



**Calyx RIM 7.1 Data Migration
Documentation**

CALYX™

Contents

Data Migration Documents	1
Calyx RIM Database Migration Release Notes	2
Calyx RIM Database Migration Details.....	2
Calyx RIM 7.1 Data Migration.....	2
Entities.....	4
Calyx RIM 7.1 Product Family Updates	4
Calyx RIM 7.1 Application Updates	4
Calyx RIM 7.1 Product Updates	4
Calyx RIM 7.1 Component Active Ingredients Updates	5
Calyx RIM 7.1 Manufactured Item.....	6
Calyx RIM 7.1 Pharmaceutical Product Updates.....	6
Calyx RIM 7.1 Pharmaceutical Product Active Ingredient.....	7
Calyx RIM 7.1 Event-Country Status Updates.....	7
Calyx RIM 7.1 Status Dates Updates.....	7
Product Detail Set/Product Detail Set Template.....	8
Calyx RIM 7.1 PDS and PDS Template Updates.....	8
Registrations.....	10
Calyx RIM 7.1 Registrations (Package Set Type).....	10
Calyx RIM 7.1 Registrations (Package Set Type).....	11
Calyx RIM 7.1 Medicinal Product.....	11
Calyx RIM 7.1 Full Product Presentation.....	12
Calyx RIM 7.1 XEVMPD.....	12
Wizards.....	13
Calyx RIM 7.1 Wizards.....	13
Queries.....	13
Calyx RIM 7.1 Queries.....	13
Data Administration Updates for Calyx RIM 7.1.....	16
Data Administration Updates: Country Values.....	16
Data Administration Updates: SPOR Master Lists.....	20

SPOR Mapping to Calyx RIM 7.1 Data Administration Lists.....	22
SPOR RMS Lists not Released by EMA.....	30
Calyx RIM 7.1 Prerequisite: Oracle Configuration Update.....	31
Increase Maximum Size of VARCHAR2, NVARCHAR2, and RAW Columns in a Non-CDB	31
Pre-Migration Manual Tasks for Calyx RIM 7.1.....	32
Taiwan: Pre-Migration Manual Tasks for Calyx RIM 7.1	32
Pre-migration Scripts.....	33
Component Active Ingredient vs PDS Active Ingredient Data Migration.....	33
Post-Migration Script Updates for Calyx RIM 7.1.....	35
Database Script Error Messages.....	36
Errors Message - Example.....	47
Index.....	49

Data Migration Documents

Document Name
Calyx RIM 7.1 Data Migration Document
Calyx RIM 7.0 Data Migration Document
Data Migration Document - Previous Versions

Calyx RIM Database Migration Release Notes

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

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

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

Prerequisites

The users and groups who will be using the Calyx RIM 7.1 system should have their accounts created in Azure AD and provide the User Object IDs for the User migration phase.

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

Calyx RIM Database Migration Details

The migration package consists of SQL database scripts that are run on an Oracle database to establish the database instance for Calyx RIM.

You can use the database scripts as a guide for migrating your earlier version of Calyx RIM to a current release.

Note: The migration scripts delete all the saved queries.

The scripts are supplied in ZIP files:

- DB Upgrade 70 to 71.zip (DB_update7_1_0_0000_0112.zip) (To migrate to Calyx RIM 7.1 from Calyx RIM 7.0. See: *Data Migration Documents*)
- DB Upgrade 62 CHF6 to 70.zip (DB_update7_0_0_0000_0095.zip) (To migrate to Calyx RIM 7.1 from either Calyx RIM 6.2 CHF 1 or later Calyx RIM. See: *Data Migration Documents*)

Calyx RIM 7.1 Data Migration

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

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

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

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

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

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

Entities

Calyx RIM 7.1 Product Family Updates

New changes and implementations are included in Calyx RIM 7.1 to conform to the regulatory requirements.

Product Family

In Calyx RIM 7.1 the **Product Family Indications/Intended Use** field is renamed to **Product Family Indication** for all the Product Family Types, except Veterinary.

IDMP

Calyx RIM 7.1 now includes the following IDMP attributes:

- **Product Family Comorbidity** - a new multi-select field under **Product Family Indication**.
- **EURD ID** - a new multi-select field, available for all the Product Family Types, except Medical Devices.

Calyx RIM 7.1 Application Updates

New features and fields are included in Calyx RIM 7.1 to conform to the regulatory requirements.

Application

The **Legal Status** attribute is renamed to **Legal Status of Supply**.

Calyx RIM 7.1 includes a new sub-entity for Application - **Orphan Designation**. To show Orphan Designation on the Application Attributes page, an application must be created for the Orphan Drug and **Yes** must be selected on the *Create Application* window..

Calyx RIM 7.1 Product Updates

New features and fields are included in Calyx RIM 7.1 to conform to the regulatory requirements.

Product Updates

To support IDMP , the following new fields are added to the Product entity and are available for Pharmaceutical, Pharma-Med Device, and Flu Vaccine Product Family Types:

- **Combined Pharmaceutical Dose Form** - This is a drop-down list field and available when there is more than one Component created for a Product and is placed under **Product Route of Administration**.
- **Product Category** - This is a multi-select field and is available under **Combined Pharmaceutical Dose Form**, if available. If not, this field is displayed under **Product Route of Administration**.
- **EURD ID** - a new multi-select field.

These new fields will show after migration requirements are met.

Calyx RIM 7.1 Component Active Ingredients Updates

New features and fields are included in Calyx RIM 7.1 to conform to the regulatory requirements.

Component Active Ingredient

In Calyx RIM 7.1, the **Component Active Ingredient** is created one-by-one and not in bulk. This is because of the change in cardinality between the **Component Active Ingredient** and the **Reference Active Ingredient**.

