a named version of our software.

As a certified hotfix, these updates have undergone Quality Control regression testing, certifying the system works as expected. These changes will not create a new code branch, but will be identified by the updated build number on the existing codeline of each version affected, not a new release number.

Entity Comments

Calyx RIM 6.2 CHF 7 enables you to add comments for create/modify functions on Event - Country Status, Sequence Status Date, and Task Status Dates:

- `Event-Country Status Comments` in **Event- Country Attributes > Add/Modify-Country Event Status**.
- `Sequence-Status Comments` in **View Sequence > Add/Modify Status**.
- `Task Status Comments` in **View Task > Add/Modify Status**.

Regulatory Updates

- Support for US FDA eCTD M1 specification v.2.5, submission standards v.4.1:
 - `http://` is changed to `https://` in DTD reference and stylesheets.
 - US 3.3 assembly template updated to include additional folders and leafs.
 - Application Form Type Values updated to include applicable Regulatory Codes.
 - Filing Type updated with additional application types for grouped submissions.
 - Form FDA 3988 and Form FDA 3938.
 - REMS Supplement enabled for grouped submission in *Data Administration*.
- Support for Taiwan eCTD Module 1 v1.1 (DTD 1.0).

BREXIT

Calyx RIM 6.2 CHF 7 includes changes and fixes necessary to support BREXIT regulatory processes.

New Fields Added: Calyx RIM 6.2 CHF 7

The following table describes fields that were added with Calyx RIM 6.2 CHF 7.

Field Name	Field Type	Entity Name	Description	Business Rules
Add Comment	Text	<ul style="list-style-type: none"> Event-Country Attributes > Status Dates > Add Event-Country Status Event-Country Attributes > Status Dates > Modify Event-Country Status 	When you create or modify an Event-Country Status, you can add a comment to it. These comments can be audited.	You can use this option to record comments for create/modify actions on Event - Country Status, Sequence Status Date, and Task Status Dates. <ul style="list-style-type: none"> Event-Country Status Comments in Event- Country Attributes > Add/Modify-Country Event Status. Sequence-Status Comments in View Sequence > Add/Modify Status. Task Status Comments in View Task > Add/Modify Status.
		<ul style="list-style-type: none"> View Sequence > Status Dates > Add Status View Sequence > Status Dates > Modify Status 	When you create or modify a Sequence Status, you can add a comment to it. These comments can be audited.	
		<ul style="list-style-type: none"> View Task > Status Dates > Add Status View Task > Status Dates > Modify Status 	When you create or modify a Task Status, you can add a comment to it. These comments can be audited.	

List of Enhancements: Calyx RIM 6.2 CHF 7

Requested new features and enhancements are included in each release. The items are listed in descending order by their tracking numbers. Customer case numbers that were recorded when the enhancements were requested are included in brackets [#####] following the tracking number.

Issue	Affected Area	Build	Hotfix Build	Description
26747	Assembly	6.2.0.7.000 6	N/A	Calyx RIM 6.2 now supports Taiwan eCTD Module 1 Version 1.1.

Issue	Affected Area	Build	Hotfix Build	Description
26700	Assembly	6.2.0.7.000 6	N/A	<p>US 3.3 assembly templates now support eCTD specification v.2.5 and include:</p> <ul style="list-style-type: none"> — the updated xml generation to use <code>https</code> instead of <code>http</code> in dtd reference and stylesheet. — two additional folders with US Forms extension: <ul style="list-style-type: none"> • 1.1.10 Form FDA 3988: Transmittal of PMR/PMC Submissions for Drugs and Biologics • 1.1.11 Form FDA 3938: Drug Master File — fdact10 and fdact11 Application Form Type Values — REMS Supplement Filing Type with NDA, BLA and ANDA application types for Grouped Submissions.
26698	Assembly	6.2.0.7.000 6	6.2.0.6.002 2	The EU National 3.0.3 template is now enabled in the Create eCTD Wizard for the Great Britain and United Kingdom regions .
26694	Assembly	6.2.0.7.000 6	6.2.0.6.002 5	<p>User authentication is now introduced for permission based access to OpenText Content Server (formerly Livelink), SharePoint, Documentum, and Secure File System repositories when the following actions are performed:</p> <ul style="list-style-type: none"> — View File on a document, leaf, or volume — View File in Link Inspector — Edit Document Links <p>If the user does not have sufficient permissions to access the document in the DMS, the user will not be able to access the document via the user interface.</p>
26688	Application	6.2.0.7.000 6	6.2.0.6.002 2	The Application UUID is now unique within a regulatory region, instead of being unique within the system.

