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# Data Migration Documentation

CALYX™

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## Data Migration Documentation

The Calyx RIM® Database Migration Release Notes and the Calyx RIM Data Migration Documents provide information about the SQL database scripts and other procedures required to perform migrations for the Calyx RIM database. The installation and migration script package provides a convenient means for distributing the Calyx RIM database scripts and clarifies the approach for upgrading the Calyx RIM database.

Calyx RIM data migration documentation site provides essential information to support new installations and upgrades, and to assist your migration planning and execution. The data migration documentation should be read in conjunction with the Calyx RIM Release Notes, which describe the updates that have been implemented in each release.

Before executing any database scripts, please verify that you have the most current version of the Calyx RIM Database Migration package. Check the FTP site or contact Technical Support to confirm that you have the latest version.

### Calyx RIM Database Migration Release Notes

The following topics provide information about the SQL database scripts used to perform upgrade migrations for the Calyx RIM database. This installation and migration script package provides a convenient means for distributing the Calyx RIM database scripts and clarifies the approach for upgrading the Calyx RIM database.

Before executing any database scripts, please verify that you have the most current version of the Calyx RIM Database Migration package. Check the FTP site or contact Technical Support to confirm that you have the latest version.

Please see the Calyx RIM Data Migration Document for your version.

### Calyx RIM Database Migration Details

This migration package consists of the SQL database scripts that are run on an Oracle database to establish the database instance for Calyx RIM. You can use these database scripts as a guide for migrating your earlier version of Calyx RIM to a current release.

The scripts are supplied in ZIP files:

- DB Upgrade 47 to 50.zip
- DB Upgrade 50 to 51.zip
- DB Upgrade 51 CHF2 to 60.zip (To migrate to Calyx RIM 6.0 from either Calyx RIM 5.1 CHF 2 or later Calyx RIM 5.1 CHFs, use DB Upgrade 51 CHF2 to 60.zip.)
- DB Upgrade 60 to 60 CHF1.zip (hotfix6\_0\_0\_chf1\_0098.zip)
- DB Upgrade 60 CHF1 to 60 CHF2.zip (DB\_hotfix6\_0\_0\_chf2\_0049.zip)
- DB Upgrade 60 CHF2 to 60 CHF3.zip (hotfix6\_0\_0\_chf3\_0031.zip)
- DB Upgrade 60 CHF3 to 61.zip (update6\_1\_0\_0000\_0215.zip)
- DB Upgrade 61 to 61 CHF1.zip (hotfix6\_1\_0\_chf1\_0115.zip)

- DB Upgrade 61 CHF1 to 61 CHF2.zip (hotfix6\_1\_0\_chf2\_0006.zip)
- DB Upgrade 61 CHF2 to 61 CHF3.zip (DB\_hotfix6\_1\_0\_chf3\_0136.zip)
- DB Upgrade 61 CHF3 to 61 CHF4.zip (DB\_hotfix6\_1\_0\_chf4\_0025.zip)
- DB Upgrade 61 CHF4 to 61 CHF5.zip (DB\_hotfix6\_1\_0\_chf5\_0013.zip)
- DB Upgrade 61 CHF5 to 61 CHF6.zip (DB\_hotfix6\_1\_0\_chf6\_0003.zip)
- DB Upgrade 61 CHF4 or later to 62.zip (DB\_update6\_2\_0\_0000\_0200.zip)
- DB Upgrade 62 to 62 CHF1.zip (DB\_hotfix6\_2\_0\_chf1\_0015.zip)
- DB Upgrade 62 CHF1 to 62 CHF2.zip (DB\_hotfix6\_2\_0\_chf2\_0062.zip)
- DB Upgrade 62 CHF2 to 62 CHF3.zip (DB\_hotfix6\_2\_0\_chf3\_0039.zip)
- DB Upgrade 62 CHF3 to 62 CHF4.zip (DB\_hotfix6\_2\_0\_chf4\_0087.zip)
- DB Upgrade 62 CHF4 to 62 CHF5.zip (DB\_hotfix6\_2\_0\_chf5\_0027.zip)
- DB Upgrade 62 CHF5 to 62 CHF6.zip (DB\_hotfix6\_2\_0\_chf6\_0003.zip)
- DB Upgrade 62 CHF6 to 62 CHF7.zip (DB\_hotfix6\_2\_0\_chf7\_0007.zip)
- DB Upgrade 62 CHF7 to 62.8.zip (DB\_hotfix6\_2\_0\_chf8\_0005.zip)
- DB Upgrade 62.8 to 62.10.zip (DB\_hotfix6\_2\_0\_chf10\_0007.zip)

## Calyx RIM 6.2 & CHFs Data Migration

### Calyx RIM 6.2.10 Data Migration

Running the migration script does not result in any functional changes to the Data Administration data. The script provided to fix issues that occur after Oracle upgrade to the 19.17.0.0.221018 version.

### Calyx RIM 6.2.8 Data Migration

Run migration script to include latest changes to the Data Administration data. The changes must be reviewed, and updated, if necessary.

Changes related to **CN-1-0** implementation:

- Associates China with China region in the **Application Maintenance - Region Values**, if it is not associated already.
- Health Authority name for China country, that already exists in the **Application Maintenance - Country Values** in *Data Administration* under the **Health Authority** tab, must be changed. It must be added, if not present:

Country Name	Health Authority Name	Health Authority Abbreviation	Health Authority Website
China	National Medical Products Administration	NMPA	<a href="https://www.nmpa.gov.cn/">https://www.nmpa.gov.cn/</a>

- Adds the **CN-1-0** assembly DTD type in the **Assembly - Assembly DTD/Schema Types** section in *Data Administration*, if it does not already exist.
- New Procedure Type value to be added to **Application Maintenance > Procedure Type Values**, if it does not already exist, with attributes as below:

Procedure Type Abbreviation	Procedure Type Name	Display Name	Countries	Internal Procedure Code	eCTD Code	Procedure Type Code	Active Flag
CN - National	CN National	National	China	NATIONAL	national	5	Active

- Application Types will have no changes.
- The Filing Type values will be added to the **Sequence Maintenance > Filing Type Values** section in *Data Administration*, if they do not already exist. If they already exist, they will be updated with an eCTD Code for the **CN-1-0** DTD/Schema based on the following approach:
  - For all the eCTD Codes from the table below, the **Filing Type** value that has the same eCTD Code will be found and updated with the new eCTD Code for the **CN-1-0** DTD/Schema. If the found **Filing Type** does not have China as an associated county, China will be added to the list of Countries.
  - If there are any other **Filing Type** values found, that are not listed in the table, they are not updated.
  - If more than one **Filing Type** is found with a matching eCTD Code, the one with the matching **Filing Type** name will be updated with the new eCTD Code for the **CN-1-0** DTD/Schema. If the **Filing Type** name does not match for any **Filing Type** with a matching eCTD Code, no **Filing Type** will be updated and the following message will be added to the log: `The Filing Type <name> with eCTD Code <code> could not be created/updated within Data Admin, please verify the configuration post-installation.`
  - If the **Filing Type** is not found based on the eCTD Code, one will be created and assigned to China. The list of Filing Types:

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Type
Original Application	CN-1-0	cnrat1	IND, NDA, ANDA
Supplement Filing	CN-1-0	cnrat2	IND, NDA, ANDA
Record	CN-1-0	cnrat3	IND, NDA, ANDA
Annual Report Filing	CN-1-0	cnrat4	IND, NDA, ANDA
New Indication and Drug Combination	CN-1-0	cnrat5	IND
New Indication	CN-1-0	cnrat6	IND, NDA, ANDA
Development Safety Report	CN-1-0	cnrat7	IND, NDA, ANDA
Renewal Filing	CN-1-0	cnrat8	NDA, ANDA
Baseline	CN-1-0	cnrat9	IND, NDA, ANDA

***Note:** The list of actual Application Types may differ from database to database. This is caused by user changes. During the migration, application types are added to fulfill the NMPA requirements, but are not removed to avoid user data corruption.*

*Differences in Filing Types and eCTD codes of China drafts 2019 and 2021.*

Differences in China Filing Types and Sub Filing Types and their eCTD codes between the draft of 2019 and the final draft of 2021.

**Filing Type and eCTD code**

Verify you have the correct data after the migration is completed.

Draft 2019 Filing Type	Draft 2019 eCTD Code	Final 2021 Filing Type	Final 2021 eCTD Code
Original Application	cnrat1	Original Application	cnrat1
Supplement Filing	cnrat2	Supplement Filing	cnrat2
New Indication	cnrat3	New Indication	cnrat6
Annual Report Filing	cnrat4	Annual Report Filing	cnrat4
Periodic Safety Update Report	cnrat5		CN eCTD code is deactivated
Renewal Filing	cnrat6	Renewal Filing	cnrat8
Baseline	cnrat7	Baseline	cnrat9
		New Indication and Drug Combination	cnrat5
		Record	cnrat3
		Development Safety Report	cnrat7

**Sub Filing Types eCTD Codes**

Sub Filing Type	Draft 2019 Filing Types	Final 2021 Filing Types	Difference
Original	Original Application, Supplement Filing, New Indication, Annual Report Filing, Periodic Safety Update Report, Renewal Filing.	Original Application, Supplement Filing, New Indication and Drug Combination, Development Safety Report, Record, Annual Report Filing, New Indication, Renewal Filing.	Added: New Indication and Drug Combination, Development Safety Report. Removed: Periodic Safety Update Report.
Response	Original Application, Supplement Filing, New Indication, Annual Report Filing, Periodic Safety Update Report, Renewal Filing, Baseline.	Original Application, Supplement Filing, New Indication and Drug Combination, Development Safety Report, Record, Annual Report Filing, New Indication, Renewal Filing, Baseline.	Added: New Indication and Drug Combination, Development Safety Report. Removed: Periodic Safety Update Report.

Sub Filing Type	Draft 2019 Filing Types	Final 2021 Filing Types	Difference
Withdrawal	Original Application, Supplement Filing, New Indication, Annual Report Filing, Periodic Safety Update Report, Renewal Filing, Baseline	Original Application, Supplement Filing, New Indication and Drug Combination, Development Safety Report, Record, Annual Report Filing, New Indication, Renewal Filing, Baseline	Added: New Indication and Drug Combination, Development Safety Report. Removed: Periodic Safety Update Report.
Reformat	Baseline	Baseline	No changes.

### Calyx RIM 6.2 CHF 7 Data Migration

Running the migration script results in multiple changes to the Data Administration data. The changes must be reviewed, and updated if necessary.

Changes related to **TW-1-0** implementation:

- Associates Taiwan with Taiwan region in the **Application Maintenance - Region Values**, if it is not associated already.
- Health Authority name for Taiwan country, that already exists in the **Application Maintenance - Country Values** in *Data Administration* under the **Health Authority** tab, must be changed to Taiwan Food and Drug Administration.
- Adds the **TW-1-0** assembly DTD type in the **Assembly - Assembly DTD/Schema Types** section in *Data Administration*, if it does not already exist.
- The Filing Type values will be added to the **Sequence Maintenance > Filing Type Values** section in *Data Administration*, if they do not already exist. If they already exist, they will be updated with an eCTD Code for the **TW-1-0** DTD/Schema based on the following approach:
  - For all the eCTD Codes from the table below, the **Filing Type** value that has the same eCTD Code will be found and updated with the new eCTD Code for the **TW-1-0** DTD/Schema. If the found **Filing Type** does not have Taiwan as an associated county, Taiwan will be added to the list of Countries.
  - If there are any other **Filing Type** values found, that are not listed in the table, they are not updated.
  - If more than one **Filing Type** is found with a matching eCTD Code, the one with the matching **Filing Type** name will be updated with the new eCTD Code for the **TW-1-0** DTD/Schema. If the **Filing Type** name does not match for any **Filing Type** with a matching eCTD Code, no **Filing Type** will be updated and the following message will be added to the log: The Filing Type <name> with eCTD Code <code> could not be created/updated within Data Admin, please verify the configuration post-installation.
  - If the **Filing Type** is not found based on the eCTD Code, one will be created and assigned to Taiwan.

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Type
New	TW-1-0	new	NDA, CTA
Change	TW-1-0	change	NDA, CTA

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Type
Extension Filing	TW-1-0	extension	NDA, CTA
Expiration	TW-1-0	expiration	NDA, CTA

Changes related to **US-3-3** implementation:

- If Form FDA 3988: Transmittal of PMR/PMC Submissions for Drugs and Biologics already exists in *Application Form Type Values*, it will be updated with **fdافت10** code and set to **Active**. Otherwise, this record will be created.
- If Form FDA 3938: Drug Master File already exist in Application Form Type Values already exists in *Application Form Type Values*, it will be updated with **fdافت11** code and set to **Active**. Otherwise, this record will be created.
- If REMS Supplement already exists in the **Filing Type Values**, it will be updated with **fdافت11** Filing Type eCTD code for **us-3-3** DTD, and **New Drug Application, Biologic License Application, Abbreviated New Drug Application** will be added to **Types Valid for Grouped Submissions**. Otherwise, this record will be created.
- For the United States in the **Country Values**, the **Health Authority Website** will be updated to `https://www.fda.gov/`.

### Calyx RIM 6.2 CHF 6 Data Migration

Running the migration script results in multiple changes to the Data Administration data. The changes must be reviewed, and updated if necessary.

Changes related to **JO-1-1** implementation:

- Associates Jordan country with Jordan region in the **Application Maintenance - Region Values** if it is not associated already.
- Adds the **JO-1-1** assembly DTD type in the **Assembly - Assembly DTD/Schema Types** section in **Data Administration**, if it does not already exist.
- Creates the **JO - National** procedure type value in **Application Maintenance - Procedure Type Values**, if it does not already exist.
- Deletes any existing associations to application procedure types for each of the Jordan country and associates it to the **JO - National** procedure type.
- Deletes any existing associations to application types for Jordan country and associates Jordan to the **CTA** and **NDA** application types.
- Adds the following values to the **Sequence Maintenance – Filing type Values** section in **Data Administration** if they do not already exist:
  - ASMF Filing
  - Biological Allergen
  - Biological Bio-similar
  - Biological Blood Product
  - Biological Drug
  - Biological Vaccine

- CEP Submission
- Extension Filing
- Generics
- Generic Narcotics
- Generic Vitamin Drug
- Herbal Drug
- MAA - Originator Drug
- MAA - Originator Vitamin Drug
- New Drug
- New Narcotics
- New Vitamin Drug
- None
- Notification with pricing
- Notification without pricing
- Originator Narcotics
- Periodic Safety Update Report
- Plasma Master File
- PSUR single assessment procedure
- Radiopharmaceutical Non-Radioactive Components (kits)
- Radiopharmaceutical Ready-for-use Radioactive Product
- Registration Department approval
- Renewal Filing
- Risk Management Plan Filing
- Technical committee approval
- Transfer MA Filing
- USR Filing
- Value added medicine
- Veterinary drug
- Withdrawal Filing
- Periodic Benefit-Risk Evaluation Report

Changes related to **Data Administration** values:

- Adds a new flag with **Yes/No** values, named **System Process Default Flag**, that indicates which status **Name** mapped to the same **Internal System Status** will be shown by default in Calyx RIM after an Event is closed manually or using a wizard. The field will be present in *Registration Status Values*.

### *Calyx RIM 6.2 CHF 5 Data Migration*

Running the migration script results in multiple changes to the Data Administration data. The changes must be reviewed, and updated if necessary.

Changes related to **CH-1-5** implementation:

- Associates Switzerland country with Switzerland region in the **Application Maintenance - Region Values** if it is not associated already.
- Adds the **CH-1-5** assembly DTD type in the **Assembly - Assembly DTD/Schema Types** section in **Data Administration**, if it does not already exist.
- Adds the following values to the **Sequence Maintenance – Filing type Values** section in **Data Administration** if they do not already exist:
  - Corrigendum Filing
  - DMF Filing
  - Follow-Up Measures
  - Known Active Substance
  - New Active Substance
  - Orphan Fast Track Filing
  - Periodic Safety Update Report
  - Plasma Master File
  - Reformat Filing
  - Renewal Filing
  - Supplement Filing
  - Transfer MA Filing
  - Withdrawal Filing
  - Used for meeting
  - Co-Marketing Medicinal Product
  - Parallel Import
  - Variation 1A Filing
  - Variation 1AIN Filing
  - Variation 1B Filing
  - Variation 2 Filing
  - Extension Filing

Changes related to **Data Administration** grids and values:

- Adds the **Last User Updated** and **Last Changed Date** fields to the user interface (UI) for every Data Administration Value.
- Adds the **Created By** and **Created Date** fields to each value of the **SPOR Maintenance** table.
- Adds a new flag with **Yes/No** values, named **System Process Default Flag** that indicates which status **Name** mapped to the same **Internal System Status** will be shown by default in Calyx RIM after an Event is closed manually or using a wizard. The field will be present in these Data Administration Values:
  - Application Status Values
  - Event-Change Detail Status Values
  - Product Status Values
  - Product Detail Set Status Values
  - Sequence Status Values

Changes related to entities:

- Adds a new flag with Yes/No values, XEVMPD Submission Required? to the Full Product Presentation entity (before the Use Reference Active Ingredient field).
- Adds the Optimize Fonts in Paper Output flag when the assembly publishing settings library or the publishing settings library template are migrated.

### *Calyx RIM 6.2 CHF 4 Data Migration*

Running the migration script results in multiple changes to the Data Administration data. The changes must be reviewed, and updated if necessary.

#### **China**

Changes related to China implementation:

- Associates China country with China region in the Application Maintenance - Region Values.
- Adds the CN-1-0 assembly DTD type in the Assembly - Assembly DTD/Schema Types section in Data Administration if it does not already exist.
- Sets the value for eCTD Code for the China country in the Application Maintenance – Country Values section of Data Administration.
- Creates the CN - National procedure type value in the Application Maintenance - Procedure Type Values.
- Removes any existing associations to application procedure types for each of the China country and associates it to the 'CN - National' procedure type in the Application Maintenance - Procedure Type Values.
- Removes any existing associations to application types for China country and associates China to the IND, NDA, and ANDA application types in the type in the Application Maintenance - Application Type Values.
- Updates Health Authority attributes for China country in the Application Maintenance – Country Values.
- Adds the following values to the Sequence Maintenance – Filing type Values in Data Administration if they do not exist already:
  - Original Application
  - Supplement Filing
  - New Indication
  - Annual Report Filing
  - Periodic Safety Update Report
  - Renewal Filing
  - Baseline
- Adds the following values to the Submission Maintenance – Submission Product Type Values section in Data Administration if they do not exist already:
  - Chemical Product
  - Biological Product
- Adds the following values to the Submission Maintenance - Sub Filing Type Values section in Data Administration if they do not exist already:
  - Original
  - Response
  - Withdrawal
  - Reformat

## EAEU

Changes related to EAEU implementation:

- Updates Health Authority attributes for Armenia, Belarus, Kazakhstan, Kyrgyzstan, and Russian Federation countries in the **Application Maintenance – Region Values**.
- Associates Armenia, Belarus, Kazakhstan, Kyrgyzstan, and Russian Federation countries with the EAEU region in **Application Maintenance – Country Values**.
- Adds the 'EAEU-1-0' assembly DTD type in the **Assembly - Assembly DTD/Schema Types** section in **Data Administration**, if it does not already exist.
- Sets the value for 'eCTD Code' for the Armenia, Belarus, Kazakhstan, Kyrgyzstan, and Russian Federation countries in the **Application Maintenance – Country Values** section of **Data Administration**.
- Creates the 'EAEU MRP', 'EAEU DCP', 'EAEU National' procedure type values in **Application Maintenance - Procedure Type Values**.
- Adds all the values to **Drug Registration File Documents Section Values**.
- Adds all the values to **Drug Registration File Documents Values**.

## Entities: Product Family

- A new field, **Show in Tree**, with **Yes/No** options has been added to the **Product Family** entity, applicable for all **Product Family Types**.
- All entities migrated from previous application versions will migrate with **Yes** selected and will be shown in the **Product Family Tree**.

### *Calyx RIM 6.2 CHF 3 Data Migration*

The database migration provides the changes for the Calyx RIM 6.2 CHF 3 release.

#### **Calyx RIM Data Administration Changes for JO eCTD Module 1 Version 1.0**

- For Data Administration Changes to JO eCTD Module 1 Version 1.0, if the JO region already exists in the **Application Maintenance > Region Values** section in **Data Administration**, it will be updated to have the code value JO in the database. Otherwise, an error message shows and the script will exit.
- The Health Authority name for the Jordan country, that already exists in the **Application Maintenance > Country Values** section in **Data Administration** under the **Health Authority** tab, should be changed to Jordan Food and Drug Administration.
- Jordan country will be updated to belong to the Jordan region if it does not belong to it already.
- If the **JO-1-0** Assembly DTD /Schema type already exists in the **Assembly > Assembly DTD/Schema Types** section in **Data Administration**, it will be activated (if inactive) and updated to have the code value **JO-1-0**. Otherwise, the **JO-1-0** Assembly DTD /Schema will be added.
- Filing Type Values will be added to the **Sequence Maintenance > Filing Type Values** section in **Data Administration**, if they do not already exist. If they already exist, they will be updated with an eCTD Code for JO-1-0 DTD/Schema.

### *Calyx RIM 6.2 CHF 2 Data Migration*

The Calyx RIM 6.2 CHF 2 database migration provides the following set of changes.

### Calyx RIM Data Administration Changes for CH eCTD Module 1 Version 1.4

- For Data Administration Changes for CH eCTD Module 1 Version 1.4, if the CH region already exists in the Application Maintenance - Region Values section in Data Administration, it will be updated to have the code value CH in the database. Otherwise, an error message will be generated and script will exit.
- Switzerland country will be updated to belong to the Switzerland region if it does not belong to it already.
- If the CH-1-4 Assembly DTD /Schema type already exists in the Assembly > Assembly DTD/Schema Types section in Data Administration, it will be activated (if inactive) and updated to have the code value CH-1-4. Otherwise, the CH-1-4 Assembly DTD /Schema will be added.
- Filing Type Values will be added to the Sequence Maintenance > Filing Type Values section in Data Administration, if they do not already exist. If they already exist, they will be updated with an eCTD Code for CH-1-4 DTD/Schema.

### PDS: Substance Details

An additional field named **Include Concentrations to XEVMPD?** with "Yes/No" values has been added to the PDS Substance Detail entity with Excipient Type only. After the migration, this field will be with "No" value.

### Submitted Available Flag

- For a Working Assembly/Working Assembly Plan that is created from a corresponding Submitted View, and when the Submitted View has been updated after a Working Assembly/Working Assembly Plan creation, the **Updated Submitted Available** attribute must be set to "Yes".
- For Working Assemblies/Working Assembly Plans that do not meet the rule above, the Updated Submitted Available attribute must be set to "No".
- Updated Submitted Available is set for both Sequence and Working Views of an Assembly or an Assembly Plan.

### Default Values in Publishing Settings Library

For the **Use Native File** flag on Create/View/Edit Default Values of the Publishing Settings Library, the new 'Use Default' must be added.

Please refer to the Calyx RIM 6.2 CHF 2 Data Migration Document for more information.

### Valid Values 5.0

The new 'stf-2-2-5-0' valid values are added and are available for selection in every XML Definitions multi select list on the **Publishing** tab of the Publishing Settings Library.

stf-2-2-5-0 value has been added to Selected XML Definition Files of the Default Publishing Settings Template.

stf-2-2-3-0 value has been moved to the available XML Definition Files list of the Default Publishing Settings Template.

### *Calyx RIM 6.2 CHF 1 Data Migration*

The Calyx RIM 6.2 CHF 1 database migration provides the following set of changes.

### Calyx RIM Data Administration

The Calyx RIM 6.2 CHF 1 database migration provides the following Data Administration changes:

- 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. This field will be blank after migration.

### *Calyx RIM 6.2 Data Migration*

The Calyx RIM 6.2 database migration provides the following set of changes.

#### **Calyx RIM Data Administration**

The Calyx RIM 6.2 database migration provides the following Data Administration changes:

- A list of Data Administration values has been updated with an **Organisation Identifier** attribute for the purpose of mapping Organisation in Calyx RIM for Registrations to Organisation in the Organisation Management System (OMS). Additional fields to support the OMS Integration have been added to the **MAH/Development Sponsor/Organisation Values** table.
- A **SPOR Maintenance** section has been added to support the Referentials management service (RMS) integration. A list of Data Administration values has been updated with **RMS Term Name** attribute for the purpose of mapping Calyx RIM for Registrations values to values in the SPOR Maintenance section.
- An additional field named **IDMP Internal Procedure Code** has been added to the **Procedure Type Values**.
- The **Region Values** table in the Application Maintenance section has been updated with a new region named IDMP Integration.
- The **Region Type Values** table in the Application Maintenance section has been updated with a new default region type named IDMP.
- In the **Manufacturer Values** table, the **Country** text field has been removed and the **Country Code** drop-down list has been renamed to be **Country** drop-down list.
- This migration will add the **Country Specific Detail Type Values** and a list of out-of-the-box values for them.
- This migration will add the **Country Specific Detail Values** and a list of out-of-the-box values for them.
- 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 in the **Data Administration > Product Maintenance** section.
- To identify, process, retrieve, transfer, and communicate data about medical devices, the **UMDNS Code Values** option has been introduced in the **Data Administration > Product Maintenance** section.
- To maintain the applicable standard version, the **Applicable Standards Values** table has been updated to include the **Version of Standard** option.