The following strength fields to indicate IDMP strength values are added to the **Component Active Ingredient**, placed under the XEVMPD strength fields divided by the UI separator:

— IDMP Concentration Measure Type

IDMP Presentation Strength

- Presentation Single or Low Limit Numerator Value
- Presentation Single or Low Limit Unit of Measurement
- Presentation Single or Low Limit Unit of Presentation
- Presentation High Limit Numerator Value
- Presentation High Limit Unit of Measurement
- Presentation High Limit Unit of Presentation

IDMP Concentration Strength

- Concentration Single or Low Limit Numerator Value
- Concentration Single or Low Limit Unit of Measurement
- Concentration Single or Low Limit Denominator Value
- Concentration Single or Low Limit Unit of Measurement
- Concentration High Limit Numerator Value
- Concentration High Limit Unit of Measurement
- Concentration High Limit Denominator Value
- Concentration High Limit Unit of Measurement

In Calyx RIM 7.1 , the grid view for this entity is updated.

Component Reference Active Ingredient

In Calyx RIM 7.1, multiple **Reference Active Ingredients** can be created for one **Component Active Ingredient** as required. The **Reference Active Ingredients** tab is available on the *Active Ingredient Attributes* window.

The following strength fields are added to the **Component Active Ingredient** to indicate IDMP strength values. The strength fields are placed under the XEVMPD and divided by the UI separator:

— IDMP Concentration Measure Type

IDMP Presentation Strength

- Presentation Single or Low Limit Numerator Value
- Presentation Single or Low Limit Unit of Measurement

- Presentation Single or Low Limit Unit of Presentation
- Presentation High Limit Numerator Value
- Presentation High Limit Unit of Measurement
- Presentation High Limit Unit of Presentation

IDMP Concentration Strength

- Concentration Single or Low Limit Numerator Value
- Concentration Single or Low Limit Unit of Measurement
- Concentration Single or Low Limit Denominator Value
- Concentration Single or Low Limit Unit of Measurement
- Concentration High Limit Numerator Value
- Concentration High Limit Unit of Measurement
- Concentration High Limit Denominator Value
- Concentration High Limit Unit of Measurement

Calyx RIM 7.1 Manufactured Item

New features and fields are included in Calyx RIM 7.1 to conform to the regulatory requirements.

Manufactured Item

To support IDMP, Calyx RIM 7.1 now includes the following new entities:

- **Manufactured Item** This is added as a child entity of **Product Component**.
- **Active Ingredient** - This is added as a child entity of **Manufactured Item**.
- **Reference Active Ingredient** - This is added as a child entity of **Active Ingredient** under **Manufactured Item**.
- **Substance** - This is added as a child entity of **Manufactured Item**.
- **Reference Substance** This is added as a child entity of **Substance** and is under **Manufactured Item**.

Calyx RIM 7.1 Pharmaceutical Product Updates

New features and fields are included in Calyx RIM 7.1 to conform to the regulatory requirements.

Pharmaceutical Product

In Calyx RIM 7.1, same Components can now be assigned to different Pharmaceutical Products under the same Product.

The unicity rule is updated to make **Pharmaceutical Product Name** unique under a Product.

To support IDMP, the following changes apply for the fields on the **Pharmaceutical Product** entity:

- **Pharmaceutical Product Summary** This is a display-only field and is available when a Pharmaceutical Product is created. By default, this field is hidden. This is available on the **Pharmaceutical Product** tab for other entities.
- **Administrable Dosage Form** - This is renamed to **Administrable Dose Form** and updated with a selection widget.

- **Route of Administration** - This is a new multi-select field.
- **Product Quantity Value** - This field is now hidden by default.
- **Product Quantity Unit** - This field is now hidden by default.
- **Product Characteristics** - This field is now hidden by default.

In Calyx RIM 7.1, the grid view for this entity is updated.

To support IDMP, Calyx RIM 7.1 now includes new PhPIDs child entity under Pharmaceutical Products.

Calyx RIM 7.1 Pharmaceutical Product Active Ingredient

New features and fields are included in Calyx RIM 7.1 to conform to the regulatory requirements.

Pharmaceutical Product Active Ingredient

Calyx RIM 7.1 now includes the following new entities for IDMP and XEVMPD support:

- **Active Ingredient** - This is added as a child entity of **Pharmaceutical Products**.
- **Reference Active Ingredient** - This is added as a child entity of **Active Ingredient** under **Pharmaceutical Products**.

Reference Substance is added as a child entity of **Substance** under **Pharmaceutical Products** (for IDMP support only).

Calyx RIM 7.1 Event-Country Status Updates

New features and fields are included in Calyx RIM 7.1 to conform to the regulatory requirements.

Event-Country Status

The **Add Comment** field is added on the **Event- Country Attributes > Add/Modify-Country Event Status** page.

The **Event-Country Status Comments** field is added on **Event- Country Attributes > Add/Modify-Country Event Status** page to display comments added. The comments can be deleted or modified.

Calyx RIM 7.1 Status Dates Updates

New features and fields are included in Calyx RIM 7.1 to conform to the regulatory requirements.

Status Dates under Sequence

The **Add Comment** field is added on the **View Sequence > Add/Modify Status** pages.

The **Sequence Status Comments** field is added on **View Sequence > Add/Modify Status** pages to display comments added., The comments can be deleted or modified.

Status Dates under Task/Sub-Task

The **Add Comment** field is added on the **View Task > Add/Modify Status** pages.

The **Task Status Comments** field is added on **View Task > Add/Modify Status** pages to display comments added. The comments can be , deleted or modified.

Product Detail Set/Product Detail Set Template

Calyx RIM 7.1 PDS and PDS Template Updates

New features and fields are included in Calyx RIM 7.1 to conform to the regulatory requirements.

