Get Started with Calyx RIM

CALYX™

Contents

Get Started with Calyx RIM

Calyx RIM® 6.2 is a comprehensive Web-based software application that supports the entire regulatory product management lifecycle from the early planning of registration targets through product retirement.
It is invaluable for regulatory planning, product detail management, dossier creation, dossier management, project planning, and more.

The Calyx RIM publishing solution simplifies, automates, and accelerates the entire regulatory publishing process. Offering the richest functionality, powerful tools, and a single, easy-to-use interface, Calyx RIM enables you to quickly and easily create, review, and amend regulatory dossiers and submit them for market approval.

Log On to Calyx RIM

You log on to Calyx RIM to access documents and applications associated with clinical trials. Your access to functionality and modules in the system is based on your security permissions.

To log on:

1. Navigate from the desktop to the Calyx RIM *Login* page.

   If you do not know your user name or password, contact your system administrator.
2. In the Username field, enter your user name.
3. In the Password field, enter your password.
4. In the Domain field, select the appropriate region.

   The Domain field appears only when Calyx RIM is configured for multiple regions. If your Calyx RIM is configured for a single region, the Domain field will not appear on your *Login* page.
5. Click Login.
   The Calyx RIM *Home Page* appears.

Change Your Password

The *login* page includes a Change Password link that may or may not be enabled for your Calyx RIM environment. Confirm with your Calyx RIM administrator as to whether this option should be available.

Note: *You can still use your old password for one hour after changing your password. This is due to a known feature of Active Directory 2012.*

To change your password:

1. On the *login* page, click Change Password.
2. On the *Change Password* page, in the Username box, type your `user name`.
3. If the Domain drop-down list box is displayed, choose the domain into which you are logging.
   Domain is displayed only when Calyx RIM is configured to prompt you for your domain.
4. In the Old Password box, type your current `password`.
5. In the New Password box, type a new `password`.
6. In the Retype New Password box, retype the new `password`.
7. Click Submit.

Home Page

The *Home Page* is the central location for accessing or viewing Calyx RIM entities, such as projects or tasks. The available *Home Page* content depends on your user role and how your organization configures Calyx RIM settings.

Several tools are available on the *Home Page* and throughout the application, including:

— Menus
— Navigation
— Alert Center
— I Want To Go To
— I Am Looking To

Homepage Display Properties

The labels for title bars, menus, tooltips, and the I am Looking To section displayed on the *Home Page* can be modified in Data Administration by your system administrator or other authorized person.

The functions and wizards that are available to you on the *Home Page* depend on your license modules and the Home Page Access settings in System Administration.

Navigation Pane

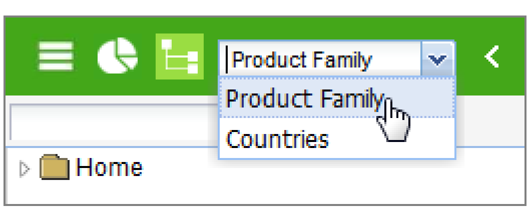
The *Navigation Pane* provides the ability to navigate to Calyx RIM entities. You can choose the *Entity* view, *Analytics* view, or *Tree* view by clicking the appropriate icon on the *Navigation* pane:

— Select Entity List icon -
— Select Analytics Tree icon -
— Select Trees icon -

List view provides links to:

— My Home
— Product Families
— Registrations
— Applications
— Events
— Full Product Presentations
— Sequences
— Submission Plans
— Standalone Assemblies
— Assembly Templates
— Publishing Templates
— Submitted Views
— Approved Views
— My Tasks
— Projects
— Changes
— Comparators
— Registration Attachments
— System Alerts
— Activities

Tree view provides the ability to view the Product Family tree or the Countries tree by using the Select Trees option.



Navigation trees provide an easy way to locate specific information in the system:

— Family Tree - Lists product families that are available to you in the system.
— Country Tree - Lists countries that are associated with the available product families.
— Analytics Tree - Provides access to Calyx RIM for Analytics reports.

The Family Tree and the Country Tree are hierarchical and consist of nodes with dependent subnodes.

The Filter Criteria (Search Option) enables you to see entities in the Family Tree and Country Tree that contain the filter criteria entered.

To clarify the nature of the node dependencies, the terms parent,sibling, and child may be used in this documentation. As with the generational relationships from which these terms were taken, the following is true for these terms:

— Parent indicates a higher-level node or attribute that has related subnodes.
— Child nodes appear below and slightly to the right of the parent node indicating a relationship.
— Sibling nodes are equal in ranking, sharing the same parent node.
— A child node can be a parent node for related subnodes.

Each product family node is the child of the Home parent node, yet each product family node is also the parent of one or more entities, such as applications, events, etc.

You can click the arrow next to any node to expand or collapse areas of the navigation tree. Click any node in the tree to view the attributes page for the entity represented by the selected node. The details appear in the pane to the right of the navigation tree.

You can expand child node by clicking right mouse button on the needed Product Family or Country entity and select Expand Range option.

To view the full width of the navigation tree or minimize its space on the screen, you can expand or reduce the size of the navigation tree pane. Hovering your pointer over the border between panes changes your cursor, indicating that you can press your left mouse button and drag the pane to the appropriate size.

Family Tree

On the *Home Page* navigation pane, the Family Tree displays a hierarchical view of product families and their associated country, application, event, and sequence entities. Product families appear in alphabetical order, providing quick access to entities.
The high level view of the navigation tree lists product families as child nodes of the `Home` folder.

When using the Product Family Tree:
— Expand the family tree view by clicking the arrow. Click the subnodes to view specific attribute details.
— Associated countries, applications, events, and sequences are child nodes of the product families.

- Only active events associated with countries and active sequences appear in the Product Family Tree.
- Events are displayed alphabetically under the product family. When a sequence is associated with multiple events, this sequence is displayed in the tree as a child node of each associated event.
- For all open events, all sequences associated with the event are displayed in descending order, regardless of status. The descending order is based on the last change date with the most current appearing at the top.
- Only applications with a status that is equivalent to the internal status of `Planned`, `Submitted`, or `Approved` are displayed. Applications are not displayed if their status is the internal equivalent of `Withdrawn` or `Not Approved`.

Country Tree

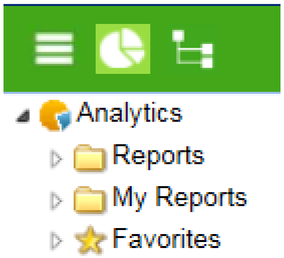
On the *Home Page* navigation pane, the Country Tree displays a hierarchical view of product family, application, event, and sequence entities grouped by country.
The Country Tree lists countries in alphabetical order and enables quick access to entities.

When using the County Tree:

- Open the country node range by clicking the arrow next to each subnode to view specific attribute details.
- Product families, applications, events, and sequences are child nodes of the country node.
- Only active applications are included in the tree, and they are displayed alphabetically. Applications with a status equivalent to the internal status of `Not Approved` or `Withdrawn` are not displayed.
- For MRP and DCP procedures, the applications appear at the next level below the country node.
- For CP procedures the country is the European Union, not a specific country associated with the application.
- Only open events associated with countries appear in the navigation tree.
- Only open sequences appear in the navigation tree.
- Sequences associated with a country appear as child nodes of that country.
- If a sequence is associated with an event, the sequence appears as its child node. If the sequence is not associated with an event, it appears as a sibling to other open events and a child of the application.

Analytics Tree on the Home Page

On the *Home Page* navigation pane, the Analytics tree provides access to the `Reports`, `My Reports`, and `Favorites` folders.
To view the Analytics tree, you must have the appropriate permissions set in the Calyx RIM system by your system administrator.



With the necessary security permissions, you can access Calyx RIM for Analytics reports in the following folders:

— `Predefined Reports` - When expanded, this node displays the reports that you are licensed to access. When you double-click a report, it opens in a separate window.
— `My Reports` - Contains ad hoc reports, which are created by using InfoAssist in the Analytics portal. When expanded, this node displays the `MyContent` folder, which is visible only to you, and `Shared` folder, which is visible to all users or some specific users. When you double-click a report, it opens in a separate window.
— `Favorites` - Contains reports (of any type) that you have saved as favorites in the Analytics portal. They are visible only to you. When you double-click a report, it opens in a separate window.

You can configure reports to run in the following output types:

— Bar Chart
— Column Chart
— Line Chart
— Heat Map
— Pie Chart
— Pivot Table (HTML Active)

The reports can include calculations, formatting of data, and nested queries to represent data in specific formats.

You can save a dashboard to either the `My Reports` folder or the `My Content` folder.

Tree Filter

The Tree Filter option on the *Navigation Pane* can be used to find a specific entity in the Product Family tree or the Country tree.
When the filter is applied, only entities that contain the filtering criteria are displayed in the tree.

The filter can be applied for entity names only. It is located on the *Navigation Pane*, and is available from the *Product Family tree* or the *Country tree* view.

You can use the following as filter values:

— Product Family name

— Application name
— Event name
— Sequence name

Your previous 10 filter criteria will persist after you log off and then log on to the system again, listed in order from the most recent to the oldest.

You must enter a minimum of 2 characters to enable filtering. You can enter a maximum of 250 characters in the **Filter** field. If you enter more than 250 characters, the filter value is highlighted and a warning message appears.

The number of matching entities displayed can be limited by defining a value in the `insight.var` file. When the search results exceed the number defined in the `insight.var` file, a message appears with the number of entities that match the search criteria and the number of entities that will be displayed.

Note: *The number of matching entities displayed can be limited by defining a value in the* `insight.var` *file. When the search results exceed the number defined in the* `insight.var` *file, a message appears with the number of entities that match the search criteria and the number of entities that will be displayed.*

Filter Tree Entities

The **Tree Filter** function on the *Navigation Pane* enables you to filter the displayed entities to find an entity in the Product Family tree or Country tree.

To filter entities:

1. Type filter criteria in the **Filter** field.

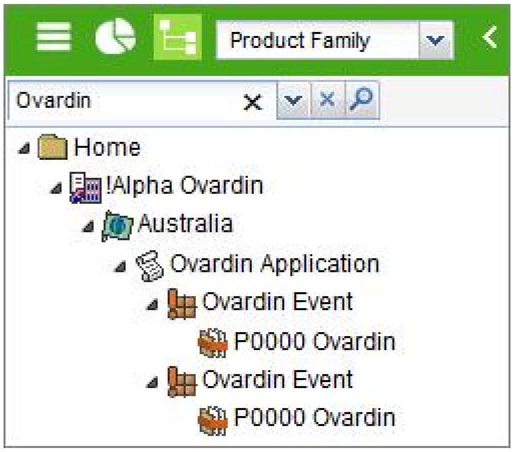
   You can enter up to 250 characters in the **Filter** field.

2. Press `Enter` or click **Search** .

   Example

   ```
   If you enter Ovardin in the filter field for Product Family, the system
   displays the entity you are searching for with all nodes that matches the
   filter values expanded.
   ```

   Any tree node that matches the filter criteria is automatically displayed in the tree.



If only the product family name matches the filter values, its subnodes are not expanded.

3. To clear a filter and reset the tree to its default state, click Reset Filter .

I Am Looking To

The I Am Looking To section on the *Home Page* provides easy access to wizards used for creating and updating entities.
The entities are available according to your role and security permissions in the system. You have an ability to minimize, maximize or hide the window. The terminology used for these features may differ in your system as Administrators do have the ability to configure certain terms.

Create a New

The Create a New section provides access to wizards developed for ease of use in performing create actions in Calyx RIM. The wizards available to you depend on your product license and your user role.

Update

The Update section provides access to wizards developed for ease of use in performing update actions in Calyx RIM. The wizards available to you depend on your product license and your user role.

Create a New

The Create a New section in the *I Am Looking To* pane on the *Home Page* provides access to wizards developed for ease of use in performing create actions in Calyx RIM.
The wizards available to you depend on your product license and your defined user role in the system. The terminology used for these features may differ in your system as Administrators do have the ability to configure certain terms.

The Create a New function provides an easy way to create:
— Application
— Assembly Template
— Bulk eCTD Import
— Comparator
— Global Project Plan
— Notification
— Publishing Setting Library Template
— Registration Attachment
— Standalone Assembly
— Submission
— Submission Plan
— System Alert
— Timeline/Event Plan
— XEVMPD Submission

When you click on the entity that you want to create, the system launches the appropriate creation wizard.

In the Global Project Plan you can:
— Create New Events Package Set Registration
— Update Product Detail Sets
— Create New Applications Package Set Registration
— Create New Events Product Registration
— Withdraw Product Package Set Registration
— Clinical Trial

Update

The Update section in the *I Am Looking To* pane on the *Home Page* provides access to wizards developed for ease of use in performing update actions in Calyx RIM.
The wizards available to you depend on your product license and your defined user role in the system. The terminology used for these features may differ in your system as Administrators do have the ability to configure certain terms.

The Update function provides an easy way to update:

— Applications
— Status
— XEVMPD Acknowledgement

When you click on the entity that you want to update, the system launches the appropriate *Updating Wizard*.

After the update action is completed, the system will return to the *home* page.

I Want To Go To

The I Want To Go To section on the *Home Page* provides quick access to the entities you use. It includes tabs for accessing recently viewed entities and entities flagged as favorites.

The entities are customizable in Data Administration, and are available according to your role and security permissions in the system. You can minimize or maximize the size of the I Want To Go To section, or simply hide it.

My Favorites

The My Favorites list displays saved hyperlinks to selected entity attribute pages for quick access to those pages you return to most often.

Recently Viewed

The Recently Viewed list displays hyperlinks to entities that you have recently viewed or edited. The listed entities are specifically associated with your account and are not shared with others. You must have READ or higher permissions to use the Recently Viewed function.

My Reports

The My Reports list allows users to see the Public Reports from the `My Content` folder. To access the My reports option, you must have security settings for Out of the Box Reports under Home Page Access set to Yes.

Favorite Reports

The Favorite Reports lists the reports, that you saved as favorites. To access Favorite Reports you must have security settings for Reports under Home Page Access set to Yes.

My Activities

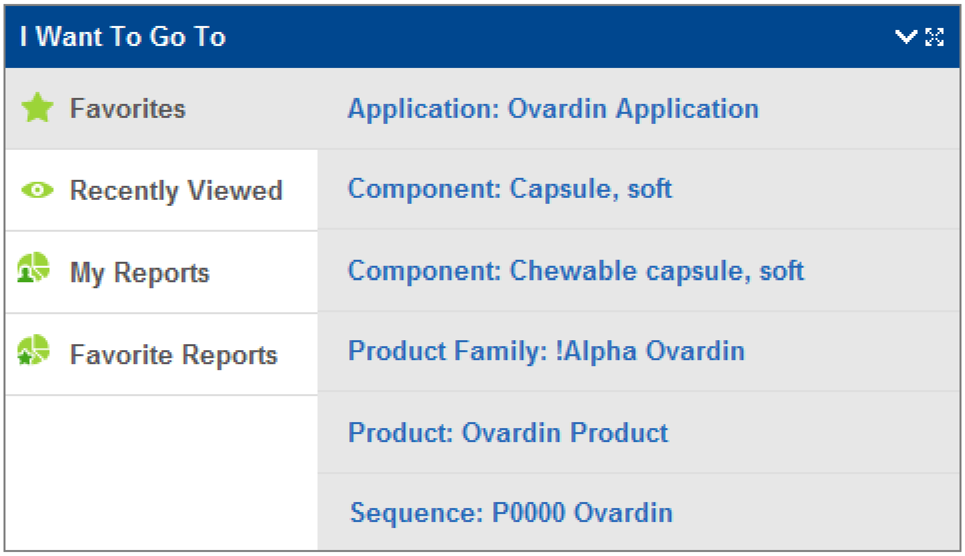
The My Activities list displays hyperlinks to activities that are active and assigned to you. You must have at least `READ` permission for Activities within the entity security to be able to view the activities.

My Favorites

The Favorites tab enables you to quickly return to the entities and entity details that you frequently use in Calyx RIM.

Each entity flagged as a favorite appears in the Favorite tab on the *Home Page*. All entities in the Favorites list are hyperlinks. The list is presented in alphabetical order sorted by the entity type and then by entity name within the entity type. The order cannot be changed. You can go to the entity attributes page by clicking on its name in the Favorites list.

You can modify or delete Favorites links.