#### **Calyx RIM Entities**

The Calyx RIM 6.2 database migration provides the changes that affect uiCalyx RIM entities:

- **Applications.** Optionally, a re-runnable migration script should be executed to copy the **Application Code** value to the **Procedure Identifier** field on Application so that **Procedure Identifier Number** in IDMP can be populated based on the integration mapping of the two fields in RIM (Regulatory Information Management).
- **Events.** For each event that does not have a unique **Event Name** and **Event Code** combination within an application, the **Event Name** will be updated to have a sequential number appended.
- **Full Product Presentations.** The additional fields **Formulation Part**, **Intended Use Part**, **Target Population Part**, **Container or Pack Part**, **Device Part**, **Time Period Part**, **Flavour Part**, and **Countries**

have been added to the Full Product Presentation entity. The **Previous EV Code** field has been deleted from the Full Product Presentation entity. If present, values from this field should migrate to the new sub-entity Registration FPP Previous EV Codes, one value per sub-entity. In addition, the comments text field has been updated for the discussion thread field type for Full Product Presentation entity.

— **Registrations:**

- **ATC.** If there is no specific ATC (Anatomical Therapeutic Chemical) value on the Product Family but it is present on the related Registration, **ATC** value should be assigned to the Product Family after migration. If there is a specific ATC value on both Product Family and the related Registration, **ATC** value on Product Family should be displayed on the **Assigned ATC** box after migration.
- **Legal Basis.** The additional field **Legal Basis** has been added to the Registration Package Set Type. The rule for migration is when there is a value in the Legal Basis field on an Application, all Package Set Registrations related to that application should have the Legal Basis field filled with the same value as the parent Application.

— **Product Detail Sets (PDS):**

- **PDS Uniqueness.** For each PDS that does not have a unique **PDS Name** and parent **Application ID** combination, the **PDS Name** will be updated to have a sequential number appended.
- **Local Route of Administration.** The additional field named **Local Route of Administration** has been added to the PDS entity. Field is hidden by default, multi-select, and non-required with values from **Data Administration > Route of Administration Values** list.

— **PDS Templates.** For each PDS Template that does not have a unique **PDS Template Name** and parent **Product ID** combination, the **PDS Template Name** will be updated to have a sequential number appended.

— **Tasks.** For each Task and Sub-Task that does not have a unique **Task Name** and parent **Entity ID** combination, the **Task Name** will be updated to have a sequential number appended.

— **References.** For each Reference that does not have a unique **Reference Name** and parent **Entity ID** combination, the **Reference Name** will be updated to have a sequential number appended.

## **Calyx RIM 6.2 Pre-Migration Scripts**

```
— rpt_pre_migration_mpid.sql
— rpt_pre_migration_procidentif.sql
— pre_migration_previouslyevcodes_authorisedprod.sql
— pre_migration_event_uniqueness.sql
— pre_migration_lic_atc.sql
— pre_migration_task_uniqueness.sql
— pre_migration_reference_uniqueness.sql
— pre_migration_pds_uniqueness.sql
— pre_migration_pds_template_uniqueness.sql
```

Please refer to the Calyx RIM 6.2 Data Migration Document for detailed information.

## ***Calyx RIM 6.1 & CHF's Data Migration***

### ***Calyx RIM 6.1 CHF 5 Data Migration***

The Calyx RIM 6.1 CHF 4 database migration provides the following set of changes:

### Calyx RIM Data Administration Changes for CH eCTD Module 1 Version 1.4

- For Data Administration Changes to CH eCTD Module 1 Version 1.4, if the CH region already exists in the Application Maintenance - Region Values section in Data Administration, it will be updated to have the code value CH in the database. Otherwise, an error message will appear and the script will exit.
- Switzerland country will be updated to belong to the Switzerland region if it does not belong to it already.
- If the CH-1-4 Assembly DTD /Schema type already exists in the Assembly > Assembly DTD/Schema Types section in Data Administration, it will be activated (if inactive) and updated to have the code value CH-1-4. Otherwise, the CH-1-4 Assembly DTD /Schema will be added.
- Filing Type Values will be added to the Sequence Maintenance > Filing Type Values section in Data Administration, if they do not already exist. If they already exist, they will be updated with an eCTD Code for CH-1-4 DTD/Schema.

### PDS: Local Route of Administration

The field named **Local Route of Administration** has been added to the product detail set (PDS) entity. This field is Hidden out-of-the-box (OOTB), is multi-select, and is non-required, with values from the **Data Administration > Route of Administration values** list.

The rules for migrating the 'extraText20' field on a PDS entity configured to capture Route of Administration values starting from Calyx RIM 6.1 CHF 4 should be as follows:

- Values that are recognized as existing in the **Data Administration > Route of Administration Values** list should migrate as is to the new field **Local Route of Administration** on the PDS entity.
- Values that are not recognized as existing in the **Data Administration > Route of Administration Values** list should not migrate to the **PDS Comments** field on PDS entity.

### Calyx RIM 6.1 CHF 4 Data Migration

The Calyx RIM 6.1 CHF 4 database migration provides the following Data Administration changes to support AU eCTD Module 1 specification v3.1 and NeeS specification v2.0.

If the **AU-3-1** Assembly DTD/Schema Type already exists in the **Assembly > Assembly DTD/Schema Types** table in Data Administration, it will be activated (if inactive) and updated to have the internal code value set to AU-3-1. Otherwise, the **AU-3-1** Assembly/DTD Schema Type will be added.

### Filing Type Values

- If they do not already exist, Filing Type Values will be added to the **Data Administration > Sequence Maintenance > Filing Type Values** table.
- If Filing Type Values already exist, they will be updated with an eCTD Code for the au-3-1 DTD/Schema.
- If the found Filing Type does not have Australia as an associated country, it will be added to the list of Countries. An appropriate Filing Type eCTD Code for au-3-1 DTD/Schema will be added to Filing Type.
- If more than one Filing Type is found with a matching eCTD Code, the one with the matching Filing Type Name will be updated with the new eCTD Code for au-3-1 DTD/Schema.

### Sequence Description Values

— If they do not already exist, Sequence Description Values will be added to the **Data Administration > Submission Maintenance > Sequence Description Values** table. The presence of the appropriate Sequence Description Value will be identified by a combination of eCTD Code and Applicable DTD/Schema

### Regulatory Activity Lead Values

— If they do not already exist, Regulatory Activity Lead Values will be added to the **Data Administration > Submission Maintenance > Regulatory Activity Lead Values** table. The presence of the appropriate Regulatory Activity Lead Value will be identified by a combination of eCTD Code and Applicable DTD/Schema.

### *Calyx RIM 6.1 CHF 3 Data Migration*

The Calyx RIM 6.1 CHF 3 database migration provides the following updates.

#### Full Product Presentation

In Calyx RIM 6.1 CHF 3, an additional security setting named **Full Product Presentations** will be added to control access to the Full Product Presentations list on the *Home Page* and *Search* menu. During the migration, the **Full Product Presentations** option under **Home Page Access** will be set to **Select** value for each User, User Group, and Role in *Security Administration*.

#### Find Activities

In Calyx RIM 6.1 CHF 3, an additional security setting named **Find Activities** will be added to control access to the Activities report under *FIND* menu on the *Home Page*. During the migration, the **Find Activities** option under **Home Page Access** will be set to **Select** value for each User, User Group, and Role in *Security Administration*.

#### Change

In Calyx RIM 6.1 CHF 3, an additional security setting named **Change** will be added to control access to the Change and Change Detail entities. During the migration, the **Change** option under **Home Page Access** will be set to **Select** value for each User, User Group, and Role in *Security Administration*.

New setting named **Change Management Wizard** will be added to control access to the Change Management wizard on the *Home Page*. During the migration, the **Change Management Wizard** option under **Home Page Access** will be set to **Select** value for each User, User Group, and Role in *Security Administration*.

#### Procedure Type Values

The **Country** column will be updated with additional value **Liechtenstein** for the following Procedure Type values:

- EU CP Bio
- EU CP New API
- EU CP Orphan

#### Registration Attachments

The **Active Flag** field with **Active** and **Inactive** values will be added to the Registration Attachment entity. All values will migrate with **Active** value.

The additional fields named **Use Rendition** and **Rendition Identifier** will be added to the Registration Attachment entity. The **Use Rendition** field will be set automatically to **No** value after migration.

### Product Detail Set

An additional text field named **Specialty Number** will be added to the Product Detail Set entity. The field will be NULL after migration.

### Product Detail Set: Active Ingredient Details

The additional strength fields will be added to the PDS Active Ingredient Details:

- Concentration Measure Type
- Low Amount Numerator Value
- Low Amount Numerator Prefix
- Low Amount Numerator Unit
- Low Amount Denominator Value
- Low Amount Denominator Prefix
- Low Amount Denominator Unit
- High Amount Numerator Value
- High Amount Numerator Prefix
- High Amount Numerator Unit
- High Amount Denominator Value
- High Amount Denominator Prefix
- High Amount Denominator Unit
- Measurement Point

Values from **Component Active Ingredient entity > Strength Fields** will be copied during migration and added in addition to the Component Active Ingredient and to the PDS Active Ingredient.

### Product Detail Set: Substance Details

An additional field named **Use as Active Ingredient for XEVMPD** will be added to the PDS Substance Details. All migrated Substance Details will have **No** value selected in the **Use as Active Ingredient for XEVMPD** drop down field.

### Product Detail Set: Indication/Intended Use Details

An additional field named **Countries** will be added to the PDS Indication/Intended Use Details. All migrated Indication/Intended Use Details will have all Application Countries as selected values in the **Countries** field.

### Product Detail Set: Indication Details

An additional field named **Countries** will be added to the PDS Indication Details. All migrated Indication/Intended Use Details will have all Application Countries as selected values in the **Countries** field.

### Full Product Presentation

The following additional fields will be added as read-only to the Full Product Presentation (FPP) entity:

- XEVMPD Marketing Authorisation Number

- XEVMPD MAH/Organisation
- 'MAH/Organisation'

Please see the Calyx RIM 6.1 CHF 3 Data Migration Document for more details.

### Registration FPP Attachment

The following additional read only fields will be added to the Registration FPP Attachment entity:

- XEVMPD Marketing Authorisation Number
- XEVMPD MAH/Organisation
- MAH/Organisation'

All migrated Registration FPP Attachments will have listed fields with data from Full Product Presentation entity they are assigned to.

The Registration Attachment entity and XEVMPD Acknowledgement wizard logic will be enhanced by a new rule to automatically update the **Validity Declaration** field on Registration FPP Attachment entity from **[Select]** value to **Previous Copy was sent (1)** value.

All migrated Registration FPP Attachments will have the **Validity Declaration** field populated with the **Previous Copy was sent (1)** value if Registration Attachment entity which is connected with this Registration FPP Attachment has an **EV Code** value added.

Please see the Calyx RIM 6.1 CHF 3 Data Migration Document for more details.

### Message Tables

Functionality to identify by EV Code Entity Name with insert of this value in addition to the EV Code to **OPERATION\_RESULT\_DESCRIPTION** column when the **MSG\_FILE\_TYPE** column has value 3 for both db tables **X\_MSG\_CONTENT** and **X\_MSG\_ERROR** is implemented.

Please see the Calyx RIM 6.1 CHF 3 Data Migration Document for more details.

### Leaf Status population during migration

Calyx RIM 6.1 CHF 3 introduces the **Leaf Status** attribute for the leaf. As part of the Calyx RIM 6.1 CHF 3 migration, the statuses of all leaves that are in lifecycle will be set to **Published**, and the statuses of the leaves that are not in lifecycle will be set to **Planned**.

Please see the Calyx RIM 6.1 CHF 3 Data Migration Document for more details.

### *Calyx RIM 6.1 CHF 2 Data Migration*

The Calyx RIM 6.1 CHF 2 database migration provides the following updates.

### Data Administration Changes for ZA eCTD Module 1 Specification v2.1

If the ZA region already exists in the Application Maintenance – Region Values section in Data Administration, it will be updated to include the internal code value ZA in the database. Otherwise, an error message appears and the script exits.

The ZA country will be updated to belong to ZA region.

If the za-2-1 Assembly DTD/Schema type already exists in the Data Administration section Assembly - Assembly DTD/Schema Types, it will be activated (if inactive) and updated to have the internal code value 'ZA-2-1'. Otherwise, the za-2-1 Assembly DTD/Schema will be added.

If they do not already exist, Filing Type Values will be added to the Data Administration section Sequence Maintenance – Filing Type Values. If Filing Type Values already exist, they will be updated with an eCTD Code for the za-2-1 DTD/Schema.

### *Calyx RIM 6.1 CHF 1 Data Migration*

The Calyx RIM 6.1 CHF 1 database migration provides the following updates.

#### **Data Administration Changes for EU eCTD Module 1 Specification v3.0.1**

If the EU region already exists in the Application Maintenance – Region Values section in Data Administration, it will be updated to include the internal code value EU in the database. Otherwise, an error message appears and the script exits.

The EU region will be updated to include the following countries: 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.

If the EDQM country exists, it will be updated to belong to the EU region and the internal code value EDQM will be set in the database. If the EDQM country does not exist, an error message appears in the log and the script does not exit.

If the eu-3-0-1 Assembly DTD/Schema type already exists in the Data Administration section Assembly - Assembly DTD/Schema Types, it will be activated (if inactive) and updated to have the internal code value 'EU-3-0-1'. Otherwise, the eu-3-0-1 Assembly DTD/Schema will be added.

If they do not already exist, Filing Type Values will be added to the Data Administration section Sequence Maintenance – Filing Type Values. If Filing Type Values already exist, they will be updated with an eCTD Code for the eu-3-0-1 DTD/Schema.

#### **Region Update**

The new table MGR.REGION\_TYPE will be created with the OOTB region type:

- NAME: Regulatory Region
- CODE: REGULATORY

All existing regions from MGR.REGION will be updated to set REGION.REGION\_TYPE\_ID to the ID of the row from MGR.REGION\_TYPE where CODE = 'REGULATORY'.

#### **Internal Type Values Update**

New values will be created in MGR.INTERNAL\_TYPE with ENTITY\_\_TYPE\_ID equal to MGR.ENTITY\_TYPE.ID where MGR.ENTITY\_TYPE.CODE = 'CHANGE\_DET\_STAT'.

New values will be created in MGR.EVT\_CHNG\_DETAIL\_STATUS\_TYPE.

Please see the Calyx RIM 6.1 CHF 1 Data Migration Document for more details.

### Reasons for Termination/Withdrawal Values Created

If the Application Status ISM.APP\_STATUS\_TYPE.NAME, selected in the Application entity, is mapped to the internal system status 'WITHDRAWN' in Data Administration, and there is a value in the 'Termination/Withdraw Reason' field ISM.APPLICATION.TERM\_WITHDRAW\_REASON, then data should migrate as follows:

- A new value should be added to the Data Administration > Other > Reason for Termination/Withdrawal Values
- Application Status should have the same value as the initial Application
- A new field, Reason for Termination/Withdrawal, should have selected values from the 'Termination/Withdraw Reason' field

If Application Status ISM.APP\_STATUS\_TYPE.NAME, selected in Application entity, is not mapped to the internal system status 'WITHDRAWN' in Data Administration, and there is a value in the 'Termination/Withdraw Reason' field ISM.APPLICATION.TERM\_WITHDRAW\_REASON, then a pre-migration report will provide notification that data needs to be corrected. Otherwise, the value for 'Termination/Withdrawal Reason' will not migrate.

### Query Migration

For reports where the field 'Termination/Withdraw Reason' from the Application entity is available, data should migrate only if Application Status is mapped to the internal system status 'WITHDRAWN' and there is a value in the 'Termination/Withdraw Reason' field. Otherwise, the column should be blank.

### EU 3.0 Assemblies Migration

For all Standalone Assemblies, Template Assemblies, Working, Sequence, and Submitted Views, where XML Definitions of the associated APL contains 'EU-3-0' and 'FORM-1-1', the folder with Number equal to '1.2' and Name equal to 'EMA-eAF' and Extension equal to 'Default' will be updated to have Extension set to "XML Application Form" (version 2.0) with the Country attribute set to 'ema'.

### Job Requests Status Migration

Job requests status 'Waiting' (ODS.REQUEST\_STATUS\_TYPE.NAME = 'Waiting') will be updated to 'Waiting for InSight'.

### Favorites and Recently Viewed Migration

A new table will be created to support the integration of Activities into the Alert Center.

- Favorites will be updated to support the integration of Activities into the Alert Center.
- Recently Viewed will be updated to support the integration of Activities into the Alert Center.

### Calyx RIM 6.1 Data Migration

Calyx RIM 6.1 introduces the new Workflow Integrations module. The migration will create two new tables for non-standalone groups within Security Administration (WF\_GROUP and WF\_GROUP\_MEMBER). The addition of the Workflow Integration module also updates existing entity names for Registration-Package Set and Registration-

Package Set Country entities, making them more intuitive for selecting entities to associate with the workflow, within the Workflow Management section in Calyx RIM Data Administration.

Two new columns are added to Favorites to enable the deletion of a Favorites record when the related entity is deleted.

The Job Requests status Cancelled (ODS.REQUEST\_STATUS\_TYPE = 'Cancelled') is updated to Canceled (spelled with one "l").

### *Calyx RIM 6.0 & CHF Data Migration*

#### *Calyx RIM 6.0 CHF 6 Data Migration*

The Calyx RIM 6.0 CHF 6 database migration provides the following updates.

### **Security Changes: Full Product Presentations**

Calyx RIM 6.0 CHF 6 has introduced an additional security setting named **Full Product Presentations** to control access to the Full Product Presentations list on the Calyx RIM *Home Page* and *Search* menu.

### **Registration Attachments**

Calyx RIM 6.0 CHF 6 has introduced the following enhancements to the Registration Attachment entity:

- A new field named **Active Flag** with Active and Inactive values has been added. All Registration Attachment entities migrate with Active value.
- New fields named **Use Rendition** and **Rendition Identifier** have been added. The **Use Rendition** field will be set to No value after the migration.

### **Product Detail Sets (PDS)**

An additional text field named **Specialty Number** has been added to the Product Detail Set entity. After the migration, the value will be set to NULL.

### **PDS: Active Ingredient Details**

Additional strength fields have been added to the PDS Active Ingredient Detail entities. Values from the **Component Active Ingredient > Strength** fields will be copied during the migration and added to the **Component > Active Ingredient** and **PDS > Active Ingredient** entities.

### **PDS: Substance Details**

An additional field named **Use as Active Ingredient for XEVMPD** has been added to the PDS Substance Detail entities. All migrated Substance Detail entities will have No value selected in the **Use as Active Ingredient for XEVMPD** drop-down field.

### **PDS: Indication/Intended Use Details**

An additional field named **Countries** has been added to the PDS Indication/Intended Use Detail entities. All migrated Indication/Intended Use Detail entities will have all Application Countries selected in the **Countries** field.

### PDS: Indication Use Details

An additional field named **Countries** has been added to the PDS Indication Detail entities. All migrated Indication/Intended Use Detail entities will have all Application Countries selected in the **Countries** field.

### Full Product Presentations

Calyx RIM 6.0 CHF 6 has added the following read-only fields to the Full Product Presentation entity:

- XEVMPD Marketing Authorisation Number
- XEVMPD MAH/Organisation
- MAH/Organisation

### Registration FPP Attachments

Calyx RIM 6.0 CHF 6 has added the following read-only fields to the Registration FPP Attachment entity:

- XEVMPD Marketing Authorisation Number
- XEVMPD MAH/Organisation
- MAH/Organisation

All migrated Registration FPP Attachment entities will have these fields assigned with data from the parent Full Product Presentation entity.

Calyx RIM 6.0 CHF 6 has introduced a new rule for the Registration Attachment entity and *XEVMPD Acknowledgement* wizard logic. The **Validity Declaration** field for the Registration FPP Attachment entity will be automatically updated from [Select] value to Previous Copy was sent (1) value. All migrated Registration FPP Attachment entities will have the **Validity Declaration** field with Previous Copy was sent (1) value selected by default if the Registration Attachment entity, connected to this Registration FPP Attachment, has an EV Code value added.

### Message Tables

Calyx RIM 6.0 CHF 6 has introduced a new functionality that is aimed to identify the Entity Name by the EV Code once this value is inserted to the OPERATION\_RESULT\_DESCRIPTION column. This functionality is applicable, if the MSG\_FILE\_TYPE column has value 3 for both X\_MSG\_CONTENT and X\_MSG\_ERROR database tables.

Please see the *Calyx RIM 6.0 CHF 6 Data Migration Document* for more details

### *Calyx RIM 6.0 CHF 5 Data Migration*

The Calyx RIM 6.0 CHF 5 database migration provides the following updates.

#### **Data Administration Changes for ZA eCTD Module 1 Specification v2.1**

If the ZA region already exists in the Application Maintenance – Region Values section in Data Administration, it will be updated to include the internal code value ZA in the database. Otherwise, an error message appears and the script exits.

The ZA country will be updated to belong to ZA region.

If the za-2-1 Assembly DTD/Schema type already exists in the Data Administration section Assembly - Assembly DTD/Schema Types, it will be activated (if inactive) and updated to have the internal code value 'ZA-2-1'. Otherwise, the za-2-1 Assembly DTD/Schema will be added.

If they do not already exist, Filing Type Values will be added to the Data Administration section Sequence Maintenance – Filing Type Values. If Filing Type Values already exist, they will be updated with an eCTD Code for the za-2-1 DTD/Schema.

### *Calyx RIM 6.0 CHF 4 Data Migration*

The Calyx RIM 6.0 CHF 4 database migration provides the following updates.

#### **Data Administration Changes for EU eCTD Module 1 Specification v3.0.1**

If the EU region already exists in the Application Maintenance – Region Values section in Data Administration, it will be updated to include the internal code value EU in the database. Otherwise, an error message appears and the script exits.

The EU region will be updated to include the following countries: 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.

If the EDQM country exists, it will be updated to belong to the EU region and the internal code value EDQM will be set in the database. If the EDQM country does not exist, an error message appears in the log and the script does not exit.

If the eu-3-0-1 Assembly DTD/Schema type already exists in the Data Administration section Assembly - Assembly DTD/Schema Types, it will be activated (if inactive) and updated to have the internal code value 'EU-3-0-1'. Otherwise, the eu-3-0-1 Assembly DTD/Schema will be added.

If they do not already exist, Filing Type Values will be added to the Data Administration section Sequence Maintenance – Filing Type Values. If Filing Type Values already exist, they will be updated with an eCTD Code for the eu-3-0-1 DTD/Schema.

#### **Reasons for Termination/Withdrawal Values Created**

If the Application Status ISM.APP\_STATUS\_TYPE.NAME, selected in the Application entity, is mapped to the internal system status 'WITHDRAWN' in Data Administration and there is a value in the 'Termination/Withdraw Reason' field ISM.APPLICATION.TERM\_WITHDRAW\_REASON, then data should migrate as follows:

- A new value should be added to the Data Administration > Other > Reason for Termination/Withdrawal Values
- Application Status should have the same value as the initial Application
- A new field, Reason for Termination/Withdrawal, should have selected values from the Termination/Withdraw Reason field

If Application Status ISM.APP\_STATUS\_TYPE.NAME, selected in Application entity, is not mapped to the internal system status 'WITHDRAWN' in Data Administration and there is a value in the 'Termination/Withdraw Reason' field ISM.APPLICATION.TERM\_WITHDRAW\_REASON, then a pre-migration report will provide

notification that data needs to be corrected. Otherwise, the value for Termination/Withdrawal Reason will not migrate.

### Procedure Type Values

For the following Procedure Types, the Country column is updated with Liechtenstein OOTB country:

- EU CP Bio
- EU CP New API
- EU CP Orphan

### Query Migration

For reports where the field Termination/Withdraw Reason from the Application entity is available, data should migrate only if Application Status is mapped to the internal system status 'WITHDRAWN' and there is a value in the 'Termination/Withdraw Reason' field. Otherwise, the column should be blank.

### EU 3.0 Assemblies Migration

For all Standalone Assemblies, Template Assemblies, Working, Sequence, and Submitted Views, where XML Definitions of the associated APL contains 'EU-3-0' and 'FORM-1-1', the folder with Number equal to '1.2' and Name equal to 'EMA-eAF' and Extension equal to 'Default' will be updated to set the Extension to 'XML Application Form' (version 2.0) with the Country attribute set to 'ema'.