PDS Component Node

In Calyx RIM 7.1, the **Pharmaceutical Product** field is no longer available on the *Component Attributes* page on the PDS.

PDS Active Ingredient Detail

In Calyx RIM 7.1, the XEVMPD strength fields are view-only with the data taken from the *Component Active Ingredient* under the Product.

The Active Ingredient node is now created automatically within the PDS.

See *Pre-Migration Scripts* section for details on how to prepare your data for migration to v7.1.

PDS Substance Detail

The following strength fields to indicate IDMP strength values are added to the Component Active Ingredient under the XEVMPD strength fields divided by the UI separator:

— IDMP Concentration Measure Type

IDMP Presentation Strength

- Presentation Single or Low Limit Numerator Value
- Presentation Single or Low Limit Unit of Measurement
- Presentation Single or Low Limit Unit of Presentation
- Presentation High Limit Numerator Value
- Presentation High Limit Unit of Measurement
- Presentation High Limit Unit of Presentation

IDMP Concentration Strength

- Concentration Single or Low Limit Numerator Value
- Concentration Single or Low Limit Unit of Measurement
- Concentration Single or Low Limit Denominator Value
- Concentration Single or Low Limit Unit of Measurement
- Concentration High Limit Numerator Value
- Concentration High Limit Unit of Measurement
- Concentration High Limit Denominator Value
- Concentration High Limit Unit of Measurement

PDS Indications/Intended Use Detail

In Calyx RIM 7.1, Indications/Intended Use details are created one at a time and not in bulk.

To support IDMP, Calyx RIM 7.1 now includes the following updates:

- **Indications/Intended Use** - This field is renamed to **Indications**.
- **Product Family Comorbidity** - This is a new multi-select field added to the Product Family.
- **Intended Effect** - This is a new multi-select field added with the values from **Data Administration**.

PDS Manufacturer Detail

To support IDMP, Calyx RIM 7.1 now includes the new fields:

- **Manufacturing Operation Start Date**, This is a new date field under **Manufacturer Status Date** and has a NULL value after migration.
- **Manufacturing Operation Stop Date** This is a new date field under **Manufacturing Operation Start Date** and has a NULL value after migration.

PDS Packaging Detail

To support IDMP, Calyx RIM 7.1 now includes the following updates:

- **Package Item Container Quantity** This is a new numeric field under the **Packaging Type** field.
- **The Container Package Material** - This field is renamed to **Package Material**.
- **The Container Package Alternate Material** - This field is renamed to **Package Alternate Material**.
- **Package Components** - This is a new multi-select field and added under the **Unit of Presentation** field
- **Manufactured Item Reference** This is a new multi-select field and added under the **Package Components** field.
- **Packaging MI Quantity** - This is a new numeric field and added under the **Manufactured Item Reference**.
- **Packaging MI Quantity Unit** - This is, a new drop-down list added under the **Packaging MI Quantity**.
- **Medical Device Reference** - This is a new drop-down list added under the **Packaging MI Quantity Unit** field. This field is, available for Medical Devices and Pharma-Med Device components.

PDS Shelf Life Detail

In Calyx RIM 7.1, one common Shelf Life Node is available - Shelf Life(s)/Storage Condition(s). If there is more than one Component for the PDS, the Shelf Life(s)/Storage Condition(s) node will be shown under each Component.

Unicity is updated to include concatenation of the following fields:

- **Shelf Life Type**
- **Shelf Life**
- **Shelf Life Unit**
- **Shelf Life Category**

Shelf Life Type is now a required field. This is available under the **Product Detail Set Name** field and available in the PDS Tree before the **PDS Details Status**.

The following migration rules apply:

- If the Shelf Life(s)/Storage Condition(s) Node is present before migration, it will migrate to the Shelf Life(s)/Storage Condition(s) with the Shelf Life Type with Code Name in original pack.
- If there is a Shelf Life(s)/Storage Condition(s) After Opening Node before migration, it will migrate with the Shelf Life Type with Code Name 'After first opening'

- If there is a Shelf Life(s)/Storage Condition(s) After Reconstitution Node before migration, it will migrate with the Shelf Life Type with Code Name 'After transformation'.
- If any of the nodes have a value in the Shelf Life Type before migration it will be added to the Comments field on the entity.
- It is now possible to update the fields on the **Shelf Life** while the node is still in **Pending Add** status.

Note: Verify the Shelf Life Type field appears on the user interface. Else, contact your Business Development Representative for assistance.

PDS Flu Strain Detail

The following strength fields to indicate IDMP strength values are added to the **Flu Strain** detail and placed under the XEVMPD strength fields divided by the UI separator:

- **IDMP Concentration Measure Type**

IDMP Presentation Strength

- Presentation Single or Low Limit Numerator Value
- Presentation Single or Low Limit Unit of Measurement
- Presentation Single or Low Limit Unit of Presentation
- Presentation High Limit Numerator Value
- Presentation High Limit Unit of Measurement
- Presentation High Limit Unit of Presentation

IDMP Concentration Strength

- Concentration Single or Low Limit Numerator Value
- Concentration Single or Low Limit Unit of Measurement
- Concentration Single or Low Limit Denominator Value
- Concentration Single or Low Limit Unit of Measurement
- Concentration High Limit Numerator Value
- Concentration High Limit Unit of Measurement
- Concentration High Limit Denominator Value
- Concentration High Limit Unit of Measurement

PDS Pack Size Detail

To support IDMP, Calyx RIM 7.1 now includes a new PDS Node Pack Size as a child of Package Set Node.

Registrations

Calyx RIM 7.1 Registrations (Package Set Type)

New features and fields are included in Calyx RIM 7.1 to conform to the regulatory requirements.