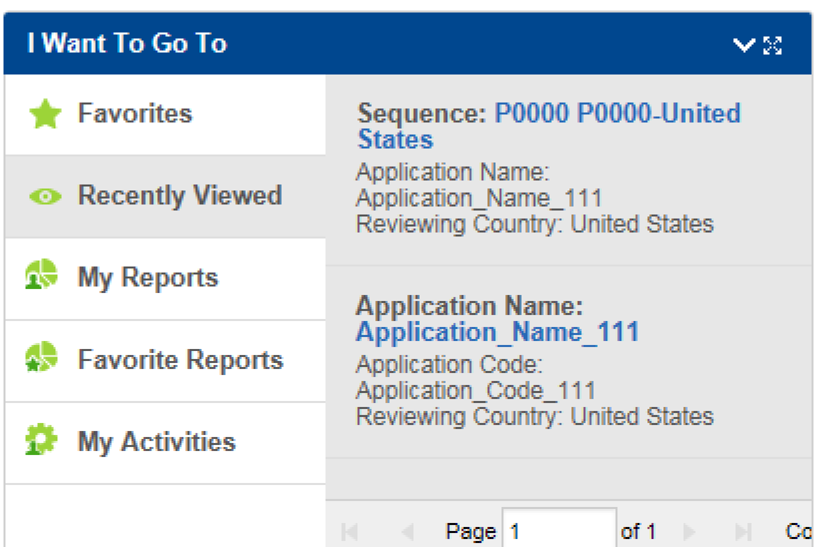


Recently Viewed

The Recently Viewed tab in the I Want To Go To section on the *Home Page* lists the entities that you have viewed when logged on to Calyx RIM, and provides an easy way to return to the entities you have used recently. You can see recently viewed or recently deleted entities according to your role and permissions in the system.

Each entity name is a hyperlink, with some additional information displayed below the name. You can click the entity name to go to the entity attributes page.

The list of entities is presented in descending order with the most recently viewed entity at the top. The oldest viewed entities are deleted automatically as you add more.



The default number of displayed entities is `10`.

All entities displayed in the Recently Viewed tab are user specific and are not shared with the other users.

The following entities can be displayed in the Recently Viewed tab:
— Product Family
— Product
— Project
— Application
— Event
— Task/Sub-Tasks
— Component
— Pharmaceutical Product
— Sequences
— CT Shared Data
— Registration
— Full Product Presentation
— Attachment
— View Reference
— Submission Plan
— Activity
— Change
— Change Detail

My Reports

The My Reports tab in the I Want To Go To section enables you to access reports saved in the `My Content` folder of the Calyx RIM for Analytics module. To view the My Reports tab, you must have the appropriate permissions set in the Calyx RIM system by your system administrator.

My Reports are ad hoc reports saved in the Calyx RIM Analytics portal. All reports listed on the My Reports tab are hyperlinks. When you click on the report entity name, that report opens in a separate window.

Favorite Reports

The Favorite Reports tab in the I Want To Go To section enables you to access the reports you have saved as favorites.
To view the Favorite Reports tab, you must have the appropriate permissions set in the Calyx RIM system by your system administrator.

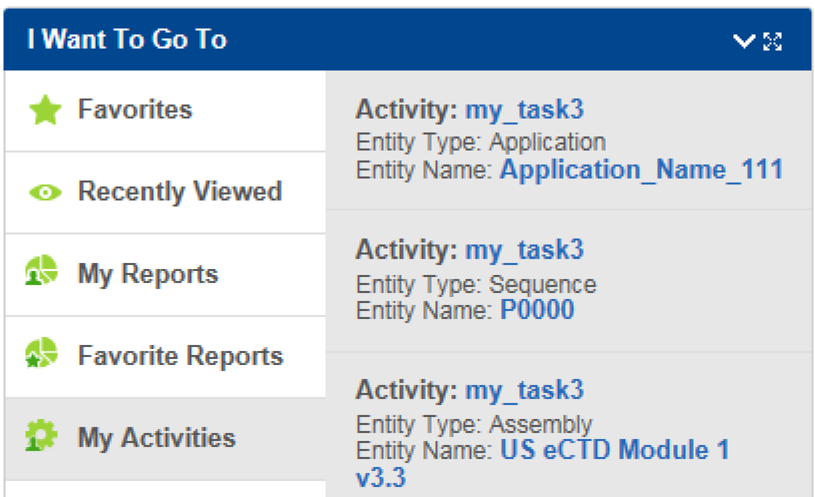
Favorite Reports

All reports that you save as favorites are displayed in the Favorite Reports tab. All reports listed on the Favorite Reports tab are hyperlinks. When you click on the report entity name, the attributes page for that report opens in a separate window.

My Activities

The My Activities tab in the I Want To Go To section on the *Home Page* lists the active activities that are assigned to you in Calyx RIM.

The activities in the list are sorted based on the earliest Due Date values, followed by activities with highest priority and then on the alphabetical order of the activity names. Each activity name is a hyperlink which navigates to an activity's page.



You must have at least `READ` permission for Activities within the entity security to be able to view the activities.

Alert Center

The Alert Center on the *Home Page* enables users to view Administrative Alerts, Notification based Alerts, and Task Alerts for the user logged into the system.
Administrative Alerts and Notification based Alerts can be distributed to Calyx RIM users and groups. Task Alerts are distributed to the Primary Assignee for an open Task.

Users will have the ability to view and remove the following in the Alert Center:
— Administrative Alerts
— Task Alerts
— Notification Alerts

System Alerts

The System Alert entity provides the ability to create and distribute important messages to Calyx RIM users and groups.
System Alerts can be created by users with at least `WRITE` permissions to the System Alert entity. The permissions are set in Calyx RIM Security Administration.

System Alerts are displayed in the Alert Center on the Effective Date set for the Alert. They are displayed for the recipients of the Alert and will automatically be removed from the Alert Center on the Expiration Date set for the Alert.

The System Alert attributes in the Alert Center include:
— Name
— Priority
— Effective Date
— Expiration Date

Removing a System Alert from your Alert Center does not affect that alert for other users. After a System Alert is removed from your Alert Center, it can only reappear in your Alert Center if Priority, Message Text, or Effective Date is modified. The modified System Alert will appear after the Alert Center is refreshed.

System Alerts can be refreshed, sorted, filtered, or exported to Excel. The default sort for System Alerts is the Valid Until date (nearest expiration date at the top) and Priority.

Create a System Alert Using the New Menu

The System Alert entity provides the ability to create and distribute important messages to Calyx RIM users and groups.
System Alerts can be viewed and modified from the System Alerts tab located in the list view of the *Navigation* pane. System Alerts can be created by users with `WRITE` or `ADMIN` permissions only. System Alerts, when distributed are displayed in the Alert Center on the Calyx RIM *Home Page*.

To create a System Alert using the New menu:

1. On the New menu located on the Calyx RIM menu bar, select System Alert.
2. On the *Create System Alert* window, enter attributes for the system alert.

   Required fields are indicated by an asterisk.
3. Click Save.

   Your newly created System Alert will appear in the Alert Center on the Effective Date for the Alert for the specified users or groups.

   Note: *You can create a System Alert without assigning recipients. It will appear in the System Alert tab and can be distributed at a later time. After recipient users or groups are assigned, the system alert is distributed and viewable by those recipients.*

   Note: *System Alerts are not in synch with LDAP. System Alerts will only be distributed to users in a group that were in the group when it was selected for the System Alert. If you know users have been added to a group after the System Alert using that group has been created you can modify the Alert, remove the group, and save the Alert. Then modify the Alert once more and re-add the group.*

   The *System Alert attributes* page appears.

Create a System Alert in the I Am Looking To Pane

The System Alert entity provides the ability to create and distribute important messages to Calyx RIM users and groups.
System Alerts can be viewed and modified from the System Alerts tab located in the list view of the *Navigation* pane. System Alerts can be created by users with `WRITE` or `ADMIN` permissions only. System Alerts, when distributed are displayed in the Alert Center on the Calyx RIM *Home Page*.

To create a System Alert using the Create a New... option in the *I Am Looking To* pane:

1. In the *I Am Looking To* pane on the Calyx RIM *Home Page*, select Create a New... > System Alert .
2. On the *Create System Alert* window, enter attributes for the system alert.

   Required fields are indicated by an asterisk.
3. Click Save.

Your newly created System Alert will appear in the Alert Center on the Effective Date for the Alert for the specified users or groups.

Note: *You can create a System Alert without assigning recipients. It will appear in the* System Alert *tab and can be distributed at a later time. After recipient users or groups are assigned, the system alert is distributed and viewable by those recipients.*

Note: *System Alerts are not in synch with LDAP. System Alerts will only be distributed to users in a group that were in the group when it was selected for the System Alert. If you know users have been added to a group after the System Alert using that group has been created you can modify the Alert, remove the group, and save the Alert. Then modify the Alert once more and re-add the group.*

The *System Alert attributes* page appears.

Update a System Alert

System Alerts are important messages that can be distributed to Calyx RIM users and groups and will appear in the Alert Center on the *Home Page*. System Alerts can be updated by users with `WRITE` or `ADMIN` permissions only.

To update a System Alert:

1. Go to the System Alert tab on the navigation pane to view the list of System Alerts, then select the Alert you want to update.
2. On the *System Alert Attributes* page, click the Modify icon and update the attributes.
3. Click Save.

   System Alerts are distributed on the Effective Date for the Alert. Alerts will only be re-distributed to the Alert Center if Priority, Message Text, or Effective Date is modified. The modified System Alert will appear after the Alert Center is refreshed.

   The *System Alert* attributes page will be displayed.

Delete a System Alert

System Alerts are important messages that can be distributed to Calyx RIM users and groups. Deleting a System Alert stops the distribution of the message.

System Alerts can be deleted by users with `ADMIN` permissions only.

To delete a System Alert:

1. Go to the System Alert tab on the navigation pane to view the list of System Alerts, then select the Alert you want to delete.
2. On the *System Alerts attributes* page, click the Delete icon.
3. On the warning message that appears, click OK.

The System Alert entity is deleted. The recently deleted System Alert is no longer listed in the Alert Center on the *Home Page* for the specified users or groups.

Notification Alerts

Notification Alerts are Calyx RIM entity notifications that are distributed to a users Alert Center on the home page. When the Calyx RIM Notificaton or Notification Specification has been setup to send notifications to the Alert Center they will be displayed in the Alert Center when the Notifications have been triggered.

Notifications sent to the Alert Center display the following information:

- Notification Name - Hyperlink to the Alert Message text. You can view the Notification Alert details by clicking the Name in your Alert Center.
- Priority - The priority will allways display as `"Low"` for notification based alerts.
- Effective Date - The date when the Notification is triggered.
- Expiration Date - The date when the notification is automatically removed from your Alert Center. The expiration date for notification alerts in the Alert Center is 120 days from the effective date.

The message text in the center pane differs depending on the type of the notification:

- When the date approaches or passes - Your notification is triggered when a date approaches or passes.
- When a record is created - Your notification is triggered when a new record is created.
- When a status changes to a specific value - Your notification is triggered when a status changes to a specific value.
- When a value changes - Your notification is triggered when a value changes.

Removing a Notification Alert from your Alert Center does not affect that alert for other users.

Notification alert entities in the Alert Center can be refreshed, sorted, filtered, or exported to Excel.

Create a Notification

You can create notifications using either the *Create Notification* wizard or the Notification option in the I Am Looking To > Create A New section on the *home page*.

You must have the appropriate security privileges to create, modify, and view notifications. Only users with administrator privileges for notifications can create a global notification.

- If you launch the *Create Notification* wizard from the *home page*, you can select a Calyx RIM entity and create a notification. See *Use the Create Notification Wizard* in the Getting Started with Liquent InSight module.
- If you launch the wizard while viewing an entity, you can create an instance notification or a global notification for the entity you are viewing.

Create Notification Wizard

The *Create Notification* wizard enables you to create a Global Notification Specification or an instance Notification for a specific entity.

The *Create Notification* wizard can be started from several locations:
— Wizards menu
— I Am Looking To > Create a New > Notificationon the *Home Page*
— Notifications tab on the *entity attributes* page

Note: *You can create* XEVMPD Acknowledgement Import *notification only using* Wizards *menu.*

The *Create Notification* wizard guides you through the following steps to create a notification:

— Choose Notification Type
— Specify Entity Specific Information
— Select Rule Settings and Delivery Destinations
— Mail Settings
— Create Notification Confirmation
— Create Notification Summary

Create Notification Wizard: Choose Notification Type

On the *Choose Notification Type* page you can set the following attributes for the notification:

Attribute	Description
Entity Type	The entity for which you create the notification. If you choose to create a specification, the field is modifiable. If you create a notification on a specific instance of an entity, the field cannot be modified.
Descendant Type	Can be selected only for Event Country entity type. Enables you to choose the Event Country Status Schedules.
Global Preset Notification	If selected, the notification will be sent not only for a specific entity, but for all entities of certain type.
Active	Identifies the status of the notification.
When a Value Changes	The notification of this type will be sent when a specific value of the entity changes.
When Status Changes to a Specific Value	The notification of this type will be sent when the status of a specific entity changes.
When a Day Approaches or Passes	The notification of this type will be sent if the predefined number of days before or after a date approaches or passes.

Attribute	Description
When a Record is Created	The notification of this type will be sent when the entity of specific type is created.

The *Specify Entity Specific Information* page appears as modifiable if you selected the Global Preset Notification option. For this option Product Family, Product, Product Component, or Application can be selected. You can also choose the Create Notification for any Type option.

The *Select Rule Settings and Delivery Destinations* page differs depending on the option selected on the the *Choose Notification Type* page.

If you select the When a Value Changes option or the When Status Changes to a Specific Value option, you need to specify:

Attribute	Description
Available Options	The value options for the specified entity. Required.
Email only	The notification will be sent to the user(s) and/or user group(s) e-mail addresses only.
Alert Center only	The notification will be sent to the user(s) and/or user group(s) Alert Center only.
Both Email and Alert Center	The Notification will be sent to the user(s) and/or user group(s) e-mail and Alert Center.

If you select the When a Date approaches or Passes option, you need to specify:

Attribute	Description
Available Options	The value options for the specified entity. Is a required field.
Days Before	The notification is sent in a predefined number of days before the date approaches.
Days After	The notification is sent in a predefined number of days after the date is acheived.
Days Repeating	The notification is sent for a predefined number of days after the date is acheived.
Email only	The notification will be sent to the user(s) and/or user group(s) by e-mail addresses only.
Alert Center only	The notification will be sent to the user(s) and/or user group(s) in the Alert Center only.
Both Email and Alert Center	The Notification will be sent to the user(s) and/or user group(s) by e-mail and to the Alert Center.

The *Mail Settings* page differs depending on the delivery mechanism selected on the *Select Rule Settings and Delivery Destinations* page. The required field common to all options is the Subject field.

Attribute	Description
E-mail Only	
Notification Name	The name of your notification. Presented as a concatenation of the entity name and the entity value.
Subject	The subject of your notification. Required.
Comment	Enables you to share comments about the notification with others.
Send to Concerned Parties	The notification can be sent to the Calyx RIM user(s) that are listed as Concerned Parties for the Entity selected for the notification. ***Note:*** *This field is empty for XEVMPD Acknowledgement Import notification type.*
Also Send To	The notification will be sent to the email addresses entered or Calyx RIM user(s)selected for the notification.
CC Concerned Parties	Calyx RIM user(s) that are listed as Concerned Parties for the Entity selected can be CC'd on the email notification. ***Note:*** *This field is empty for XEVMPD Acknowledgement Import notification type.*
Also CC	The notification will be CC'd to the email addresses entered or Calyx RIM user(s)selected for the notification.
BCC Concerned Parties	Calyx RIM user(s) that are listed as Concerned Parties for the Entity selected can be BCC'd on the email notification. ***Note:*** *This field is empty for XEVMPD Acknowledgement Import notification type.*
Also BCC	The notification will be BCC'd to the email addresses entered or Calyx RIM user(s)selected for the notification.
Alert Center Only	
Notification Name	The name of your notification. Presented as a concatenation of the entity name and the entity value.
Subject	The subject of your notification. Required.

Attribute	Description
Comment	Enables you to share comments about the notification with others.
Recipient User Groups	User groups who will receive the notification.
Recipient Users	Users who will receive the notification.