### *Calyx RIM 6.0 CHF 3 Data Migration*

Calyx RIM 6.0 CHF 3:

- adds one new field to the Application entity to capture the Universal Unique Identifier (UUID)
- updates Assembly Specific Publishing Settings Library (APL) and Publishing Settings Library Template (PLT) to add one new field
- adds one mandatory field to the Pharmaceutical Product entity

Also, uniqueness for the Full Product Presentation is updated to make it unique within the registration, and the Language field on the PDS Label Detail is updated to capture multiple languages.

This release provides support for TH eCTD Module 1 Specification v1.0 and EU eCTD Module 1 Specification v3.0.

There are two pre-migration scripts, one to identify duplicate Full Product Presentation names and another to identify the missing Dosage Forms from Products or Components.

### *Calyx RIM 6.0 CHF 2 Data Migration*

Calyx RIM 6.0 CHF 2 adds one new entity, updates ten existing entities, and updates twelve out of the box (OOTB) reports. This release provides support for Swiss eCTD Module 1 Specification v1.3 and GCC eCTD Module 1 Specification v1.5.

Also, Concentration Measures for Substances that were not migrated as part of the Calyx RIM v.6.0 migration will be migrated.

There are two pre-migration scripts, one to identify duplicate ATC Codes, and another to identify concentration measures that cannot be migrated. An optional migration script is also included to provide Additional Monitoring settings for Package Set Registrations.

### *Database Migration Notes*

#### **Database Migration 1.40 Notes**

Calyx RIM Data Migration 1.40 introduces the migration scripts necessary to migrate to Calyx RIM 6.2 CHF 7. Calyx RIM Data Migration 1.40 also updates Data Administration data, as described in the topic *Calyx RIM 6.2 CHF 7 Data Migration*.

#### **Database Migration 1.39 Notes**

Calyx RIM Data Migration 1.39 introduces the migration scripts necessary to migrate to Calyx RIM 6.2 CHF 6. Calyx RIM Data Migration 1.39 also updates Data Administration data, as described in the topic *Calyx RIM 6.2 CHF 6 Data Migration*.

#### **Database Migration 1.38 Notes**

Calyx RIM Data Migration 1.38 introduces the migration scripts necessary to migrate to Calyx RIM 6.2 CHF 5. Calyx RIM Data Migration 1.38 also updates Data Administration data, as described in the topic *Calyx RIM 6.2 Data Migration*.

#### **Database Migration 1.37 Notes**

Calyx RIM Data Migration 1.37 introduces the migration scripts necessary to migrate to Calyx RIM 6.2 CHF 4. Calyx RIM Data Migration 1.37 also resolves reported issues, which are described in the topic *Issues Resolved in the Migration Scripts: 26337/26316 and 26281*

#### **Database Migration 1.36 Notes**

Calyx RIM Data Migration 1.36 introduces the migration scripts necessary to migrate to Calyx RIM 6.2 CHF 3. Calyx RIM Data Migration 1.36 also includes a script to upgrade to Calyx RIM 6.2 CHF 2 to resolve the issue related to the defect 26207.

#### **Database Migration 1.35 Notes**

Calyx RIM Data Migration 1.35 introduces the migration scripts necessary to migrate from Calyx RIM 6.1 CHF 5 to Calyx RIM 6.1 CHF 6.

#### **Database Migration 1.34 Notes**

Calyx RIM Data Migration 1.34 introduces the migration scripts necessary to migrate from Calyx RIM 6.1 CHF 4 to Calyx RIM 6.1 CHF 5.

#### **Database Migration 1.33 Notes**

Calyx RIM Data Migration 1.33 introduces the migration scripts necessary to migrate from Calyx RIM 6.2 CHF 1 to Calyx RIM 6.2 CHF 2.

#### **Database Migration 1.32 Notes**

Calyx RIM Data Migration 1.32 resolves the following reported issues, which are described in the Issues Resolved in the Migration Scripts table: 25986, 25971, and 25920.

### Database Migration 1.31 Notes

Calyx RIM Data Migration 1.31 introduces the migration scripts necessary to migrate from Calyx RIM 6.1 to Calyx RIM 6.2.

### Database Migration 1.30 Notes

Calyx RIM Data Migration 1.30 introduces the migration scripts necessary to migrate from Calyx RIM 6.0 to Calyx RIM 6.1.

### Database Migration 1.29 Notes

Calyx RIM Data Migration 1.29 resolves the following reported issues, which are described in the Issues Resolved in the Migration Scripts table: 24594, 23873, 23788, 23706, and 22760.

Two post-migration scripts are added to the DB Upgrade 50 to 51.zip file to check shelf life details for partial migration issues: `rpt_problematic_shelf_life_details.sql` and `rpt_pds_with_duplicates_removed.sql`.

### Database Migration 1.28 Notes

Calyx RIM Data Migration 1.28 resolves the following reported issues, which are described in the Issues Resolved in the Migration Scripts table: 24342 and 24279.

### Database Migration 1.27 Notes

Calyx RIM Data Migration 1.27 supports the new Calyx RIM for XEVMPD and Calyx RIM for Analytics modules, along with Security, Data Administration, new and updated entities to support the new features introduced in Calyx RIM 6.0.

### Database Migration 1.26 Notes

The Oracle sequence value for `doc_link_output_channel` was migrated using an incorrect sequence. This incorrect migration of sequence values resulted in extraction jobs failing in Calyx RIM with a Unique Constraint Violation. This migration package now migrates the `doc_link_output_channel` value from the proper oracle sequence.

### Database Migration 1.25 Notes

Calyx RIM Data Migration 1.25 provides support for the functionality introduced in Calyx RIM 5.0 CHF 8 to automatically populate the Output Folder attribute when folders, or nested folders, are added to the Assembly via the DMS Browser window (such as when adding site folders). The Unmigratable Shelf Life SQL query was also enhanced to report the Event-Country field.

### Database Migration 1.24 Notes

Calyx RIM Data Migration 1.24 supports updates to Shelf Life Details, DMS Repository, Publishing Settings, Publishing Elements within an Assembly, new and updated Data Administration pick lists, EVMPD field deletions, and the deletion of custom queries that use deleted fields.

### Database Migration 1.23 Notes

The DB Upgrade 47 to 50.zip file was updated to increase the field size to 500 characters for Country Trade Name on the Country Details tab, and for Associated Trade Names and Approved Trade Names on the Product Family tabs, and to remove the migration of comparators.

*Issues Resolved in the Migration Scripts*

The following migration script issues are resolved in the database migration package.

Issue	Migration script	Description
26337, 26316; [INC0014239, INC0012933 ]	DB_update6_2_0_0000_0200.zip, DB_hotfix6_2_0_chf1_0015.zip, DB_hotfix6_2_0_chf2_0062.zip	Starting from Calyx RIM 6.1 CHF 4, the migration to Calyx RIM 6.2 and CHFs failed with an ORA error in logs for some customers. This issue is resolved by removing the “select * from dv_user_workflow_secure” query from the migration package.
26281; [INC0011491]	DB_hotfix6_2_0_chf2_0062.zip	The Calyx RIM 6.2 CHF 2 migration script failed to complete after more than 12 hours for some customers. The migrate_asm_update_submit_avbl_flag.sql script was updated to greatly improve the performance of the Calyx RIM 6.2 CHF 2 migration script.
26207	DB_hotfix6_2_0_chf2_0060.zip	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.
25986; [00060676]	DB_update6_2_0_0000_0199.zip	The pre_migration_reference_uniqueness.sql report was updated to make names unique within the reference table (within a parent) by suffixing the Name with "-<row_id>" and to add a column for the new unique name.
25971; [00060660]	DB_update6_2_0_0000_0199.zip	The new table product_country_uda was created and populated during the Calyx RIM 6.2 migration, but extra_fields_id was left null. This issue is resolved.
25920; [00059826]	DB_update6_2_0_0000_0199.zip	The pre_migration_reference_uniqueness.sql report was updated to show references that do not have a unique reference name, parent entity ID combination (instead of those not having a unique reference name, parent entity type combination).
25754; [00058206]	DB_hotfix6_1_0_chf4_0025.zip	The originally released Calyx RIM 6.1 CHF 4 migration script had an incorrect RPT_Schema_Diff.lst report. This hotfix contains the corrected RPT_Schema_Diff.lst report.

Issue	Migration script	Description
25750; [00058083]	DB_hotfix6_1_0_chf4_0025.zip	The following error occurred during the Calyx RIM 6.1 CHF 4 migration: ORA-01436: CONNECT BY loop in user data This issue is resolved.
25745; [00058838, 00058176]	DB_hotfix6_1_0_chf4_0025.zip	This hotfix includes a fix to reduce the execution time of the Calyx RIM 6.1 CHF 4 migration script.
25465	DB_hotfix6_1_0_chf3_0136.zip	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. This updated trigger was omitted in Calyx RIM 6.1 CHF 1 and CHF 2, but reinstated in CHF 3. The trigger, however, denotes updates to the content table as inserts instead of updates. The trigger was corrected. An optional script to fix existing incorrect data will be provided in a subsequent Calyx RIM 6.1 CHF 3 hotfix.
25414; [00054605]	DB_hotfix6_1_0_chf3_0136.zip	The FLASHBACK_TIME=SYSTIMESTAMP parameter was added to the expdp commands in the dpexportinsight.sql to keep all exported tables synchronized to the same point of time.
25391; [00054454, 00054327, 00053609]	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. Also, the RULE hint is added to improve the migration performance.
25345; [00053849]	DB_hotfix6_1_0_chf3_0136.zip	The odsnew/migrations/migrate_leaf_status.sql script was updated to improve its execution time.

Issue	Migration script	Description
25225; [00052241]	DB_hotfix6_1_0_chf1_0115.zip	<p>There was no password validation for the database user accounts in the migration scripts. This could result in issues with the execution of upgrade scripts. This issue is resolved by adding the password validation to the <code>master.sql</code> script for the following database user accounts:</p> <ul style="list-style-type: none"> <li>– ACTIVITI</li> <li>– DM</li> <li>– MGR</li> <li>– MIGRATION</li> </ul>
25209; [00053438, 00052279, 00052147, 00052137]	DB_hotfix6_1_0_chf1_0115.zip	<p>The following error occurred during the LIQUENT InSight 6.1 CHF 1 migration: <code>ORA-01555: snapshot too old</code>. This issue is resolved.</p>
25197; [00052103]	DB_hotfix6_1_0_chf1_0115.zip	<p>Data being 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"> <li>– <code>ORA-12899: value too large for column</code></li> <li>– <code>ORA-00001: unique constraint</code></li> </ul> <p>This issue is resolved.</p>

Issue	Migration script	Description
25134; [00052137, 00051492, 00051212]	DB_hotfix6_1_0_chf1_0115.zip	<p>Some customers migrating from Calyx RIM 5.1 to Calyx RIM 6.1 CHF 1 encountered a problem with empty GUID column values for leafs and folders resulting in the following errors:</p> <ul style="list-style-type: none"> <li>– Error adding new not null constraint on FOLDER.GUID ORA-02296: cannot enable (ODS.) - null values found</li> <li>– Error adding new not null constraint on LEAF.GUID ORA-02296: cannot enable (ODS.) - null values found</li> </ul> <p>This issue is resolved.</p>
24594	DB Upgrade 51 CHF2 to 60.zip	The Calyx RIM 5.1 to Calyx RIM 6.0 migration did not include MGR in the initial password check. This issue is resolved.
23873	DB Upgrade 50 to 51.zip	In the Calyx RIM 5.1 Publishing Settings Library, you must have a Default TOC for Document, Extract, Folder, Leaf, and TOC. This was not mandatory in Calyx RIM 5.0. If you tried to modify and then save a migrated TOC type, but did not have a default TOC type for every aforementioned object type in this Publishing Settings Library, you would get an Invalid Reference java error. This issue is resolved.
23788	DB Upgrade 50 to 51.zip	The Calyx RIM 5.1 migration used the ods.SEQ_SETTINGS_ID oracle sequence to populate the ods.overlay_settings table but the ods.SEQ_OVERLAY_ID sequence should be used. This issue is resolved.
23706	DB Upgrade 50 to 51.zip	Customers without the R_884 constraint enabled in the Calyx RIM database had duplicate values in the TOC_TYPE table resulting in migration errors. This issue is resolved.
22760	DB Upgrade 50 to 51.zip	The “Force New Volume” value defaulted to Yes instead of No for folders that had a null value for this field. This issue is resolved.

Issue	Migration script	Description
24342	51 CHF2 to 60 CHF1.zip	The Calyx RIM 6.0 migration can fail if the data was entered into Calyx RIM 5.0 or earlier. The grants required for the migration may not exist, depending on the migration path. This issue is resolved.
24279	51 CHF2 to 60 CHF1.zip	The Calyx RIM 6.0 migration generated an error when attempting to copy data with no associated records in the EVMPD_PDS_HISTORY_CHANGE table to the newly created FULL_PRODUCT_PRESENTATION table. This issue is resolved.
22318	DB Upgrade 50 to 51.zip	<p>The Calyx RIM Assembly Variables IES (Event Status) and IED (Event Status Date) have been removed from Calyx RIM. If you are upgrading from a previous Calyx RIM version, you must deactivate the IES and IED variables via Calyx RIM Data Administration.</p> <ol style="list-style-type: none"> <li>1. Open the Calyx RIM Go To menu and select <b>Data Administration</b>.</li> <li>2. Click <b>InSight Assembly Variables</b>.</li> <li>3. Click <b>Event Status</b>, then click <b>Deactivate</b>.</li> <li>4. Repeat these steps to deactivate <b>Event Status Date</b>.</li> </ol>
22748	DB Upgrade 47 to 50.zip	Application products with a product role of comparator will not be migrated to the new standalone comparator entity in Calyx RIM 5.0. The application product associated with a CTA type application (regardless of its role) must retain its hierarchical relationship to maintain the integrity of data associated with the existing products. The reason for this is because previous versions of LIQUENT InSight support the process of tracking PDS details for comparator products. The focus changed with the release of Calyx RIM 5.0. With this release, a comparator is a standalone entity that does not support the tracking of PDS details.

Issue	Migration script	Description
22361, 22317	DB Upgrade 47 to 50.zip	The field size has been increased to 500 characters for Country Trade Name on the Country Details tab, and for Associated Trade Names and Approved Trade Names on the Product Family tabs. This new character limit is now consistent with XEVMPD field sizes.

### *Migrating to 6.0*

Calyx RIM 6.0 contains many updates that will need to be considered when migrating. Some key points:

#### **New modules are available in 6.0**

- Calyx RIM for Analytics
- Calyx RIM for XEVMPD

#### **Major new features implemented in 6.0 have upgrade and migration impacts**

- Home Page functionality
- Grouped Submissions

#### **Data model changes address XEVMPD and IDMP**

- New entity: Pharmaceutical Product
- New entity: Full Product Presentation
- New Entity: Attachment

#### **Security updates in 6.0**

- Home Page Security
- Analytics Security
- Full Product Presentation Security

#### **Updates and additions to Data Administration**

- Substances: Consolidation of Active Ingredients and Excipients
- New and updated data administration entities to support XEVMPD data
- New and updated data administration entities to support IDMP data

#### **New entities and updates to existing entities**

- Migration of Indication and Intended Use values for XEVMPD
- Migration of concentration unit for Active Ingredient and Excipient, for XEVMPD
- Additional and updated attributes to support XEVMPD and IDMP data collection
- Updates to PDS to support substance consolidation

#### **Post Migration tasks**

- Post migration updates to support Grouped Submissions
- Post migration updates to Language values, Procedure Types and Concentration measure Types

### *Migrating to 5.1*

The Calyx RIM Assembly Variables IES (Event Status) and IED (Event Status Date) have been removed from Calyx RIM. If you are upgrading from a previous Calyx RIM version, you must deactivate the IES and IED variables via Calyx RIM Data Administration.

Calyx RIM 5.1 provides security settings to control access to Publishing Settings Library Templates (PLT) and greater control over Renditions and Extractions. The DMS Repository Screen in Calyx RIM Technical Administration includes two new options: Force New Renditions and Extractions and Limit Access to Specific Users.

In Calyx RIM 5.1, the Product Detail Set (PDS) has the ability to manage multiple shelf life updates occurring simultaneously across multiple Events for an Application with the addition of several new grouping nodes. Shelf Life Category is a new attribute on the shelf life detail that further defines the Shelf Life (i.e.: Registered, Labeled, etc.). The primary key (or identifier) of a Shelf Life/Storage Condition Detail is the concatenation of the Shelf Life number, Shelf Life Unit, and Shelf Life Category. Shelf Life Category values are managed in Data Administration. Shelf Life details will be migrated to Calyx RIM 5.1 with a category of “Registered”.

When a Shelf Life detail is approved in Calyx RIM 5.1 and the PDS contains a previously approved Shelf Life detail for the same category and grouping, the status of the previously approved shelf life detail is automatically updated to the new PDS Detail Status of “Superseded”.

Nine Shelf Life fields have been removed from the Package Detail Set. Shelf life data that cannot be migrated to the new shelf life details will be migrated to the comments field on the package set detail. Shelf Life Migration Rules are described in the Calyx RIM 5.1 Data Migration Document.

In Calyx RIM 5.0 there is no equivalent entity to a Publishing Settings Library Template (PLT), so no migration will occur in this area. A Default PLT will be created during the Calyx RIM 5.1 upgrade. For each Assembly that contains Publishing Settings, a new Assembly Specific Publishing Settings Library (APL) will be created according to the business rules described in the Calyx RIM 5.1 Data Migration Document.

The IS\_DUPLEX\_FLAG field will not be migrated to Calyx RIM 5.1 as it was never used within Calyx RIM Publisher.

The Application Types within Data Administration have been updated to allow for multiple eCTD Codes to be assigned to a specific Application Type.

### *Migrating to 5.0*

In Calyx RIM 5.0, the entity XML for Clinical Trial Application (CTA) has been updated to support enhancements for CTAs submitted in the European Union. When a new CTA is created, it will use the updated Clinical Trial Application Entity XML type. Investigational New Drug (IND) applications for the U.S. have also been updated. When a new IND or IND CDN application is created, it will use the new Investigational New Drug Entity XML type. Additional steps are needed for post-migration for IND applications.

Users now have the ability to define and share the data elements that are common for a particular protocol. Comparators and placebos can be tracked on applications tracking one protocol (i.e., CTA Types) as well as on applications that track all the protocols for the life of a product (i.e., IND Types).

## Data Administration Tables

### *Calyx RIM 6.2 & CHF's Data Administration Tables*

#### *Calyx RIM 6.2.8 Data Administration Tables*

Requirements for the standard migration of Calyx RIM 6.2 Certified Hotfix (CHF) 7 to Calyx RIM 6.2.8 are provided in this topic.

#### **Data Administration Updates: China**

If the CN region already exists in the *Application Maintenance - Region Values* section in Data Administration, it will be updated to include the code value CN in the database. Else, an error message will be generated and the script will skip China updates.

Health Authority name for China country, that already exists in the *Application Maintenance – Country Values* in *Data Administration* under the **Health Authority** tab, must be changed to **National Medical Products Administration**.

The country value **China** will be updated to belong to China region, if it does not belong to it already.

#### **Data Administration Updates: Assembly DTD/Schema Type**

If the **CN-1-0** Assembly DTD /Schema type already exists in the **Assembly > Assembly DTD/Schema Types** section in Data Administration, it will be activated (if inactive) and updated to have the code value **CN-1-0**. Else, **CN-1-0** Assembly DTD/Schema will be added.

#### **Data Administration Updates: Application Type Values**

There will be no changes to **Application Maintenance > Application type Values**.

#### **Data Administration Updates: Filing Type Values**

Filing Type Values that do not already exist are added to the **Sequence Maintenance > Filing Type Values** section in Data Administration. If they already exist, they will be updated with an eCTD Code for **CN-1-0** DTD/Schema depending on the following conditions:

- For all eCTD Codes from the following table, the Filing Type Value that has the same eCTD Code will be found and updated with the new eCTD Code for the **CN-1-0** DTD/Schema. If the found Filing Type does not have China as an associated county, China will be added to the list of Countries.
- If there are any other Filing Type values found, that are not listed in the table, they are not updated.
- If more than one Filing Type is found with a matching eCTD Code, the one with the matching Filing Type Name will be updated with the new eCTD Code for the **CN-1-0** DTD/Schema. If the Filing Type Name does not match for any Filing Type with a matching eCTD Code, no Filing Type will be updated and the following message will be added to the log: `The Filing Type <name> with eCTD Code <code> could not be created/updated within Data Admin, please verify the configuration post-installation.`
- If the Filing Type is not found based on the eCTD Code, a Filing Type will be created and assigned to China. This list shows the Filing Types added with their eCTD Codes:
  - New Indication and Drug Combination.

- Record.
  - Development Safety Report.
- This list shows the Filing Types updated with their eCTD Codes:
- New Indication - cnrat6.
  - Renewal Filing - cnrat8.
  - Baseline - cnrat9.
  - New Indication and Drug Combination - cnrat5.
  - Record - cnrat3.
  - Development Safety Report - cnrat7.
- This Filing Type will be deactivated: Periodic Safety Update Report - cnrat5.
- New Indication and Drug Combination, Development Safety Report Filing Type Values will be associated to Original, Response, Withdrawal Sub Filing Type eCTD Code Values.
- Periodic Safety Update Report Filing Type Value will be disassociated from Original, Response, Withdrawal Sub Filing Type eCTD Code Values.
- Application values will be associated to these Filing Type eCTD Code values:
- Abbreviated New Drug Application to cnrat3.
  - New Drug Application , Abbreviated New Drug Application to cnrat4.
  - New Drug Application , Abbreviated New Drug Application to cnrat8.
  - Investigational New Drug, New Drug Application , Abbreviated New Drug Application to cnrat9.

### *Calyx RIM 6.2 CHF 7 Data Administration Tables*

Requirements for the standard migration of Calyx RIM 6.2 Certified Hotfix (CHF) 6 to Calyx RIM 6.2CHF 7 are provided in this topic.

#### **Data Administration Updates: Taiwan**

If the TW region already exists in the *Application Maintenance - Region Values* section in Data Administration, it will be updated to include the code value TW in the database. Else, an error message will be generated and the script will skip Taiwan updates.

Health Authority name for Taiwan country, that already exists in the *Application Maintenance – Country Values* in *Data Administration* under the **Health Authority** tab, must be changed to **Taiwan Food and Drug Administration**.

The country value **Taiwan** will be updated to belong to Taiwan region, if it does not belong to it already.

#### **Data Administration Updates: Assembly DTD/Schema Type**

If the **TW-1-0** Assembly DTD /Schema type already exists in the **Assembly > Assembly DTD/Schema Types** section in Data Administration, it will be activated (if inactive) and updated to have the code value **TW-1-0**. Else, **TW-1-0** Assembly DTD/Schema will be added.

## Data Administration Updates: Filing Type Values

Filing Type Values that do not already exist are added to the **Sequence Maintenance > Filing Type Values** section in Data Administration. If they already exist, they will be updated with an eCTD Code for TW-1-0 DTD/Schema depending on the following conditions:

- For all eCTD Codes from the following table, the Filing Type Value that has the same eCTD Code will be found and updated with the new eCTD Code for the **TW-1-0** DTD/Schema. If the found Filing Type does not have Taiwan as an associated county, Taiwan will be added to the list of Countries.
- If there are any other Filing Type values found, that are not listed in the table, they are not updated.
- If more than one Filing Type is found with a matching eCTD Code, the one with the matching Filing Type Name will be updated with the new eCTD Code for the **TW-1-0** DTD/Schema. If the Filing Type Name does not match for any Filing Type with a matching eCTD Code, no Filing Type will be updated and the following message will be added to the log: `The Filing Type <name> with eCTD Code <code> could not be created/updated within Data Admin, please verify the configuration post-installation.`
- If the Filing Type is not found based on the eCTD Code, a Filing Type will be created and assigned to Taiwan. This list shows the Filing Types added with their eCTD Codes:
  - New
  - Change
  - Extension Filing
  - Expiration

## Data Administration Updates: US

If Form FDA 3988: Transmittal of PMR/PMC Submissions for Drugs and Biologics already exists in *Application Form Type Values* it will be updated with `fdaf10` code and set to Active. Else, this record will be created.

If Form FDA 3938: Drug Master File already exist in *Application Form Type Values*, it will be updated with `fdaf11` code and set to **Active**. Else, this record will be created.

If REMS Supplement already exists in the **Filing Type Values**, it will be updated with `fdaf11` Filing Type eCTD code for **us-3-3** DTD, and New Drug Application, Biologic License Application, Abbreviated New Drug Application will be added to **Types Valid for Grouped Submissions**. Else, this record will be created.

For the United States in the **Country Values**, the **Health Authority Website** will be updated to `https://www.fda.gov/`.