Registrations (Package Set Type)

In Calyx RIM 7.1, the Registrations with the Package Sets with **Pending Add** status can now be created.

To support IDMP, Calyx RIM 7.1 now includes:

- **ATC Code Flag** - This new drop-down list is under the **Registered ATC** field.
- **Package Sets** - This field displays for both the **Package Set Name** and the **Package Set Status** for the PDS Detail.

Calyx RIM 7.1 Registrations (Package Set Type)

New features and fields are included in Calyx RIM 7.1 to conform to the regulatory requirements.

Registration-Package Sets

To support IDMP, Calyx RIM 7.1 now includes:

- **Legal Basis**, a new drop-down list under **Package Set Name**
- **Authorisation Status**, a new drop-down list under **Legal Basis**
- **Authorisation Status Date**, a new date field under **Authorisation Status**
- **Status**, a new display-only field with data driven from PDS Package Set Detail
- **Status Date**, a new display only field with data driven from PDS Package Set Detail
- **EU Presentation Number** renamed to **Package Set License Code**

The grid view for this entity is updated for Calyx RIM 7.1 release.

Package Set-Country

To support IDMP, Calyx RIM 7.1 now includes:

- **Data Carrier Type**, a new drop-down list under **Legal Status of Supply**
- **Data Carrier Identifier**, a new text field under **Data Carrier Type**
- **Data Carrier Language**, a new drop-down list under **Data Carrier Identifier**
- **Risk of Supply Shortage**, a new field with **Yes** or **No** selection.
- **Risk of Supply Shortage Comment**, a new text field.
- **Marketing Status Reason**, a new drop-down list with values from **Data Administration > Marketing Status Reasons Values**.

Package Set-Package Description

To support IDMP, Calyx RIM 7.1 now includes a new **Reference Substance** entity, a child entity of **Registration Package Sets**.

Calyx RIM 7.1 Medicinal Product

New features and fields are included in Calyx RIM 7.1 to conform to the regulatory requirements.

Medicinal Product

To support IDMP, Calyx RIM 7.1 now includes:

- **Medicinal Product** - This is included as a child entity for **Registration Package Set Type**.
- **Medicinal Product Names** - This is included as a child entity for **Medicinal Product**.
- **Product Cross-Reference** - This is included as a child entity for **Medicinal Product**.
- **MPIDs** - This is included as a child entity for **Medicinal Product**.

- **Medicinal Product Actions** - This is included as a child entity for **Medicinal Product** under the Registrations (Package Set Type).
- **Attached Documents** - This is included as a child entity for **Medicinal Product Actions**.

Calyx RIM 7.1 Full Product Presentation

New features and fields are included in Calyx RIM 7.1 to conform to the regulatory requirements.

Full Product Presentation

Calyx RIM 7.1 now includes the following changes for **Full Product Presentation**:

- The **Use Reference Ingredient for XEVMPD** option is removed from Full Product Presentation. This option will not be available after migration.
- The working logic of the XEVMPD Submission wizard is also changed to comply to the latest requirement. For more details, see Calyx RIM 7.1 XEVMPD
- **Pharmaceutical Product** - This is a new multi-select field that is available in Calyx RIM 7.1 .

If there is an existing **Full Product Presentation** that is associated to a **Product** through the **Package Set** and this **Product** has a **Pharmaceutical Product**, after migration it will be shown as selected in the new **Pharmaceutical Products** tab on the **Full Product Presentation Attributes** page.

IDMP Tab

Calyx RIM 7.1 now includes a new **IDMP** tab to support IDMP information visibility on the **Registration Attributes** page.

Calyx RIM 7.1 XEVMPD

New features and fields are included in Calyx RIM 7.1 to conform to the regulatory requirements.

XEVMPD

Starting with Calyx RIM 7.1, the XEVMPD Submission wizard includes the following updates:

- Instead of Component Active Ingredient/Component Reference Active Ingredient, the values of Active Ingredient will be taken from Pharmaceutical Product Reference Active Ingredient, if present. Else, it will be taken from Pharmaceutical Product Active Ingredient.
- The Pharmaceutical Product information, as well as the entities data associated with it and with a Product, will be taken for XEVMPD submission. This is based on the Pharmaceutical Product association with **Full Product Presentation** and not from the PDS as it was before the new updates. For details of the **Full Product Presentation** association with **Pharmaceutical Product** after migration, see the *Full Product Presentation* section of this document.

The following rules apply when migrating XEVMPD strength data for Component Active Ingredient/Component Reference Active Ingredient and affects Full Product Presentation when the Use Reference Active Ingredient field is deleted.:

- When there is a Component Active Ingredient with values for XEVMPD strength fields and there is a **Full Product Presentation** with the **Use Reference Active Ingredient for XEVMPD** with No or NULL for the EU Country package set registration for the Product where component with active ingredient is assigned to, a Pharmaceutical Product Active Ingredient with XEVMPD data will be created after the migration.

- When there is a Component Active Ingredient with Reference Active Ingredient with values for XEVMPD strength fields and there is a **Full Product Presentation** with the **Use Reference Active Ingredient for XEVMPD** with Yes for the EU Country package set registration for the Product where component with active ingredient is assigned to, a Pharmaceutical Product Active Ingredient with Reference Active Ingredient with XEVMPD data will be created after migration.

Wizards

Calyx RIM 7.1 Wizards

New features and fields are included in Calyx RIM 7.1 to conform to the regulatory requirements.