When the **Both E-mail and Alert Center** option is selected, the notifications will be distributed to the user(s) email and the Alert Center.

Not all notification types are available for every entity. There are 3 entities for which the options are limited by the following:

— Pharmaceutical Product - When a Value Changes, When a Record is created
— Product Component - When a Value Changes, When a Record is created
— XEVMPD Acknowledgement Import - When a Value Changes

Use the Create Notification Wizard

From the Calyx RIM *Home Page*, you can create Global Notifications. From an *entity attributes* page, you can create either an instance Notification or a Global Notification.

To create a notification:

1. Start the *Create Notification* wizard:
   — From the *Home* Page, click Wizards > Create Notification or in the *I Am looking To* window Create a New > Notification. The *Choose Notification Type* page appears. Go to step 2.
   — From an *entity attributes* page, click Wizards > Create Notification or Notifications tab > Create Notification icon. The *Choose Notification Type* page appears. Go to step 3.
2. On *Choose Notification Type* page select the entity type if you started the Wizard from the *Home Page*.
3. On *Choose Notification Type* page select one of the available notification type options. Notification types include:
   — When a Value Changes, When Status Changes to a Specific Value, When a Date Approaches or Passes, and When a Record is Created.

   Note: *The availability of these options for selection depends on the entity type selected, whether a descendant is selected, whether the notification is global, and the location from which you started the* Create Notifications *wizard. For example,* When a Record is Created *is not available for a specific instance notification.*

   — To create a global notification, select Global Preset Notification, and then specify the type of notification you want to create.
   — To create a notification for a specific instance, do not select Global Preset Notification, just specify the type of notification you want to create.

4. Click **Next**.

   The *Specify Entity Specific Information* page appears. One of the following occurs:

   — If you selected Global Preset Notification and you selected Product Family, Product, Product Component, or Application as the entity on the previous page, you must either select a specific entity type for notifications or check Create Notification for any Type.

   — If you did not select Global Preset Notification and Product Family, Product, Product Component, or Application as the entity, no input is required.

5. Click Next. On the *Select Rule Settings* page, do the following based on the type of notification you are creating:

   — For a value change, select the attribute that will trigger a notification.

   — For a status change to a specific value, select the status change that will trigger a notification.

   — For a date notification, select the date that will trigger a notification, enter the number of days before the date to send a notification, enter the number of days after the date to send a notification, and enter how often the notification should be resent.

6. Click Next.

7. On the *Mail Settings* page, do the following:

   a) Enter a subject line for the notification e-mail in Subject.

   b) Enter a comment to be sent with the notification in Comment.

      This field is optional, but provides text for the email notification.

   c) Select one or more entities whose associated users should receive the notification in Concerned Parties.

   d) Optionally, enter the e-mail addresses of other users or click the Search Person icon to use the *e-mail browse* dialog box to add e-mail addresses in Also Send To.

      Separate multiple e-mail addresses with a semi-colon (;). Special characters cannot be used in email addresses.

   e) Optionally, make selections for CC Concerned Parties / Also CC and BCC Concerned Parties / Also BCC.

8. Click Next.

   A confirmation page appears, listing the actions that will be taken.

9. Click Finish.

   After the Notification is triggered, it appears in the Alert Center for predefined users or groups, if this option was selected.

Modify a Notification

When modifying a notification you can activate or deactivate a notification, or change e-mail options for the notification.
A deactivated notification is not sent even when its criteria is met, however, the notification remains available for later use.

Note: *Only an administrator can modify a global notification specification.*

To modify a notification:

1. Navigate to the entity that has the notification you want to modify.
2. Click the Notifications tab.
3. Click the notification link.
   The *Create Notification* wizard opens to the *Choose Notification Type* page.
4. To change the active status, click select or deselect the Active check box.
5. Click Next.
   The *Specify Entity Specific Information* page opens. You can view the current setting, but cannot make changes.
6. Click Next.
   The *Select Rule Settings* page opens. You can view the current setting, but cannot make changes.
7. Click Next.
   The *Mail Settings* page opens.
8. Change the subject and e-mail recipients as needed.

   The e-mail notification name is read-only and cannot be modified.
9. Click Next.
   A confirmation page listing the revised notification attributes opens.
10. Click Next.
    The *Create Notification Summary* page indicates that the notification is updated.
11. Click Finish.

Note: *You can select the notification from the* Notifications *tab for all entities except XEVMPD Acknowledgement Import. For this entity you need to select* *Go To > Data Administration > Notification Specification*.

Delete a Notification

You can delete notifications if you have the appropriate security privileges.

To delete a notification you have created:

1. Navigate to the entity associated with the notification that you want to delete.
2. Click the Notifications tab.
3. Click the notification.
   The *Choose Notification Type* page opens.
4. Select the Delete the Notification option.
5. Click Next on each consecutive page.
   The deletion is confirmed on the final page.
6. Click Finish.

Note: *The XEVMPD Acknowledgement Import notification can be deleted using* *Go To > Data Administration > Notification Specifications* *only.*

Task Alerts

The Alert Center enables users to quickly identify open tasks assigned to them with their due dates.
The Task name in the Alert Center is a hyperlink to the Task entity. Clicking the Task name navigates the user to the *Task attributes* page.

The task attributes displayed in the Alert Center are as follows:

— Task Name
— Status
— Due Date
— Task Type
— Secondary Task Type

Task alert entities can be refreshed, sorted, filtered, or exported to Excel. The default sort for tasks is the Task Due Date. The approaching due dates are displayed at the top.

When you remove a Task Alert from your Alert Center, it will still appear in the My Tasks tab. After a Task Alert is removed from your Alert Center, it can only reappear in your Alert Center if Task Status or Due Date is modified. The modified Task Alert will appear after the Alert Center is refreshed.

For more information about tasks, see *Tasks and Sub-tasks.*

Delete a Task Alert

You can remove Task Alerts from the Alert Center, or completely delete the task if it is no longer needed. Task Alerts are displayed in the *Alert Center* pane on the *Home Page*.

You can delete the task.

To delete the task:

1. Navigate to the *task attributes* page by clicking the task name in the *Alert Center* pane.
2. On the *task attributes* page, click the Delete icon.
3. On the confirmation message that appears, click OK.
   The task attributes are deleted and the task alert no longer appears in the *Alert Center* pane.

Activity Alerts

The Alert Center enables users to quickly identify open activities assigned to them with their due dates. The Activity name in the Alert Center is a hyperlink to the Activity entity. Clicking the Activity name navigates the user to the *Activity attributes* page.
The activity attributes displayed in the Alert Center are as follows:

— Activity Name
— Status
— Due Date
— Task Type
— Secondary Task Type

Activity alert entities can be refreshed, sorted, filtered, or exported to Excel. The default sort for activities is the Activity Due Date. The approaching due dates are displayed at the top.

An Activity is automatically removed from the Alert Center when:
— a workflow is deleted
— a workflow is canceled when adding a sequence to life cycle
— an activity is completed
— an activity is unclaimed or transferred to another user

Note: *Activities are not removed from the Alert Center when they are paused. However, when the paused state changes, the activity will be displayed again.*

When you manually remove an Activity Alert from your Alert Center, it will still appear in the My Activities tab. After an Activity Alert is removed from your Alert Center, it can only reappear in your Alert Center if Activity Status or Due Date or Paused value is modified. The modified Activity Alert will appear after the Alert Center is refreshed.

XEVMPD Alerts

The information in the *Alert Center* screen and in email notification regarding the XEVMPD Acknowledgement file import is presented as follows:

First screen with common information	Second screen after the Details hyperlink is selected from the Alert Center or form Email Notification
Entity Name: *<Subject>* from Notification Message Text: *<Status of XEVMPD Acknowledgement fileimport>* URL: Details *<hyperlink to entity>*	Import Result: EMA Acknowledgement file <file name> was processed //with error(s):...(if any errors appeared) Acknowledgement Message Name: <xml file name> Acknowledgement Message Date: <from XML file> Acknowledgement Message Type: <2 or 3> Entities Acknowledged: — Organisations: [number] <InSight entity Name coma delimited> — Sources: [number] <InSight entity Name coma delimited> — Attachments: [number] <InSight entity Name coma delimited> — Master File Locations: [number] <InSight entity Name coma delimited> — Pharmaceutical Forms: [number] <InSight entity Name coma delimited> — Routes of Administration: [number] <InSight entity Name comadelimited> — ATCs: [number] <InSight entity Name coma delimited> — Authorised Products: [number] <InSight entity Name coma delimited> — Errors: <error description if any appeared>

Note: *If you want to receive a notification regarding the autou ploaded XML acknowledgement file you need to create an XEVMPD Import Result notification first.*

Export Alert Entities to Excel

Calyx RIM enables you to export data related to System Alert, Task Alert, or Notification Alert entities to Microsoft ® Excel ® spreadsheets.

To export System Alert, Task Alert, or Notification Alert entities data to Excel:

1. Navigate to your *Alert Center* pane and click the Export to Excel icon at the bottom of *System Alerts or Task Alerts* window.
2. Follow the prompts in the *File Download* dialog box.

   System Alert attributes exported to Excel:

- Name
- Priority
- Effective Date
- Expiration Date

Task Alert Attributes exported to Excel:

- Task Name
- Status
- Due Date
- Task Type
- Secondary Task Type

Notification Alert attributes exported to Excel:

- Name
- Priority
- Effective Date
- Expiration Date

Once you apply any sorting to System, Task or Notification Alerts, the entities data will be exported the same way it is presented in the *Alert Center* pane. If the sort is default the list will be displayed with default sorting in the spreadsheet.

Remove an Alert from the Alert Center

Users will have the ability to remove an Alert from the Alert Center when they no longer want it displayed in the *Alert Center* window. Task Alerts are presented in the top window of the Alert Center. The System Alerts and Notification based Alerts are displayed in the lower window of the Alert Center. Removing an Alert from the Alert Center does not delete the entity, it only removes if from the Alert Center window.

To remove an alert from the Alert Center:

1. In the *Alert Center* pane on the home page, select the alert to remove and click the Remove from Alert Center icon .
2. On the confirmation screen, click OK.
   The selected alert is removed from the Alert Center.

Menus

The Calyx RIM menu bar appears throughout the user interface. The available menus and the options they provide is based on your security privileges. Some menu options may be unavailable when you are viewing specific pages in the user interface.

Option	Description
Search	The **Search** menu enables you to locate entities for which you have security privileges using information available in certain text fields.
Analytics	The **Analytics** menu option opens the Calyx RIM for Analytics portal in a new browser window or tab. Calyx RIM for Analytics enables you to generate reports about Calyx RIM activities. See *LIQUENT InSight for Analytics.*
Go To	The **Go To** menu contains options that enable you to move quickly to different areas of Calyx RIM, including: — Activities - Accesses the **My Activities**, **Unclaimed Activities**, **All Activities** and **Workflows** tabs. — Querying - Accesses multiple queries currently in the system that you can select and run — Data Administration - Opens the ***Data Administration*** page, which contains links to specify the options available for selection by users (available only for administrators) — Security Administration - Opens the ***Security Administration*** page for adding users, groups, and roles, and specify security privileges (available only for administrators) — Technical Administration - Opens the ***Technical Administration*** page for creating and maintaining document repositories and servers (available only for administrators) — Job Requests - Enables administrators to monitor all queued publishing job requests
Find	The **Find** menu enables you to search for specific attribute values for a selected entity type, returning results for those that you have permission to view.

Option	Description
New	The **New** menu enables you to create entities for which you have security privileges. The **New** menu includes: — Assembly Template — Change — Comparator — Publishing Settings Library Template — Registration Attachment — Standalone Assembly — Submission Plan — System Alert
Favorites	The **Favorites** menu enables you to add and manage links to locations within the system that you frequently access.
Wizards	The **Wizards** menu enables you to invoke wizards developed for ease of use. The options available to you depend on your product license and your user role. The **Wizards** menu can include: — Bulk eCTD Import — Change Management — Change Submittal Status — Copy Event — Create Application — Create Notification — Create Study Reports — Create Submission — Create Submission Plan — Create Timeline/Event Plan — Create eCTD — Global Project Plan — Ready For Submission — Update Applications — Update Status — XEVMPD Acknowledgement — XEVMPD Submission

Search

The **Search** function on the menu bar can be used to perform broad searches for all entities of a certain type (such as Product Families and Events). It can also be used to search for entities filtered by specific text found in the Name, Code, Keywords, or Description attributes.
You can search for specific entities or for specific entities filtered by text attributes.

You can search for:

- Product Families
- Applications
- Events
- Sequences
- Assemblies
- Registrations
- Full Product Presentations
- Products
- Components
- Projects
- Tasks/Sub-tasks
- Submission Plans

Keep in mind the following when enter the search criteria:
- Calyx RIM searches for entities data exactly as you enter it.
- Calyx RIM searches for text exactly as you enter it. You can use specific words to search for entities that contain the word you entered in their Name, Code, Keywords or Description attributes. For example, if you select **Product Families** from the list and enter *`Denzine`* in the search field, in the search results you will see all product families which contain `Denzine` in their Name, Code, Keyword, or Description attributes.
- Search option supports partial word searches. For example, if you select **Applications** from the list and enter *`De`* in the search field, the search results will display all applications which contain `De` in their Name, Code, UUID, Keyword, or Description attributes.

Note: *You cannot use the asterisk character [*] as a search criteria. The search will not be performed.*

Search Entities

The **Search** function on the ***Home*** page menu provides a quick method for searching entity types (such as Product Families or Events). You can search for entities filtered by specific text found in the Name, Code, Keywords, or Description attributes.

Searching for an Entity Type

1. Go to the menu bar and click Search>>.
   A selection list and text field appear.
2. Select an entity from the list.
3. Click Go.

   Example

   ```
   Selecting Product Families in the list displays all product families in the system in the Search Results.
   ```

   The *Search Results* page displays the results.
4. To hide the search fields in the menu bar, click Search<<.

Searching for Entities that Include Specific Text Attributes

1. Select an entity from the list.
2. In the text field, enter text to filter the results of the selected entity group.
3. Click Go.

   Example

   ```
   Selecting Product Families in the list, and adding Wisherut in the text field displays only those product families that include Wisherut in their names.
   ```

   The *Search Results* page displays the results.
4. To hide the search fields in the menu bar, click Search<<.

Favorites

The Favorites feature enables you to save locations in Calyx RIM, providing an easy way to return to entities and entity details that you use.

You can:

— Add a Favorite
— Modify a Favorite
— Remove a Favorite

View List of Favorites

To view your list of Favorites:

1. On the menu bar click **Favorites**.
   Your saved favorites are listed in the **Favorites** menu. In the **I Want To Go To** section on the *Home* page, your saved favorites are listed on the **Favorites** tab.
2. Click the name in the list to view the entity.
   By default, all Favorites are listed alphabetically by entity type and then alphabetically by name within the entity type. This order cannot be changed.

Add a Favorite

Adding favorites enables you to return to frequently used entities and entity details in Calyx RIM. The entities and entity details that you choose as favorites are displayed in the **I Want To Go To** section on the *Home Page*, and in the **Favorites** menu. Favorites can be added, modified, and deleted.

To add a Favorite:

1. Go to the *attribute* page for the entity.
2. Click **Add entity to Favorites** .

Favorite Entity Types

The following entities can be added to Favorites:

- Product Family
- Product
- Project
- Application
- Event
- Task/Sub-Tasks
- Component
- Pharmaceutical Product
- Sequences
- CT Shared Data
- Registration
- Full Product Presentation
- FPP Previous EV Code
- View Reference
- Submission Plan
- Registration Attachment
- Activity
- Change

The entity is added to the Favorites list in both the **I Want To Go To** area on the *Home Page* and the **Favorites** menu. Favorites are listed alphabetically by entity type and then alphabetically by name within the entity type. The listed order cannot be changed.

Modify a Favorite

You can modify a favorite from the **Favorites** menu.
You can modify the name of saved favorites to make it easier for you to recall frequently used entities and entity details in Calyx RIM. Your favorites are displayed in the **I want to go to** section on the **My Favorites** tab on the *Home* Page, and in the **Favorites** menu. Favorites can be added, modified, and deleted.

To modify a favorite from the Calyx RIM menu bar:

1. On the Calyx RIM menu bar, click **Favorites > Manage Favorites**.
2. Select the favorite that you want to edit and click **Edit Link**.
3. On the *Edit Link* page, enter a new `name` for the favorite.