## Calyx RIM 6.2 CHF 6 Data Administration Tables

Requirements for the standard migration of Calyx RIM 6.2 Certified Hotfix (CHF) 5 to Calyx RIM 6.2CHF 6 are provided in this topic.

## Data Administration Updates: Default Flag for Statuses

The updated **System Process Default Flag (Yes/No values)** provides the ability to assign several external statuses to the same Internal System Status in Data Administration for **Registration Status Values**. 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. The field is added to

### Data Administration Updates: Region

If the JO region already exists in the *Application Maintenance - Region Values* section in Data Administration, it will be updated to include the code value JO in the database. Otherwise, an error message will be generated and the script will skip Jordan updates.

The country value 'Jordan' will be updated to belong to Jordan region, if it does not belong to it already.

### Data Administration Updates: Assembly DTD/Schema Type

If the **JO-1-1** Assembly DTD /Schema type already exists in the **Assembly > Assembly DTD/Schema Types** section in Data Administration, it will be activated (if inactive) and updated to have the code value **JO-1-1**. Otherwise, **JO-1-1** Assembly DTD/Schema will be added.

### Data Administration Updates: Filing Type Values

Filing Type Values are added to the **Sequence Maintenance > Filing Type Values** section in Data Administration, if they do not already exist. If they already exist, they will be updated with an eCTD Code for JO-1-1 DTD/Schema based on the following approach:

- For all eCTD Codes from the following table, the Filing Type Value that has the same eCTD Code will be found and updated with the new eCTD Code for the **JO-1-1** DTD/Schema. If the found Filing Type does not have Jordan as an associated county, Jordan will be added to the list of Countries.
- If more than one Filing Type is found with a matching eCTD Code, the one with the matching Filing Type Name will be updated with the new eCTD Code for the **JO-1-1** DTD/Schema. If the Filing Type Name does not match for any Filing Type with a matching eCTD Code, no Filing Type will be updated and the following message will be added to the log: `The Filing Type <name> with eCTD Code <code> could not be created/updated within Data Admin, please verify the configuration post-installation.`
- If the Filing Type is not found based on the eCTD Code, one will be created and assigned to Jordan. This list shows the Filing Types added with their eCTD Codes:
  - ASMF Filing
  - Biological Allergen
  - Biological Bio-similar
  - Biological Blood Product
  - Biological Drug
  - Biological Vaccine
  - CEP Submission
  - Extension Filing
  - Generics
  - Generic Narcotics
  - Generic Vitamin Drug
  - Herbal Drug

- MAA - Originator Drug
- MAA - Originator Vitamine Drug
- New Drug
- New Narcotics
- New Vitamin Drug
- None
- Notification with pricing
- Notification without pricing
- Originator Narcotics
- Periodic Safety Update Report
- Plasma Master File
- PSUR single assessment procedure
- Radiopharmaceutical Non-Radioactive Components (kits)
- Radiopharmaceutical Ready-for-use Radioactive Product
- Registration Department approval
- Renewal Filing
- Risk Management Plan Filing
- Technical committee approval
- Transfer MA Filing
- USR Filing
- Value added medicine
- Veterinary drug
- Withdrawal Filing
- Periodic Benefit-Risk Evaluation Report

### *Calyx RIM 6.2 CHF 5 Data Administration Tables*

Requirements for the standard migration of Calyx RIM 6.2 Certified Hotfix (CHF) 4 to Calyx RIM 6.2CHF 5 are provided in this topic.

#### **Data Administration Updates: Audit Fields**

Two fields, **Last User Updated** and **Last Changed Date**, are added to the user interface (UI) for every Data Administration Value, including sub-tables. After migrating from a previous Calyx RIM version to Calyx RIM 6.2 CHF 5, these fields are present in the grids with data from the database, similar to the other windows for the value.

Another two fields, **Created By** and **Created Date**, are added to each value of the **SPOR Maintenance** table. After migrating from a previous Calyx RIM version to Calyx RIM6.2 CHF 5, these fields are present with data from the database in the grids, similar to the other windows for the value.

#### **Data Administration Updates: Default Flag for Statuses**

The **System Process Default Flag** (Yes/No values) provides the ability to assign several external statuses to the same Internal System Status in Data Administration for Application, Product, Event, or 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. The field is added to the these Data Administration Values:

- Application Status Values
- Event-Change Detail Status Values
- Product Status Values
- Product Detail Set Status Values
- Sequence Status Values

### Data Administration Updates: Region

If the CH region already exists in the *Application Maintenance - Region Values* section in Data Administration, it will be updated to include the code value CH in the database. If the CH region does not exist in the *Application Maintenance - Region Values* section in Data Administration, an error message is shown and the script will exit.

The country value 'Switzerland' will be updated to belong to Switzerland region, if it does not belong to it already.

### Data Administration Updates: Assembly DTD/Schema Type

If the **CH-1-5** Assembly DTD /Schema type already exists in the **Assembly > Assembly DTD/Schema Types** section in Data Administration, it will be activated (if inactive) and updated to have the code value **CH-1-5**. Otherwise, **CH-1-5** Assembly DTD /Schema will be added.

### Data Administration Updates: Filing Type Values

Filing Type Values are added to the **Sequence Maintenance > Filing Type Values** section in Data Administration, if they do not already exist. If they already exist, they will be updated with an eCTD Code for CH-1-4 DTD/Schema. Following are the list of Filing Types added with their eCTD Codes:

- Corrigendum Filing: corrigendum
- DMF Filing: dmf
- Follow-Up Measures: fum
- Known Active Substance: na-bws
- New Active Substance: na-nas
- Orphan Fast Track Filing: orphan-fasttrack
- Periodic Safety Update Report: psur
- Plasma Master File: pmf
- Reformat Filing: reformat
- Renewal Filing: renewal
- Supplement Filing: supplemental-info
- Transfer MA Filing: transfer
- Withdrawal Filing: withdrawal
- Used for meeting: advice
- Co-Marketing Medicinal Product: na-co-marketing
- Parallel Import: na-pi
- Variation 1A Filing: var-type1a
- Variation 1AIN Filing: var-type1ain
- Variation 1B Filing: var-type1b

- Variation 2 Filing: var-type2
- Extension Filing: extension

## Entities Updates

### Full Product Presentation

#### Optimize Fonts in Paper Output Flag

A new flag **XEVMPD Submission Required?** with **Yes/No** values, is added to the **Full Product Presentation** entity (before the **Use Reference Active Ingredient** field) to indicate that an XEVMPD Submission for a current Full Product Presentation is ready to be submitted to the EMA authority. The default flag value is **Yes**.

After migration from a previous Calyx RIM version to Calyx RIM 6.2 CHF 5, the new flag will be **Yes** if Full Product Presentation does not have an EV Code value and **No** if there is an EV Code value for the entity.

In addition, this new field is available as a column on the **Full Product Presentations** tabs on the *Registration Attributes* and *Home* page windows, and in the *Notifications* when a Value Changed flow as an option for selection.

When the assembly publishing settings library or the publishing settings library template are migrated, the **Optimize Fonts in Paper Output** flag is added and set to **No** by default.

### *Calyx RIM 6.2 CHF 4 Data Administration Tables*

All migration requirements for the standard migration of Calyx RIM 6.2 Certified Hotfix (CHF) 3 to Calyx RIM 6.2 CHF 4 are provided below.

#### **Data Administration Updates: China**

During data migration, if the CN (China) region is found to already exist in the **Application Maintenance > Region Values** section in **Data Administration**, it will be updated to have the code value **CN** in the database. If the China (CN) region is missing, an error message will be generated and the migration script will terminate. The country value 'China' will be updated to belong to the China region, if it does not belong to it already.

#### **Data Administration Updates: Assembly DTD/Schema Type**

If the **CN-1-0** Assembly DTD /Schema type already exists in the **Assembly > Assembly DTD/Schema Types** section in **Data Administration**, it will be activated (if inactive) and updated to have the code value **CN-1-0**. Otherwise, the **CN-1-0** Assembly DTD /Schema will be added.

#### **Data Administration Updates: Filing Type Values**

Filing Type Values are added to the **Sequence Maintenance > Filing Type Values** section in **Data Administration**, if they do not already exist. If they already exist, they will be updated with an eCTD Code for the CN-1-0 DTD/Schema. The following list shows the added Filing Types with their eCTD Codes:

- Original Application: cnrat1
- Supplement Filing: cnrat2
- New Indication: cnrat3
- Annual Report Filing: cnrat4
- Periodic Safety Update Report: cnrat5

- Renewal Filing: cnrat6
- Baseline: cnrat7

### Data Administration Updates: Application Type Values

Application Type Values are added to the **Application Maintenance > Application Type Values** section in Data Administration, if they do not already exist. If they already exist, they will be updated with an Application Type eCTD Code for the CN-1-0 DTD/Schema. The following list shows the added Application Types with their eCTD Codes:

- Investigational New Drug (IND): cnrat1
- New Drug Application (NDA): cnrat2
- Abbreviated New Drug Application (ANDA): cnrat3

### Data Administration Updates: Submission Product Type Values

The new Submission Product Type Values are added to the new **Submission Maintenance > Submission Product Type Values** section in Data Administration. The following list shows the added Submission Product Type Values with their eCTD Codes:

- Chemical Product: cnprt1
- Biological Product: cnprt2

### Data Administration Updates: Sub Filing Type Values

Sub Filing Type Values are added to the new **Submission Maintenance > Sub Filing Type Values** section in Data Administration, if they do not already exist. If they already exist, they will be updated with an Sub Filing Type eCTD Code for the CN-1-0 DTD/Schema. The following list shows the added Sub Filing Types with their eCTD Codes:

- Original: cnsqt1
- Response: cnsqt2
- Withdrawal: cnsqt3
- Reformat: cnsqt4

### Data Administration Updates: EAEU

During data migration, if the Eurasian Economic Union (EAEU) region is found to already exist in the **Application Maintenance > Region Values** section in Data Administration, it will be updated to have the code value EAEU in the database. If the Eurasian Economic Union (EAEU) region is missing, an error message will be generated and the migration script will terminate.

The country value EAEU will be updated to belong to the Eurasian Economic Union region, if it does not belong to it already.

### Data Administration Updates: Health Authority

The Health Authority name for EAEU countries, that already exists in the **Application Maintenance > Country Values** in Data Administration under the **Health Authority** tab, must be changed or added, if absent, to those listed in the following table:

Country Name	Health Authority Name	Health Authority Website
Armenia	Ministry of Health of the Republic of Armenia	http://www.moh.am/#1/0
Belarus	Ministry of Health of the Republic of Belarus	http://minzdrav.gov.by
Kazakhstan	Ministry of Health of Kazakhstan	http://dsm.gov.kz
Kyrgyzstan	Ministry of Health of the Kyrgyz Republic	http://www.med.kg/ru/
Russian Federation	Ministry of Health of the Russian Federation	http://www.rosminzdrav.ru

**Data Administration Updates: Assembly DTD/Schema Type**

If the EAEU-1-0 Assembly DTD /Schema type already exists in the Assembly > Assembly DTD/Schema Types section in Data Administration, it will be activated (if inactive) and updated to have the code value EAEU-1-0. Otherwise, the EAEU-1-0 Assembly DTD /Schema will be added.

**Data Administration Updates: Filing Type Values**

The Filing Type Values are added to the Sequence Maintenance > Filing Type Values section in Data Administration, if they do not already exist. If the Filing Type Values already exist, they will be updated as per the EAEU-1-0 DTD/Schema.

**Data Administration Updates: Drug Registration File Documents Section Values**

The new Drug Registration File Documents Section Values are added to the new Submission Maintenance > Drug Registration File Documents Section Values and Submission Maintenance > Drug Registration File Documents Values sections in Data Administration. The following lists show the added Drug Registration File Documents Section Values and Drug Registration File Documents Values:

**Drug Registration File Documents Section Values**

The Drug Registration File Documents Section Values table is presented in Russian until an English translation is approved by the EAEU agency.

Section Code	Section Name	Active Flag
1	Документы, оформляемые при предоставлении заявителем дополнительных и уточняющих сведений.	Active
2	Документы, оформляемые в результате экспертизы регистрационного досье лекарственного препарата.	Active
3	Документы, оформляемые при проведении инспектирования производства в процессе регистрации лекарственного препарата.	Active

Section Code	Section Name	Active Flag
4	Документы, оформляемые в процессе взаимодействия уполномоченных органов государств - членов Евразийского экономического союза при рассмотрении регистрационного досье лекарственного препарата.	Active

### Drug Registration File Documents Values

The Drug Registration File Documents Values table is presented in Russian until an English translation is approved by the EAEU agency.

Section Code	Code	Section Name
1	101	Запрос о предоставлении недостающей дополнительной информации, необходимых разъяснений или уточнений документов и данных, представленных в регистрационном досье лекарственного препарата.
1	102	Запрос государства признания в отношении документов регистрационного досье лекарственного препарата.
1	103	Замечания к регистрационному досье лекарственного препарата от государства признания.
1	104	Ответ на запрос о предоставлении недостающей дополнительной информации, необходимых разъяснений или уточнений документов и данных, представленных в регистрационном досье лекарственного препарата.
1	105	Запрос о предоставлении копии мастер-файла системы фармаконадзора.
1	106	Ответ заявителя на запрос государства признания в отношении документов регистрационного досье лекарственного препарата.
1	107	Ответ заявителя на замечания от государства признания.
1	199	Другое
2	201	Экспертный отчет по оценке результатов доклинических (неклинических) исследований.
2	202	Отчет эксперта по оценке клинических исследований.
2	203	Экспертный отчет по критической оценке аспектов качества лекарственного препарата.
2	205	Экспертный отчет по присвоению статуса новой активной фармацевтической субстанции.
2	206	Протокол испытаний.

Section Code	Code	Section Name
2	207	Экспертный отчет об оценке безопасности, эффективности и качества.
2	299	Другое
3	301	Предписание о проведении инспекции производства на соответствие требованиям Правил надлежащей производственной практики Евразийского экономического союза.
3	302	Отчет об инспекции производства на соответствие требованиям Правил надлежащей производственной практики Евразийского экономического союза.
3	399	Другое
4	401	Экспертный отчет об оценке безопасности, эффективности и качества.
4	402	Экспертное заключение о возможности (невозможности) внесения изменений в регистрационное досье лекарственного препарата.
4	403	Запрос уполномоченного органа (экспертной организации) государства признания, направленный в уполномоченный орган референтного государства.
4	404	Ответ уполномоченного органа (экспертной организации) референтного государства, направленный в уполномоченный орган государства признания.
4	405	Замечания государства признания в отношении заключительного экспертного отчета по качеству.
4	406	Предложение уполномоченного органа (экспертной организации) государства признания в отношении заключительного экспертного отчета по качеству, направленное в уполномоченный орган референтного государства.
4	407	Подтверждение согласования (несогласования) в отношении заключительного экспертного отчета по качеству референтного государства по результатам экспертизы безопасности, эффективности и качества медицинских изделий.
4	499	Другое

### *Calyx RIM 6.2 CHF 3 Data Administration Tables*

#### **Data Administration Updates: Region**

If the JO region already exists in the **Application Maintenance > Region Values** section in Data Administration, it will be updated to have the code value JO in the database. Otherwise, an error message will be generated and the script will exit.

The country value 'Jordan' will be updated to belong to the Jordan region, if it does not belong to it already.

### Data Administration Updates: Assembly DTD/Schema Type

If the **JO-1-0** Assembly DTD /Schema type already exists in the **Assembly > Assembly DTD/Schema Types** section in Data Administration, it will be activated (if inactive) and updated to have the code value **JO-1-0**. Otherwise, the **JO-1-0** Assembly DTD /Schema will be added.

### Data Administration Updates: Filing Type Values

Filing Type Values are added to the **Sequence Maintenance > Filing Type Values** section in Data Administration, if they do not already exist. If they already exist, they will be updated with an eCTD Code for the **JO-1-0** DTD/Schema. The following list shows the added Filing Types with their eCTD Codes:

- ASMF Filing: asmf
- Biological Allergen: bla
- Biological Bio-similar: bls
- Biological Blood Product: blb
- Biological Drug: bld
- Biological Vaccine: blv
- CEP Submission: cep
- Extension Filing: extension
- Generics: bgd
- Generic Narcotics: bgn
- Generic Vitamin Drug: bgv
- Herbal Drug: hrd
- MAA - Originator Drug: ord
- MAA - Originator Vitamin Drug: orv
- New Drug: mnd
- New Narcotics: nnd
- New Vitamin Drug: nvd
- None: none
- Notification with pricing: var-n2
- Notification without pricing: var-n1
- Originator Narcotics: orn
- Periodic Safety Update Report: psur
- Plasma Master File: pmf
- PSUR single assessment procedure: psusa
- Radiopharmaceutical Non-Radioactive Components (kits): rnr
- Radiopharmaceutical Ready-for-use Radioactive Product: rrp
- Registration Department approval: var-ra
- Renewal Filing: renevar
- Risk Management Plan Filing: risk
- Technical committee approval: var-tca
- Transfer MA Filing: transfer-ma

- USR Filing: usr
- Value added medicine: vam
- Veterinary drug: vrt
- Withdrawal Filing: withdrawal

### *Calyx RIM 6.2 CHF 2 Data Administration Tables*

#### **Data Administration Updates: Region**

If the CH region already exists in the Application Maintenance - Region Values section in Data Administration, it will be updated to have the code value CH in the database. Otherwise, an error message will be generated and script will exit.

The country value 'Switzerland' will be updated to belong to Switzerland region, if it does not belong to it already.

#### **Data Administration Updates: Assembly DTD/Schema Type**

If the **CH-1-4** Assembly DTD /Schema type already exists in the **Assembly > Assembly DTD/Schema Types** section in Data Administration, it will be activated (if inactive) and updated to have the code value **CH-1-4**. Otherwise, **CH-1-4** Assembly DTD /Schema will be added.

#### **Data Administration Updates: Filing Type Values**

Filing Type Values are added to the **Sequence Maintenance > Filing Type Values** section in Data Administration, if they do not already exist. If they already exist, they will be updated with an eCTD Code for CH-1-4 DTD/Schema Following are the list of Filing Types added with their eCTD Codes:

- Application for 5 years Data Protection: eas
- Co-Marketing Medicinal Product: co-marketing
- Corrigendum Filing: corrigendum
- DMF Filing: dmf
- Follow-Up Measures: fum
- Known Active Substance: na-bws
- New Active Substance: na-nas
- Orphan Fast Track Filing: orphan-fasttrack
- Parallel Import: pi
- Periodic Safety Update Report: psur
- Plasma Master File: pmf
- Reformat Filing: reformat
- Renewal Filing: renewal
- Supplement Filing: supplemental-info
- Transfer MA Filing: transfer
- Variation Requiring Product information Authorisation: var-pi
- Withdrawal Filing: withdrawal
- Used for meeting: advice
- New Application- Co-Marketing: na-co-marketing
- New Application- Parallel Import: na-pi

- Variation 1A Filing: var-type1a
- Variation 1AIN Filing: var-type1ain
- variation 1B Filing: var-type1b
- Variation 2 Filing: var-type2
- Extension Filing: extension

### Data Administration Updates: Valid Values 5.0

The new STF-2-2-5-0 entry has been added to the Assembly DTD/Schema Types section in Data Administration with the Region and Country details. The following regions are added to the list:

- Canada
- European Union
- Switzerland
- United States

### *Calyx RIM 6.2 CHF 1 Data Administration Tables*

### Data Administration Updates: Procedure Type Values

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 Data Administration Tables*

### Data Administration Updates: Organisation Management System (OMS) Integration

The following Data Administration values have been updated with an Organisation Identifier attribute for the purpose of mapping Organisation in Calyx RIM for Registrations to Organisation in the Organisation Management System (OMS):

- Other > MAH/Development Sponsor/Organisation Values
- Application Maintenance > Country Values > Health Authority Values
- Product Detail Set Maintenance > Manufacturer Values

The Organisation Identifier attribute for all Data Administration tables is not updated with a value post migration. This value needs to be updated manually or via Data Exchange.

---

*Note: The Health Authority values are not Data Exchange aware.*

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Additional fields to support the OMS Integration have been added to the MAH/Development Sponsor/Organisation Values:

- Location Identifier
- Location Status

### Data Administration Updates: Referentials management service (RMS) Integration

An additional Data Administration section named SPOR Maintenance has been added to support the Referentials management service (RMS) integration. This section contains the following tables:

- 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

The SPOR Maintenance section is based on the custom lists in database.

The following Data Administration values have been updated with **RMS Term Name** attribute for the purpose of mapping Calyx RIM for Registrations values to value in the SPOR Maintenance section:

- 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 Values
- Other > Unit of Measure Prefix
- Product Family Maintenance > ATC Values
- Product Maintenance > Compendial Designation/Source Values
- Product Maintenance > Dosage/Pharmaceutical Form Values
- Product Maintenance > Medical Device Values
- Product Maintenance > Route of Administration
- Registration Maintenance > EMA Authorisation Status Values
- Registration Maintenance > Medicinal Product Type Values

The **RMS Term Name** attribute for all Data Administration tables is not updated with a value post-migration. This value needs to be updated manually or via Data Exchange.

### **Data Administration Updates: Procedure Type Values**

An additional field named **IDMP Internal Procedure Code** has been added to the **Procedure Type Values**. The field will be empty after the migration.

### Data Administration Updates: Region Values

The *Region Values* table in the Application Maintenance section has been updated with a new region named IDMP Integration.

### Data Administration Updates: Region Type Values

The *Region Type Values* table in the Application Maintenance section has been updated with a new default region type named IDMP.

### Data Administration Updates: Manufacturer Values

The following changes to the Data Administration section are introduced:

- **Country** text field has been deleted.
- **Country Code** drop-down field has been updated with a **Country** label and changed to be displayed as **Country** instead of **Country Code**.

The migration rules are described in the *Calyx RIM 6.2 Data Migration Document*.

### Data Administration Updates: Country Specific Detail Type Values

Within Data Administration, the following **Country Specific Detail Type Values** will be created with the following types:

- US FDA Regulation Number
- FDA Device Class
- EU Device Class

### Data Administration Updates: Country Specific Detail Values

All existing values on Product for the entity named **FDA Regulatory Number** will be migrated under the Data Administration entity named **Country Specific Detail Values** with a parent **Country Specific Detail Type** of **US FDA Regulatory Number** with **Country United States**.

All existing values on Product for the entity named **FDA Device Class** will be migrated under the Data Administration entity named **Country Specific Detail Values** with a parent **Country Specific Detail Type** of **FDA Device Class** with **Country United States**.

All existing values on Product for the entity named **EU Class** will be migrated under the Data Administration entity named **Country Specific Detail Values** with a parent **Country Specific Detail Type** of **EU Device Class** with all countries in European Union region including European Union country.

### Data Administration Updates: Global Medical Device Nomenclature (GMDN) Code Values

All existing values on Product for the entity named **Global Medical Device Nomenclature (GMDN) Code** (where the Product Family type is Medical Device or Pharmaceutical-Medical Device) will be added to the **Global Medical Device Nomenclature (GMDN) Code Values** table in Data Administration.

### Data Administration Updates: UMDNS Code Values

All existing values on Product for the entity named **UMDNS Code** (where the Product Family type is Medical Device or Pharmaceutical-Medical Device) will be added to the **UMDNS Code Values** table in Data Administration.

### Data Administration Updates: Applicable Standards Values

The **Version of Standard** field for the Applicable Standards Values tables will be blank after migration.

#### *Calyx RIM 6.1 & CHF's Data Administration Tables*

#### *Calyx RIM 6.1 CHF 4 Data Administration Tables*

### Data Administration changes to support AU eCTD Module 1 specification v3.1 and NeeS specification v2.0

If the AU-3-1 Assembly DTD/Schema Type already exists in the **Assembly > Assembly DTD/Schema Types** section in Data Administration, it will be activated if inactive and updated to have the internal code value **AU-3-1**. Otherwise, **AU-3-1** Assembly DTD/Schema Type will be added.

### Filing Type Values

Under the **Sequence Maintenance**, the **Filing Type Values** table will be updated with the following new sequence types:

- Provisional Registration - TGA initiated variation
- Notification
- CN
- Extension of Provisional Registration
- Duplicate

Under the **Sequence Maintenance > Filing Type Values** table, the following sequence type will be updated:

- **Withdrawal** filing type will be updated to be **Product Withdrawal**

### Sequence Description Values

Under the **Submission Maintenance**, the **Sequence Type Values** table will be updated with the following new Sequence Description:

- Provisional approval - rolling data submission - {date: d} (with eCTD code **seq-desc-26**)

### Regulatory Activity Lead Values

Under the **Submission Maintenance**, the **Regulatory Activity Lead Values** table will be updated with the following new Regulatory Activity Lead:

- Prescription meds-chemical (with eCTD code **reg-act-lead-7**)

#### *Calyx RIM 6.1 CHF 3 Data Administration Tables*

### Procedure Type Values

Under the **Procedure Type Values** table, the **Country** column will be updated with additional value **Liechtenstein** for the following Procedure Type values:

- EU CP Bio
- EU CP New API
- EU CP Orphan

### Leaf Status Values

Under **Submission Maintenance**, new table will be added named **Leaf Status Values**. Three "out-of-the-box" statuses will be provided:

- Planned
- Ready for Publish
- Published

The default value will be set to **Planned**.