Issue	Affected Area	Build	Hotfix Build	Description
26686	Application	6.2.0.7.000 6	N/A	<p>You can record comments for create/modify actions on Event - Country, Sequence Status Date, and Task Status Dates.</p> <ul style="list-style-type: none"> – Event-Country Status Comments in Event-Country Attributes > Add/Modify-Country Event Status. – Sequence-Status Comments in View Sequence > Add/Modify Status. – Task Status Comments in View Task > Add/Modify Status. <hr/> <p><i>Note: Comments on status are not modified/deleted by Admin.</i></p> <hr/>
26682	XEVMPD	6.2.0.7.000 6	6.2.0.6.002 2	The <i>XEVMPD Wizard</i> is updated to support the EMA XEVMPD requirement for BREXIT to generate 'XI' as the Authorisation country code in the EVPRM message for all United Kingdom registrations.
26681	Application	6.2.0.7.000 6	6.2.0.6.002 2	The UUID field is now available on View and Edit Application pages for the United Kingdom and Great Britain regions.
26674	XEVMPD	6.2.0.7.000 6	6.2.0.6.002 2	The United Kingdom country is now available for selection in the Country field in the Authorized Product Selection tab of the <i>XEVMPD Submission</i> wizard.

Resolved Issues: Calyx RIM 6.2 CHF 7

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their internal tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets following the internal tracking number.

Calyx RIM 6.2 CHF 7 resolves the following issues.

Issue	Build	Hotfix Build	Description
26790; [CS0401640, INC0058360]	6.2.0.7.0006	N/A	When a Veeva document with overlay was assigned to an assembly and the <i>Prepare to Publish</i> query was run with the Generate Missing Renditions and Extractions option selected, the extract document data request failed to process correctly. This issue is resolved. Now, the extraction request is sent only if document with overlay is updated since last data retrieval.
26789; [INC0061160]	6.2.0.7.0006	N/A	In FPP for Package Set Registrations with Yes value for XEVMPD Submission Required? , after processing the XEVMPD Acknowledgement, the XEVMPD Submission Required? field did not change its value to No . This issue is resolved. After processing the XEVMPD Acknowledgement, the XEVMPD Submission Required? field shows as No . After the update of XEVMPD related fields in FPP, XEVMPD Submission Required? field value previously set up to No shows as Yes .
26784; [INC0061598]	6.2.0.7.0006	N/A	When nodes were updated in a Working view via Mass Update Properties , the changes were not applied to the Sequence and Publishing views. The issue occurred for both common and extended attributes of the node. This issue is resolved. The changes made using Mass Update Properties show in the Sequence and Publishing views.
26778; [INC0057113]	6.2.0.7.0006	N/A	If a Veeva document was versioned before the DMS cache timeout expired, the cached version of the document was used during a DMS Synchronization instead of the recently versioned document. This issue is resolved. Now, the system takes the recently versioned document and processes it successfully.
26738; [INC0056197]	6.2.0.7.0006	N/A	For some of the OOTB and extra fields of the newTextAreaView and adminTextAreaView types, the length limit was broken in the UI and after entering, the system showed only 50 characters in the UI. This issue is resolved. Length in the UI is fixed and corrected for the OOTB and extra fields to show more than 50 characters.

Issue	Build	Hotfix Build	Description
26705	6.2.0.7.0006	6.2.0.7.0002	Performance issue related to the Synchronize with the Submitted View job resulted in a timeout. Changes have been made to the synchronization mechanism and now the job request passes with efficiency.
26692	6.2.0.7.0006	6.2.0.6.0023	A mismatch between a Publishing Settings database sequence used by the code and the database sequence used in the corresponding database function caused the following error: <code>ORA-00001 : unique constraint (ODS.PKSLIP_SETTING) violated</code> . This issue is resolved. The database function is updated to use the same database sequence the code uses and ensuring that the sequence values are unique going forward.
26687; [INC0033088, INC0030024]	6.2.0.7.0006	6.2.0.6.0009	The variables specified in the Default Values section of the <i>Publishing Settings Library</i> failed to resolve in the submission output if an assembly root was not selected during publishing. However, the variables set in places such as leaf properties resolved successfully. This issue is resolved. Now, the variables specified in the <i>Default Values</i> section of the <i>Publishing Settings Library</i> are resolved.