   This change affects only the name displayed in the *My Favorites* section. The actual entity name will not be changed.
4. **Save**.

Remove a Favorite

You can remove saved favorites to clear entities and entity details that are no longer needed from your list.

Your favorites are displayed in the **I Want to Go to** section in **My Favorites** tab on the *Home Page*, and in the **Favorites** menu. Favorites can be added, modified, and deleted.

There are two ways to remove a favorite:

— Use the **Manage Favorites** option on the **Favorites** menu.
— Remove the favorite status while viewing the *entity attribute* page that was previously marked as a `Favorite`.

Remove a Favorite Using the Manage Favorites Option

1. Click the **Favorites > Manage Favorites** option in the toolbar.
   The list of favorites appears.
2. Select the favorite you want to remove and click the **Remove from Favorites** icon .
3. On the confirmation message that appears, click **OK**.

Remove a Favorite While Viewing the Entity

1. Go to the *attribute* page for the entity.
2. Under the title bar, click **Remove from Favorites**.

Wizards

The **Wizards** menu enables you to invoke wizards developed for ease of use. The options available to you depend on your product license and your user role permissions in the system.

The **Wizards** menu can be invoked from the Calyx RIM menu bar.

The Wizards:

Wizard	Description
Bulk eCTD Import	You can use the *Bulk eCTD Import Wizard* to migrate multiple eCTD submissions to Calyx RIM from another system in a supported document management system (DMS).
Change Management	The Change Management wizard guides you through the process to create a project and associate change details to the events of the project.
Change Submittal Status	You can change the submission status of sequences using the *Change Submittal Status* wizard. You can use the *Change Submittal Status* wizard under specific conditions only.
Copy Event	You can use the *Copy Event* wizard to copy an event to multiple applications within the product family associated with a source event.
Create Application	To invoke the *Create Application* wizard, you should have `WRITE` permissions for events. The options available to you to create events, sequences, and PDS also require `WRITE` permissions.
Create Notification	You can create notifications with the *Create Notification Wizard*. When you create a notification from the Calyx RIM *home* page, you can only create global notifications for the Calyx RIM entity you select (product, application, event, and so on).
Create Study Reports	The *Create Study Reports* wizard enables you to add study report structures (folders and leaf elements) to an existing eCTD or CTD.
Create Submission	The *Create Submission* wizard enables you to create an assembly within the context of its appropriate Calyx RIM relationship.
Create Submission Plan	The *Create Submission Plan* wizard enables you to create submission plans and associate entities such as applications, events, and sequences to the submission plans.
Create Timeline/Event Plan	You can create a timeline/event plan using this wizard.
Create eCTD	The *Create eCTD* wizard enables you to create and organize structured and compliant eCTD assemblies.

Wizard	Description
Global Project Plan	You can create a project plan using the GPP wizard.
Ready for Submission	The *Ready for Submission* wizard enables an assembly plan to be merged into the lifcycle of the existing applications applicable to the assembly plan.
Update Applications	You can update the attributes of one or more applications using this wizard.
Update Status	You can use the *Update Status Wizard* to update event-country statuses and information about related entities.
XEVMPD Acknowledgement	You can upload the Acknowledgement XML file, received from the EMA, to Calyx RIM using the *XEVMPD Acknowledgement* wizard.
XEVMPD Submission	The *XEVMPD Submission* wizard enables you to collect data and files from the database to include in XEVMPD submissions, and to generate `.zip` files that include the collected data and attachment files to submit to the EMA.

New Menu

The New menu enables you to create entities for which you have security privileges. The New menu can be invoked from the Calyx RIM menu bar.

The New menu includes:

Entity	Description
Assembly Template	Opens the *Create Template* page. An assembly template enables you to set up an assembly structure that you can use to create similar assemblies.
Comparator	Opens the *Create Comparator* page. Comparators are used in clinical trials to compare the success of a medicine under study to another medicine or placebo.
Change	Opens the *Create Change* page. Change enables you to plan and track regulatory changes with Change numbers that refer to additional tools or software.
Submission Plan	Opens the *Create Submission Plan* page. Submission Plans facilitate the creation of submissions for multiple similar applications.
Publishing Settings Library Template	Opens the *Create Publishing Settings Library* page. The Calyx RIM Publishing Settings Library separates the publishing settings from the assembly structure, enabling you to control different overlay settings, cover page settings, TOC types, slip sheet settings, and tab settings for use within the assembly.

Entity	Description
Standalone Assembly	Opens the *Create Assembly* page. A standalone assembly is an assembly that is not associated with an application or sequence. You can create an Empty Standalone Assembly, a Standalone Assembly from a Template, Assembly, or View, a Standalone Assembly from an Assembly File, or a Standalone Assembly from a Virtual Document.
System Alert	Opens the create *System Alert* page. The System Alert entity provides the ability to create and distribute important messages to users or groups about the system.
Registration Attachment	Opens the create *Registration Attachment* page. The *Registration Attachment* entity is a Printed Product Information (PPI) attachment type created to be attached to a Full Product Presentation (FPP).

Find Menu

The Find menu on the Calyx RIM *Home* page enables you to perform advanced searches for entities based on one or more values for entity attributes.
You can locate the following entity types using the Find menu:

- Product Families
- Applications
- Pack Set Registrations
- Product Registrations
- Events
- Sequences
- Assemblies
- Tasks
- References
- Activities
- Run Last Query

Run Last Query enables you to return more quickly to the last set of search results after navigating to an entity from that result set.

Find vs. Search

The Find function on the *Home* page menu bar provides detailed entity search options.

The Search function on the *Home* page menu bar provides a quick search that lists all of the existing entities of the type selected for the search.

Find and Search functions work with five of the same entities, but differ in several other entities that are available to each of them.

- Both Find and Search functions can search the following entities: Product Families, Applications, Registrations, Events, Sequences, Assemblies
- Find can also search: Tasks, References, Run Last Query
- Search can also search: Products, Components, Projects

Find Entities

The Find function on the Calyx RIM *Home Page* menu bar enables you to perform advanced searches for entities based on one or more attribute values.

To use the Find menu:

1. On the menu bar, click Find.
   A list of entity types appears.
2. Select an entity type.
   A query page appears.
3. If you select Run Last Query, the last report you generated is displayed and the following steps are not necessary.
4. On the *query* page, do the following:
   a) Select values for the required entity attributes, indicated by an asterisk.
   b) Select additional values for the attributes presented, as needed.

   Note: *The selected search values remain active until you reset them.*

   Example

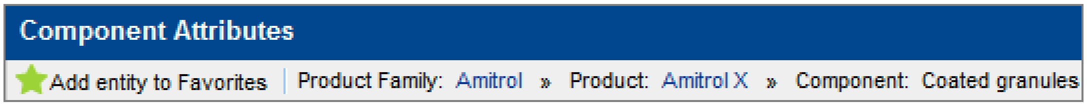
   ```
   If you previously performed a search for a Product Family and entered one or more searching values, when you start a new search for Product Family the query page will display the previously entered values. To clear the query page, Reset.
   ```
5. Search.
   The results appear on the *Search Results* page. The results can be sorted or exported to Excel.

Entity Trail Navigation

Entity Trail Navigation enables you to quickly open the attribute page of an entity to view the entity details. A wide range of the attribute pages in Calyx RIM provide a horizontal navigation path that lists entities associated with the one you are currently viewing. The entity trail appears below the title bar, following the Add entity to Favorites icon.

You can open the *attributes* page for the selected entity by clicking on its hyperlink.

You can add the entity to your Favorites list by clicking Add entity to Favorites. You can remove a viewed entity from your saved Favorites list by clicking Remove from Favorites.


Component Attributes
Add entity to Favorites
Product Family: Amitrol » Product: Amitrol X » Component: Coated granules

Icons

Calyx RIM enables you to perform common functions for the entities you create and maintain. Icons appear on the toolbar at the top right of the attributes pages, and they are specific to the current entity.

When you position the pointer over an icon, the icon name appears in a tooltip. Some tooltips provide a description of the action that can be performed by clicking the icon.

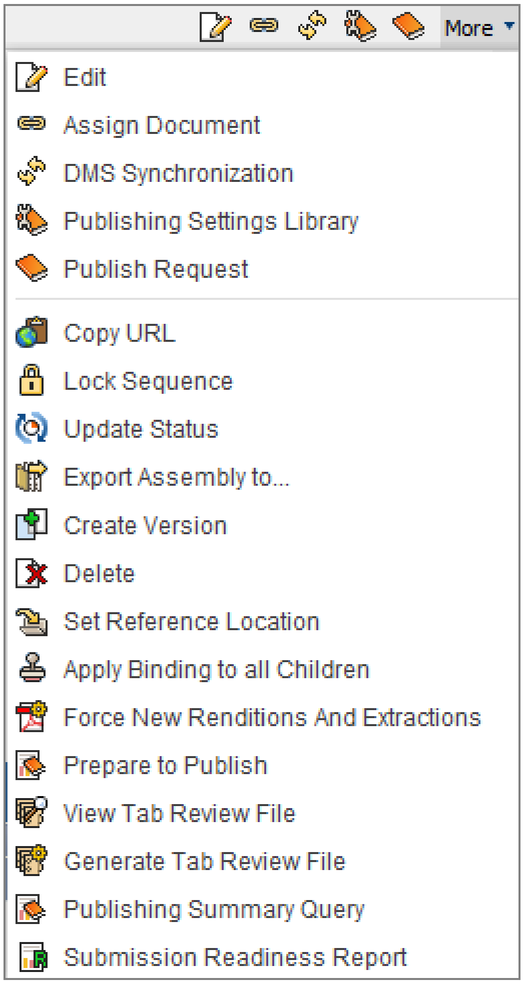
Tooltip Example

Icons are either enabled or disabled.

 = `Enabled` - An enabled icon is displayed in full color and means you are authorized to perform its action on the Entity displayed on the page.

 = `Disabled` - A disabled icon appears grayed or dimmed to indicate that the action is unavailable. Either you are not authorized to perform the action or the action does not apply to the entity.

You can perform a large number of actions for assemblies. Most of these actions are available in a drop-down list that you can display by clicking the More button next to the icons.



Icons Reference

Calyx RIM icons enable you to quickly identify functions and actions that you can perform in the system.

The following command and status icons are used on the Calyx RIM interface.

Icon	Name	Purpose
	Add Approved	Add an entity to the *Approved Status* view.
	Add Folder	Add a folder in an assembly.
	Add Group	Create virtual groups to use within workflows.
	Add Leaf	Add a Leaf in an assembly.
	Add Placeholder	Add a document placeholder in an assembly.

Icon	Name	Purpose
	Advanced Assembly Tree Search Settings	Opens the *Search* window for advanced filtering of an assembly tree.
	Apply Binding to All Children	Apply binding rules to all children of the selected assembly node.
	Assign Document	Assign a document within an assembly when an element is selected.
	Assign Related Documents	Assign related documents to the selected Document.
	Associate/Disassociate	Associate/Disassociate an entity with another entity or add a PDS detail. Associate or disassociate Products on the Events entity. Also used to assign a document within an assembly (using the right-click options).
	Associate Workflow	Associate workflows to entities.
	Associate Workflow to Events or Sequences	Associate workflows to events or sequences.
	Bulk Update Events Bulk Update Sequences	Modify the attributes of multiple events, or sequences, associated with a project. Use the icon tooltip on the *Project Attributes* page.
	Calculate Projected Dates	Open a page for recalculating projected dates based on a selected pivot status.
	Calendar	Open a calendar tool for setting a date.
	Cannot Delete Due to Data Dependencies	(Status icon) Indicates that the entity cannot be deleted because of the related data.
	Change Type	Open a dialog box for changing an element type.
	Claim	Claim activities.
	Clear Filter	Deletes the search criteria entered in the search field.
	Close/Cancel	Cancel or close an operation, generally without saving changes.
	Collapse	Collapse a tree node to hide child nodes. On the *Home* page, collapse the *I Want To Go To* or the *I Am Looking To* pane.
	Convert to Reference Leaf	Converts the selected leaf to a reference leaf.
	Copy	Create a copy of a selected entity.

Icon	Name	Purpose
	Copy URL	Copy a URL to an operating system clipboard.
	Cover Page	Indicates where a cover page has been inserted for an element in the assembly tree.
	Create	Open a page for creating a new entity.
	Create Missing Renditions and Extractions	Starts the process of creating missing renditions and extractions.
	Create New (Home Page)	Provides access to wizards developed for ease of use in performing create actions.
	Create Product Registration	Open the *Create Product Registrations* wizard.
	Create Publishing Settings Library Template; Insert Volume	Open a page for creating a new Publishing Settings Library Template (PLT). Insert new volume to the assembly.
	Create Reference	Open the *Create Reference* page for adding a reference to an entity, such as a document file or a URL to a Web site.
	Create Sequence	Open the *Create Sequence* page for associating a new sequence with an entity such as a project or event.
	Create Role	Open the *Create Role* wizard for creating a new user role for system security.
	Create Version	Create a version of a template or assembly.
	Delete; Delete All Volumes	Delete or remove an entity.
	Delete (Withdraw)	Mark the selected leaf in the assembly as deleted.
	Delete	Delete a workflow.
	Demote	Demote the selected item in the list hierarchy.
	Duplicate Leaf Append Leaf	Make a duplicate copy of the selected leaf. Make an appended leaf as a child node of a selected leaf.
	Duplicate Folder	Make a duplicate copy of the selected folder.
	Edit/Modify	Open a window for editing/modifying an entity.
	Edit Document Bookmarks	Edit the extracted bookmarks of the selected document.
	Edit Document Links	Edit the hyperlinks of the selected document.

Icon	Name	Purpose
	Edit icon not available	(Status icon) Indicates read-only status.
	Publishing Setting Library	View or modify Publishing Settings.
	Entity History Query	Opens the search window to track the entities modifications.
	Expand	Expand a tree node to show child nodes. On the *Home* page, expand the *I Want To Go To* or the *I Am Looking To* pane.
	Expand Range	Expand a TOC or navigation tree to view all elements.
	Export Assembly	Opens a dialog box for exporting an assembly outside of the system in another format, such as a spreadsheet or XML file.
	Export to Microsoft Excel	Export data in spreadsheet format.
	Export Published Output	Distribute published output as a rendition of a virtual document or a file system document.
	Favorite Reports (Home Page)	The Favorite Reports lists the reports that you saved as favorites, from within the Calyx RIM for Analytics portal.
	Favorites (Home Page) Add to/Remove from Favorites	Opens the list view of entities that you frequently use. Add or remove the entity to or from Favorites.
	Filter for Link Inspector	Apply filter criteria to Link Inspector query results.
	Find and Replace	Find and replace specific text within an assembly structure (SPT license required).
	Find Reference Leaf Elements	Lists all reference leafs referencing the selected leaf.
	Find Reference Leaf Targets	Opens the search results page for the reference leaf targets.
	Folder closed	(Status icon) Indicates that the contents of a folder are not shown or the folder is closed.
	Folder open	(Status icon) Indicates that the contents of a folder can be shown and the folder is open.
	Force New Renditions and Extractions	Create renditions and extractions, overwrite all existing renditions and extractions.

Icon	Name	Purpose
	Generate	Generate a file or a TOC.
	Generate Tab Review File	Generates the assembly tabs in a PDF file.
	Help	Open the online help documentation.
	Hide	Close an expanded area to hide details.
	Import Assembly Wizard	Start the wizard to import an assembly.
	Import from eCTD	Open the Import to ***eCTD Application*** window.
	Inline Edit or Modify	Change attributes or settings.
	Inline Hide	Close an expanded area to hide the attributes.
	Inline Required	(Status icon) Indicates that there are fields that need to be filled.
	Inline Show	Expand the collapsed area to show the attributes.
	Inline Warning	(Status icon) Indicates that errors occurred during the work.
	Insert Page Marker	An assembly element used to mark a specific page in a document. Most often used to indicate where a volume break may occur. You can also use page markers to insert TOCs, tab sheets, and other publishing effects in a document.
	Insert Volume	Insert a volume in an assembly.
	Leaf	Leaf node in an assembly.
	Leaf Update	Update the list of document assemblies for projects.
	Lifecycle	Add an assembly to the lifecycle.
	Link Applicability	Change where a link is applicable (for example, globally to each occurrence of the link pair in any assembly or for this application only.
	Link Output Channel	Change link properties to activate or deactivate output channels.
	Link Profile	Change link properties to change settings for each link.
	Lock	Lock an entity, saving the existing settings and preventing further changes unless the entity is subsequently unlocked.
	Locked	(Status icon) Appears next to Calyx RIM attributes that are mapped to their DMS repository or file system attributes.
	Mark Activity as Complete	Mark an activity assigned to you as complete.