The following table lists the new and renamed fields in Calyx RIM 7.1

Change	Field Name	Wizard Name
Field renamed	Legal Status Type to Legal Status of Supply	<ul style="list-style-type: none"> — Create Application — Update Application
	Indications/Intended Use to Indications	Global Project Plan > Update Product Detail Sets
New field added	Comorbidity	Global Project Plan > Update Product Detail Sets
	Intended Effect	

Queries

Calyx RIM 7.1 Queries

New features and fields are included in Calyx RIM 7.1 to conform to the regulatory requirements.

The following table lists the new and renamed fields in Calyx RIM 7.1 .

Change	Field Name/Entity Name	Query Name
Field Renamed	Dosage Form to Administrable Dosage Form	Entity Audit Query for Pharmaceutical Product
	Indications/Intended Use to Indications	<ul style="list-style-type: none"> – Application History Query – Application QC Status History Report
	Legal Status Type or Application Legal Status Type to Legal Status of Supply	<ul style="list-style-type: none"> – List of Package Set Registrations with Application and Product Detail Properties – List of Product Registrations with Application and Product Detail Properties – List of Applications – List of Applications with Products – List of Events with Application Properties – List of Application Countries – List of Registrations with Application Properties – List of Sequences with Application and Event Properties – List of Application Countries with Registration Details
Field Deleted	<ul style="list-style-type: none"> – Product Characteristics – Product Quantity Unit – Product Quantity Value 	Entity Audit Query for Product
	Use Reference Ingredient for XEVMPD	XEVMPD Submissions - QC Verification and Audit

Change	Field Name/Entity Name	Query Name
New Added	<ul style="list-style-type: none"> – Attached Document entity – Manufactured Item entity – Medicinal Product entity – Medicinal Product Action entity – Medicinal Product Name entity – Product Cross Reference entity – Product Detail-Pack Size PDS detail 	Entity Audit Query
	<ul style="list-style-type: none"> – Manufacturing Operation Start Date – Manufacturing Operation Stop Date 	<ul style="list-style-type: none"> – Entity Audit Query for Product Detail-Manufacturer – List of Component Manufacturers – List of Package Set Manufacturers – List of PDS Manufacturers – List of Excipient Manufacturers – List of Active Ingredient Material Manufacturers – List of Active Ingredient Function Manufacturers – List of Active Ingredient Manufacturers – Application History Query – Application QC Status History Report
	<ul style="list-style-type: none"> – Packaging MI Quantity – Packaging MI Quantity Unit – Medical Device Reference – Device Quantity – Package Item Container Quantity – Package Material – Package Alternate Material – Package Components – Manufactured Item Reference 	<ul style="list-style-type: none"> – Application History Query – Application QC Status History Report
	<ul style="list-style-type: none"> – Pharmaceutical Product – Manufactured Item – Medicinal Product 	<ul style="list-style-type: none"> – List of References – List of Tasks
	<ul style="list-style-type: none"> – Pharmaceutical Product – Manufactured Item 	<ul style="list-style-type: none"> – List of References -Rollup by Product Family – List of Tasks -Rollup by Product Family
	Medicinal Product	<ul style="list-style-type: none"> – List of References - Rollup by Application – List of Tasks - Rollup by Application
© Calyx™ 2021. Calyx.ai	Combined Pharmaceutical Dose Form	<ul style="list-style-type: none"> – Entity Audit Query for Product – List of Pharmaceutical Products – List of Pharmaceutical and Medical Device Products

Data Administration Updates for Calyx RIM 7.1

Data Administration Updates: Country Values

Calyx RIM 7.1 includes the changes and updates related to **Country Values** and **Data Administration**.

Data Administration Updates

In preparation for Data Module changes in Calyx RIM 7.1, the Data Administration sections are revised and the actions described below are provided:

Country Values

Calyx RIM 7.1 introduces a new **Languages** sub-tab for **Application Maintenance > Country Values**. This enables you to map language values to a specific country value and define the default one.

After migrating to Calyx RIM 7.1, OOTB mapping for Country - Language values should be as follows:

Country	Language
Angola	Portuguese
Antigua and Barbuda	English
Australia	English
Austria	English; German
Bahamas	English
Belgium	Dutch; Flemish; English; French; German
Belize	English
Benin	French
Bosnia and Herzegovina	Croatian
Botswana	English
Brazil	Portuguese
Brunei Darussalam	English
Bulgaria	Bulgarian; English
Burkina Faso	French
Burundi	English; French
Cameroon	English; French
Canada	English; French
Cape Verde	Portuguese

Country	Language
Central African Republic	French
Chad	French
Christmas Island	English
Cocos (Keeling) Islands	English
Comoros	French
Cook Islands	English
Croatia	Croatian; English
Cyprus	English; Greek
Czech Republic	Czech; English; Slovak
Denmark	Danish; English
Djibouti	French
Dominica	English
Equatorial Guinea	French; Portuguese
Estonia	English; Estonian
Ethiopia	English
Fiji	English
Finland	English; Finnish; Swedish
France	English; French
Gabon	French
Gambia	English
Germany	English; German
Ghana	English
Greece	English; Greek
Grenada	English
Guinea	French
Guinea-Bissau	Portuguese
Guyana	English
Haiti	French
Hungary	English; Hungarian
Iceland	English; Icelandic

Country	Language
India	English
Ireland	English; Irish
Italy	English; Italian
Jamaica	English
Kenya	English
Kiribati	English
Latvia	English; Latvian
Lesotho	English
Liberia	English
Liechtenstein	English; German
Lithuania	English; Lithuanian
Luxembourg	English; French; German
Madagascar	French
Malawi	English
Malaysia	English
Mali	French
Malta	English; Maltese
Marshall Islands	English
Mauritius	English
Micronesia, Federated States Of	English
Moldova, Republic Of	Romanian; Moldavian; Moldovan
Monaco	French
Montenegro	Croatian
Mozambique	Portuguese
Namibia	English
Nauru	English
Netherlands	Dutch; Flemish; English
New Zealand	English
Niger	French
Nigeria	English