### *Calyx RIM 6.1 CHF 2 Data Administration Tables*

#### Region

If the 'ZA' region already exists in the Application Maintenance – Region Values section in Data Administration, it will be updated to have the internal code value 'ZA' in the database.

The country value 'South Africa' will be updated to belong to the ZA region.

#### Assembly DTD/Schema Type

If the 'za-2-1' Assembly DTD/Schema type already exist, but is not active, in the Assembly - Assembly DTD/Schema Types section in Data Administration, it will be activated and updated to have the internal code value 'ZA-2-1'. If it does not already exist, the 'za-2-1' Assembly DTD/Schema will be added.

#### Filing Type Values

Filing Type Values will be updated with a new Name and Display Name for the following Filing Types:

- Pharmaceutical & Analytical (post-reg-pa)
- Pharmaceutical & Analytical (pre-reg-pa)

Filing Type Values will be added to the Sequence Maintenance – Filing type Values section in Data Administration, if they do not already exist. If they already exist, they will be updated with an eCTD Code for za-2-1 DTD/Schema.

### *Calyx RIM 6.1 CHF 1 Data Administration Tables*

Calyx RIM 6.2 CHF 1 includes the following updates to the Data Administration tables.

The new table MGR.REGION\_TYPE will be created. All existing regions from MGR.REGION will be updated to set REGION.REGION\_TYPE\_ID to the ID of the row from MGR.REGION\_TYPE where CODE = 'REGULATORY'

#### Internal Type Values

New values will be created in MGR.INTERNAL\_TYPE with ENTITY\_\_TYPE\_ID equal to MGR.ENTITY\_TYPE.ID where MGR.ENTITY\_TYPE.CODE = 'CHANGE\_DET\_STAT'.

New values will be created in MGR.EVT\_CHNG\_DETAIL\_STATUS\_TYPE.

## Reasons for Termination/Withdrawal Values

Be sure to run the pre-migration script `rpt_pre_migration_application_list_withdrawals.sql` to ensure that Reasons for Termination/Withdrawal values are mapped and migrated correctly. The pre-migration report will indicate which data needs to be corrected. Otherwise, the value for 'Termination/Withdrawal Reason' will not migrate.

## Queries

For the reports where the 'Termination/Withdraw Reason' field from the Application entity is available, the query has been updated to display the migrated data from the new Reason for Termination/Withdrawal field. If there is no value, the field will continue to remain blank.

## EU 3.0 Assemblies

For Standalone Assemblies, Template Assemblies, Working, Sequence, and Submitted Views where XML Definitions of the associated APL contains 'EU-3-0' and 'FORM-1-1', the folder with Number equal to '1.2' and Name equal to 'EMA-eAF' and Extension equal to 'Default' will be updated to set Extension to 'XML Application Form' (version 2.0) with the Country attribute set to 'ema'.

## Job Request Status

The Job Requests status 'Waiting' (ODS.REQUEST\_STATUS\_TYPE.NAME = 'Waiting') will be updated to 'Waiting for InSight'.

## Activities in the Alert Center

A new table will be created to support the integration of Activities into the Alert Center.

- Favorites will be updated to support integration of Activities into the Alert Center.
- Recently Viewed will be updated to support integration of Activities into the Alert Center.

## Calyx RIM 6.2

A new Data Administration selection list, Workflow Management, has been added in Calyx RIM 6.2 to support the new Calyx RIM Workflow Integrations module.

### *Calyx RIM 6.1 Data Administration Tables*

A new Data Administration selection list named **Workflow Management** has been added in Calyx RIM 6.2 to support the new Calyx RIM Workflow Integrations module.

### *Calyx RIM 6.0 & CHF's Data Administration Tables*

### *Calyx RIM 6.0 CHF 5 Data Administration Tables*

## Region

If the 'ZA' region already exists in the Application Maintenance – Region Values section in Data Administration, it will be updated to have the internal code value 'ZA' in the database.

The country value 'South Africa' will be updated to belong to the ZA region.

### Assembly DTD/Schema Type

If the 'za-2-1' Assembly DTD/Schema type already exists, but is not active in the Assembly - Assembly DTD/Schema Types section in Data Administration, it will be activated and updated to have the internal code value 'ZA-2-1'. If it does not already exist, the 'za-2-1' Assembly DTD/Schema will be added.

### Filing Type Values

Filing Type Values will be updated with a new Name and Display Name for the following Filing Types:

- Pharmaceutical & Analytical (post-reg-pa)
- Pharmaceutical & Analytical (pre-reg-pa)

If they do not already exist, Filing Type Values will be added to the Sequence Maintenance – Filing type Values section in Data Administration. If they already exist, they will be updated with an eCTD Code for za-2-1 DTD/Schema.

### *Calyx RIM 6.0 CHF 4 Data Administration Tables*

Calyx RIM 6.0 CHF 4 includes the following updates to the Data Administration tables.

### Reasons for Termination/Withdrawal Values

Be sure to run the pre-migration script `rpt_pre_migration_application_list_withdrawals.sql` to ensure that Reasons for Termination/Withdrawal values are mapped and migrated correctly. Otherwise, the value for 'Termination/Withdrawal Reason' will not migrate. The pre-migration report will indicate data that needs to be corrected.

### Queries

For the reports where the 'Termination/Withdraw Reason' field from the Application entity is available, the query has been updated to display the migrated data from the new Reason for Termination/Withdrawal field. If there is no value, the field will continue to remain blank.

### Procedure Type Values

For the following Procedure Types, the Country column is updated with Liechtenstein:

- EU CP Bio
- EU CP New API
- EU CP Orphan

### EU 3.0 Assemblies

For Standalone Assemblies, Template Assemblies, Working, Sequence, and Submitted Views where XML Definitions of the associated APL contains 'EU-3-0' and 'FORM-1-1', the folder with Number equal to '1.2' and Name equal to 'EMA-eAF' and Extension equal to 'Default' will be updated to set Extension to 'XML Application Form' (version 2.0) with the Country attribute set to 'ema'.

### *Calyx RIM 6.0 CHF 2 Data Administration Tables*

Calyx RIM 6.0 CHF 2 includes the following Data Administration changes:

- The new option Substance Attachment Values is added to Product Family Maintenance section.
- The Attachment Values option is removed from the Other section.

## *Calyx RIM 6.0 Data Administration Tables*

### **New Data Administration Selection Lists**

New Data Administration selection lists have been added in Calyx RIM 6.0 to support the new Calyx RIM Home Page, XEVMPD, and IDMP functionalities. The selection list for the Home Page provides the ability to customize tooltips and change the naming of wizards and windows on the Calyx RIM Home Page. The selection lists that support XEVMPD and IDMP can be used to capture Product data currently required for XEVMPD submissions and additional data that will be required for IDMP submissions.

### **Updated Data Administration Selection Lists**

Data Administration selection lists have been updated to support XEVMPD functionality. New fields have been added to a number of selection lists while other lists also contain updated fields. A few of the Data Admin selection lists have been consolidated to a single list. One of the most notable updates is the consolidation of Active Ingredients and Excipients into one Substance selection list. The Substance consolidation provides the ability to track Active Ingredients, Excipients, Adjuvants, and other Substances in a single Substance table.

## *Calyx RIM Versions Prior to 6.0 Data Administration Tables*

Improvements and defect fixes for some of the data administration tables in Calyx RIM are included in the migration from 3.6 to 3.6.1, from 3.6 or 3.6.1 to 3.6.2, from 3.6.1 to 4.0.0.1, from 4.5 to 4.6, from 4.6 to 4.7, and from 4.7 to 5.0. These changes reflect regulatory and agency changes, and other critical items. Specifically, these changes are concerned with application types, filing types, countries, and regions.

The upgrade scripts do not remove existing custom values. The scripts only add types or countries if they do not already exist. The scripts were designed this way to prevent upgrading issues and to meet any concerns about existing data used in applications, events, or sequences throughout the system. Nothing in these data administration update scripts will affect your existing data.

The following lists summarize the data administration table changes in these update scripts. This summary is provided should you wish to manually update your custom values to incorporate some of these recommended changes. Manually updating your custom values is entirely optional, with the caveat that (in some cases) values that should go into the eCTD assembly regional envelopes may not be fully transported by the eCTD Wizard if these codes have not been manually updated in cases where a type or country already existed.

- Lithuania and European Union countries have been added to all Filing Types for the European Union.
- Newly added countries such as Bulgaria and Romania have been added to all Filing Types for the European Union.
- New Filing Types for EU 1.4 support have been added.
- A series of Application Types specific to Japan have been added, but their names in Japanese characters have not – please consult the tables in the Administration Guide for the actual Japanese characters relevant to these new types.
- Application Types have been split apart by region in some cases. Countries were not removed from the old types, so in some cases it may be advisable to remove these countries from the old types, as long as there are no Applications assigned to the old types for those countries.
- A new CH region has been added for Switzerland to use the default Swiss eCTD templates, which will enable the use of eCTD wizards.

- CT Shared Data is a new entity that belongs to the product family. This new entity is where protocol data fields that can be shared across clinical trials is stored. This new entity was introduced in version 5.0
- Also introduced in version 5.0 is new field mapping for migration of Clinical Trial Applications (CTAs) and CT Shared Data records. Refer to the *InSight 5.0 Data Migration Document* for more information.
- The Entity XML for "Clinical Trial Application" has been updated to support enhancements for CTAs in the European Union.
- Introduced first in version 5.0, a new "Liquent\_Ind" Entity XML has been added to manage Investigational New Drugs in the United States and Canada.

Regarding default values, please note that the application types DMF and MASTER both have the same display name value of 'Drug Master File'.

## Calyx RIM Database Migration Path

Perform the migration steps to migrate your data from the previous versions of Calyx RIM.

The order in which the migration scripts should be run is indicated by the name of the individual ZIP files containing the database scripts. Please refer to the respective release notes for each database migration script.

Here are some noteworthy steps in the DB migration flow:

- Follow the database migration path from Calyx RIM 4.7 to the database migration for Calyx RIM 5.0.
- The upgrade to Calyx RIM 5.1 can only be done from the Calyx RIM 5.0 base installation, or from Calyx RIM 5.0 Certified Hotfix (CHF) 6. Follow the database migration path from your current version to Calyx RIM 5.0, 5.0 CHF 6, or 5.0 CHF 8 before proceeding to the database migration for Calyx RIM 5.1.
- The upgrade to Calyx RIM 6.0 can only be done from Calyx RIM 5.1 CHF 2 and later. Follow the database migration path from your current version to Calyx RIM 5.1 CHF 2 and later before proceeding to the database migration for Calyx RIM 6.0, and then to Calyx RIM 6.0 CHF 2.

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*Note: To migrate to Calyx RIM 6.0 from Calyx RIM 5.1 CHF 2 and later 5.1 CHFs, use DB Upgrade 51 CHF2 to 60.zip.*

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- The upgrade to any Calyx RIM 6.0 CHF can only be done from Calyx RIM 6.0 or previous 6.0 CHFs. Follow the database migration path from your current version to Calyx RIM 6.0 before proceeding to the database migration for Calyx RIM 6.0 CHFs.
- The upgrade to any Calyx RIM 6.1 CHF can only be done from Calyx RIM 6.1 or previous 6.1 CHFs. Follow the database migration path from your current version to Calyx RIM 6.1 before proceeding to the database migration for Calyx RIM 6.1 CHFs.
- The upgrade to Calyx RIM 6.2 can only be done from Calyx RIM 6.1 CHF 4 and later CHFs. Follow the database migration path from your current version to Calyx RIM 6.1 CHFs before proceeding to the database migration for Calyx RIM 6.2.
- The upgrade to any Calyx RIM 6.2 CHF can only be done from Calyx RIM 6.2. Follow the database migration path from your current version to Calyx RIM 6.1 CHFs before proceeding to the database migration for Calyx RIM 6.2 CHFs.

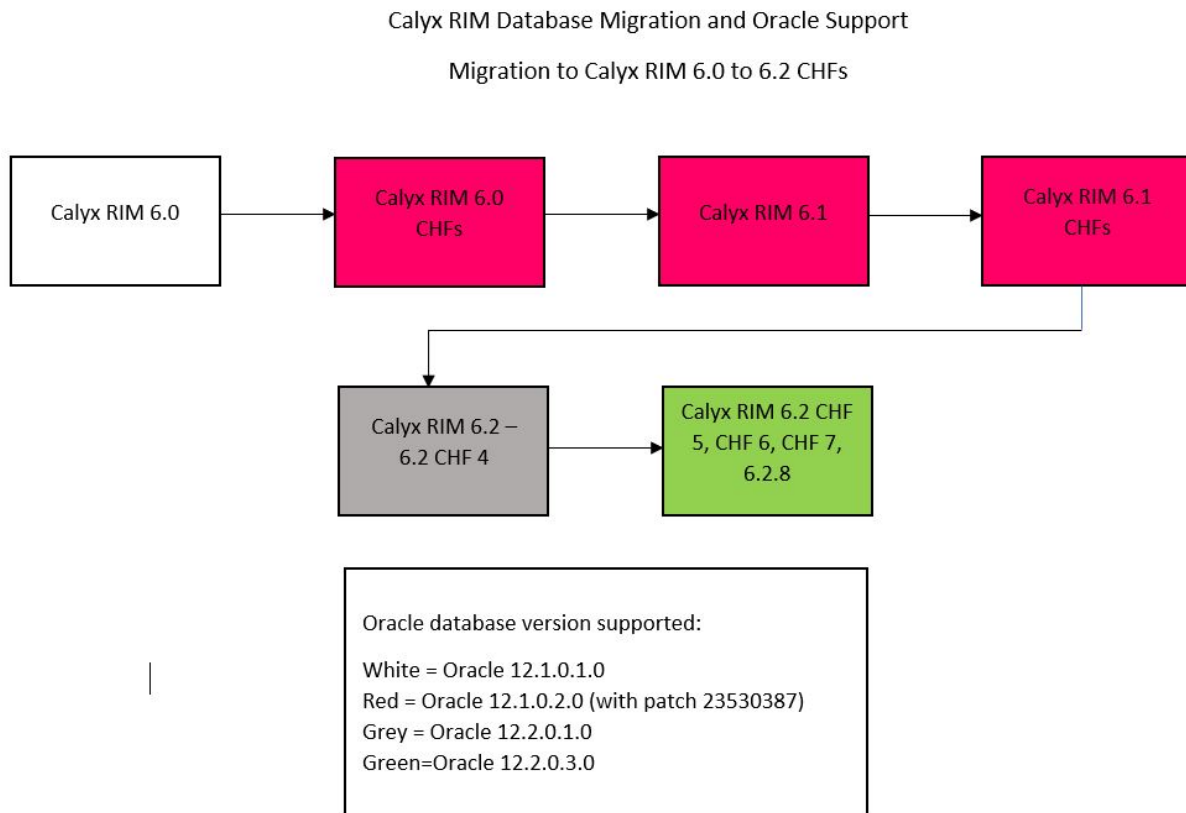
### Migration and Saved Public and Private Queries

When migrating from a previous version of Calyx RIM to a newer, major version of the product, your saved Public and Private queries will not be saved. After your migration is completed, if an error appears when running a query saved in your previous version, use the selected values on the query page to create a new saved query.

### Database Migration Path

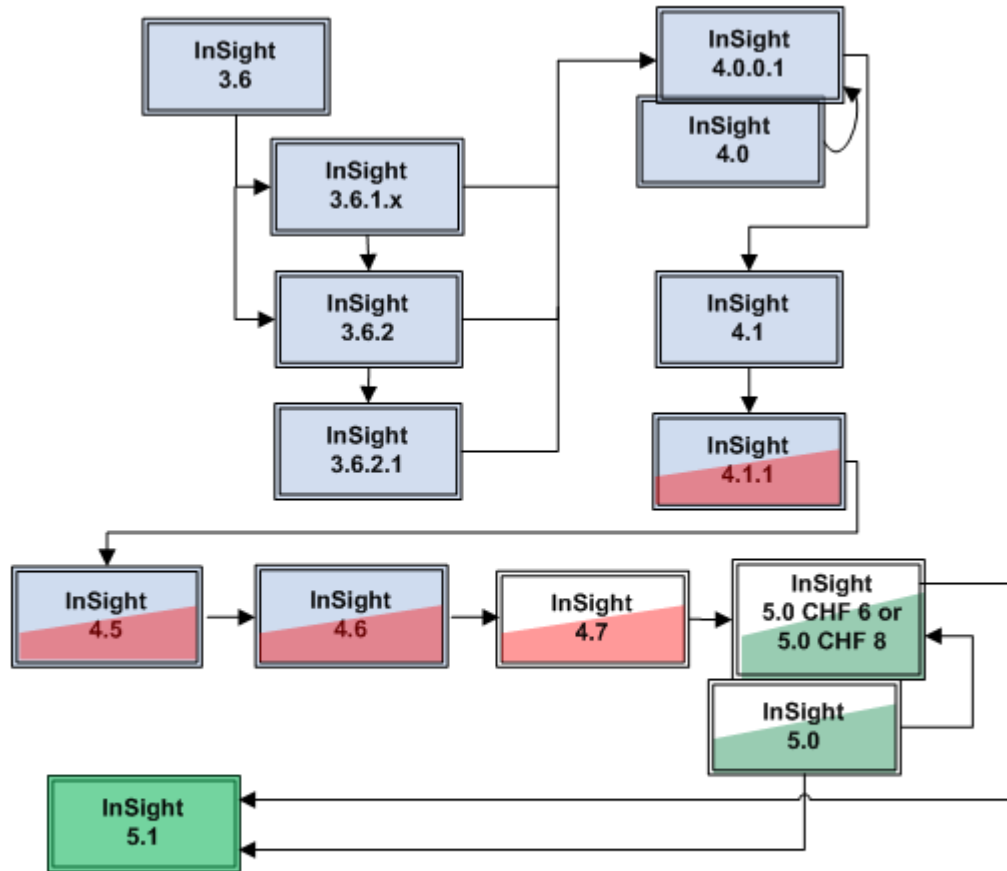
The following flowcharts illustrate the database migration path for Calyx RIM and the supported Oracle database version for each Calyx RIM version.

Database Migration from Calyx RIM 6.0 to the current Calyx RIM version:



Database Migration from Calyx RIM 3.6 to Calyx RIM 5.1:

Database Migration flowchart



**Oracle database version supported:**  
 Yellow = Oracle 9.2      Blue = Oracle 10.2.04      White = Oracle 10.2.05  
 Red = Oracle 11.1.07      Green = Oracle 11.2.0.3

**Calyx RIM 6.2 Prerequisite: Oracle Configuration Update**

The following Oracle configuration modifications must be performed on your database server before migrating any data and before installing Calyx RIM 6.2.

Please note the following descriptions and settings when performing the Oracle configuration update:

- MAX\_STRING\_SIZE controls the maximum size of VARCHAR2, NVARCHAR2, and RAW data types in SQL.
- STANDARD means that the length limits for Oracle Database releases prior to Oracle Database 12c apply (for example, 4000 bytes for VARCHAR2 and NVARCHAR2, and 2000 bytes for RAW).
- EXTENDED means that the 32767 byte limit introduced in Oracle Database 12c applies.
- The COMPATIBLE initialization parameter must be set to 12.0.0.0 or higher to set MAX\_STRING\_SIZE = EXTENDED.

— You can change the value of `MAX_STRING_SIZE` from `STANDARD` to `EXTENDED`. However, you cannot change the value of `MAX_STRING_SIZE` from `EXTENDED` to `STANDARD`.

### *Increasing the Maximum Size of VARCHAR2, NVARCHAR2, and RAW Columns in a Non-CDB*

To increase the maximum size of `VARCHAR2`, `NVARCHAR2`, and `RAW` columns in a non-CDB:

1. Shut down the database.
2. Restart the database in `UPGRADE` mode.
3. Change the setting of `MAX_STRING_SIZE` to `EXTENDED`.
4. Run the `rdbms/admin/utl32k.sql` script.  
You must be connected as `SYSDBA` to run the script.
5. Restart the database in `NORMAL` mode.

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*Note: The `utl32k.sql` script increases the maximum size of the `VARCHAR2`, `NVARCHAR2`, and `RAW` columns for the views where this is required. The script does not increase the maximum size of the `VARCHAR2`, `NVARCHAR2`, and `RAW` columns in some views because of the way the SQL for those views is written.*

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6. Run the `rdbms/admin/utl1rp.sql` script to recompile invalid objects. You must be connected as `SYSDBA` to run the script.

### Pre-Migration Manual Tasks for Calyx RIM 6.2 CHF 7

#### *Taiwan: Pre-Migration Manual Tasks for Calyx RIM 6.2 CHF 7*

To support TW implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 6.2 CHF 7, the TW regions must be added to your Calyx RIM Data Administration configuration section before executing the migration.

To add the TW region to Calyx RIM:

1. On the Calyx RIM application *home* page, click **Go To > Data Administration**.
2. Under **Application Maintenance**, click **Region Values**.
3. Click **Create** .
4. Enter the following:


Field Name	Value
Region Type	Regulatory Region
Region Abbreviation	TW
Region Name	Taiwan
Countries	Taiwan, Province of China

5. Click **Save**.
6. Click **Return to menu**.


*Brexit: Pre-Migration Manual Tasks for Calyx RIM 6.2 CHF 7*

*Create Country Values*


To support a country implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 6.2 CHF 7, the country values must be added to your Calyx RIM Data Administration configuration section before executing the migration.

1. Click **Go To > Data Administration**.
2. Under **Application Maintenance**, click **Country Values**.
3. Click **Create** .  
The **Country** page appears.
4. Enter the following:


Field Name	Value
Country Code	XU
Country Name	Great Britain
eCTD Code	uk

5. **Save**.
6. Click **Create** .
7. Enter the following:

Field Name	Value
Country Code	XI
Country Name	Northern Ireland
eCTD Code	uk

8. **Save**.
9. Find the Great Britain in the countries list and click the **XU** link.
10. From the **Heath Authority** tab, click **Create** .
11. Enter the following:

Field Name	Value
Health Authority Name	Medicines and Healthcare Products Regulatory Agency
Default Flag	Yes

12. **Save**.
13. Click **Back**.
14. Find the Northern Ireland country and click the **XI** link.
15. From the **Heath Authority** tab, click **Create** .

16. Enter the following:

Field Name	Value
Health Authority Name	Medicines and Healthcare Products Regulatory Agency
Default Flag	Yes

17. Save.

18. Click **Back** and **Return Menu**.


### Associate Region Values

To support a region implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 6.2 CHF 7, the region must be associated in your Calyx RIM Data Administration configuration section before executing the migration.

1. On the Calyx RIM *home* page, click **Go To > Data Administration**.
2. Under **Application Maintenance**, click **Region Values**.
3. Select the **EU** hyperlink.
4. In the **Selected** Countries list, select United Kingdom and move it to the **Available** Countries list.
5. In the **Available** Countries list select Northern Ireland and move it to **Selected** Countries list.
6. **Save**, and then click **Return to menu**.

### Create Region Values

To support a region implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 6.2, the region must be added to your Calyx RIM Data Administration configuration section before executing the migration.

1. On the Calyx RIM *home* page, click **Go To > Data Administration**.
2. Under **Application Maintenance**, click **Region Values**.
3. Click **Create** .
4. Enter the following:

Field Name	Value
Region Type	Regulatory Region
Region Abbreviation	XU
Region Name	Great Britain
Countries	Great Britain

5. **Save**.

6. Click the **Create**  and enter the following:

Field Name	Value
Region Type	Regulatory Region
Region Abbreviation	UK
Region Name	United Kingdom
Countries	United Kingdom

7. **Save**, and then click **Return to menu**.


### Modify Application Type Values

To support a region implementation by the database upgrade from Calyx RIM6.2 CHF 6 to Calyx RIM 6.2 CHF 7, the application type values must be modified to your Calyx RIM Data Administration configuration section before executing the migration.

1. On the Calyx RIM *home* page, click **Go To > Data Administration**.
2. Under **Application Maintenance**, click **Application Type Values**.
3. Find the Marketing Authorisation Application in the list and click the **MAA** link.
4. Click the **Edit** icon.
5. In the **Available** Countries list, select Northern Ireland and Great Britain.
6. Move them to the **Selected** Countries list.
7. **Save**, and then click **Return to menu**.


### Create Procedure Type Values

To support a region implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 6.2 CHF 7, the procedure type values must be created in your Calyx RIM Data Administration configuration section before executing the migration.