Icon	Name	Purpose
	Mass Update Properties	Update the properties of multiple folders, leafs, reference leafs, documents, and/or placeholders within an assembly (SPT license required).
	Mass Insert/Update Publishing Elements	Insert, modify, or delete multiple publishing elements (TOCs, tab sheets, cover pages, or slip sheets) for a specific range within an assembly.
	Maximize	On the *Home* page, maximize the size of the *I Want To Go To* or the *I Am Looking To* pane.
	Metadata Library	Opens the *View Metadata Library* page.
	Minimize	On the *Home* page, return the size of the *I Want To Go To* or the *I Am Looking To* pane to the default view after it has been maximized.
	Modify TOC Tree	Display entries in the selected TOC for modification.
	Move Down	Move the selected item down in the list.
	Move Task	Open the *Move Task* wizard to move a task from any entity to an event.
	Move Up	Move the selected item up in the list.
	My Activities	Displays all active activities currently assigned to a current user.
	My Reports (Home Page)	The *My Reports* list allows users to see the Reports from the `My Content` folder, found within the Calyx RIM for Analytics Portal.
	Create Notification	Use the *Create Notification* wizard for to create e-mail notifications for specific triggering events.
	Page Marker	An assembly element used to mark a specific page in a document; can indicate where a volume break may occur, or to insert other publishing elements such as TOCs, tab sheets, and other publishing effects in a document.
	Pane Expand	Cursor indicator used to expand a pane in the user interface.
	Pause Until	Stop workflows until a specified date.
	Pause	Temporarily stop workflows that are started.
	Placeholder; Unassigned Document	Indicates a document placeholder in an assembly. This icon also replaces the usual document icon when you unassign a document.
	Prepare Documents for Linking	Prepares documents for use in linking tools.

Icon	Name	Purpose
	Publish Request	Choose a submission output location and document type, specify whether to create renditions automatically, and what to publish.
	Promote	Promote the selected item in the list hierarchy.
	Publishing Readiness Query; Publishing Summary Query; Prepare for Publishing	The Publishing Readiness Query enables you to view your assembly metadata at a glance and find predicted errors and warnings that may occur at publishing time if an issue is not remedied. The Publishing Summary Query displays each component in the assembly, its types and sub-types, and indicates whether a leaf has at least one child document and whether the leaf has any overridden attributes with renditions. Prepare to Publishing opens the webpage dialog box to prepare the assembly element for publishing.
	QC Failed	Assign the QC Failed status to a PDS detail to indicate that it failed a check to verify that it is correct.
	QC Passed	Assign the QC Passed status to a PDS detail to indicate that it passed a check to verify that it is correct.
	Recently Viewed	Opens the list view of the entities that you have viewed when logged on.
	Reference Leaf	Appears before a reference leaf in an assembly tree.
	Reference Location	Specify a different location for the assembly reference location.
	Refresh; Refresh Tree	Update a navigation tree to show recent changes.
	DMS Synchronization	Synchronizes all child documents of the selected node to the associated DMS.
	Recalculate Checksums	Recalculate checksums for content that has been changed post publishing.
	Reset Sort	Clears the previously set sorting.
	Reorder; Reorder Child Leafs	Specify the order of nodes in a hierarchy (such as the relationship and order of child nodes to parent nodes).
	Remove Approved	Removes an event from the Approved status view.
	Remove from Alert Center	Removes a Task Alert or a System Alert from the Alert Center.
	Replace Leaf	In the working assembly replace the selected leaf, already existed in the assembly.

Icon	Name	Purpose
	Report	Generate an Entity History Query for an event.
	Reset TOC Content	Remove unsaved TOC changes.
	Resume	Resume workflows that are paused.
	Revert	Revert the selected leaf to the previous lifecycle operation.
	Run Link Inspector	The Link Inspector query enables you to view the status of all hyperlinks and cross references, and make any necessary changes prior to publishing.
	Save Baseline	Create a baseline of the Assembly at a specific point in time, allowing users to track changes to its structure and content from that point onwards.
	Search	Starts the search according to the entered search criteria.
	Search Person	Search for a user within the system.
	Select	Select a row in a table.
	Select Analytics Tree	On the *Home* page, displays the reporting trees.
	Select Entity List	On the *Home* page, display the list of entities that you have permission to view.
	Select Trees	On the *Home* page, Select Trees provides the option to select the Product Family, Countries, or Regulatory Intelligence trees.
	Set Binding	Change the binding rule for documents that are currently assigned to the assembly.
	Set Filter	Open a dialog box for creating or changing filters that are used to focus the results listed on tabbed pages or further focus results from certain queries.
	Set Target	Change the location of the target document to a leaf or bookmark.
	Show	Expand a closed area to reveal additional details.
	Slip Sheet	Indicates where a slip sheet has been inserted for an element in the assembly tree.
	Submission Readiness Report	For each module in an assembly, the Submission Readiness report shows the number and percentage of documents that fall into each of ten categories. Each category is related to a document assignment status, approval status if assigned, due date of the parent leaf, and whether a document is in Documentum.

Icon	Name	Purpose
	Start	Start the time tracking for an activity.
	Stop	Stop the time tracking for an activity.
	Start Workflow	Start client-specific workflows that are not associated to any entities.
	Tab	Indicates where a tab sheet has been inserted for an element in the assembly tree.
	Text Area (Expand)	Expand a hidden area on the screen.
	Text Area (Shrink)	Hide an area shown on the screen.
	TOC	Indicate where a table of contents (TOC) has been inserted in an assembly tree.
	Transfer	Assign an activity to a specific user, or set claim rules to users or user groups for claiming activities.
	Unassign; Unassign Document	Remove a placeholder assignment. Remove the link to a document from the assembly tree.
	Unclaim	Release an activity from a claimed state to make it available to other users to claim.
	Unlock	Release an entity from a locked state.
	Update (Home Page)	Provides access to wizards developed for ease of use in performing update actions.
	Update Overlay Settings	Update the overlays used for documents, TOCs, and/or cover pages for a specific range within an assembly.
	Update Status	Change the status.
	User Group	Open the *Add User/Group* wizard for creating a new user group for system security.
	View Baseline Differences	Enables changes to its structure and content to be viewed from the time of the baseline creation (Save Baseline must be run first).
	View Activities List	Displays all activities associated to a selected section and all its sub-sections.
	View Document List	The Document List query provides a view of the placeholders and assigned documents associated with an assembly structure.
	View Lifecycle History	Lifecycle History provides a view of the lifecycle history of the selected leaf.
	View File	Preview an assigned file or document.

Icon	Name	Purpose
	View Tab	View an example of the selected tab sheet attributes.
	View Tab Review File	Opens the PDF file with the generated tab review.
	View Where Used Query	Determine where a document is used across applications, countries, products, versions, and assemblies.
	Volumize	Generate volumes within an assembly structure based on the volume settings within the associated Publishing Settings Library.
	Withdraw	Remove or delete a pending detail.
	Workflow Admin	Open the *Workflow Admin* page for managing the workflow users and groups.
	Workflow Diagram	From *Workflow* view, highlights all currently active activities in the diagram. From Activity view, highlights only the current selected activity in the diagram.

Special Characters

Output locations, file names, and user names that include certain special characters might not be interpreted correctly by the system and can cause unexpected results.

With the exception of document names, overlay and cover page template names, and variables, avoid the use of these characters in Calyx RIM :

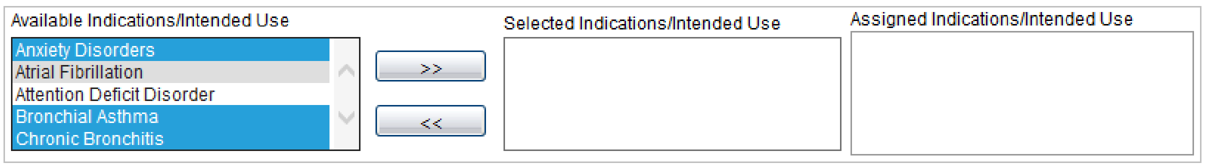
Special character	Description
\	backslash
/	slash, or forward slash
"	quotation mark
`	apostrophe, single quotation mark ***Note:*** *On most keyboards, this character shares a key with the ~ character.*
< >	left and right angle brackets ***Note:*** *Due to the thin-client Web interface of Calyx RIM, avoid using angle brackets (< >) in attributes. While these characters will be saved correctly, they will not display correctly when you view the page or entity.*
:	colon
#	number
&	ampersand
$	dollar
+	plus

Multi-Select Lists

There are two conventions for selecting multiple values: Available selection lists and Searchable selection lists.

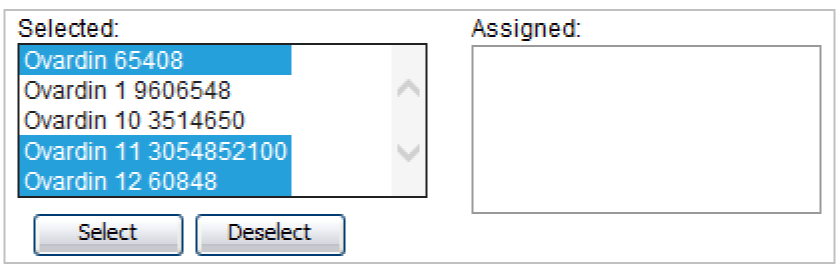
Available Selection Lists

In these selection lists, choose more than one item by pressing the `Ctrl` key and clicking to highlight each item. To add the highlighted items, click the >> button. The highlighted items are moved from the Available list to the Selected list. To remove selected items, use `Ctrl+click` to highlight the items in the Selected list and click the << button to move them back to the Available list. Items that appear in the Assigned list represent previously selected items that are currently associated with other Calyx RIM entities. These cannot be deselected.



Searchable Selection Lists

With searchable selection lists, you click Select to open a list from which you choose items.

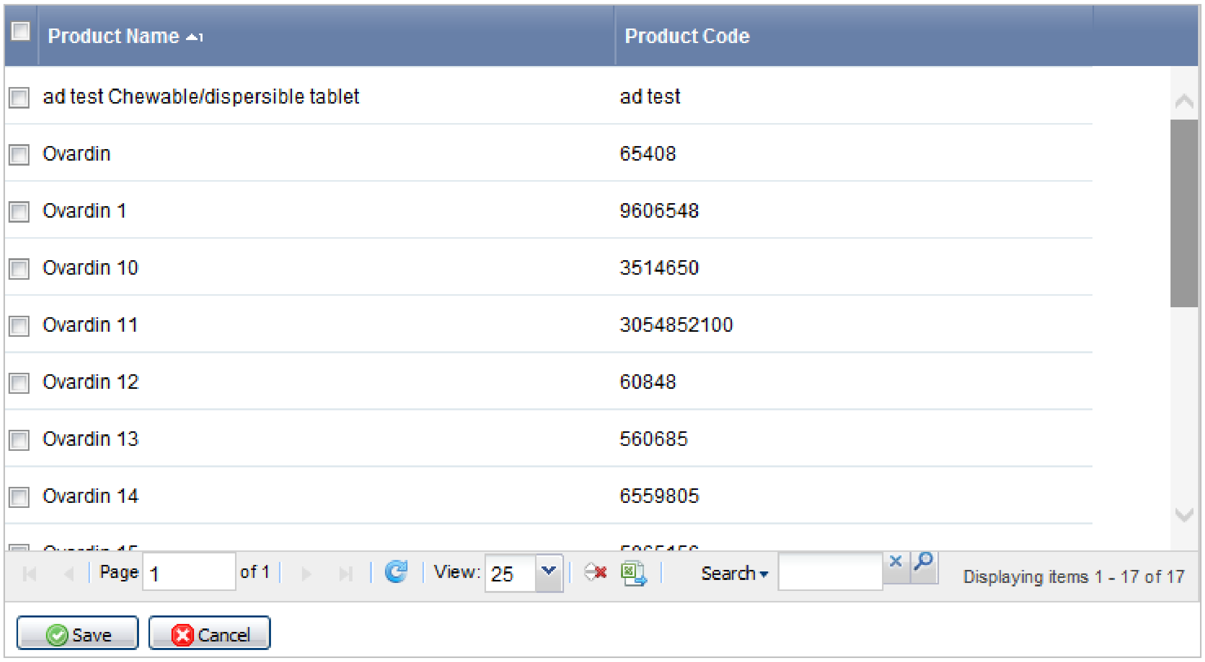


Using the sorting, paging, and data refresh tools available for all tables, you can locate the items you want to select. To refine the number of items listed, enter a search parameter in the Search field and click the Search icon. To limit the search to a column in the table, click Search and choose the column on which to perform the search. To clear the current search, click Cancel.

To choose an item, select the check box next to the item. You can choose all items on the current page by selecting the check box in the header row.

If you want to select every item returned by the search, change the number of items to display. In the View drop-down list, choose a value greater than the total number of items indicated next to `Displaying items` and then select the check box in the header row. Click Save and the items you have checked are populated in the *Selected* list.

To clear selected items, use `Ctrl+click` to highlight the items in the **Selected** list and click **Deselect**. Items that appear in the **Assigned** list represent previously selected items that are currently associated with other Calyx RIM entities. These cannot be deselected.



Set Date Attributes

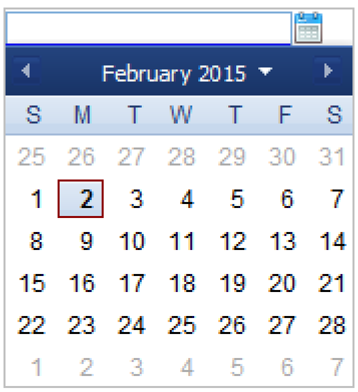
To set date attributes, you can choose dates using the calendar tool or you can enter them in the space provided. Using the calendar tool reduces data entry errors caused by mistakes in date formatting or keyed entries.

If the date is entered in the wrong format, or has invalid values, the invalid value will not be saved.

Calyx RIM supports the international date format `DD-MM-YYYY` by default. This format can be customized with a Calyx RIM override properties file.

Custom configurations must be coordinated with the Consulting Services Organization (CSO) group. Furthermore, regardless of the date format or your browser's language preference setting, Calyx RIM only supports English for dates.

To open the calendar tool and choose a date, click the Calendar icon.

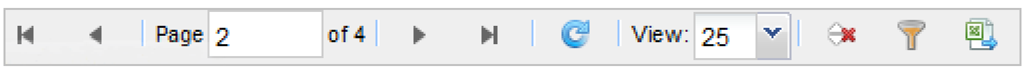


Tables

In Calyx RIM, tables provide the list view of entities and their details, displaying the number of data rows on a page and the total number of rows in an entire table.
When the tabular data spans more than one page, the range of data rows is displayed. You can change the number of data rows displayed by selecting a different value from the View drop-list located at the bottom of the page.

The default number of rows displayed on a page is 100. You can view and select up to 5000 rows. To change the default number and maximum number of data rows on a page, contact your Calyx account executive.

Viewing too many data rows on a page can reduce the speed and efficiency of processing and displaying the data.



Sort Columns

Calyx RIM enables you to specify up to four levels of sorting for columns in tables.
The example of the Applications tab table below shows three levels, where the table is sorted by application name within family type within application code. The blue column headers indicate the columns with which you are sorting the table. The numbered arrows next to the column name show the sorting level hierarchy (1st, 2nd, 3rd), and whether the column values are in ascending or descending order.