Issue	Build	Hotfix Build	Description
26675	6.2.0.7.0006	6.2.0.6.0022	Timeline/Event Plans did not work as expected when adding or removing a country from an existing Event Plan for MRP, DCP, or CP Procedure Types. Countries already associated with the existing Timeline/Event Plan were incorrectly listed in the Countries Available box and were not available in the Copy Default Lead Times from the following Country drop-down list. Also, when deleting countries from an Event Plan, no countries were listed in the Associated with Plan area. These issues are resolved to support the requirement for BREXIT. Now, the Timeline/Event Plans work as expected when adding or removing a country from an existing Event Plan for MRP, DCP, or CP Procedure Types. Countries already associated with the existing Timeline/Event Plan are correctly listed in the Countries Available box and are also available in the Copy Default Lead Times from the Following Country drop-down list. When deleting countries from an Event Plan, countries are now listed in the Associated with Plan area.
26673	6.2.0.7.0006	6.2.0.6.0022	When Northern Ireland (XI) was added to the EU Region in Data Administration, the XEVMPD wizard did not recognize it and showed a warning message. This issue is resolved. Now, the new Northern Ireland country is recognized as an in-scope country with a country code of XI for an XEVMPD submission to support the EMA XEVMPD requirement for BREXIT.
26672	6.2.0.7.0006	6.2.0.6.0022	After Northern Ireland was added as a new country for EU CP registrations and an existing EU CP application, it was not available for selection when adding a country in the Registration Package Set. This issue is resolved. Now, Northern Ireland is listed as a country for selection for Registration Package Set.
26670; [INC0045661]	6.2.0.7.0006	N/A	An EAEU published submission output contained incorrect values in the <code><hcsdo:RegistrationFileIndicator></code> tag. This issue is resolved.

Issue	Build	Hotfix Build	Description
26477; [INC0023763]	6.2.0.7.0006	N/A	After Product Family information with its metadata was updated and then moved from Calyx RIM to D2 LSRD, subforms on the <i>Properties</i> tab were empty for the Application in D2 LSRD. When the Application information was updated separately in Calyx RIM, subforms on the <i>Properties</i> tab contained the appropriate information. This issue is resolved. The <i>Properties</i> tab of D2 LSRD Application shows correct information when you update a Product Family or an Application in Calyx RIM.

Calyx RIM 6.2.8 Release Notes

This document describes the updates in Calyx RIM 6.2.8 for China specification and Microsoft Graph API implementation.

Regulatory Updates

Support for China (CN) eCTD Module 1 version 1.0 (dated 29 September 2021).

Microsoft Graph API

Microsoft Graph API is implemented for Calyx RIM 6.2.8 and replaces the Azure AD Graph API used by previous Calyx RIM 6.2 versions to query users and groups from AAD. The Azure AD Graph API is no longer supported. The changes include the following:

- Removal of all Azure AD Graph API calls from application logic.
- Transition of all Azure AD graph calls to Microsoft Graph API methods for groups and users and any other methods currently used.

Resolved Issues: Calyx RIM 6.2.8

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their internal tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets following the internal tracking number.

Calyx RIM 6.2.8 resolves the following issues.

Issue	Build	Hotfix Build	Description
26825	6.2.0.8	N/A	EAEU: If the Drug Registration Document Code field had a value in a submission, the Drug Registration Document Name was not included in the <code>index-r-022.xml</code> file after publishing. The Drug Registration Document Name was also not saved in the leaf after an eCTD import. The issue is resolved. Now, both Drug Registration Document Name and Drug Registration Document Code are included in the <code>index-r-022.xml</code> file after publishing and in the leaf after an eCTD import.