1. On the Calyx RIM *home* page, click **Go To > Data Administration**.
2. Under **Application Maintenance**, click **Procedure Type Values**.
3. Click **Create** .
4. Enter the following:

Field Name	Value
Procedure Type Abbreviation	National GB
Procedure Type Name	National GB
Display Name	National Great Britain
Internal Procedure Code	NATIONAL
eCTD Code	national

Field Name	Value
Countries	Great Britain

5. Save.
6. Click **Create** .
7. Enter the following:

Field Name	Value
Procedure Type Abbreviation	National UK
Procedure Type Name	National UK
Display Name	National United Kingdom
Internal Procedure Code	NATIONAL
eCTD Code	national
Procedure Type Code	4
Countries	United Kingdom

8. **Save**, and then click **Return to menu**.

### Modify Country Values

To support a country implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 6.2, the country values must be modified in your Calyx RIM Data Administration configuration section before executing the migration.

1. On the Calyx RIM *home* page, click **Go To > Data Administration**.
2. Under **Application Maintenance**, click **Country Values**.
3. Find the United Kingdom and click the **GB** link.
4. From the **Procedure Type Details** tab, select **National United Kingdom**.
5. Click the **Set to Default** icon, and then **Back**.
6. Find Great Britain and click the **XU** link.
7. From the **Application Type Details** tab, select **Marketing Authorisation Application**.
8. Click the **Set to Default** icon.
9. From the **Procedure Type Details** tab select **National Great Britain**.
10. Click the **Set to Default** icon, and then **Back**.
11. Find Northern Ireland and click the **XI** link.
12. From the **Application Type Details** tab, select **Marketing Authorisation Application**.
13. Click the **Set to Default** icon, and then **Back**.
14. Click **Return to menu**.

### *Modify Procedure Type Values*


To support a region implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 6.2 CHF 7, the procedure type values must be modified in your Calyx RIM Data Administration configuration section before executing the migration.


1. Click **Go To > Data Administration**.
2. Under **Application Maintenance**, click **Procedure Type Values**.
3. Search for EU CP procedure and click the **EU CP** link.
4. In the **Available Countries** list, select Northern Ireland and move it to the **Selected Countries** list.
5. In the **Selected Countries** list, select United Kingdom and move it to the **Available Countries** list.
6. **Save**.
7. Search for the EU DCP procedure and click the **EU DCP** link.
8. In the **Available Countries** list, select Northern Ireland and move it to the **Selected Countries** list.
9. In the **Selected Countries** list, select United Kingdom and move it to the **Available Countries** list.
10. **Save**.
11. Search for the EU MRP procedure and click the **EU MRP** link.
12. In the **Available Countries** list, select Northern Ireland and move it to the **Selected Countries** list.
13. In the **Selected Countries** list, select United Kingdom and move it to the **Available Countries** list.
14. **Save**.
15. Find the EU - National procedure and click the **EU - National** link.
16. In the **Selected Countries** list, select United Kingdom and move it to the **Available Countries** list.
17. **Save** and then click **Return to menu**.
18. Repeat steps 3-6 for any other EU procedure.

### *Event Type and Secondary Event Types*

To support a region implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 6.2 CHF 7, the event type values must be created in your Calyx RIM Data Administration configuration section before executing the migration.

To create a new Event Type /Secondary Event Type:

1. Click **Go To > Data Administration**.
2. Under **Event Maintenance**, click **Event Type Values**.
3. Click **Create** .
4. In the **Name** field, enter `Data Administration Activities`
5. **Save**.
6. Click **Return Menu**.
7. Under **Event Maintenance**, click **Secondary Event Type Values**.

8. Click **Create** .
9. Enter the following:

Field Name	Value
Name	Brexit Conversion
Primary Event	Data Administration Activities

10. **Save.**
11. Click **Return Menu.**

### *Timeline/Event Plan Values (TEP)*

To support a region implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 6.2 CHF 7, the event type values must be modified in your Calyx RIM Data Administration configuration section.

To enable region changes by database upgrade, you must:

- Modify existing Procedure Based Timeline/Event Plans to remove the United Kingdom and to add Northern Ireland
- Modify existing Event Based Timeline/Event Plans to add Great Britain
- Create new Timeline/Event Plans as applicable

### *Modify Existing Timeline/Event Plan Values*

To support a region implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 6.2 CHF 7, the event type values must be modified in your Calyx RIM Data Administration configuration section.

To modify existing Timeline/Event Plan Values:

1. Click **Go To > Data Administration.**
2. Under **Event Maintenance**, click **Timeline/Event Plan Values.**
3. Select the impacted timeline value from the list.
4. Click on the **Delete Countries** icon.
5. In the Countries list select United Kingdom and move it to the **Disassociated from Plan** list.
6. **Save.**
7. Click the **Add Countries** icon.
8. In the Countries list select Northern Ireland and move it to the **Countries Selected** list.
9. Set **Copy Default Lead Times** from the following Country as required.
10. **Save.**
11. Click **Back.**
12. Click **Return to menu.**

### *Change Type*

To support a region implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 6.2 CHF 7, new values must be created in Calyx RIM Data Administration configuration section.

Create new values to capture specific activities related with BREXIT, where no existing terms can be used.


### Modify Assembly DTD/Schema Values

To support a region implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 6.2 CHF 7, the assembly values must be modified in your Calyx RIM Data Administration configuration section before executing the migration.

1. On the Calyx RIM *home* page, click **Go To > Data Administration**.
2. Under **Assembly**, click **Assembly DTD/Schema Types**.
3. Find the **EU-3-0-1** and click the **EU-3-0-1** link.
4. In the **Available** Regions list, select **United Kingdom** and **Great Britain** and move them to the **Selected** Regions list.
5. Verify that all EU Countries, Northern Ireland, Great Britain, and United Kingdom exist in the **Selected** Countries list.
6. **Save**, and then click **Return to menu**.

### Create Filing Type Values

To support a region implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 6.2, the filing type values must be added to your Calyx RIM Data Administration configuration section before executing the migration.

1. On the Calyx RIM *home* page, click **Go To > Data Administration**.
2. Under **Sequence Maintenance**, click **Filing Type Values**.
3. Click **Create** .  
The *Filing Type Values* page appears.
4. Enter the following:

Field Name	Value
Filing Type	CAP Grandfathering Full Initiating Sequence
Display Name	CAP Grandfathering Full Initiating Sequence
Countries	Great Britain


5. **Save**.  
The filing type is created.
6. To create the filing types in the table below, perform the steps 1 to 5 and in step 4, use the filing type and display name value from the table.

Filing Type	Display Name	Countries
CAP Grandfathering Full Initiating Sequence	CAP Grandfathering Full Initiating Sequence	Great Britain

Filing Type	Display Name	Countries
CAP Grandfathering Full Initiating Sequence Incorporating Change of Ownership (COA)	CAP Grandfathering Full Initiating Sequence Incorporating Change of Ownership (COA)	Great Britain
CAP Grandfathering Minimal Initiating Sequence	CAP Grandfathering Minimal Initiating Sequence	Great Britain
CAP Grandfathering Minimal Initiating Sequence Incorporating Change of Ownership (COA)	CAP Grandfathering Minimal Initiating Sequence Incorporating Change of Ownership (COA)	Great Britain
Variation 1A Filing - Establishing UK QPPV-PSMF	Variation 1A Filing - Establishing UK QPPV-PSMF	Great Britain
Ownership Application (COA) - EU to UK MAH	Ownership Application (COA) - EU to UK MAH	Great Britain

### Modify Filing Type Values

To support a country implementation by the database upgrade from Calyx RIM6.2 CHF 6 to Calyx RIM 6.2 CHF 7, the filing type values must be modified in your Calyx RIM Data Administration configuration section before executing the migration.

1. On the Calyx RIM *home* page, click **Go To > Data Administration**.
2. Under **Sequence Maintenance**, click **Filing Type Values**.
3. Find the ASMF Filing and click the **ASMF Filing** link.
4. On the **Filing Type eCTD Code** tab, click **Create** .
5. Enter the following:

Field Name	Value
Applicable DTD/Schema	eu-3-0-1
Countries	Great Britain

6. **Save.**  
The filing type eCTD code is created.
7. To modify other filing type values, perform the steps above and in step 3, use a different filing type from the table below each time. Do this for Great Britain and Northern Ireland.

For Great Britain:

Filing Type	Display Name	Countries
ASMF Filing	ASMF Filing	Great Britain
Follow-Up Measures	Follow-Up Measures	Great Britain
Notification 61-3 Filing	Notification 61-3 Filing	Great Britain

Filing Type	Display Name	Countries
Original Filing	Original Filing	Great Britain
PAED Article 46	PAED Article 46	Great Britain
Plasma Master File	Plasma Master File	Great Britain
Renewal Filing	Renewal Filing	Great Britain
Transfer MA Filing	Transfer MA Filing	Great Britain
Variation 1A Filing	Variation 1A Filing	Great Britain
Variation 1B Filing	Variation 1B Filing	Great Britain
Variation 2 Filing	Variation 2 Filing	Great Britain
Withdrawal Filing	Withdrawal Filing	Great Britain

For Northern Ireland:

Filing Type	Display Name	Countries
Additional PV Activity in the RMP Related to PAM	Additional PV Activity in the RMP Related to PAM	Northern Ireland
Annex II Condition Related to PAM	Annex II Condition Related to PAM	Northern Ireland
Annual Reassessment Filing	Annual Reassessment Filing	Northern Ireland
Arbitration Filing	Arbitration Filing	Northern Ireland
Article 107i Referral	Article 107i Referral	Northern Ireland
Article 16c (1c)i Referral	Article 16c (1c)i Referral	Northern Ireland
Article 16c(4) Referral	Article 16c(4) Referral	Northern Ireland
Article 20 Referral	Article 20 Referral	Northern Ireland
Article 29 Paediatric Referral	Article 29 Paediatric Referral	Northern Ireland
Article 29(4) Referral	Article 29(4) Referral	Northern Ireland
Article 30 Referral	Article 30 Referral	Northern Ireland
Article 31 Referral	Article 31 Referral	Northern Ireland
Article 35 Referral	Article 35 Referral	Northern Ireland
Article 5(3) Referral	Article 5(3) Referral	Northern Ireland
Article 58 Filing	Article 58 Filing	Northern Ireland
Clinical Data for Publication - Final Version	Clinical Data for Publication - Final Version	Northern Ireland

Filing Type	Display Name	Countries
Clinical Data for Publication - Redacted Proposal	Clinical Data for Publication - Redacted Proposal	Northern Ireland
Conditional Specific Obligation Filing	Conditional Specific Obligation Filing	Northern Ireland
Corrective/Preventative Action Related to PAM	Corrective/Preventative Action Related to PAM	Northern Ireland
DMF Filing	DMF Filing	Northern Ireland
Extension Filing	Extension Filing	Northern Ireland
Follow-up Filing	Follow-up Filing	Northern Ireland
Follow-up Measures	Follow-up Measures	Northern Ireland
Legally Binding Measure Related to PAM	Legally Binding Measure Related to PAM	Northern Ireland
Lifting Suspension Filing	Lifting Suspension Filing	Northern Ireland
Marketing Authorisation Application	Marketing Authorisation Application	Northern Ireland
National Variation Filing	National Variation Filing	Northern Ireland
Notification 61-3 Filing	Notification 61-3 Filing	Northern Ireland
Original filing	Original filing	Northern Ireland
PAED Article 29 Filing	PAED Article 29 Filing	Northern Ireland
PAED Article 45	PAED Article 45	Northern Ireland
PAED Article 46	PAED Article 46	Northern Ireland
PAED Related to PIP (Article 7, 8, 30)	PAED Related to PIP (Article 7, 8, 30)	Northern Ireland
Paediatric Submission Related to PAM (Article 45)	Paediatric Submission Related to PAM (Article 45)	Northern Ireland
Paediatric Submission Related to PAM (Article 46)	Paediatric Submission Related to PAM (Article 46)	Northern Ireland
PAES Submission Related to PAM	PAES Submission Related to PAM	Northern Ireland
PASS Protocol Submission (Article 107n)	PASS Protocol Submission (Article 107n)	Northern Ireland
PASS Report Submission (Article 107q)	PASS Report Submission (Article 107q)	Northern Ireland
Plasma Master File	Plasma Master File	Northern Ireland
Periodic Safety Update Report	PSUR Filing	Northern Ireland
PSUR single assessment procedure	PSUR single assessment procedure	Northern Ireland
Recommendation Related to PAM	Recommendation Related to PAM	Northern Ireland

Filing Type	Display Name	Countries
Referral Filing	Referral Filing	Northern Ireland
Reformat Filing	Reformat Filing	Northern Ireland
Renewal Filing	Renewal Filing	Northern Ireland
Repeat Use Procedure	Repeat Use Procedure	Northern Ireland
Safety Filing	Safety Filing	Northern Ireland
SDA Submission Related Filing	SDA Submission Related Filing	Northern Ireland
Specific Obligation Filing	Specific Obligation Filing	Northern Ireland
Specific Obligation Related to PAM	Specific Obligation Related to PAM	Northern Ireland
Supplement Filing	Supplement Filing	Northern Ireland
Transfer MA Filing	Transfer MA Filing	Northern Ireland
USR Filing	USR Filing	Northern Ireland
Variation 1A Filing	Variation 1A Filing	Northern Ireland
Variation 1AIN Filing	Variation 1AIN Filing	Northern Ireland
Variation 1B Filing	Variation 1B Filing	Northern Ireland
Variation 2 Filing	Variation 2 Filing	Northern Ireland
Withdrawal Filing	Withdrawal Filing	Northern Ireland

## Entity Updates

### *Calyx RIM 6.2 Entities Updates*

#### **Event-Country Status**

A new field **Add Comment** is added to the **Event- Country Attributes > Add/Modify-Country Event Status** page.

A new field **Event-Country Status Comments** is added on **Add/Modify-Country Event Status** pages to display added comments, without ability to delete or modify for the current release.

#### **Status Dates under Sequence**

A new field **Add Comment** is added to the **View Sequence > Add/Modify Status** page.

A new field **Sequence Status Comments** is added on **Add/Modify-Country Sequence Status** pages to display added comments, without ability to delete or modify for the current release.

#### **Status Dates under Task/Sub-Task**

A new field **Add Comment** is added to the **View Task > Add/Modify Status** page for Tasks and Sub-Tasks.

A new field **Task Status Comments** is added on Add/Modify Status pages for Tasks and Subtasks to display added comments, without ability to delete or modify for the current release.

## Calyx RIM 6.2 & CHF Migration Tasks

### *Post-migration Script Updates for Calyx RIM 6.2 CHF 5*

The migration script will perform multiple changes to the Data Administration. These must be verified, and updated where necessary.

Changes related to **CH-1-5** implementation:

- Associates Switzerland country with Switzerland region in the **Application Maintenance - Region Values**.
- Adds the **CH-1-5** assembly DTD type in the **Assembly - Assembly DTD/Schema Types** section in **Data Administration**, if it does not already exist.
- Adds the following values to the **Sequence Maintenance – Filing type Values** section in **Data Administration** if they do not already exist:
  - Corrigendum Filing
  - DMF Filing
  - Follow-Up Measures
  - Known Active Substance
  - New Active Substance
  - Orphan Fast Track Filing
  - Periodic Safety Update Report
  - Plasma Master File
  - Reformat Filing
  - Renewal Filing
  - Supplement Filing
  - Transfer MA Filing
  - Withdrawal Filing
  - Used for meeting
  - Co-Marketing Medicinal Product
  - Parallel Import
  - Variation 1A Filing
  - Variation 1AIN Filing
  - Variation 1B Filing
  - Variation 2 Filing
  - Extension Filing

Changes related to Data Administration grids and values:

- Adds the **Last User Updated** and **Last Changed Date** fields to the user interface (UI) for every Data Administration Value.
- Adds the **Created By** and **Created Date** fields to each value of the **SPOR Maintenance** table.

- Adds a new flag named **System Process Default Flag** with **Yes/No** values that indicates which status **Name** mapped to the same **Internal System Status** will be shown by default in Calyx RIM after an Event is closed manually or using a wizard. The field will be present in these Data Administration Values:
  - Application Status Values
  - Event-Change Detail Status Values
  - Product Status Values
  - Product Detail Set Status Values
  - Sequence Status Values

Changes related to entities:


- Adds a new flag with **Yes/No** values, **XEVMPD Submission Required?** to the **Full Product Presentation** entity (before the **Use Reference Active Ingredient** field).
- Adds the **Optimize Fonts in Paper Output** flag when the assembly publishing settings library or the publishing settings library template are migrated.

### *Pre-Migration Manual Tasks for LIQUENT InSight 6.2 CHF 4*


To support CN and EAEU implementation by the database upgrade from Calyx RIM 6.2 CHF 3 to Calyx RIM 6.2 CHF 4, the CN and EAEU regions must be added to your Calyx RIM Data Administration configuration section before executing the migration.

#### **China and EAEU Data Administration**

To add the CN region to Calyx RIM:

1. On the Calyx RIM application *home* page, click **Go To > Data Administration**.
2. Under **Application Maintenance**, click **Region Values**.
3. Click **Create** .  
The Region page appears.
4. Enter the following:

Field Name	Description
Region Type	Regulatory Region
Region Abbreviation	CN
Region Name	China
Countries	China

5. **Save**, and then click **Return to menu**.  
To add the EAEU region to Calyx RIM:
6. On the Calyx RIM application *home* page, click **Go To > Data Administration**.
7. Under **Application Maintenance**, click **Region Values**.
8. Click **Create** .  
The Region page appears.
9. Enter the following:

Field Name	Description
Region Type	Regulatory Region
Region Abbreviation	EAEU
Region Name	Eurasian Economic Union
Countries	Armenia, Belarus, Kazakhstan, Kyrgyzstan, Russian Federation

10. **Save**, and then click **Return to menu**.

### Post-Migration Script Updates for Calyx RIM 6.2 CHF 4

The migration script will perform multiple changes to the Data Administration. These should be verified, and where necessary, updated.

Following are the set of changes for China and EAEU:

- Associates China country with China region in the **Application Maintenance - Region Values**.
- **CN-1-0** Assembly DTD /Schema type will be added to the **Assembly > Assembly DTD/Schema Types** section in Data Administration section, if it does not already exist.
- The **Application Maintenance > Country Values** section of Data Administration will be updated to set the value for the eCTD Code for the China country.
- A procedure type value *CN-National* will be created in the **Application Maintenance - Procedure Type Values** section.
- Existing associations to application procedure type will be deleted for China country and will be associated to **CN-National** procedure type.
- Existing associations to application types for China country will be deleted and will be associated to the IND, NDA, and ANDA application types.
- Updates Health Authority attributes for China country region in the **Application Maintenance – Country Values**.
- Filing Type Values will be added to the **Sequence Maintenance > Filing Type Values** section in Data Administration, if they do not already exist.
  - Original Application
  - Supplement Filing
  - New Indication
  - Annual Report Filing
  - Periodic Safety Update Report
  - Renewal Filing
  - Baseline
- Adds the following values to the **Submission Maintenance – Submission Product Type Values** section in Data Administration if they do not exist already:
  - Chemical Product
  - Biological Product


- Adds the following values to the **Submission Maintenance - Sub Filing Type** section in Data Administration if they do not already exist:
  - Original
  - Response
  - Withdrawal
  - Reformat
- Updates Health Authority attributes for Armenia, Belarus, Kazakhstan, Kyrgyzstan, and Russian Federation countries in the **Application Maintenance > Region Values**.
- Associates Armenia, Belarus, Kazakhstan, Kyrgyzstan, and Russian Federation countries with EAEU region in **Application Maintenance > Country Values**.
- *EAEU-1-0* Assembly DTD /Schema type will be added to the **Assembly > Assembly DTD/Schema Types** section in the Data Administration section, if it does not already exist.
- The **Application Maintenance > Country Values** section of Data Administration will be updated to set the value for the *eCTD Code* for the Armenia, Belarus, Kazakhstan, Kyrgyzstan, and Russian Federation countries.
- A procedure type value *EAEU MRP* will be created in the **Application Maintenance > Procedure Type Values** section.
- Existing associations to application procedure type will be deleted for EAEU and will be associated to the *EAEU - MRP, EAEU - DCP, EAEU - National* procedure type.
- Adds all the values to **Drug Registration File Documents Section Values**.
- Adds all the values to **Drug Registration File Documents Values**.

*Pre-Migration Manual Tasks for LIQUENT InSight 6.2 CHF 3*

**Jordan Data Administration**

To support JO implementation by the database upgrade from Calyx RIM 6.2 CHF 2 to Calyx RIM 6.2 CHF 3, the JO region must be added to your Calyx RIM Data Administration configuration section before executing the migration.

To add the JO region to Calyx RIM:

1. On the Calyx RIM application *home* page, click **Go To > Data Administration**.
2. Under **Application Maintenance**, click **Region Values**.
3. Click **Create** .  
The Region page appears.
4. Enter the following:

Field Name	Description
Region Type	Regulatory Region
Region Abbreviation	JO
Region Name	Jordan
Countries	Jordan

5. **Save**, and then click **Return to menu**.

### *Post-Migration Script Updates for Calyx RIM 6.2 CHF 3*

The migration script will perform multiple changes to the Data Administration. Following are the set of changes:

- **JO-1-0** Assembly DTD /Schema type will be added to the **Assembly > Assembly DTD/Schema Types** section in Data Administration section, if it does not already exist.
- The **Application Maintenance > Country Values** section of Data Administration will be updated to set the value for the eCTD Code for the Jordan country.
- A procedure type value *JO-National* will be created in the Application Maintenance - Procedure Type Values section.
- Existing associations to application procedure type will be deleted for each of the Jordan country and will be associated to JO-National procedure type.
- Existing associations to application types for Jordan country will be deleted and will be associated to the CTA and NDA application types.
- Filing Type Values will be added to the **Sequence Maintenance > Filing Type Values** section in Data Administration, if they do not already exist.
  - ASMF Filing
  - Biological Allergen
  - Biological Bio-similar
  - Biological Blood Product
  - Biological Drug
  - Biological Vaccine
  - CEP Submission
  - Extension Filing
  - Generics
  - Generic Narcotics
  - Generic Vitamin Drug
  - Herbal Drug
  - MAA - Originator Drug
  - MAA - Originator Vitamin Drug
  - New Drug
  - New Narcotics
  - New Vitamin Drug
  - None
  - Notification with pricing
  - Notification without pricing
  - Originator Narcotics
  - Periodic Safety Update Report
  - Plasma Master File
  - PSUR single assessment procedure
  - Radiopharmaceutical Non-Radioactive Components (kits)

- Radiopharmaceutical Ready-for-use Radioactive Product
- Registration Department approval
- Renewal Filing
- Risk Management Plan Filing
- Technical committee approval
- Transfer MA Filing
- USR Filing
- Value added medicine
- Veterinary drug
- Withdrawal Filing

### *Updated Submitted Available Flag - Calyx RIM 6.2 CHF 2*

The following example provides information about the status of the Updated Submitted Available flag in sequences before and after migrating to Calyx RIM 6.2 CHF 2.

Consider an initial sequence P0000 created in a version prior to Calyx RIM 6.2 CHF 2. For this example, the initial sequence was created in Calyx RIM 6.2 CHF 1.

- P0000 is a submitted sequence in Calyx RIM 6.2 CHF 1.
- P0001 and P0002 are working assemblies created in parallel.
- P0001 is added to the lifecycle.
- The P0003 working assembly is created from submitted view containing P0001.
- Sequence P0002 in a working assembly has information inherited from P0000, and P0003 in a working assembly has the latest information inherited from P0001.

After running the Calyx RIM 6.2 CHF 2 migration script, the status of the Updated Submitted Available flag can be noted.

- P0002 Working Assembly will have the Updated Submitted Available flag set to **Yes**. This indicates that a new Submitted View version is available.
- P0003 Working Assembly will have the Updated Submitted Available flag set to **No**. This indicates that this sequence has the latest information.

### *Pre-Migration Scripts for Calyx RIM 6.2*

It is recommended that you run the following scripts before starting your database migration to conform to new requirements. Running these scripts will not affect the database. See the *LIQUENT InSight 6.2 Data Migration Document* (PDF) for more information.

The scripts should be run by an ISM user.

Pre-Migration Script Name	Pre-Migration Script Description	Pre-Migration Script Output
rpt_pre_migration_mpid.sql	<ul style="list-style-type: none"> <li>— The script is used to identify data that may have been captured for MPID in Calyx RIM so you can take appropriate steps to move data elsewhere.</li> <li>— This script is optional.</li> </ul>	The pre-migration script output is a report in a <code>txt</code> file format that identifies the <b>MPID</b> data with Full Product Presentation that have values that cannot be migrated because they do not meet the business rules for the MPID values.
rpt_pre_migration_procidentif.sql	<ul style="list-style-type: none"> <li>— The script is used to identify data that may have been captured for <b>Application Identifier</b> in Calyx RIM so you are notified that this data will not be overridden within the migration script.</li> <li>— This script is optional.</li> </ul>	The pre-migration script output is a report in a <code>txt</code> file format that identifies the <b>Procedure Identifier</b> data with <i>Application</i> that have values that cannot be overridden because they do not meet the business rules for the <b>Application Code</b> migration.
pre_migration_previouslyevcodes_authorizedprod.sql	The pre-migration script is used to identify previous <b>EV Code</b> values that are not assigned to any of the <i>Full Product Presentation</i> entity.	The pre-migration script output is a report in a <code>txt</code> file format that identifies the <b>Previous EV Code</b> values that are not assigned to any of the Full Product Presentation and which will be hidden during a migration to Calyx RIM 6.2.