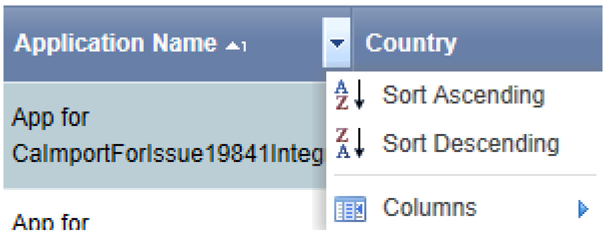
Family Type ▲2	Application Code ▲3	Application Name ▲1	Country	Keywords	Description
Pharmaceutical	1	1	United States		
Pharmaceutical	ad test	ad test	Azerbaijan		
Pharmaceutical	ad test 1	ad test 1	Bahrain		
Pharmaceutical	Application_code_222	Application_name_222	United States		
Pharmaceutical	eutest1	eutest1	Austria		
Medical Devices	pachage reg	pachage reg	United States		
Medical Devices	product reg	product reg	United States		
Pharmaceutical	000001	YK	United States		

To add a column to the sort, click the column header. The color of the header changes. You can specify up to four levels of column sorting. Sorting occurs as follows:

— Sorting begins with the first column you choose.
— The second column you choose is sorted within the first column.
— The third column you choose is sorted within the second column.
— The fourth column you choose is sorted within the third column.

If you choose a fifth column to sort, the first column you chose is removed from the sort order and the primary sorting begins with the second column.

The sort order of the column values is indicated by the up or down direction of the arrow in the header. An up arrow indicates ascending order (from A–Z), and a down-pointing arrow indicates descending order (Z–A). You can change the sort order of a column by either clicking the column header to toggle the direction of the arrow, or by hovering over the column header and clicking the menu arrow to choose a sort order, as shown in the following image.



To remove the sorting on a table, click the Clear Sort icon at the bottom of the table. Most Calyx RIM table views open with a default column already sorted, so you may want to clear the default sort first before specifying a custom sort.

Customizing Columns

Column Width

In a table, you can customize the column width, the column position, and whether the column is hidden or displayed.

1. To adjust the width of a column, hover your pointer over the border between two column headers. Your pointer will become a double-sided arrow.
2. Press and hold your left mouse button, then move the pointer left or right to adjust the column width.

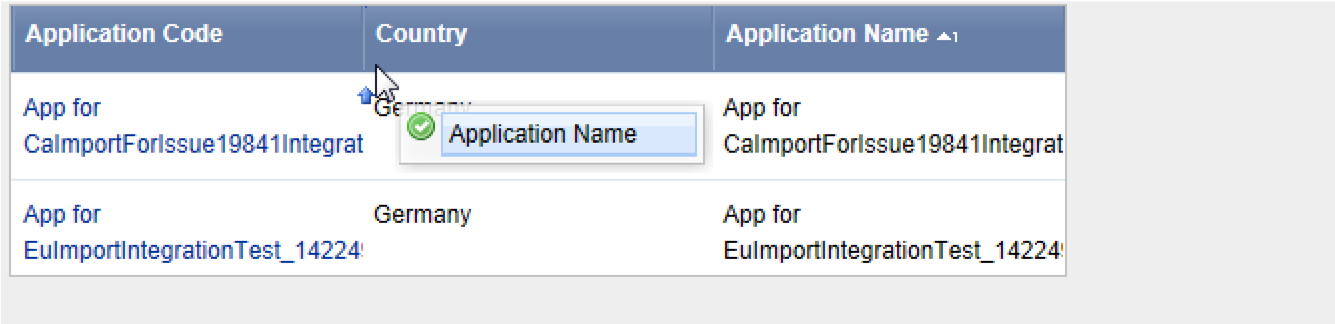
Column Position

In a table, you can customize the column width, the column position, and whether the column is hidden or displayed.

To change where a column appears in the table, press and hold your left mouse button on the column header, drag the column to the desired position.

Example

In the following image, the Application Name column is being positioned between the Application Code and Country columns.



A blue arrow appears to indicate where the column will be positioned.

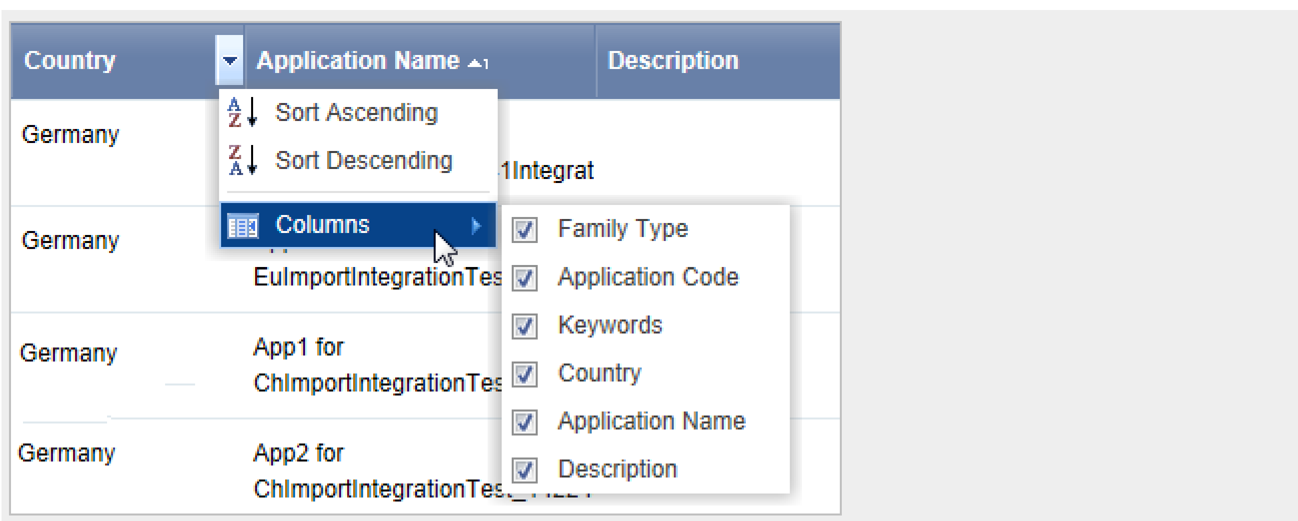
Hide Columns

In a table, you can customize the column width, the column position, and whether the column is hidden or displayed.

1. To hide a column, hover your pointer over any column header and click the menu arrow that appears to the right of the header.

   On the pop-up menu, hover your pointer over Columns to see the list of columns available for the table.
2. Select or clear the check boxes to show or hide columns.

   Example

   Selected columns are shown, cleared columns are hidden.

Navigate Pages of Table Data

Navigation icons on table data pages enable you to move forward, back, and to specific pages in large tables with multiple pages.

Use the following icons to navigate through multiple pages of table data:

Icon	Description
or	Go to the first or last page of table data.
or	Go to the previous or next page of table data.
Page 3 of 7	Go to a specific page.

Hyperlinks

Hyperlinks (also called links in this documentation) appear as blue text to differentiate them from regular text. As you position the pointer over a blue text link, it changes color. When you click the link, you are sent to the target page.

In the following image, the values in the Application Code column are links. These links open the *Application Attributes* page for the selected application name.

Family Type	Application Code	Application Name	Country
Pharmaceutical	App for CaImportForIssue19841Integrat	App for CaImportForIssue19841Integrat	Germany
Pharmaceutical	App for EuImportIntegrationTest_14224	App for EuImportIntegrationTest_14224	Germany

Reference Links

References can be linked to sources of information, such as documents, external URLs, and assemblies.

You can create reference links for the following entities:

- Product families
- Products
- Applications
- Events
- Sequences
- Registrations

- Tasks
- Submission Plan

Filters

Filters are useful for limiting search results to records that meet specific criteria. Basic filters are simple statements that consist of fields, operators, and values.

The following elements are included in a simple filter statement:

Element	Description
Field	The label that you see on an attributes page that identifies certain values (attributes). For example, a field on the *Product Attributes* page is `Product Name`.
Operator	A term used to test the relationship between values. For example, the operator `Equals` compares the value stored in the system to the value set in the filter and returns only the records that have equivalent values.
Value	The assigned attribute. For example, a value for Product Family Type could be `Pharmaceutical` or `Medical Device`.

When you set a filter, you are presented only with selectable options based on the entity you are filtering or the original query you selected to filter. For example, if you are filtering a list of product families, only fields and values related to product families are presented.

The same is true for operators. When adding a date value to a filter, the only operators available for you to select will be those relevant for date fields only.

Filter Duration

After setting a filter, the filter remains in effect until you change or clear it. Logging on and logging off of Calyx RIM does not affect the filter settings. For reference, the currently active filter statement appears above the listed items, so you can easily see the criteria that affects the listed results.

Group Filters

When you create a filter, you can use grouping operators (parentheses) to determine how filter statements are applied.

Do not create a group within a group. Nested grouping is not supported.

Filter Group Examples

The following statement returns results that have only `Medical Device` as the product family and may have the term `forceps` or `clamps` included in the product family name:

```
'Product Family Type' equals 'Medical Devices' and ('Family Name' contains
'forceps' or 'Family Name' contains 'clamp')
```

Compare this to a similar statement:

```
'Product Family Type' equals 'Medical Devices' and 'Family Name' contains
'forceps' or 'Family Name' contains 'clamp'
```

Without the parentheses, this filter returns records that can include other product family types in addition to `Medical Devices`, such as `Pharma-Med Device`, because the terms `forceps` or `clamp` appear in the product family name.

Filter Operators

You can apply operators to field values to refine the filter results.

This table lists typical filter operators, their descriptions, and the values to which they can be applied.

Operator	Field type	Description
Equals	All	Include only records that have the exact value selected. When Equals Empty is selected, only records with no value in the selected field are listed.
Not Equals	All except text	Exclude records that do not have the exact value selected. When Not Equals Empty is selected, only records that have any value in the selected field are listed.
Starts With	Text	Include records that contain values that begin with the value(s) selected.
Ends With	Text	Include records that contain values that end with the value(s) selected.
Contains	Text	Include records that contain selected values.
Does Not Contain	Text	Exclude only those records that contain values that end with the value(s) selected. To return results that do not contain any data, be sure to include a condition where the result should equal an empty value (i.e., Equals empty).
Before	Date	Include records assigned a date before the date selected in the filter statement.
After	Date	Include records assigned a date after the date selected in the filter statement.
Between	Date	Include records assigned between the dates selected in the filter statement.
In	Multi-select	Include records that have a specific value as one of the values selected for the field. You can use comma-delimited fields when setting up the filter criteria.

Operator	Field type	Description
Not In	Multi-select	Exclude records that have a specific value as one of the values selected for the field. You cannot use comma-delimited fields when setting up filter criteria.

Filter Symbols

Oracle is used as the basis for the Set Filter function, and some special characters should be used carefully.

Special characters that should be used with caution in a filter:

Symbol	Issue
% (Percent symbol)	Oracle perceives the percent sign as a wildcard. When the percent sign is entered as filtering criteria, the results are not filtered.
_ (Underscore)	The following occurs when using underscores in a filter: — No filtering occurs if you set a filter with only an underscore. — Inserting an underscore before or after characters (e.g., _abc, abc_, or _abc_) returns all records that contain the underscore character. — Inserting an underscore between characters (i.e., a_b or a_b_c) returns records that contain the characters presented in the designated order that have any single character between them.

Set Filter

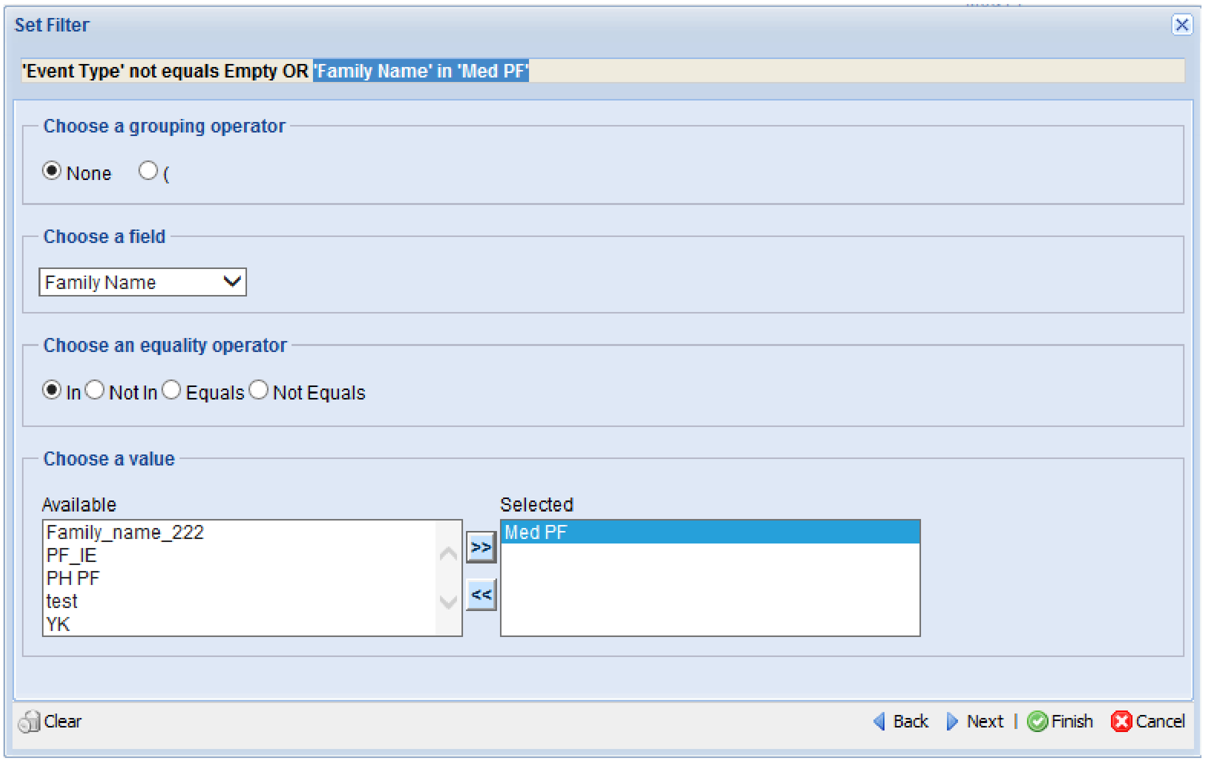
The Set Filter option offers flexibility in its ability to locate and quickly access entity-specific information stored in Calyx RIM based on the selected settings.
The Set Filter option is available on several tabbed pages, such as *Product Families*, *Registrations*, *Events*, and others.

The *Set Filter* dialog box, which is invoked by clicking the Filter icon on tabbed pages, offers the same filter setting capability as the Querying option available through the Go To menu. The difference is that filters for Querying are applied to queries, rather than entity-specific items listed on a tabbed page.

As you make selections, additional options become available. You may use drop-down lists, radio buttons, multi-select fields, or text boxes to build the filter.

Note: *Using symbols in the filter, such as the underscore (_) or percent sign (%), may return unexpected results.*

As the filter is developed by selecting options, text appears in the field at the top of the dialog box showing the filter statement. This information is read-only. The portion of the filter under construction is highlighted for reference.



Set Filter Options

The following options are available as the filter is set:

Icon	Description
Clear	Remove all filter settings, regardless of the portion of the filter being viewed.
Back	Go back to the previous view of the *Set Filter* dialog box where settings can be reviewed or changed.
Next	Go forward to the next view of the *Set filter* dialog box where settings can be reviewed or changed.
Finish	Apply the filter settings. The filter results are maintained until the filter settings are cleared.
Cancel	Cancel the filter settings in progress.

Set Filter Criteria

After setting filter criteria, the filter statement is displayed at the top of the listed results. The filter settings remain in effect until you modify or clear the filter.

To set a filter:

1. Click Filter.

2. On the Set Filter dialog box, select a `grouping operator` or a `field` to query.
3. Select an equality operator.
4. Select a value.
5. Do one of the following:
   — Click Next to set additional filter criteria, and proceed to the next step.
   — Click Finish to view the results, and skip the remaining steps in this procedure.
6. Select an operator.
7. Select a start grouping operator, if needed.

   If you select a start grouping operator (left parentheses) at any point in the filter statement, you must select the close grouping operator (right parentheses) to close the grouping.
8. Repeat as needed to complete the filter statement.
9. Click Finish.

Modify a Filter

Filter settings remain in effect until you modify or clear the filter. You can modify the existing filter to create a new filter.

To modify a filter:

1. Click the Filter icon.
2. On the *Set Filter* dialog box, use the Back and Next buttons to view the portion of the statement you want to edit.
3. Modify the settings as needed.
4. Click Finish.

Clear a Filter

You cannot recover a filter after it has been removed. Before you clear a filter, consider whether modifying the filter is a more efficient option.