Issue	Build	Hotfix Build	Description
26768; [INC0058320]	6.2.0.8	N/A	<p>The /all and /query endpoints did not work via API for the package set registration, product registration, full product presentation, package set - country entities and resulted with an error. This issue is resolved. The following endpoints work correctly via API:</p> <ul style="list-style-type: none"> – /insight/api/v2/license/packageset-registration/all – /insight/api/v2/license/product-registration/all – /insight/api/v2/license/full-product-presentation/all – /insight/api/v2/license/packageset/all – /insight/api/v2/license/packageset/country/all

Calyx RIM 6.2.9 Release Notes

Updates in Calyx RIM 6.2.9 for EAEU.

Regulatory Updates

EAEU v1.0:

- The `index-r-022.xml` file now includes new checksum attributes to conform to EAEU v1.0 eCTD requirements.
- Publishing functionality is updated with the checksum information in `index-r-022.xml` for each document. The checksum attributes are removed for EAEU XML with embedded PDFs during the export and import of EAEU submissions.
- The *Export Publish Output* page is updated to get the copy of submission without checksums with the help of the `XML without checksum` option.

Database and Additional Configuration

No changes have been made to the database and Azure AD configuration. Therefore, the Calyx RIM 6.2.9 Database Server Installation Qualification and Azure Active Directory Configuration IQ scripts are not available on the *Calyx RIM 6.2.9 IQ Scripts* page.

Functionality and Technology Removed

SharePoint and Open Text Content Server (Livelink) DMSs are no longer supported in Calyx RIM.

Prerequisites

A new Calyx RIM Rendering license file must be installed in order to support the new EAEU request.

Note: For installation assistance, please contact your Business Development Representative.

Entity Fields Updated: Calyx RIM 6.2.9

The following table describes fields that were updated with Calyx RIM 6.2.9.

Field Name	Field Type	Entity Name	Description	Business Rules
Embed PDFs into EAEU XML?	Box	This field is renamed to EAEU Output and updated to the list with the Embed PDFs and XML without checksum options on the Export Published Output page.	EAEU Output	You can use EAEU Output to export EAEU submissions. See: <i>Calyx RIM Best Practice: EAEU Submissions</i> .

Calyx RIM 6.2.10 Release Notes

This document describes a sub-minor release provided to fix one or more defects found in the previous versions of Calyx RIM 6.2.

The Quality Control team performed first product install and regression testing on this sub-minor release.

Resolved Issues: Calyx RIM 6.2.10

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their internal tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets following the internal tracking number.

Calyx RIM 6.2.10 resolves the following issues.

Issue	Build	Hotfix Build	Description
DE28913 [INC0136665, CS0629164, PRB0044005]	6.2.0.10.000 1	N/A	After updating Oracle from 19.16.0.0.220719 to 19.17.0.0.221018 version, a column ambiguity error occurred when using the <i>XEVMPD Submission</i> wizard. This issue is resolved. Now, you can use the <i>XEVMPD Submission</i> wizard without errors.
DE28427 [INC0102271,TAS K0042192]	6.2.0.10.000 1	N/A	API: It was not possible to update a PDS that was already assigned to a new <i>Event</i> . This issue is resolved. Now, a PDS can be updated even if it is already assigned to a new <i>Event</i> .

Calyx RIM 6.2.11 Release Notes

This document describes a sub-minor release provided to fix one or more defects found in the previous versions of Calyx RIM 6.2.

The Quality Control team performed first product install and regression testing on this sub-minor release.

Resolved Issues: Calyx RIM 6.2.11

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their internal tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets following the internal tracking number.

Calyx RIM 6.2.11 resolves the following issue.

Publishing

Issue	Build	Hotfix Build	Description
DE30161	6.2.0.11.000 5	N/A	After publishing the EAEU assembly and recalculating checksums, the <code>index-r-022/xml</code> file was generated in the <code>//file system/Folder1</code> location instead of <code>//file system/Folder1/Folder2</code> . The checksums were also not updated for the documents added to the assembly. This issue is resolved.
DE29791 [INC0088918]	6.2.0.11.000 5	N/A	When an EAEU submission was published after a leaf was deleted, the attributes <code>CHECKSUM</code> and <code>CHECK_ALG</code> were included in the <code><hccd:RegistrationDossierDocDetails></code> element. This issue is resolved. Now, the <code>CHECKSUM</code> and <code>CHECK_ALG</code> attributes are not included in the <code><hccd:RegistrationDossierDocDetails></code> element. Also, now in the <code>index-r-022.xml</code> file, the <code>CHECKALG</code> attribute is generated as <code>CHECK_ALG</code> .