Country	Language
Niue	English
Norfolk Island	English
Norway	English; Norwegian Nynorsk; Nynorsk, Norwegian
Pakistan	English
Palau	English
Papua New Guinea	English
Philippines	English
Poland	English; Polish
Portugal	English; Portuguese
Romania	English; Romanian; Moldavian; Moldovan
Rwanda	English; French
Saint Kitts and Nevis	English
Saint Lucia	English
Saint Vincent and The Grenadines	English
Samoa	English
San Marino	Italian
Senegal	French
Seychelles	English; French
Sierra Leone	English
Singapore	English
Slovakia	English; Slovak
Slovenia	English
Solomon Islands	English
South Africa	English
Spain	English
Sudan	English
Suriname	Dutch; Flemish
Sweden	English; Swedish
Switzerland	French; German; Italian
Togo	French

Country	Language
Tokelau	English
Tonga	English
Trinidad and Tobago	English
Tunisia	French
Tuvalu	English
Uganda	English
United Kingdom	English
United Republic Of Tanzania	English
United States	English
Vanuatu	English; French
Zambia	English
Zimbabwe	English

You can manage the migrated Language values under Country manually.

Data Administration Updates: SPOR Master Lists

Calyx RIM 7.1 includes changes related to **SPOR Master Lists** Data Administration Updates.

Data Administration Updates

The Data Administration section has been updated to include the changes for SPOR Master Lists.

SPOR Master Lists

SPOR is the European Medicines Agency's (EMA) Master Data Management service that complies with ISO Identification of Medicinal Products (IDMP). There are two sub sections of SPOR that have controlled vocabularies supported in Calyx RIM 7.1:

- OMS (Organisation Management Services)
- RMS (Referentials Management Services)

Calyx RIM 7.1 will maintain local master copies of the SPOR source lists for OMS and RMS. The following SPOR data value lists are supported:

- Anatomical Therapeutic Chemical Classification System – Human
- Application Legal Basis
- Application Submission Type
- Combination Package
- Combined Pharmaceutical Dose Form
- Combined Term
- Contact Party Role

- Country
- Data Classification
- Domain
- EU Regulatory Authorisation Procedure
- Ingredient Role
- Language
- Legal Status for the Supply
- Manufacturing Activity
- Marketing Status
- Master File Type
- Material
- Medical Dictionary For Regulatory Activities
- Medicinal Product Name Party Type
- Organization
- Packaging
- Pharmaceutical Dose Form
- Product Category
- Product Cross Reference Type
- Product Information Document Type
- Quantity Operator
- Regulatory Entitlement Status
- Regulatory Entitlement Type
- Routes and Methods of Administration
- Shelf Life Type
- Special Precaution for Storage
- Units of Measurement
- Units of Presentation
- XEVMPD Medical Devices
- XEVMPD Medicinal Product Type

SPOR Mapping to Calyx RIM 7.1 Data Administration Lists

To support mapping EMA SPOR terms to Calyx RIM value lists, new RMS and OMS tabs are added to applicable value lists.

Name of the SPOR Master List in Calyx RIM	Existing Calyx RIM Value List Mapping	NewCalyx RIM Value List Mapping	New RMS Tab with Fields	New OMS Tab with Fields
Anatomical Therapeutic Chemical Classification System – Human	Product Family > ATC Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	N/A
Application Legal Basis	Other > Legal Basis Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	N/A
Application Submission Type	N/A	Other > Application Submission Type Values	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	
Combination Package	Product Maintenance > Dosage/ Pharmaceutical Form Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	

Name of the SPOR Master List in Calyx RIM	Existing Calyx RIM Value List Mapping	NewCalyx RIM Value List Mapping	New RMS Tab with Fields	New OMS Tab with Fields
Combined Pharmaceutical Dose Form	Product Maintenance > Dosage/ Pharmaceutical Form Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	
Combined Term	Product Maintenance > Dosage/ Pharmaceutical Form Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	
Contact Party Role	Registration Maintenance > Qualified Person Responsible for Pharmacovigilance (QPPV) Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	
Country	Application Maintenance > Country Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	
Data Classification	Product Detail Set Maintenance > Manufacturer Values – Global Detail Sets	N/A	Confidentiality Indicator on the <i>Global Detail Sets</i> attribute page.	

Name of the SPOR Master List in Calyx RIM	Existing Calyx RIM Value List Mapping	NewCalyx RIM Value List Mapping	New RMS Tab with Fields	New OMS Tab with Fields
Domain	N/A	Product Family Maintenance > Domain Type Values	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	
EU Regulatory Authorisation Procedure	Application Maintenance > Procedure Type Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	
Ingredient Role	Product Detail Set Maintenance > Substance Role Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	
Language	Other > Language Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	
Legal Status for the Supply	Application Maintenance > Legal Status Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	

Name of the SPOR Master List in Calyx RIM	Existing Calyx RIM Value List Mapping	NewCalyx RIM Value List Mapping	New RMS Tab with Fields	New OMS Tab with Fields
Manufacturing Activity	Product Detail Set Maintenance > Manufacturing Function Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	
Marketing Status	Registration Maintenance > Marketing Status Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	
Master File Type	N/A	Registration Maintenance > Master File Type Values	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	
Material	Product Detail Set Maintenance > Product Material Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	
Medical Dictionary For Regulatory Activities	Other > Indications/ Intended Use Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	