To clear a filter:

1. Navigate to the page affected by the filter.
2. Click the Clear button on the upper filter field.
   The filter is removed and cannot be recovered.
3. In addition to this method of clearing an existing filter, you can remove the filter by selecting a similar option in the *Set Filter* dialog box.

Export to Excel

You can export records listed on a tabbed page (such as the ***Product Family*** page) or query results to a Microsoft® Excel® spreadsheet.

When you export records to Excel, the resulting spreadsheet contains all listed information, including data that appears under columns that you cannot see in the immediate viewing area without scrolling.

When a filter is set to limit query results or records listed on a tabbed page, only those records that appear after the filter is applied will be included in the Excel spreadsheet.

Export Records to Excel

You can export records from Calyx RIM to Microsoft® Excel®.

With Office 2003, Excel supports a limit of 65,536 records. With Office 2007 and greater, Excel supports one million records.

To export records to Excel:

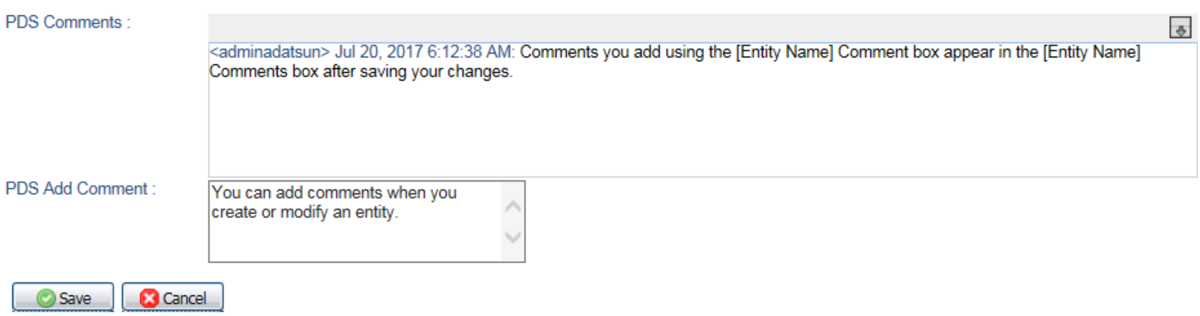
1. Click the tab that lists the data you want to export.
2. At the bottom of the page, click the **Export to Excel** icon .
3. Follow the prompts in the ***File Download*** dialog box.

Discussion Threads

You can view and contribute to discussion threads for entities to which you have security privileges. The Comments attribute enables you to add text about any entity in Calyx RIM.
Comments are stamped with your user ID and date of the entry. Security applies to the entire discussion thread, and only an administrator can modify a saved comment.

When using Comments:

- For assembly templates, you can use the Add Comment box to provide instructions to users about how to use the templates and provide a broader instruction to help users standardize the submission creation processes for your organization.
- When using multi-byte character sets (Russian, Japanese, etc.) an error may occur when persisting strings to the database that exceed the byte length set for the column even when the string length validation is successful. For example: If you are using a Russian character set (which contains two byte characters), you can enter a 2001-character string in the Comments attribute (which can contain 4000 characters). Calyx RIM will treat the entry as a valid length string. Oracle however, will generate an error because a 2001-character length string consisting of two byte characters will in fact be 4002 bytes. This exceeds the Oracle limit for the column (4000 bytes).
- The Comments text box is not displayed on *View and Modify* pages if there are no existing comments.
- If you create a discussion thread on a Product Detail Set or Product Detail Set Template and query on it by executing the Entity Audit Trail query, choosing an Entity Type of Discussion Thread, and selecting an Action (I/U/D), the Associated Entity Type and Parent ID columns for the records returned are blank.



Configurable Browse and Link

Configurable Browse and Link functionality provides the ability to link to documents within a Calyx RIM entity. This functionality is available for all entities except assemblies.

Using an XML configuration file, you can add a link attribute to an entity, which consists of a link type drop-down list and hyperlink text box. Then, as you would for a reference entity, you define a link type and a hyperlink that targets DMS content (including file system), a Calyx RIM assembly, the URL to an external site, or the URL to an internal Calyx RIM location using the Copy URL function.

The following conditions apply to the configurable browse and link functionality:

- All XML configurations should be made through the Regulatory Information Management (RIM) Client Enablement group.
- To create the link type drop-down list and hyperlink text box, the XML configuration file uses two extra text fields per link. All Calyx RIM entities have 20 extra text fields, except for PDS details which have 10 extra text fields. This means you can have a maximum of 10 links per Calyx RIM entity, and a maximum of 5 links per PDS detail.
- Standard DMS security applies to DMS content links. You are prompted for your DMS ID and password if you are not already logged in.
- For DMS content links, if the most current version is selected (whether it is the only version, or one of many), the link binds to `CURRENT`. If a non-current version is selected, the link binds to that specific version.
- Calyx RIM assembly links can be made to standalone assemblies, assembly templates, views, and sequence assemblies.
- External URL links must include the `http://` prefix.
- Configurable browse and link functionality is not available for the data administration pages.

Configurable browse and link attribute values are not copied as part of the following copy features in Calyx RIM:

- Copy product
- Copy component
- Copy application
- Copy task
- Copy event
- Creating a PDS from a PDS template
- Creating a PDS template from a PDS
- Copy PDS details

Electronic Signatures (E-Signature)

The Calyx RIM Electronic Signature (E-Signature) feature can capture electronic signatures for add, modify, and delete activities for specific entities indicated by system administration. This creates an audit trail event for valid and invalid signatures.

Electronic signature functionality is an optional feature that requires special configuration in Calyx RIM. Contact Client Enablement to enable electronic signatures for your Calyx RIM version.

Add, modify, or delete pages for following entity types:

- Product Family
- Product
- Pharmaceutical Product
- Application
- Event
- Event Country (Event Country Attributes/Status Dates Tab, and Lock/Unlock Event Country for adding pages only)
- Event Closure (Modify Event page, Update Status Wizard, and Update Event-Country Wizard only)
- Sequence (Sequence/Status Dates Tab)
- Registration (*Registration Attributes*, *Copy Package Set Registration* Wizard)
- Product Detail Set
- Full Product Presentation (*Full Product Presentation Attributes*, *Copy Full Product Presentation* Wizard)
- Registration Attachment (*Registration Attachment Attributes*, *Copy Registration Attachment* Wizard)
- Registration FPP Attachment
- References
- Tasks (Task/Sub Task Status Dates Tab)

All wizards except the following can be configured for electronic signature:

- Create Study Report
- Bulk eCTD Import
- Create eCTD
- Create Timeline/Event Plan
- XEVMPD Acknowledgement
- XEVMPD Submission

Save an Electronic Signature (E-Signature)

When the Electronic Signature (E-Signature) feature is enabled for an entity type in Security Administration, you must provide your user name and password for each activity you perform on that type of entity. You must also choose a reason for performing the activity.

Calyx RIM validates your signature and enables you to complete the activity. If you enter an invalid user name or password, Calyx RIM prevents you from completing the activity and logs the error in an audit log.

1. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature and SSO are enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click Next. c. Validate your identity by entering your user credentials in the dialog box.
When electronic signature is enabled and SSO is disabled	a. Select a reason and enter comments for the reason. b. Enter user ID and password and click Next.

2. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature and SSO are enabled	a. Select a reason and enter comments for the reason. b. Select Save. c. Validate your identity by entering your user credentials in the dialog box.
When electronic signature is enabled and SSO is disabled	a. Select a reason and enter comments for the reason. b. Enter user ID and password and click Save.

Calyx RIM License Modules

The Calyx RIM® modules enable different organizational roles and functions within the regulatory lifecycle of a drug product. Each module focuses on one particular area of expertise and includes the ability to control access permissions within the module for specified users and groups.

By assigning access permissions to users or roles, you can enable some users to merely observe or access queries and summaries while enabling others to perform the daily operations of project management, research, planning, and publishing.

Available Modules	Description
Calyx RIM Workflow Integration	Enables you to utilize client-specific workflows that contain multiple activities, with dependencies and preset fields, that guide processes within the system.
Calyx RIM for XEVMPD	Enables you to capture, maintain, and submit data about pharmaceutical products to comply with the Extended EudraVigilance Medicinal Product Database (XEVMPD) directive.
Calyx RIM for Analytics	Enables you to generate reports about Calyx RIM activities. These reports include dashboard reports, predefined reports, guided ad hoc reports, and ad hoc reports (which you define from scratch). ***Note:*** *This module includes the Calyx InSight Dashboard module, but you can have InSight Dashboard without the rest of the Analytics module.*
Calyx InSight Dashboard	Provides analysis reports of key performance indicators. Dashboard reports provide senior management with an at-a-glance perspective of the current status of a product, unlocking the business value of Calyx RIM data. Viewing Calyx InSight Dashboard reports, senior managers can quickly understand the current product posture, enabling rapid and informed business decisions. ***Note:*** *This module is included in the Calyx RIM for Analytics module, but you can have InSight Dashboard without the rest of the Analytics module.*
Registration Planning and Tracking	(RPT) enables you to plan registration activities and collect registration data without product formulation details. It improves affiliate communication, enables you to track the status of overall global product registration activities, and maintain product registration compliance.

Available Modules	Description
Product Detail Management	(PDM) enables you to track product formulation and SPL exports. It also provides queries about where products are registered and other registration information.
Submission Planning and Tracking	(SPT) enables you to create, review and track submissions from planning to publishing. It also automates assembly creation and enables you to monitor the authoring process.
Registered Document Analysis	(RDA) leverages lifecycle submission information to enhance the DMS repository for better decision support based on usage information. It enables you to query for the external approval status of documents and to perform impact analysis of registered document changes.
Electronic Lifecycle Publishing	(ELP) simplifies eCTD creation and is required to publish assemblies as eCTD submissions.
Paper Review Publishing	(PRP) enables you to build assemblies for publishing to paper. PRP enables you to add paper elements such as TOCs, cover pages, overlays, and cross references to electronically published submissions suitable for generating study report submissions, hybrids, and other electronic submission formats. Using both the ELP and PRP licenses enables you to add these publishing elements to eCTD lifecycle submissions. Finally, PRP also enables you to publish an entire assembly to a single file electronically.

License Modules: Product Families, Clinical Trial Shared Data

Subfeature	Subfeature Description	License Modules
Product family categorization	Define parent active substance family	— Electronic Lifecycle Publishing — Paper Review Publishing — Product Detail Management — Registered Document Analysis — Registration Planning and Tracking — Submission Planning and Tracking
Product family extended attributes	Full support includes product family attributes	— Registration Planning and Tracking — Product Detail Management
CT Shared Data	Clinical Trial Shared Data for a product family	— Registration Planning and Tracking — Product Detail Management

License Modules: Products, Pharmaceutical Products

Subfeature	Subfeature Description	License Modules
Product detail	Define consumable products (for example, dosage forms)	— Registration Planning and Tracking — Product Detail Management
Pharmaceutical product detail	Define a product used to treat disease (for example medicines or drugs)	— Registration Planning and Tracking — Product Detail Management

License Modules: Registrations, Full Product Presentations, Registration FPP Attachments and FPP Previous EV Codes

Subfeature	Subfeature Description	License Modules
Registration detail	Define registration details, including those that vary by country for MRP applications.	— Registration Planning and Tracking — Product Detail Management
Copy Package Set Registration	Copy a package set registration. At least `WRITE` permissions for the Registrations and Full Product Presentation (FPP) (applicable to the *New Package Set specific Registration(s)* flow) in Entity Security section.	— Registration Planning and Tracking — Product Detail Management
Full product presentation detail	Define detailed information about the product (for example Special Measures, Product Strength).	— Registration Planning and Tracking — Product Detail Management
FPP previous EV code detail	Define the previous EV code for the full product presentation.	— Registration Planning and Tracking — Product Detail Management
Registration FPP attachment detail	Presents an attachment for the detailed product information.	— Registration Planning and Tracking — Product Detail Management

Subfeature	Subfeature Description	License Modules
Copy full product presentation	Copy a full product presentation under the same registration, or under different registrations. Requires at least `WRITE` permissions for the Full Product Presentation (FPP) in the Entity Security section.	— Registration Planning and Tracking — Product Detail Management

License Modules: Registration Attachment

Subfeature	Subfeature Description	License Modules
Registration Attachment	Registration Attachment entity is a Printed Product Information (PPI) attachment type and should be created to later attach it to the Full Product Presentation.	— Registration Planning and Tracking — Product Detail Management
Copy registration attachment	Copy a registration attachment. — At least `WRITE` permissions for the Registration Attachment in Entity Security section. — At least `WRITE` permissions for the Full Product Presentation (FPP) in Entity Security section.	— Registration Planning and Tracking — Product Detail Management

License Modules: Applications

Subfeature	Subfeature Description	License Modules
Application detail	Ability to define overall marketing authorization (for example, NDA)	— Electronic Lifecycle Publishing — Paper Review Publishing — Product Detail Management — Registered Document Analysis — Registration Planning and Tracking — Submission Planning and Tracking

Subfeature	Subfeature Description	License Modules
Application Countries tab	Support for European procedures (MRP and CP) including collection of country-specific data (primarily dates) for the application	— Electronic Lifecycle Publishing — Paper Review Publishing — Product Detail Management — Submission Planning and Tracking — Registration Planning and Tracking
Copy application	Copy an application	— Registration Planning and Tracking — Submission Planning and Tracking — Registered Document Analysis

License Modules: Comparators

Subfeature	Subfeature Description	License Modules
Comparators	Comparators are used in clinical trials to compare the success of a medicine under study to another medicine or placebo.	— Registration Planning and Tracking — Submission Planning and Tracking

License Modules: Events

Subfeature	Subfeature Description	License Modules
Event detail	Define initial filing event and other major updates (for example, variations) to an application	— Electronic Lifecycle Publishing — Paper Review Publishing — Product Detail Management — Registered Document Analysis — Registration Planning and Tracking — Submission Planning and Tracking
Copy Event Wizard	Copy an event to multiple applications in the product family associated with a source event.	— Electronic Lifecycle Publishing — Product Detail Management — Registration Planning and Tracking — Submission Planning and Tracking

Subfeature	Subfeature Description	License Modules
Create Submission wizard	Automates creation of initial applications, major updates and amendments	— Electronic Lifecycle Publishing — Paper Review Publishing — Registered Document Analysis — Registration Planning and Tracking — Submission Planning and Tracking
Event country status schedule	Define projected event status dates, track status history, and compare actual and planned dates for major milestones	— Registration Planning and Tracking — Submission Planning and Tracking

License Modules: Sequences

Subfeature	Subfeature Description	License Modules
Sequence detail	Define filings/amendments (regulatory submission correspondence to authorities in support of an application)	— Electronic Lifecycle Publishing — Paper Review Publishing — Registered Document Analysis — Registration Planning and Tracking — Submission Planning and Tracking
Sequence status schedule	Define projected sequence status dates, track status history, and compare actual and planned dates for major milestones	— Registration Planning and Tracking — Submission Planning and Tracking

License Modules: Product Detail Sets (PDS)

Subfeature	Subfeature Description	License Modules
Product detail set detail	Capture product detail approvals, such as for substance, product, packaging manufacturers, labeling, and product indications	Product Detail Management
PDS templates	Save PDS information within a product family as a template	Product Detail Management

License Modules: Assembly Types

Subfeature	Subfeature Description	License Modules
Lifecycle sequence assemblies	Build hierarchical collections of source documents associated with specific regulatory activities and sequences, and add to the current view for lifecycle	— Electronic Lifecycle Publishing — Registered Document Analysis — Submission Planning and Tracking — Paper Review Publishing
Supporting sequence assemblies	Build hierarchical collections of source documents associated with specific regulatory activities and sequences	— Electronic Lifecycle Publishing — Paper Review Publishing — Registered Document Analysis — Submission Planning and Tracking
Standalone assemblies	Build hierarchical collections of source documents for miscellaneous use	— Electronic Lifecycle Publishing — Paper Review Publishing — Registered Document Analysis — Submission Planning and Tracking
Assembly templates	Build an assembly template	— Electronic Lifecycle Publishing — Paper Review Publishing — Registered Document Analysis — Submission Planning and Tracking

License Modules: Activity Workflow

Subfeature	Subfeature Description	License Modules
Activities	Activities are steps within the Workflow that are required to complete the assigned Workflow. Workflows can contain multiple Activities, with dependencies and pre-set values.	Calyx RIM Workflow Integrations