Clarification of Behavior

Some instances of functionality are reported as an issue, but are in fact working as designed. Information about system behavior observed during testing that is not an issue, but of which Calyx wants you to be aware, is also included. The explanations contained here will be added to the product documentation at the earliest opportunity.

The following are clarifications of behavior for Calyx RIM 6.2.

Issue	Calyx RIM® Version	Description
26683; [INC0042848 , CS0283604]	Calyx RIM 6.2 CHF 5	When publishing a Job Request, the status message <code>Completed with no errors or warnings</code> shows at the top of the page, even though the job is still running. Workaround: While the publish job is in progress, you can see the <code>Completed</code> column of the table to verify <code>Completed=True</code> for each row. When the job is completed, refresh the <i>Details</i> window to see the correct status message.
26642	Calyx RIM 6.2 CHF 4	Assembly files created by exporting an assembly to the Assembly File (XML) on versions of Calyx RIM starting with 6.2 CHF 4 cannot be imported to Calyx RIM versions 6.2 CHF 3 and earlier.
26518; [INC0028282 , CS0199557]	Calyx RIM 6.2 CHF 3	When using the Google Chrome or Microsoft Edge web browsers, selecting documents in the <i>Browse Documents > Assign Document</i> window sends the <i>Browse Documents</i> window to the background (behind the Assembly window), making a user activate the window for subsequent document assignment.
26418	Calyx RIM 6.2 CHF 3	Duplicating Browser Tabs: Prior to Calyx RIM CHF 3, duplicating a browser tab of an active Calyx RIM session DID NOT require login for the duplicated session created on the new tab. From Calyx RIM CHF 3 onward, duplicating a browser tab of an active Calyx RIM session WILL require login for the duplicated session created on the new tab.
N/A	Calyx RIM 6.2 CHF 1	Performing any actions from Calyx RIM 6.2 CHF 1 against a Veeva repository on limited release version 18R2.2 will result in an exception caused by an unexpected error response from Veeva Vault. If you experience this issue, please contact Veeva Support .
25662; [00057090; 00057174]	Calyx RIM 6.2	For the EU eCTD Module 1 Specification Version 3.0.3, it is recommended to use the Import Assembly wizard if there is a working assembly created from the EU version 3.0.1 and the 1.2 Application Form section exists. The Create eCTD wizard will not update the existing 1.2 Application Form section to be compliant with the 3.0.3 version structure.

Issue	Calyx RIM® Version	Description
24987; [00048397, 00050948, 00054137, 00054290, 00055315, 00055766]	Calyx RIM 6.2	If you are using network security products to scan your local intranet hosts for vulnerabilities, be aware that these products have a specific scan used against a JBoss server at TCP/IP port AJP/8009. Scanning the Calyx RIM server with a network security product will cause an outage, requiring a restart. To avoid issues caused by network security scanning products, see <i>Firewall Rule for TCP_IP Port AJP_8009</i> in the Calyx RIM Installation Guide.
24513	Calyx RIM 6.2	When searching against a Veeva repository using DMS Search in Calyx RIM, an error may appear about exceeding the API calls limit. By default, Veeva Vault has an API burst limit of 2,000 API calls within a 5-minute period, and 100,000 API calls daily. These limits help to prevent runaway script scenarios (e.g. where the logic creates an infinite loop that continuously calls the Vault APIs). To request an increase to this limit, please contact Veeva Support .
N/A	Calyx RIM 6.2	For opening and viewing published XML files, Calyx recommends using the Microsoft Internet Explorer Web browser. Although Calyx RIM 6.2 supports other Web browsers (Google Chrome and Microsoft Edge), opening published XML files is best accomplished using Internet Explorer.

Known Issues

The following general issues and module-specific issues were known at the time this document was published.

The following are known issues for Calyx RIM 6.2.