Name of the SPOR Master List in Calyx RIM	Existing Calyx RIM Value List Mapping	NewCalyx RIM Value List Mapping	New RMS Tab with Fields	New OMS Tab with Fields
Medicinal Product Name Part Type	N/A	Registration Maintenance > Medicinal Product Name Part Type Values	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	
Organization	Other > MAH/ Development Sponsor/Organisation Values	N/A	N/A	<ul style="list-style-type: none"> – Organization ID – Location ID – Organization Name – Address – City – Post Code – Country – Last User Updated – Last Changed Date – Active Flag
Organization	Product Detail Set Maintenance > Manufacturer Values	N/A	N/A	<ul style="list-style-type: none"> – Organization ID – Location ID – Manufacturer Name – Address – City – Post Code – Country – Last User Updated – Last Changed Date – Active Flag

Name of the SPOR Master List in Calyx RIM	Existing Calyx RIM Value List Mapping	NewCalyx RIM Value List Mapping	New RMS Tab with Fields	New OMS Tab with Fields
Organization	Application Maintenance > Country Values - Health Authority	N/A	N/A	<ul style="list-style-type: none"> – Organization ID – Location ID – Health Authority – Name – Address – City – Post Code – Country – Last User Updated – Last Changed Date – Active Flag
Packaging	Product Detail Set Maintenance > Packaging Type Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	N/A
Pharmaceutical Dose Form	Product Maintenance > Dosage/ Pharmaceutical Form Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	N/A
Product Category	N/A	Product Maintenance > Product Category Values	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	N/A

Name of the SPOR Master List in Calyx RIM	Existing Calyx RIM Value List Mapping	NewCalyx RIM Value List Mapping	New RMS Tab with Fields	New OMS Tab with Fields
Product Cross Reference Type	N/A	Product Maintenance > Product Cross Reference Type Values	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	N/A
Product Information Document Type	N/A	Application > Product Information Document Type	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	N/A
Quantity Operator	Other > Concentration Measure Type Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	
Regulatory Entitlement Status	N/A	Application Maintenance > Orphan Status Values	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	N/A
Regulatory Entitlement Type	N/A	Application Maintenance > Regulatory Entitlement Type Values	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	N/A

Name of the SPOR Master List in Calyx RIM	Existing Calyx RIM Value List Mapping	NewCalyx RIM Value List Mapping	New RMS Tab with Fields	New OMS Tab with Fields
Routes and Methods of Administration	Product Maintenance > Routes of Administration Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	N/A
Shelf Life Type	Product Detail Set Maintenance > Shelf Life Type Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	N/A
Special Precaution for Storage	Product Detail Set Maintenance > Storage Condition Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	N/A
Units of Measurement	N/A	Other > Units of Measurement Values	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	N/A
Units of Presentation	Other > Unit of Presentation Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	N/A

Name of the SPOR Master List in Calyx RIM	Existing Calyx RIM Value List Mapping	NewCalyx RIM Value List Mapping	New RMS Tab with Fields	New OMS Tab with Fields
XEVMPD Medical Devices	Product Maintenance > Medical Device Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	N/A
XEVMPD Medical Product Type	Registration Maintenance > Medicinal Product Type Values	N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	N/A

Mapping of RMS and OMS is facilitated by a new selection widget.

SPOR RMS Lists not Released by EMA

There are new data value lists created to map to SPOR RMS lists that have not yet been released by EMA.

SPOR RMS List not yet released by EMA	Existing Calyx RIM Value List Mapping	New Calyx RIM Value List Mapping
Attached Document Content Type	N/A	Other > Attached Document Content Type Values
Component Type	N/A	Product Detail Set Maintenance > Component Type Values
Device Type	N/A	Product Detail Set Maintenance > Medical Device UDI Values
Device - Type of Combination	N/A	Product Detail Set Maintenance > Device - Type of Combination Values
Provenance Reason	N/A	Registration Maintenance > Provenance Reason Values

Calyx RIM 7.1 Prerequisite: Oracle Configuration Update

The following Oracle configuration modifications must be performed on your database server before migrating any data and before installing Calyx RIM 7.1.

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

- `MAX_STRING_SIZE` controls the maximum size of `VARCHAR2`, `NVARCHAR2`, and `RAW` data types in SQL.
- `STANDARD` means that the length limits for Oracle Database releases prior to Oracle Database 12c apply (for example, 4000 bytes for `VARCHAR2` and `NVARCHAR2`, and 2000 bytes for `RAW`).
- `EXTENDED` means that the 32767 byte limit introduced in Oracle Database 12c applies.
- The `COMPATIBLE` initialization parameter must be set to 12.0.0.0 or higher to set `MAX_STRING_SIZE = EXTENDED`.
- You can change the value of `MAX_STRING_SIZE` from `STANDARD` to `EXTENDED`. However, you cannot change the value of `MAX_STRING_SIZE` from `EXTENDED` to `STANDARD`.

Increase Maximum Size of VARCHAR2, NVARCHAR2, and RAW Columns in a Non-CDB

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

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

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


6. Run the `rdbsms/admin/utl1rp.sql` script to recompile invalid objects.

Pre-Migration Manual Tasks for Calyx RIM 7.1

Taiwan: Pre-Migration Manual Tasks for Calyx RIM 7.1

Add Taiwan region values to include the new Taiwan updates in Calyx RIM 7.1

To add the TW region to Calyx RIM:

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

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

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

Pre-migration Scripts

Component Active Ingredient vs PDS Active Ingredient Data Migration

Calyx RIM 7.1 changes the way how PDS Active Ingredients are created.

When there are Component Active Ingredients under Product, a PDS is created from this Product with Active Ingredient PDS Details added automatically with the strength information from Component Active ingredient.

After migration to Calyx RIM 7.1 strength data in the existing PDS Active Ingredients will become equal to Component Active Ingredients.

To avoid missing data there is a pre-migration script which helps to identify if values for existing PDS Active Ingredient strength fields are different from Component Active Ingredients.

You can make any correction to the Component Active Ingredient data before the migration. The data correction for Component Active Ingredient is done in in user interface.