Pre-Migration Script Name	Pre-Migration Script Description	Pre-Migration Script Output
pre_migration_event_uniqueness.sql	The pre-migration script is used to identify events that do not have a unique <b>Event Name, Event Code</b> combination within an <i>Application</i> .	The pre-migration script output is a report in a <code>txt</code> file format that identifies the <i>Events</i> that are not uniquely identified within an <i>Application</i> and which will be change during a migration to Calyx RIM 6.2.
pre_migration_lic_atc.sql	The pre-migration script is used to identify <b>ATC</b> values that are not assigned to the <i>Product Family</i> but remained in the related <i>Registration</i> .	The pre-migration script output is a report in a <code>txt</code> file format that identifies <i>Product Families</i> with no <b>ATC</b> values but with <b>ATC</b> values under related <i>Registration</i> that will be changed during migration to Calyx RIM 6.2.
pre_migration_task_uniqueness.sql	The pre-migration script is used to identify <i>Tasks</i> and <i>Sub-Tasks</i> that are not uniquely identified within its parent entity.	The pre-migration script output is a report in a <code>txt</code> file format that identifies <i>Tasks</i> and <i>Sub-Tasks</i> that are not uniquely identified within the parent entity and which will be changed during a migration to Calyx RIM 6.2.

Pre-Migration Script Name	Pre-Migration Script Description	Pre-Migration Script Output
pre_migration_reference_uniqueness.sql	The pre-migration script is used to identify <i>References</i> that are not uniquely identified within a parent entity.	The pre-migration script output is a report in a <code>txt</code> file format that identifies <i>References</i> that are not uniquely identified within the parent entity and which will be changed during a migration to Calyx RIM 6.2.
pre_migration_pds_uniqueness.sql	The pre-migration script is used to identify <i>PDS</i> (Product Detail Set) that are not uniquely identified within an <i>Application</i> .	The pre-migration script output is a report in a <code>txt</code> file format that identifies <i>PDSs</i> that are not uniquely identified within the <i>Application</i> and which will be changed during a migration to Calyx RIM 6.2.
pre_migration_pds_template_uniqueness.sql	The pre-migration script is used to identify <i>PDS Templates</i> that are not uniquely identified within a <i>Product</i> .	The pre-migration script output is a report in a <code>txt</code> file format that identifies <i>PDS Templates</i> that are not uniquely identified within the <i>Product</i> and which will be changed during a migration to Calyx RIM 6.2.

## Calyx RIM 6.1 & CHF Migration Tasks

### *Pre-Migration Scripts for Calyx RIM 6.1 to Calyx RIM 6.1 CHF 1*

#### **rpt\_pre\_migration\_application\_list\_withdrawals.sql**

It is recommended that you run this script before starting your database migration to identify potential migration problems where data does not conform to the new requirements.

The `rpt_pre_migration_application_list_withdrawals.sql` script should be run by an ISM user.

The `rpt_pre_migration_application_list_withdrawals.sql` script produces an Excel report that identifies application names with Application Statuses that are not mapped to any internal system status, or are mapped to the incorrect values and have data in the 'Termination/Withdraw Reason' field that cannot be migrated because they do not meet the criteria for migration.

Report Column	Value
PRODUCT FAMILY NAME	Displays the Product Family Name.
APPLICATION NAME	Displays the Application Name.
APPLICATION STATUS	Displays the Application Status mapped to the incorrect internal system status.
INTERNAL SYSTEM STATUS	Displays Internal System Status for Application Status value.
TERMINATION/WITHDRAW REASON	Displays the Termination/Withdraw Reason field data.

### master\_pre.sql

The `master_pre.sql` script should be run by a system user. You must run the `master_pre.sql` script before running the `master.sql` script.

### Pre-Migration Mandatory Scripts for Calyx RIM 5.1 to Calyx RIM 6.1

#### Pre-Migration Scripts

There are a number of pre-migration scripts. It is recommended the scripts are run to identify potential migration problems where data does not conform to the new requirements. These scripts are listed below with a brief description of their use.

Script Number	Script Name	Description	Type of Output
Script 1	<code>rpt_pre_migration_substances.sql</code>	<p>Prior to the consolidation into a single Substance list in Data Administration.</p> <p>Identifies data conflicts in the Active Ingredient and Excipient Values tables.</p>	Excel
Script 2	<code>rpt_pre_migration_excipient.sql</code>	<p>Prior to migrating the Excipient role.</p> <p>Identifies PDS Excipients that would result in duplicate Excipients in the PDS if the Excipient Role is not migrated.</p>	Excel

Script Number	Script Name	Description	Type of Output
Script 3	rpt_pre_migration_concentration.sql	<p>Prior to migrating concentration measures to a format that conforms with XEVMPD and IDMP.</p> <p>Identifies concentration measures for a Substance that cannot be migrated to the new measure fields because the values do not meet the criteria for migration.</p>	Excel
Script 4	rpt_pre_migration.sql	<p>Identifies:</p> <ul style="list-style-type: none"> <li>-Substances with a CAS Number greater than 15 characters for Active Ingredients and Excipients. The CAS Number field has been restricted to 15 characters to support Calyx RIM for XEVMPD;</li> <li>- Indications/Intended Use that contain values for Lower Level Term Code (LLT) and/or Preferred Term Code (PT Code) that do not meet the criteria for migration;</li> <li>- MAH/Development Sponsor/ Legal Representative Name Values that do not contain a Country value that meets the criteria for migration.</li> </ul>	Text
Script 5	master-pre.sql	Pre-migration script for database upgrade to Calyx RIM 6.0 Certified Hotfix (CHF) 1	None

Script Number	Script Name	Description	Type of Output
Script 6	rpt_pre_mig_name_uniqueness.sql	Identifies duplicate of Full Product Presentation entities with same Full Product Name within the Registration entity.  Pre-migration script for database upgrade to Calyx RIM 6.0 Certified Hotfix (CHF) 3	Excel
Script 7	rpt_pre_mig_missing_dosage_forms.sql	Identifies missing Dosage Forms from Products or Components for Pharmaceutical Product entity.  Pre-migration script for database upgrade to Calyx RIM 6.0 Certified Hotfix (CHF) 3	Excel

## Calyx RIM 6.0 & CHF Migration Tasks

### *Pre-Migration Scripts for Calyx RIM 6.0 CHF 2 to Calyx RIM 6.0 CHF 3*

#### **rpt\_pre\_migration\_name\_uniqueness.sql**

To identify duplicates of Full Product Presentation entities with the same Full Product Name within the Registration entity, it is recommended that you run the `rpt_pre_migration_name_uniqueness.sql` script before starting your database migration.

The `rpt_pre_migration_name_uniqueness.sql` script should be run by the mgr user.

The `rpt_pre_migration_name_uniqueness.sql` script produces an Excel report that identifies duplicates of Full Product Name under the same Registration that cannot be migrated because they do not meet the criteria for migration to the Full Product Presentation entity.

Report Column	Value
FPP_NAME	Displays the Full Product Name.
FPP_ID	Displays the Full Product Presentation ID.
PRODUCT FAMILY NAME	Displays the Product Family Name.
APPLICATION NAME	Displays the Application Name.
LICENSE CODE	Displays the License Code.
PRODUCTS	Displays the Product Name.

### rpt\_pre\_migration\_missing\_dosage\_forms.sql

To identify missing Dosage Forms from single Component Products for Pharmaceutical Product entity, it is recommended that you run the `rpt_pre_migration_missing_dosage_forms.sql` script before starting your database migration.

The `rpt_pre_migration_missing_dosage_forms.sql` script should be run by the mgr user.

The `rpt_pre_migration_missing_dosage_forms.sql` script produces an Excel report that identifies single Component Products with missing component dosage form or multiple Component Products with missing product dosage form.

Report Column	Value
PRODUCT_FAMILY_NAME	Displays the Product Family Name
PRODUCT_FAMILY_ID	Displays the Product Family ID
PRODUCT_NAME	Displays the Product Name
PRODUCT_ID	Displays the Product ID
COMPONENT_NAME	Displays the Component Name
COMPONENT_ID	Displays the Component ID
XPHARMA_PRODUCT_ID	Displays the Pharmaceutical Product Name
XPHARMA_PRODUCT_ID	Displays the Pharmaceutical Product ID

### *Pre-Migration Scripts for Calyx RIM 6.0 CHF 3 to Calyx RIM 6.0 CHF 4*

### rpt\_pre\_migration\_application\_list\_withdrawals.sql

To identify potential migration problems where data does not conform to the new requirements, it is recommended that you run the `rpt_pre_migration_application_list_withdrawals.sql` script before starting your database migration.

The `rpt_pre_migration_application_list_withdrawals.sql` script should be run by an ism user.

The `rpt_pre_migration_application_list_withdrawals.sql` script produces an Excel report that identifies application names with Application Statuses that are not mapped to any internal system status, or are mapped to the incorrect values and have data in the 'Termination/Withdraw Reason' field that cannot be migrated because they do not meet the criteria for migration.

Report Column	Value
PRODUCT FAMILY NAME	Displays the Product Family Name.
APPLICATION NAME	Displays the Application Name.
APPLICATION STATUS	Displays the Application Status mapped to the incorrect internal system status.

Report Column	Value
INTERNAL SYSTEM STATUS	Displays Internal System Status for Application Status value.
TERMINATION/WITHDRAW REASON	Displays the Termination/Withdraw Reason field data.

### rpt\_pre\_migration\_fpp\_uniqueness.sql

To identify duplicate of Full Product Presentation entities with the same Full Product Name within the Registration entity, it is recommended that you run the `rpt_pre_migration_fpp_uniqueness.sql` script before starting your database migration.

The `rpt_pre_migration_fpp_uniqueness.sql` script should be run by an mgr user.

The `rpt_pre_migration_fpp_uniqueness.sql` script produces a report that identifies duplicates of LST Full Product Name under the same Registration.

Report Column	Value
FPP_NAME	Displays the Full Product Presentation Name.
FPP_ID	Displays the Full Product Presentation entity ID.
PRODUCT_FAMILY_NAME	Displays the Product Family Name.
APPLICATION_NAME	Displays the Application Name.
IDENTIFICATION_CODE	Displays the License Code.
AUTHORISATION_DATE	Displays the Authorisation/Renewal Date on Full Product Presentation.
PACKAGE_DESCRIPTION	Displays the Package Description on Full Product Presentation.

### master\_pre.sql

The `master_pre.sql` script should be run by a system user. You must run the `master_pre.sql` script before running the `master.sql` script.

### Post-Migration Tasks for Calyx RIM 6.0

Defining Application Types Under Filing Type eCTD Code for Grouped Submissions

You can define the US FDA eCTD Module 1 Specification v2.3 / DTD v3.3 Grouped Submission application types using Filing Type Values in the Sequence Maintenance section in Data Administration.

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**Note:** *The procedure must be performed after the migration scripts have been completed.*

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To define the application types for grouped submissions:

1. On the Calyx RIM application *home* page, click **Go To > Data Administration**
2. Under **Sequence Maintenance**, click **Filing Type Values**.
3. Click **Annual Report Filing**.

4. Under **Applicable DTD/Schema**, click **us-3-3**.
5. In the **Types Valid for Grouped Submissions** box, select **Investigational New Drug**.
6. Click **>>** to move **Investigational New Drug** to the **Selected** box.
7. Click **Save** and then click **Back**.
8. Click **CMC Supplement**.
9. Under **Applicable DTD/Schema**, click **us-3-3**.
10. In the **Types Valid for Grouped Submissions** box, select **Abbreviated New Drug Application**, **Biologic License Application** and **New Drug Application**.  
To select multiple application types simultaneously, press the **Ctrl** key and click the left mouse button.
11. Click **>>** to move the selected application types to the **Selected** box.
12. Click **Save** and then click **Back**.
13. Click **Efficacy Supplement**.
14. Under **Applicable DTD/Schema**, click **us-3-3**.
15. In the **Types Valid for Grouped Submissions** box, select **Biologic License Application** and **New Drug Application**.
16. Click **>>** to move the selected application types to the **Selected** box.
17. Click **Save** and then click **Back**.
18. Click **Labeling Supplement**.
19. Under **Applicable DTD/Schema**, click **us-3-3**.
20. In the **Available for Application Types** box, select **Abbreviated New Drug Application**, **Biologic License Application** and **New Drug Application**.
21. Click **>>** to move the selected application types to the **Selected** box.
22. Click **Save** and then click **Back**.
23. Click **Product Correspondence**.
24. Under **Applicable DTD/Schema**, click **us-3-3**.
25. In the **Types Valid for Grouped Submissions** box, select **Abbreviated New Drug Application**, **Biologic License Application**, **Drug Master File (DMF)**, **Investigational New Drug** and **New Drug Application**.
26. Click **>>** to move the selected application types to the **Selected** box.
27. Click **Save** and then click **Back**.
28. Click **Promotional Labeling Advertising**.
29. Click **us-3-3** under **Applicable DTD/Schema**.
30. In the **Types Valid for Grouped Submissions** box, select **Abbreviated New Drug Application**, **Biologic License Application** and **New Drug Application**.
31. Click **>>** to move the selected application types to the **Selected** box.
32. Click **Save** and then click **Back**.  
The defined application types will be available for selection while creating submission plans for grouped submissions.

## Pre-Migration Mandatory Scripts for Calyx RIM 5.0 to Calyx RIM 5.1

### Duplicate Data Report

A few missing uniqueness constraints on the database will be added during the 5.1 migration. Run the duplicate report (`find_duplicates.sql`) as ISM prior to running the migration. Fix the duplicated values.

### GCC 1.2 Manual InSight Data Administration Updates

To support GCC implementation by the database upgrade from InSight 5.0 GA to 5.1, you must perform the following procedure to update your InSight Data Administration configuration before executing the 5.1 migration.

If you have already performed these updates as part of InSight 5.0 CHF 4, you do not need to repeat these manual updates.

For instructions on performing these updates, see the *InSight 5.1 Data Migration Document*.

### EU 2.0 Manual InSight Data Administration Updates (Part 1)

To support EU M1 v2.0 implementation by the database upgrade from InSight 5.0 GA to 5.1, you must perform the following procedure to update your InSight Data Administration configuration before executing the 5.1 migration. If you have already performed these updates as part of InSight 5.0 CHF 6, you do not need to repeat these manual updates.

For instructions on performing these updates, see the *InSight 5.1 Data Migration Document*.

### Pre Migration Filing Type and Application Report

A pre-migration report has been provided named “`rpt_pre_dtd_data.sql`”. For instructions on running this report, see the *InSight 5.1 Data Migration Document*.

### Shelf Life Data

The shelf life data on the package set detail must comply with the following business rules to be migrated to a shelf life detail in InSight 5.1.

- The shelf life and shelf life unit fields must both contain values. Example – Shelf Life: 10, Shelf Life Unit: Week(s)
- The shelf life, shelf life after first opening, and shelf life after reconstitution fields must contain an integer value

Each set of shelf life data is considered independently for migration.

- The migration script will only migrate a pair if both the value and the unit type are filled in.
- Shelf life attributes on the package set detail that cannot be migrated to the new shelf life details will be migrated to the package set comments field.

Prior to migrating to InSight 5.1, run the `rpt_unmigratable_shelf_life.sql` script to identify the shelf life data on the package set detail that will NOT be migrated to the new shelf life details. For instructions on running this script, see the *InSight 5.1 Data Migration Document*.

## Post-Migration Tasks for Calyx RIM 5.1

Perform these tasks after you migrate to Calyx RIM 5.1.

## EU 2.0 Manual Calyx RIM Data Administration Updates

To support EU M1 v2.0 implementation after the database upgrade from Calyx RIM 5.0 GA to 5.1, you must perform the procedure to update your Calyx RIM Data Administration configuration after executing the 5.1 migration.

If you have already performed these updates as part of Calyx RIM 5.0 CHF 6, you do not need to repeat these manual updates.

You must:

- Update Country values
- Add Filing Types
- Update Region values
- Update Procedure Types values
- Update Event Plan values

For details, see the *Calyx RIM 5.1 Data Migration Document*.

## US M1 3.3 Manual Calyx RIM Data Administration Updates

You must create:

- Application Type eCTD Code values in Calyx RIM after migration for specific Application types. If the Application Type does not already exist, it must also be created.
- Filing Type eCTD Code values in Calyx RIM after migration for specific filing types. If the filing type does not already exist, it must be created.

For details, see the *Calyx RIM 5.1 Data Migration Document*.

## GCC 1.2 Manual Data Administration Updates

To support GCC M1 v1.2 implementation after the database upgrade from Calyx RIM 5.0 GA to 5.1, you must perform procedure to update your Calyx RIM Data Administration configuration after executing the 5.1 migration.

You must:

- Update region values. For details, see the *Calyx RIM 5.1 Data Migration Document*.
- Verify migration script updates

If you have already performed these updates as part of Calyx RIM 5.0 CHF 4, you do not need to repeat these manual updates.

For details, see the *Calyx RIM 5.1 Data Migration Document*.

## Post-Migration Filing Type and Application Report

A post-migration report has been provided named “rpt\_post\_dtd\_data.sql”. For details, see the *Calyx RIM 5.1 Data Migration Document*.

## Calyx RIM Publisher Templates

All templates that are shipped with Calyx RIM 5.1 have been recreated based on the new Publishing Settings Library, however, the templates currently in the Calyx RIM 5.0 system will be available with the new Publishing Settings Library post migration as well. Templates were introduced in various Calyx RIM 5.0 Certified Hot Fixes and Hot Fixes. If the templates were not updated in Calyx RIM 5.0, they should be updated post migration to ensure the latest templates are being used. For details, see the *Calyx RIM 5.1 Data Migration Document*.

## EVMPD Queries

The following OOTB EVMPD queries will not be available in Calyx RIM 5.1:

- EVMPD Codes Query
- EVMPD Analysis Query

If any of these queries have been saved as public or private queries they will not be migrated to Calyx RIM 5.1. For details, see the *Calyx RIM 5.1 Data Migration Document*.

## Shelf Life Queries

In Calyx RIM 5.1 the shelf life and storage conditions fields on the package set detail will be migrated to the new shelf life details. As a result, some default queries have been updated to remove the shelf life and storage conditions fields associated with the package set detail.

Saved public and private queries created in releases prior to 5.1 that have the capability to report on shelf life and storage conditions from the package set detail will not be migrated to Calyx RIM 5.1. These queries will be deleted as a result of the migration to 5.1.

**rpt\_problematic\_shelf\_life\_details.sql** – Run this script post-migration to determine if there were shelf life details partially migrated. Partially migrated means that although the current shelf life detail was unmigratable, previous shelf life details were migrated and are now considered current.

**rpt\_pds\_with\_duplicates\_removed.sql** – This script can be run post-migration to identify any PDS with duplicate shelf life details where one of shelf life details was ignored, potentially causing a partial migration. Constraints in the new data model prevent duplicate details. In some cases, customers had the same modification under two different events, resulting in duplicate data. Post-migration, only one event will be associated with the detail as a result of the new constraints. Historical information will remain in the audit trail.

See the *Calyx RIM 5.1 Data Migration Document*.

## Calyx RIM 5.1 Database Migration Scripts



---

*Warning: The CNTNT Audit Migration portion of this migration is optional and can be bypassed. If you decide to migrate the CNTNT audit data, this procedure can be performed at any time before or after the section labeled Installing the Database Upgrade. This allows you to migrate your CNTNT audit data independently of your standard migration to Calyx RIM 5.1. The migration of the CNTNT audit data can be done in full, or based on date ranges.*

---

## CNTNT Audit Migration

Perform CNTNT audit migration before running the migration script to migrate from Calyx RIM 5.0 to Calyx RIM 5.1.

There are three options when handling the migration of the CNTNT audit table. You can choose to do one of the following:

- Drop the table
- Save the old CNTNT table
- Run pre-migration while preserving audit data in a live production system

### Drop the Table Entirely

1. Connect to the database as aud.
2. Enter the following sql command:

- drop table aud.cntnt;
- drop trigger ods.icntnt;
- drop trigger ods.ucntnt;
- drop trigger ods.dcntnt;

### Save the Old CNTNT Table

1. Connect to the database as aud.
2. Enter the following sql command:

- rename aud.cntnt to aud.dep\_cntnt;
- drop trigger ods.icntnt;
- drop trigger ods.ucntnt;
- drop trigger ods.dcntnt;

---

***Note:** ODS triggers should be dropped as the ODS schema, and the AUD.cntnt table should be dropped as system or AUD schema.*

---

### Run Pre-Migration while Preserving Audit Data in a Live Production System

This pre-migration must be run before running the standard 5.0 to 5.1 migration. Please perform the following steps exactly. Failure to do so will result in an invalid pre-migration.

1. Enter the correct database information into the `define.audit_migration sql` file.
2. Add the following parameters to the oracle initialization file.
  - `parallel_degree_policy=AUTO`
  - `parallel_threads_per_cpu=2`
  - `#parallel_automatic_tuning=TRUE`

```
—parallel_degree_limit=160
—parallel_max_servers=160
—parallel_min_percent=0
—parallel_min_servers=0
—parallel_min_time_threshold=AUTO
—fast_start_parallel_rollback=HIGH
—parallel_adaptive_multi_user=FALSE
```

3. Edit all scripts and make changes regarding the oracle SID, passwords, start\_date and end\_date. Please note that this pre-migration can be run in parts, so make sure the start and end dates are specified correctly in ALL the scripts.
4. Test: The format of the start\_date and end\_date is 'MM/DD/YYYY'.
  - For example, in the first run the start\_date is 02/21/2007 and the end\_date is 05/18/2008 in all scripts. Then in the second run the dates MUST be ...start\_date as 05/19/2008 and the end\_date can be any date after 05/19/2008.
  - Please note that the start\_date of the next run cannot be the same as the end\_date of the previous run. If overlapping dates are used, then duplicate data will be entered in the aud tables resulting in data errors and rendering the pre-migration useless. Also, if date ranges are skipped then not all audit data will get migrated.
  - The easiest thing is to run this pre-migration for the entire audit data and not split into date ranges. The date ranges are provided as a convenience for long running migrations. Splitting dates can make the migration faster as long as the disk I/O can support it.
5. To determine the first start\_date run the following sql: 

```
SELECT MIN(BEG_DATE) AS START_DATE
FROM AUD.CNTNT;
```
6. To determine the last end\_date run the following sql: 

```
SELECT MAX(BEG_DATE) AS END_DATE FROM
AUD.CNTNT;
```

  - You can use the system date (i.e. today) as the end\_date to run the migration for entire data. Add the dates into all the pre-migration scripts to run the audit data pre-migration for entire audit data.
  - Please note that any dates specified will be for that specific entity. For example, dates specified when running 2-folders.sql will migrate only folders in the date range specified. Dates can be different for different entities (leafs, documents, etc.).
7. Run the 0-prescript.sql script first. Do not run anything else until this script finishes without errors. If you encounter any errors, stop at this script and report the errors to Calyx.
8. Scripts 1-assemblies.sql, 2-folders.sql, 3-leaves.sql, 4-docs.sql and 5-content.sql MUST be run in parallel by running each script simultaneously from a different DOS prompt. Doing this, the scripts will use all available memory, CPU, and SAN i/o and finish this pre-migration much faster.
9. When you are satisfied that everything has migrated properly, the cntnt table can be dropped from the audit schema or saved, due to its potentially large size.
  - To drop the table entirely: Connect to the database as aud, then enter the sql command - 

```
drop table cntnt;
```
  - To save the old CNTNT table: Connect to the database as aud, then enter the sql command - 

```
rename cntnt to dep_cntnt;
```

## Installing the Database Upgrade

The database upgrade is installed by executing the supplied `master.sql` script either directly on the database server or remotely from a client running Windows with Oracle's SQL\*Plus installed on it. Additionally, we recommend that you run the supplied `stats.sql` script to refresh Calyx RIM's database statistics.

To install the database upgrade:

1. Back up your existing Calyx RIM Database Server database.
2. Verify that all users are logged off the Calyx RIM system.
3. Stop the Calyx RIM Manager service on the Calyx RIM application server:
  - a) Choose **Start > Administrative Tools > Services**.
  - b) Double-click the **Calyx RIM Manager** service.
  - c) In the Calyx RIM Manager Service Properties dialog box, click **Stop** and then click **OK**.
4. Based on the version of Calyx RIM from which you will be starting the upgrade, determine each of the ZIP files containing the migration scripts that you need to run.