Issue	Build	Resolved in	Description
26807 (Added on 20th Aug 2021)	6.2.0.7.0007	N/A	When updating a leaf in an assembly, selecting OnLoad for the Actuate option results in an error message. This is because of the default security settings. Workaround: Update the leaf using API.
26799	6.2.0.7.0003	N/A	After you use the Bulk eCTD Import for TW submission, the Job Status is set to Scheduled instead of Completed . This is because the <code>tw-regional.xml</code> file does not contain the application code. Workaround: Use Import eCTD to Application instead of Bulk eCTD Import . See: <i>Import eCTD to Application</i> .
26784; [INC0061598]	6.2.0.6.0007	N/A	When nodes are updated in a Working view via Mass Update Properties , the changes are not applied to the Sequence and Publishing views. The issue occurs for both common and extended attributes of the node. Workaround: Use the same values for the Mass Update Properties attributes for both Working and Publishing views.
26637; [INC0045216]	6.2.0.5.0055	N/A	In Data Administration , the Check for Date-based Notifications menu is not available on the Notification Specifications grid.
26604; [INC0037291]	Calyx RIM 6.2 CHF 4	N/A	Before Calyx RIM 6.2 CHF 4, a session time-out would return you to the login window. Now, a session time-out shows the message, "You do not have the appropriate privileges to access the requested resource" instead of the login window.

Issue	Build	Resolved in	Description
26561; [CS0156826]	6.2.0.5.0055	N/A	After running the GPP Calculate Projected Dates wizard, the Target Submitted column value is not updated. This happens if multiple display statuses are mapped to the same Internal status. As a workaround, use only one display status (not multiple) mapped to one Internal System Status value.
26476; [INC0029689]	6.2.0.5.0055	6.2 CHF 6	After the Product Family information with its metadata is moved from Calyx RIM to D2 LSRD, making changes to Product Family Indications/ Intended Use in Calyx RIM results in the Submission Country value getting deleted in D2 LSRD. The application in Calyx RIM continues to display the Reviewing Country .
25259; [00052856]	6.1.0.3.0084	N/A	When modifying Applicant Contact Values for M1 in a US 3-3 assembly, if you Deselect a value it does not re-appear in the selection box. As a workaround, you must save an entry with other contact values and then edit M1 again and select the Applicant Contact Value.
25084; [00051037, 00052759, 00056925, 00058862]	6.1.0.0.0112	N/A	Deleting large applications or removing multiple sequences from a lifecycle can take much longer than expected to produce results.
24019	6.0.0	6.0 CHF 2	eCTD import of a US v2.3 (DTD v3.3) application containing sequences submitted as part of a grouped submission is not supported.
22716; [00028730]	5.0.4	N/A	A hyphen "-" in the service account name prevents the ability to use that service account when adding a SharePoint repository.
20270; [136797FW]	4.1.1	N/A	Links for External Bookmarks are incorrect for split documents in paper published output.

Access the Customer Service Portal

If you have issues when working in the system that you cannot resolve with the Help documentation, you can access the Service Portal to view knowledge articles or log a support ticket.

To access the Service Portal:

1. Navigate to mytrials.com.
The Perceptive MyTrials log in page appears.
2. Enter your user name and password, and click **Log On**.
If you do not have a Perceptive MyTrials account, click **Join Perceptive MyTrials** and register. Perceptive MyTrials confirms your account with an email.
The home page appears.
3. Do one of the following:
 - Click **Customer Care** at the bottom of the page.
 - In the *My Weblinks* portlet, click **Customer Service Portal**.

The home page for the [Service Portal](#) appears. You can browse and search for the information you need.

Index

C

Clarification of Behavior [227](#)

N

New Features [1](#), [21](#), [33](#), [123](#), [124](#), [128](#), [133](#), [151](#), [156](#), [167](#), [171](#), [188](#), [190](#)

R

Release Notes [1](#), [51](#), [57](#), [61](#), [77](#), [97](#), [125](#), [134](#), [135](#), [159](#), [172](#), [191](#), [195](#), [198](#), [210](#), [211](#), [214](#), [215](#), [222](#), [224–226](#), [229](#)

Resolved Issues [97](#), [125](#), [126](#), [129](#), [135](#), [153](#), [159](#), [173](#), [178](#), [199](#), [203](#), [211](#), [212](#), [215](#), [217](#), [222](#), [225](#), [226](#)

S

support [231](#)