License Modules: Projects

Subfeature	Subfeature Description	License Modules
Global Project Planning (GPP) wizard	Facilitates planning and data entry for multiple countries or applications At least `WRITE` privileges for Projects and Events *Home* page access security enabled for *GPP* wizard	— Registration Planning and Tracking — Submission Planning and Tracking

License Modules: Tasks, Notifications, and References

Subfeature	Subfeature Description	License Modules
Task detail	Define hierarchical to-do lists associated with other entities	— Registration Planning and Tracking — Submission Planning and Tracking
Task status schedule	Define the sequence of statuses for a task, and for each status, the projected date when the task first has the status.	— Registration Planning and Tracking — Submission Planning and Tracking
Notification detail	Define and automatically send e-mail notifications based on data updates, approvals, and other changes in Calyx RIM	— Registration Planning and Tracking — Submission Planning and Tracking
Reference detail	Associate external documents, URLs, and internal links with entities; supports correspondence and DMS integration	— Registration Planning and Tracking — Submission Planning and Tracking

License Modules: Change, Change Details

Subfeature	Subfeature Description	License Modules
Change	Defines the actual regulatory change being planned or requested and have specific metadata associated.	Registration Planning and Tracking

Subfeature	Subfeature Description	License Modules
Change details	Capture details of the Change as a sub-entity to the Change entity.	Registration Planning and Tracking

License Modules: Reports

The reports listed in the following table include:

— Reports that you can generate by using Calyx RIM queries
— Reports that you can generate by using Calyx RIM for Analytics

Subfeature	Subfeature Description	License Modules
Querying menu	Run queries and quick search; not all quick search entities may apply to the module; available queries vary by module; see Queries available by license.	The modules related to the kind of query that you run.
Public/private customized queries	Create both private and public custom queries.	— Electronic Lifecycle Publishing — InSight for Analytics — Paper Review Publishing — Product Detail Management — Registered Document Analysis — Registration Planning and Tracking — Submission Planning and Tracking
Ad hoc Reporting	Create and execute ad hoc reports against the Calyx RIM reporting schema.	— Calyx RIM for Analytics — Product Detail Management — Registered Document Analysis — Registration Planning and Tracking — Submission Planning and Tracking
Specialized assembly queries	Execute specialized queries directly from the assembly tree.	— Electronic Lifecycle Publishing — Paper Review Publishing — Registered Document Analysis — Submission Planning and Tracking

Subfeature	Subfeature Description	License Modules
Dashboard reports	Provides an analysis of key performance indicators that show the current status of a product.	Calyx RIM for Analytics or Dashboard, and one or more of the following: — Electronic Lifecycle Publishing — Paper Review Publishing — Product Detail Management — Registered Document Analysis — Registration Planning and Tracking — Submission Planning and Tracking
Application, Event, Sequence report	Provides information that you select about product families, applications, events, and sequences.	Calyx RIM for Analytics and at least one of the following: — Registration Planning and Tracking — Submission Planning and Tracking
Global Registration Activity by Product Family (Top 10 Countries) report	Provides an overview of the top 10 countries with the highest registration count for the selected product family.	— Dashboard — Registration Planning and Tracking
Registration Status with Product report	Provides the following information: — For each product in the report, the total number of registrations that have a specific status — For each registration status, whether the registrations are currently marketed — The total number of registrations for all specified product families	— InSight for Analytics — Registration Planning and Tracking

Subfeature	Subfeature Description	License Modules
Registration Status Summary report	Provides the: — Number of registrations for a specific product family or country — For each product associated with the product family or country, the number of registrations for each registration status (planned, pending, withdrawn, or expired)	To generate the report, Calyx RIM for Analytics or Dashboard, and at least one of the following: — Product Detail Management — Registration Planning and Tracking To add the report to the *Dashboard* page: — Dashboard — Registration Planning and Tracking
Registration Submissions Due by Month report	Shows the number of registration submissions that are due in each month in a specific time period.	— Dashboard — Registration Planning and Tracking
Regulatory Maintenance Submissions report	Queries Calyx RIM event data and provides metrics on regulatory maintenance submissions for a specific time period, for specific regions and countries.	Dashboard and at least one of the following: — Electronic Lifecycle Publishing — Paper Review Publishing — Registration Planning and Tracking — Submission Planning and Tracking
Status of Planned Submissions report	Lists planned submissions by sequence. A planned submission is an open sequence with the status mapped to the internal status submitted.	— Calyx RIM for Analytics — Submission Planning and Tracking
Submission Status Dates by Country and Event Type report	Shows the projected status dates and actual status dates for events, listed by product family, for each country.	— Calyx RIM for Analytics — Submission Planning and Tracking
Task Status by Application report	Provides, for each specified application and task type, the number of uncompleted tasks that have had the current status for a time period that falls in a specific range of days.	Dashboard and at least one of the following: — Registration Planning and Tracking — Submission Planning and Tracking

Subfeature	Subfeature Description	License Modules
Task Status by Event report	Provides, for each specified event and task type, the number of uncompleted tasks that have had the current status for a time period that falls in a specific range of days.	Dashboard and at least one of the following: — Registration Planning and Tracking — Submission Planning and Tracking
Task Status by Sequence report	Provides, for each specified sequence and task type, the number of uncompleted tasks that have had the current status for a time period that falls in a specific range of days.	Dashboard and at least one of the following: — Registration Planning and Tracking — Submission Planning and Tracking
Total Product Registrations by Month Dashboard report	Provides information for detecting monthly trends in the volume of registration submissions.	— InSight for Analytics — Registration Planning and Tracking
Total Product Registrations by Month report	Provides information for detecting monthly trends in the volume of registration submissions.	— Dashboard — Registration Planning and Tracking
Total Pending Approvals (Top 10 Products) report	Provides information about pending approvals for the 10 countries that have the largest numbers of pending approvals.	— Dashboard — Registration Planning and Tracking
Total Tasks by Task Type report	Provides the following for each task type that users are performing during a specified time period: — The number of tasks performed — For each month, the number of tasks that reached each stage of completion: 0% complete, 30% complete, 45% complete, 80% complete, and 100% complete	Dashboard and at least one of the following: — Registration Planning and Tracking — Submission Planning and Tracking

Subfeature	Subfeature Description	License Modules
Total Submissions by Month	Illustrates the trend in submission volume on a monthly basis in a line chart.	Dashboard and at least one of the following: — Electronic Lifecycle Publishing — Paper Review Publishing — Submission Planning and Tracking
Worldwide Approvals (Top 10 Regions) report	Graphically depicts an overview of the top 10 regions based on the number of approvals. The report also includes an analysis of application types and activity types.	Dashboard and at least one of the following: — Electronic Lifecycle Publishing — Paper Review Publishing — Registration Planning and Tracking — Submission Planning and Tracking

License Modules: Approval Management

Subfeature	Subfeature Description	License Modules
Approved views	Create and view document collections consisting of currently approved versions for a particular country; full support includes ability to create new assemblies from these views	Registered Document Analysis
Update Status wizard	Automate approval of an application or major update	— Registered Document Analysis — Registration Planning and Tracking — Submission Planning and Tracking

License Modules: Submittal Management and Lifecycle

Subfeature	Subfeature Description	License Modules
Submitted view	Create and view document collections consisting of currently submitted versions for a particular country; create and manage eCTD lifecycle; full support includes ability to create new assemblies from these views	— Electronic Lifecycle Publishing — Registered Document Analysis — Submission Planning and Tracking (does not enable you to create new assemblies)
Change Submittal Status wizard	Automate submittal of an application or major update and creation of lifecycle	— Electronic Lifecycle Publishing — Paper Review Publishing — Registered Document Analysis — Submission Planning and Tracking — Registration Planning and Tracking
Add to/remove from lifecycle	Manually create and manage lifecycle	— Electronic Lifecycle Publishing — Registered Document Analysis
Working view	Assign changes and leaf operations from a cumulative view of the eCTD submission's sequences	— Electronic Lifecycle Publishing — Registered Document Analysis — Submission Planning and Tracking
Sequence view	View the current cumulative sequence	— Electronic Lifecycle Publishing — Paper Review Publishing — Registered Document Analysis — Submission Planning and Tracking
Publishing view	Publish the current cumulative sequence and add publishing effects	— Electronic Lifecycle Publishing — Paper Review Publishing — Registered Document Analysis — Submission Planning and Tracking

License Modules: General Assembly

Subfeature	Subfeature Description	License Modules
General assembly features and functions	Expand/collapse all, edit hierarchical assembly structure (including lifecycle actions, if applicable), browse or search document repositories and assign documents, retrieve document properties from DMS, view DMS documents, modify assembly attributes, delete assemblies.	— Electronic Lifecycle Publishing — Paper Review Publishing — Registered Document Analysis — Submission Planning and Tracking
Import/export	Create an assembly from a template, XML assembly file, or VDM. Export assemblies to XML assembly files and VDMs.	— Electronic Lifecycle Publishing — Paper Review Publishing — Registered Document Analysis — Submission Planning and Tracking
Document placeholders	Create a planned document in the assembly.	— Electronic Lifecycle Publishing — Paper Review Publishing — Registered Document Analysis — Submission Planning and Tracking
Mass-apply version bindings	Incrementally set bindings across the assembly, including locking the binding to the current version.	— Electronic Lifecycle Publishing — Paper Review Publishing — Registered Document Analysis — Submission Planning and Tracking
View file from document and leaf	Viewing in-place repository, submission, and published content.	— Electronic Lifecycle Publishing — Paper Review Publishing — Registered Document Analysis — Submission Planning and Tracking
Document status awareness	Binding icons and View Document List query.	— Electronic Lifecycle Publishing — Paper Review Publishing — Registered Document Analysis — Submission Planning and Tracking
Support and assignment of unfinalized documents	View status of unfinished documents for assembly.	Submission Planning and Tracking

License Modules: Planning and Tracking

Subfeature	Subfeature Description	License Modules
Planning and tracking assembly features and functions	Edit document path and binding information, view/assign related documents, export assembly to Microsoft Excel.	— Submission Planning and Tracking — Registration Planning and Tracking
Assembly search and replace	Search and replace text in assembly element attributes for planning and creating templates of document locations and assignments.	Submission Planning and Tracking
Assembly Status query	Provides the current assembly status including performance metrics.	Submission Planning and Tracking

License Modules: Review and Approval

Subfeature	Subfeature Description	License Modules
Review and approval assembly features and functions	Version assemblies with assembly currency	Submission Planning and Tracking
Incremental locking	Incrementally lock assembly by module and by section or folder hierarchy	Submission Planning and Tracking
Assembly baselines and baseline querying	Create baselines for assembly comparison querying	Submission Planning and Tracking
Assembly reference location	Create and set reference locations and synchronize with DMS	Submission Planning and Tracking
Assembly status change	Change status of assembly including automatic lock down if assembly is finalized	Submission Planning and Tracking
Unlock the folder	Unlock the locked assembly folder.	Submission Planning and Tracking

License Modules: Document Analysis

Subfeature	Subfeature Description	License Modules
Document analysis features and functions	Create approved views, query and view registered documents, query and view lifecycle history.	Registered Document Analysis
Where Used query	Determine where a document is used across applications, countries, products, versions, and assemblies. The Output File hyperlink in the Where Used query is supported only for sequence assemblies, not standalone and template assemblies.	— Registered Document Analysis — Submission Planning and Tracking

License Modules: General Publishing

Subfeature	Subfeature Description	License Modules
Publishing job queue and audit trail	View the status of all publishing jobs; sort, export, and cancel jobs.	— Electronic Lifecycle Publishing — Paper Review Publishing
Publishing Readiness query, Summary query, Link Inspector, and publishing log	View eCTD conformity and status before and after the publishing job is executed.	— Electronic Lifecycle Publishing — Paper Review Publishing
Repository export utility	Transfer published output from any repository source to any repository destination (DMS or File/Folder).	— Electronic Lifecycle Publishing — Paper Review Publishing
Automatic extractions	Create document extractions for use in bookmarks, TOCs, and links automatically upon assignment.	— Electronic Lifecycle Publishing — Paper Review Publishing (with Calyx RIM Rendering only)

Subfeature	Subfeature Description	License Modules
Automatic renditions	Create PDF renditions automatically and by request upon publishing or Prepare to Publish when existing renditions are missing or outdated. Requires an additional license for Calyx RIM Rendering.	— Electronic Lifecycle Publishing — Paper Review Publishing (with Calyx RIM Rendering only)

License Modules: eCTD Publishing

Subfeature	Subfeature Description	License Modules
eCTD publishing assembly features and functions	Create eCTD and electronic output, specify assembly-level publishing options for eCTD, links, and variables, change element types to specify leaf-specific publishing properties, request generated published output (eCTD and electronic).	Electronic Lifecycle Publishing
Electronic hyperlinks	Create, retarget, and set channel and settings on hyperlinks.	— Electronic Lifecycle Publishing — Paper Review Publishing
Reference leaf elements	Create leaf elements to reference other leaf elements with querying on referenced leaf elements for a specific submission.	— Electronic Lifecycle Publishing — Registered Document Analysis (query only)
eCTD import and merge	Import one or multiple eCTD sequences; merge eCTD sequences.	Electronic Lifecycle Publishing
Create eCTD wizard	Create or update an eCTD sequence.	Electronic Lifecycle Publishing
Bulk eCTD Wizard	Migrate multiple eCTD submissions to Calyx RIM from another system in a supported document management system (DMS).	Electronic Lifecycle Publishing
Create Study Reports wizard	Add study reports to an eCTD sequence.	Electronic Lifecycle Publishing
Create Submission Plan Wizard	Create a submission plan and associate entities such as applications, events, and sequences to the submission plan.	— Electronic Lifecycle Publishing — Submission Planning and Tracking

License Modules: Paper Publishing

Subfeature	Subfeature Description	License Modules
Paper publishing assembly features and functions	Create paper and electronic output, specify assembly-level publishing options for publishing effects, change folder and document attributes for publishing effects, request published output (paper and electronic).	Paper Review Publishing
Table of contents	Create, edit, generate, and modify TOCs. Access the TOC editor.	— Electronic Lifecycle Publishing — Paper Review Publishing
Special sheets	Create, edit, generate, and modify special sheets including slip sheets, tabs, and cover pages.	Paper Review Publishing
Volumes	Create and modify volumes, bulk volumize, move, lock, and manipulate volumes.	Paper Review Publishing
Overlays	Define and use overlays; define page size, shape, scaling, and format for output.	Paper Review Publishing
Paper cross-references	Create, retarget, and set channel, stamp, and settings on paper cross-references.	Paper Review Publishing

License Modules: Administration

Subfeature	Subfeature Description	License Modules
Administration menus (Data, Security and Technical)	Modify data picklists, connect to and define DMS and file system repositories, administer security. Not all options displayed to an administrator are available in all modules. For example, picklist options for data admin may not be displayed in an application. Notification administration does not apply to all modules. Includes all audit trail querying.	— Electronic Lifecycle Publishing — Paper Review Publishing — Registered Document Analysis — Registration Planning and Tracking — Product Detail Management — Submission Planning and Tracking

Learn About Calyx RIM

Calyx RIM® 6.2 user assistance documentation is available for more information on the release.

The following documentation is available for Calyx RIM:

— Calyx RIM Database Migration Release Notes - Provides information about the SQL database scripts used to perform new installations and upgrade migrations for the Calyx RIM database.
— Calyx RIM Release Notes - Provides last-minute information about issues that may not yet be fixed and, when available, alternative procedures to work around these issues.
— Calyx RIM System Support Documentation (SSD) - The SSD for Calyx RIM specifies the hardware and software prerequisites for installing and operating Calyx RIM , and for the supporting software and utilities for Calyx RIM .
— Calyx RIM Installation Guide - Provides installation instructions and information about configuring Calyx RIM.
— Validation Sourcebook (VSB) - As part of the Calyx RIM Validation Service, the VSB provides validation-ready documentation to expedite the validation and implementation of Calyx RIM. The Calyx RIM VSB includes thorough installation and operation qualification (IQ and OQ) scripts that ensure proper installation and test the functional requirements. Furthermore, a traceability matrix is included to map specific test scripts back to the corresponding functional requirement. For more information on the Calyx RIM VSB, contact your Account Representative.

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