The list of ZIP files is provided in the *Calyx RIM Database Migration Details* topic. You must repeat this database upgrade procedure for each script to be run.

5. On the computer where you are running the installation script, create as many temporary install directories as needed, according to the ZIP files determined in [step 4](#).

The installation script can be run either directly on the database server or remotely from a client running Windows with Oracle's SQL\*Plus installed on it.

Example - D:\Install\Calyx RIMDBUpgrade1 D:\Install\InSightDBUpgrade2 D:\Install\InSightDBUpgrade3

6. Verify that you are running the Oracle Database installation SQL script on a Windows based computer. If your Oracle Database is hosted by a Unix server, you must run the Oracle Database installation SQL script on a Windows client that can remotely access the database server using Oracle's SQL\*Plus.
7. Copy the ZIP file from the Calyx RIM database server installation media to the appropriate temp directory created in [step 5](#), and then unzip the ZIP file to this directory.

8. Navigate to the newly created folder.

Example - D:\Install\InSightDBUpgrade1\DB Upgrade xx to yy.

9. Open the `define.migration` file in Notepad.
10. Set the value to the right of the equals sign for the following ID or passwords in the `define.migration` file you are editing.

Only define the settings from this list that are already present in the `define.migration` file. Do not add any settings to the file from this list.

- define `sid`=name of the database instance for the existing Calyx RIM database
- define `audpass`=password for the AUD user
- define `dbopass`=password for the DBO user
- define `ismpass`=password for the ISM user
- define `odspass`=password for the ODS user
- define `pubpass`=password for the PUB user

- define `secpass=password` for the SEC user
  - define `syspass=password` for the Oracle system
  - define `sysuser=ID` of the Oracle administrative user. The default Oracle administrative user ID is `sys`.
  - define `orapath=`the directory location for the database data files. *Example* - `C:\oracle\oraXX\insight` or `\apps\oracle\oradata\insight`
  - define `sec_user=ID` of the SEC user
  - define `ods_user=ID` of the ODS user
  - define `jmsadminpass=s98$h32*` (`s98$h32*` is the default password, but it can be modified.)
  - define `quartzpass=password` for the QUARTZ user (Last used in Calyx RIM version 2.2. Use for migration only, if necessary.)
  - define `mgrpas=mgr (`
- 

*Note: leave as default*

---

- )
- define `migrationpass=r45$x*94`
- To prevent connection errors when modifying database execution scripts, enter database passwords containing the character `@` using quotes. *Example* - password `abc@123` should be entered as `'"abc@123"'` (single quotes, double quotes, password, double quotes, single quotes)

#### Default Passwords

- · define `audpass="i73%r49^"`
- · define `dbopass="h01%q34@"`
- · define `ismpass="f78#o98*"`
- · define `odspass="e45!n65("`
- · define `secpass="g01$p34)"`
- · define `pubpass="r74$i64*"`
- · define `jmspass="s98$h32*"`
- · define `insight_userpass="uv5~hi9%"`

11. Save and close the modified `define.migration` file.
12. Open a command prompt and navigate to the newly created folder.  
Example— `cd D:\Install\InSightDBUpgrade1\DB Upgrade xx to yy.`
13. At the command prompt enter `sqlplus /nolog`. Ensure that the forward slash (`/`) character is included when the above statement is input.
14. At the **sqlplus** prompt, enter `@master.sql`.  
Once the database upgrade process completes successfully, you are returned to a `sql>` prompt.
15. Check for errors in the `<DB script name>.log` file generated for this update. This file is generated in the directory where the script was executed, and should be the same directory created in [step 7](#).
16. All database passwords are validated at the beginning of the migration script.

If you received the error message `ORA-01017: invalid username/password; logon denied` and the script terminates without connecting, repeat the procedure from step 8 and correct the password values in step 9.

17. Repeat the procedure from step 6 for each migration script you need to run.

18. At the `sqlplus` prompt, enter `Exit`.

19. At the command prompt, enter `Exit`.

A script named `stats.sql` is included in each database upgrade zip file for the purpose of refreshing database statistics after the migration script has been executed. Your DBA can refresh database statistics either using this script or your own in-house utilities.

## Running the Calyx RIM 5.1 Database Migration Scripts

### Preparing to Run the Scripts

Before you run the Calyx RIM 5.1 database migration scripts, please note the following:

- Calyx does not currently support character columns that use char semantics. Calyx supports only byte semantics. If you changed your database or specific columns in it to use char semantics, and if the data length in bytes exceeds what a column that uses byte semantics can hold, the migration might fail. To ensure that the migration succeeds, shorten the data or customize the migration.
- Delete all adhoc tables that you do not need. If they are part of Calyx RIM, they generate many significant migration errors.

### Running the Scripts

#### Error from Using Char Semantics

---



*Warning: If you encounter the error shown below when you run a script, your database or specific columns in it are using char semantics. To prevent this error, shorten the data or customize the migration. If you encounter this error, inform Calyx Technical Support about it.*

---

```
ORA-01450: maximum key length (6398) exceeded
```

#### Error from an Oracle Index or Constraint Creation Failure

---



*Warning: If you encounter an error indicating an Oracle index or constraint creation failure when you run a script, contact Calyx Technical Support for help. Do not try to resolve the problem yourself.*

---

The following are examples of such an error:

```
ORA-01452: cannot CREATE UNIQUE INDEX; duplicate keys found
```

```
ORA-02298: cannot validate (.R_<constraint number>) - parent keys not found
```

```
ORA-02296: cannot enable (constraint name) - null values found
```

ORA-02299: cannot validate (<index\_name>) - duplicate keys found

### Error from an Adhoc Table

If you encounter an error caused by an adhoc table:

- If the table is not part of Calyx RIM, ignore the error or delete the table and rerun the migration script.
- If the table is part of Calyx RIM, contact Calyx Technical Support for help.

### Database Script Error Messages

The following table represents previously detected database script errors that you might encounter when running the scripts.

#### Liquent InSight 6.2

Upgrade Path	Error	Description/Resolution
6.2.9 to 6.2.10	<ul style="list-style-type: none"> <li>— drop table dbcommon.role * ERROR at line 1: ORA-00942: table or view does not exist</li> <li>— drop table dbcommon.entity_type * ERROR at line 1: ORA-00942: table or view does not exist</li> </ul>	Ignore
6.2 CHF 7 to 6.2.8	<ul style="list-style-type: none"> <li>— drop table dbcommon.role * ERROR at line 1: ORA-00942: table or view does not exist</li> <li>— drop table dbcommon.entity_type * ERROR at line 1: ORA-00942: table or view does not exist</li> </ul>	Ignore
6.2 CHF 6 to 6.2 CHF 7	<ul style="list-style-type: none"> <li>— drop table dbcommon.role * ERROR at line 1: ORA-00942: table or view does not exist</li> <li>— drop table dbcommon.entity_type * ERROR at line 1: ORA-00942: table or view does not exist</li> </ul>	Ignore
6.2 CHF 5 to 6.2 CHF 6	<ul style="list-style-type: none"> <li>— drop table dbcommon.role * ERROR at line 1: ORA-00942: table or view does not exist</li> <li>— drop table dbcommon.entity_type * ERROR at line 1: ORA-00942: table or view does not exist</li> </ul>	Ignore

Upgrade Path	Error	Description/Resolution
6.2 CHF 4 to 6.2 CHF 5	<ul style="list-style-type: none"> <li>- drop table dbcommon.role * ERROR at line 1: ORA-00942: table or view does not exist</li> <li>- drop table dbcommon.entity_type * ERROR at line 1: ORA-00942: table or view does not exist</li> </ul>	Ignore
6.2 CHF 3 to 6.2 CHF 4	<ul style="list-style-type: none"> <li>- drop table assembly_totals * ORA-00942: table or view does not exist</li> <li>- drop index XAK1CONTENT * ERROR at line 1: ORA-01418: specified index does not exist</li> <li>- drop view vw_assembly_totals * ERROR at line 1: ORA-00942: table or view does not exist</li> <li>- drop table dbcommon.role * ERROR at line 1: ORA-00942: table or view does not exist</li> <li>- drop table dbcommon.entity_type * ERROR at line 1: ORA-00942: table or view does not exist</li> <li>- drop table view_column_name_overrides * ERROR at line 1: ORA-00942: table or view does not exist</li> </ul>	Ignore
6.2 CHF 2 to 6.2 CHF 3	<ul style="list-style-type: none"> <li>- drop table dbcommon.role * ERROR at line 1: ORA-00942: table or view does not exist</li> <li>- drop table dbcommon.entity_type * ERROR at line 1: ORA-00942: table or view does not exist</li> </ul>	Ignore
6.2 CHF 1 to 6.2 CHF 2	<ul style="list-style-type: none"> <li>- dbcommon.role *ERROR at line 1:ORA-00942: table or view does not exist</li> <li>- drop table dbcommon.entity_type *ERROR at line 1:ORA-00942: table or view does not exist</li> </ul>	Ignore

Upgrade Path	Error	Description/Resolution
6.2 (new installation only)	drop table d_date * ERROR at line 1: ORA-00942: table or view does not exist	Ignore This error does not appear during the migration from the previous Calyx RIM versions to Calyx RIM 6.2. It may be seen only if you install a new Calyx RIM 6.2 database. If you see this error, you can ignore it.

## Liquent InSight 6.1

Upgrade path	Error	Description/Resolution
6.1 to 6.1 CHF 1	<pre> - *****   fix EU-3-0 EMA-eAF   *****   declare * ERROR at   line 1: ORA-01403: no   data found ORA-06512:   at line 9 - drop table   tmp_ind_expressions   * ERROR at line 1:   ORA-00942: table or   view does not exist           </pre>	Ignore

Upgrade path	Error	Description/Resolution
6.1 to 6.1 CHF 1	<ul style="list-style-type: none"> <li>— ORA-00955: name is already used by an existing object</li> <li>— ORA-02260: table can have only one primary key</li> <li>— ORA-24344: success with compilation error</li> <li>— ORA-06512: at line 115</li> </ul>	Ignore. These errors can be ignored if the migration path contained Calyx RIM 6.0 CHF 6 or Calyx RIM 6.0 CHF 7.
6.1 to 6.1 CHF 1 to 6.1 CHF 2	ERROR at line 1: ORA-04043: object WRITE_STORAGE_REQUIREMENTS does not exist	Ignore
6.1 CHF 1 to 6.1 CHF 2	<ul style="list-style-type: none"> <li>— ORA-24344: success with compilation error</li> <li>— ORA-06512: at line 115</li> </ul>	Ignore. These errors can be ignored if the migration path contained Calyx RIM 6.0 CHF 6 or Calyx RIM 6.0 CHF 7.
6.1 CHF 2 to 6.1 CHF 3	<ul style="list-style-type: none"> <li>— ORA-01918: user 'DBCOMMON' does not exist</li> <li>— ORA-04043: object GET_DIRLIST does not exist</li> <li>— ORA-00904: "SUB_TO_ADD_MONITOR_CODE": invalid identifier</li> <li>— ORA-00904: "ORPHAN_DRUG_FLAG": invalid identifier</li> </ul>	Ignore
6.1 CHF 2 to 6.1 CHF 3	ORA-02298: cannot validate (MGR.T_1671) - parent keys not found	Ignore

Upgrade path	Error	Description/Resolution
6.1 CHF 2 to 6.1 CHF 3 to 6.1 CHF 4	ORA-02298: cannot validate (MGR.T_1671) - parent keys not found	Ignore
6.1 CHF 2 to 6.1 CHF 3	<ul style="list-style-type: none"> <li>— ORA-00001: unique constraint (MGR.AK0BROAD_INDC_COUNTRY) violated</li> <li>— ORA-00955: name is already used by an existing object</li> </ul>	Ignore. These errors can be ignored if the migration path contained Calyx RIM 6.0 CHF 6 or Calyx RIM 6.0 CHF 7.
6.1 CHF 3 to 6.1 CHF 4	<ul style="list-style-type: none"> <li>— ORA-00001: unique constraint (MGR.UX1REGULATORY_ACT_LEAD) violated</li> <li>— ORA-00001: unique constraint (MGR.UX1SEQ_DESCR_TYPE) violated</li> </ul>	Ignore. These errors can be ignored if the migration path contained Calyx RIM 6.0 CHF 6 or Calyx RIM 6.0 CHF 7.
6.1 to 6.2	ORA-01418: specified index does not exist	Ignore
6.1 CHF 4 to 6.2 CHF 1	<ul style="list-style-type: none"> <li>— ORA-24344: success with compilation error</li> <li>— Any errors for the PACKAGE BODY ISM.PRODUCT_FAMILY_COPY:</li> <li>— ORA-02298: cannot validate (MGR.T_1671) - parent keys not found</li> </ul>	Ignore

**Liquent InSight 6.0**

Upgrade path	Error	Description/Resolution
6.0 to 6.0 CHF 1	ORA-01952: system privileges not granted.	Ignore. This error can appear when running the master-pre.sql script. It means that the system privileges are not granted to MGR, ODS, or SEC.
6.0 CHF 1 to 6.0 CHF 2 to 6.0 CHF 3	<pre>drop table view_column_metadata       * ERROR at line 1: ORA-00942: table or view does not exist comment on column vd_conten.logical_parent _id is 'Reserved for Internal Use; Do not Use'       * ERROR at line 1: ORA-00942: table or view does not exist</pre>	Ignore

Upgrade path	Error	Description/Resolution
6.0 CHF 2 to 6.0 CHF 3	<pre> ***** ***** build dimension views ***** ***** ORA-24344: success with compilation error VD_PDS_LAB_HIST.R_VD_PDS _LAB_HIST6 ORA-24344: success with compilation error VD_PDS_LAB_HIST.R_VD_PDS _LAB_HIST1  ORA-24344: success with compilation error VD_PDS_LAB_HIST.R_VD_PDS _LAB_HIST3  ORA-24344: success with compilation error VD_PDS_LAB_HIST.R_VD_PDS _LAB_HIST2  ORA-24344: success with compilation error VD_PDS_LAB_HIST.R_VD_PDS _LAB_HIST4  ORA-24344: success with compilation error VD_PDS_LAB_HIST.R_VD_PDS _LAB_HIST5  PL/SQL procedure successfully completed.                     </pre>	Ignore
6.0 CHF 2 to 6.0 CHF 3 to 6.0 CHF 4 to 6.0 CHF 5	<pre> from dba_views v           * ERROR at line 36:                     </pre>	Ignore

Upgrade path	Error	Description/Resolution
6.0 CHF 3 to 6.1	<pre>drop table tmp_ind_expressions           * ERROR at line 1: ORA-00942: table or view does not exist</pre>	Ignore
6.0 CHF 3 to 6.1	<p>When executing the data migration from 6.0 CHF 3 to Calyx RIM 6.1 (script DB Upgrade 60 CHF3 to 61), the following error messages appeared:</p> <ul style="list-style-type: none"> <li>— Line 146: Error creating indexes on table aud.GENERICLOAD ORA-00904: "DATASET_NAME":</li> <li>— Line 363: ORA-00942: table or view does not exist</li> <li>— Line 4344: ORA-02437: cannot validate (AUD.PKAPPLICANT_CONTACT) - primary key violated</li> <li>— Line 4345: ORA-06512: at line 58</li> <li>— Line 9644: ORA-00942: table or view does not exist</li> <li>— Line 15517: Error creating indexes on table aud.GENERICLOAD ORA-00904: "DATASET_NAME":</li> </ul>	Resolved with the Calyx RIM 6.1 CHF 1 database migration script.
6.0 CHF 7 to 6.1	<ul style="list-style-type: none"> <li>— ORA-24344: success with compilation error</li> <li>— ORA-06512: at line 115</li> </ul>	Ignore

**Liquent InSight 5.1**

Upgrade path	Error	Description/Resolution
5.1 to 6.0	<p>Any indexing or constraint errors regarding the following tables can be ignored:</p> <ul style="list-style-type: none"> <li>– Excipient</li> <li>– Active_ingredient</li> <li>– Prod_acting</li> <li>– Prodfam_acting</li> <li>– Pds_excip</li> <li>– Pds_excip_change</li> <li>– Concentration_unit_type</li> <li>– Fda_device_class_type</li> <li>– Eu_class_type</li> </ul> <p>Also ignore the following error messages:</p> <ul style="list-style-type: none"> <li>– Warning: Package Body created with compilation errors. Errors for PACKAGE BODY ISM.PRODUCT_FAMILY_COPY: 285/26 PL/SQL: ORA-00942: table or view does not exist</li> <li>– Revoke inherit privileges on system from dbo ERROR at line 1: ORA-00990: missing or invalid privilege revoke select any table privilege from aud ERROR at line 1: ORA-00990: missing or invalid privilege</li> </ul>	<p>Ignore Example:</p> <p>Error dropping constraint ACTIVE_INGREDIENT:PKACTIVE_INGREDIENT</p> <p>ORA-02273: this unique/primary key is referenced by some foreign keys</p> <p>Dropping index: ACTIVE_INGREDIENT:PKACTIVE_INGREDIENT Columns: ID--&gt;</p> <p>Error dropping index ACTIVE_INGREDIENT:PKACTIVE_INGREDIENT</p> <p>ORA-02429: cannot drop index used for enforcement of unique/primary key</p>
5.1 to 6.0	ORA-01543: tablespace 'IDX_IDMP' already exists	Ignore

Upgrade path	Error	Description/Resolution
5.1 to 6.0	ORA-01543: tablespace 'DAT_IDMP' already exists	Ignore
5.1 to 6.0	ORA-01543: tablespace 'IDX_DM' already exists	Ignore
5.1 to 6.0	ORA-01543: tablespace 'DAT_DM' already exists	Ignore
5.1 to 6.0	ORA-01918: all ORA-01918 messages	Ignore
5.1 to 6.0	ORA-01919: all ORA-01919 messages	Ignore
5.1 CHF 3 to 6.0 to 6.0 CHF 1	<p>ORA-00955: name is already used by an existing object</p> <pre>CREATE TABLE MGR.REGULATORY_ACT_LEAD (</pre> <p>ERROR at line 1:</p> <p>ORA-00955: name is already used by an existing object</p> <pre>CREATE TABLE MGR.SEQ_DESCR_TYPE (                 *</pre> <p>ORA-00001: unique constraint (MGR.UX1REGULATORY_ACT_LEAD) violated</p> <p>ORA-00001: unique constraint (MGR.UX1SEQ_DESCR_TYPE) violated</p>	Ignore

**Liquent InSight 5.0**

Upgrade path	Error	Description/Resolution
5.0 or 5.0 CHF 6 to 5.1	ORA-01920: user name 'MIGRATION' conflicts with another user or role name	The migration user already exists.
5.0 or 5.0 CHF 6 to 5.1	ora-01543: tablespace 'IDX_MIG' already exists	The migration tablespace already exists.
5.0 or 5.0 CHF 6 to 5.1	ora-01543: tablespace 'DAT_MIG' already exists	The migration tablespace already exists.
5.0 or 5.0 CHF 6 to 5.1	ORA-02296: cannot enable (ODS.) - null values found	The data will be updated later in the migration, and the constraint on SETTINGS_PROFILE.LINK_STYLE_TYPE_ID will be added at that point.
5.0 or 5.0 CHF 6 to 5.1	ORA-02273: this unique/primary key is referenced by some foreign keys	Ignore any index and constraint errors on asm_pub_settings/asm_pub_settings_profile tables.
5.0 or 5.0 CHF 6 to 5.1	ORA-02429: cannot drop index used for enforcement of unique/primary key	Ignore any drop index errors on “enforcement of unique/primary key”.
5.0 or 5.0 CHF 6 to 5.1	ORA-00936: missing expression	Ignore
5.0 or 5.0 CHF 6 to 5.1	ORA-04098: trigger 'ODS.UCNTNT' is invalid and failed re-validation	Ignore
5.0 or 5.0 CHF 6 to 5.1	Any errors for the PACKAGE BODY ISM.PRODUCT_FAMILY_COPY:	Ignore

The following are the common errors you might encounter when migrating to a subsequent version.

**Table 1: Common Errors**

Error	Description
SP2-0310: unable to open file "define.passwords"	Ignore
SP2-0310: unable to open file "define.application"	Ignore

Error	Description
ORA-02264: name already used by an existing constraint	DO NOT IGNORE. Call Technical Support

### Errors Message - Example

Errors for PACKAGE BODY ISM.PRODUCT\_FAMILY\_COPY

LINE/COL ERROR

```

-----
971/11 PL/SQL: SQL Statement ignored
973/21 PL/SQL: ORA-00942: table or view does not exist
977/9 PLS-00364: loop index variable 'IREC' use is invalid
977/9 PL/SQL: Statement ignored
978/9 PLS-00364: loop index variable 'IREC' use is invalid
978/9 PL/SQL: Statement ignored
979/9 PLS-00364: loop index variable 'IREC' use is invalid
979/9 PL/SQL: Statement ignored
980/9 PLS-00364: loop index variable 'IREC' use is invalid
980/9 PL/SQL: Statement ignored
982/9 PL/SQL: SQL Statement ignored
LINE/COL ERROR
-----
991/35 PL/SQL: ORA-00904: "IREC"."PRODUCT_ID": invalid identifier
993/9 PL/SQL: SQL Statement ignored
993/25 PL/SQL: ORA-00942: table or view does not exist
1004/11 PL/SQL: SQL Statement ignored
1006/21 PL/SQL: ORA-00942: table or view does not exist

```

```
1010/9 PLS-00364: loop index variable 'IREC' use is invalid
1010/9 PL/SQL: Statement ignored
1011/9 PLS-00364: loop index variable 'IREC' use is invalid
991/35 PLS-00364: loop index variable 'IREC' use is invalid
```

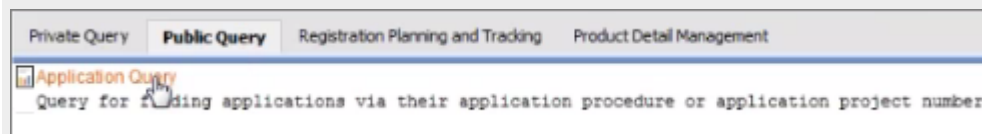
### Public and Private Queries

When migrating from a previous version of Calyx RIM to a newer, major version of the product, your public and private queries will not be saved. After your migration is completed, if an error message appears when running a query saved in your previous version, you can use the selected values on the query page to create a new saved query.

To salvage a broken public or private query after a migration:

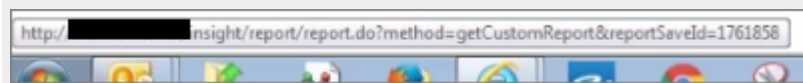
1. Log on to Calyx RIM, and in the **GO TO** menu click **Querying**.
2. On either the **Public Query** tab or the **Private Query** tab, locate a saved query that is broken. (When you left-click on a query, an error message appears if the query is broken.)

#### Example



3. Hover your pointer over the query link and copy the numeric identifier of the hyperlink target of the query. (In this example image, the numeric identifier value is 1761858.)

#### Example



4. Execute the SQL using the copied numeric identifier value.

#### Example

```
delete from mgr.report where id = 1761858;
```

## Data Migration Documents

Document Name
<a href="#">Calyx RIM 6.2.8 Data Migration Document</a>
<a href="#">Calyx RIM 6.2CHF 7 Data Migration Document</a>

Document Name
Calyx RIM6.2 CHF 6 Data Migration Document
Calyx RIM 6.2 CHF 5 Data Migration Document
Calyx RIM 6.2 CHF 4 Data Migration Document
Calyx RIM 6.2 CHF 3 Data Migration Document
Calyx RIM 6.2 CHF 2 Data Migration Document
Calyx RIM 6.2 CHF 1 Data Migration Document
Calyx RIM 6.2 Data Migration Document
Calyx RIM 6.1 CHF 5 Data Migration Document
Calyx RIM 6.1 CHF 4 Data Migration Document
Calyx RIM 6.1 CHF 3 Data Migration Document
Calyx RIM 6.1 CHF 2 Data Migration Document
Calyx RIM 6.1 CHF 1 Data Migration Document
Calyx RIM 6.1 Data Migration Document
Calyx RIM 6.0 CHF 6 Data Migration Document
Calyx RIM 6.0 CHF 5 Data Migration Document
Calyx RIM 6.0 CHF 4 Data Migration Document
Calyx RIM 6.0 CHF 3 Data Migration Document
Calyx RIM 6.0 CHF 2 Data Migration Document
Calyx RIM 6.0 CHF 1 Data Migration Document
Calyx RIM 6.0 Data Migration Document
Calyx RIM 5.1 CHF 6 Data Migration Document
Calyx RIM 5.1 CHF 5 Data Migration Document
Calyx RIM 5.1 CHF 4 Data Migration Document
Calyx RIM 5.1 Data Migration Document
Calyx RIM 5.0 Data Migration Document

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