Migration script that identifies Active Ingredients from entity level Component that are different from PDS Active Ingredients for Calyx RIM 7.1 (output is txt):

Table 1: Report Column Definition

pre_mig_rpt_ai_diff.sql	
Report Column	Value
PRODUCT FAMILY NAME	Displays the Product Family Name.
APPLICATION NAME	Displays the Application Name.
PRODUCT NAME	Displays the Product Name.
COMPONENT NAME	Displays the Component Name.
ACTIVE INGREDIENT NAME	Displays the Active Ingredient Name.
CONCENTRATION MEASURE TYPE	Displays the Concentration Measure Type.
LOW AMOUNT NUMERATOR VALUE	Displays the Low Amount Numerator Value.
LOW AMOUNT NUMERATOR PREFIX	Displays the Low Amount Numerator Prefix.
LOW AMOUNT NUMERATOR UNIT	Displays the Low Amount Numerator Unit.
LOW AMOUNT DENOMINATOR VALUE	Displays the Low Amount Denominator Value.
LOW AMOUNT DENOMINATOR PREFIX	Displays the Low Amount Denominator Prefix.
LOW AMOUNT DENOMINATOR UNIT	Displays the Low Amount Denominator Unit.

pre_mig_rpt_ai_diff.sql

Report Column	Value
HIGH AMOUNT NUMERATOR VALUE	Displays the High Amount Numerator Value.
HIGH AMOUNT NUMERATOR PREFIX	Displays the High Amount Numerator Prefix.
HIGH AMOUNT NUMERATOR UNIT	Displays the High Amount Numerator Unit.
HIGH AMOUNT DENOMINATOR VALUE	Displays the High Amount Denominator Value.
HIGH AMOUNT DENOMINATOR PREFIX	Displays the High Amount Denominator Prefix.
HIGH AMOUNT DENOMINATOR UNIT	Displays the High Amount Denominator Unit.
MEASUREMENT POINT	Displays the Measurement Point.

Note: The output will be in the following format [COMPONENT AI VALUE] --->[PDS AI VALUE].

Post-Migration Script Updates for Calyx RIM 7.1

Changes affected by the migration script.

Migration affects the following changes:

- Adds TW-1-0assembly DTD type in the **Assembly - Assembly DTD/Schema Types**, if it does not already exist.
- Sets the value for 'eCTD Code' for the Taiwan country in the **Application Maintenance > Country Values** section of Data Administration.
- Adds the following values to the **Sequence Maintenance > Filing Type Values** in Data Administration if they do not exist already:
 - New
 - Change
 - Extension Filing
 - Expiration

Database Script Error Messages

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

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

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

Upgrade path	Error	Description/Resolution
5.1 to 6.0	ORA-01543: tablespace 'IDX_DM' already exists	Ignore
5.1 to 6.0	ORA-01543: tablespace 'DAT_DM' already exists	Ignore
5.1 to 6.0	ORA-01918: all ORA-01918 messages	Ignore
5.1 to 6.0	ORA-01919: all ORA-01919 messages	Ignore
5.1 CHF 3 to 6.0 to 6.0 CHF 1	<p>ORA-00955: name is already used by an existing object</p> <pre>CREATE TABLE MGR.REGULATORY_ACT_LEAD(</pre> <p>ERROR at line 1:</p> <p>ORA-00955: name is already used by an existing object</p> <pre>CREATE TABLE MGR.SEQ_DESCR_TYPE(*</pre> <p>ORA-00001: unique constraint (MGR.UX1REGULATORY_ACT_LEAD) violated</p> <p>ORA-00001: unique constraint (MGR.UX1SEQ_DESCR_TYPE) violated</p>	Ignore
6.0 to 6.0 CHF 1	ORA-01952: system privileges not granted.	Ignore. This error can appear when running the master-pre.sql script. It means that the system privileges are not granted to MGR, ODS, or SEC.

Upgrade path	Error	Description/Resolution
6.0 CHF 1 to 6.0 CHF 2 to 6.0 CHF 3	<pre>drop table view_column_metadata * ERROR at line 1: ORA-00942: table or view does not exist comment on column vd_conten.logical_parent _id is 'Reserved for Internal Use; Do not Use' * ERROR at line 1: ORA-00942: table or view does not exist</pre>	Ignore

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

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

Upgrade path	Error	Description/Resolution
6.1 to 6.1 CHF 1	<pre> - ***** fix EU-3-0 EMA-eAF ***** declare * ERROR at line 1: ORA-01403: no data found ORA-06512: at line 9 - drop table tmp_ind_expressions * ERROR at line 1: ORA-00942: table or view does not exist </pre>	Ignore
6.1 to 6.1 CHF 1	<pre> - ORA-00955: name is already used by an existing object - ORA-02260: table can have only one primary key - ORA-24344: success with compilation error - ORA-06512: at line 115 </pre>	Ignore. These errors can be ignored if the migration path contained Calyx RIM 6.0 CHF 6 or Calyx RIM 6.0 CHF 7.
6.1 to 6.1 CHF 1 to 6.1 CHF 2	<pre> ERROR at line 1: ORA-04043: object WRITE_STORAGE_REQUIREMEN TS does not exist </pre>	Ignore
6.1 CHF 1 to 6.1 CHF 2	<pre> - ORA-24344: success with compilation error - ORA-06512: at line 115 </pre>	Ignore. These errors can be ignored if the migration path contained Calyx RIM 6.0 CHF 6 or Calyx RIM 6.0 CHF 7.

Upgrade path	Error	Description/Resolution
6.1 CHF 2 to 6.1 CHF 3	<ul style="list-style-type: none"> — ORA-01918: user 'DBCOMMON' does not exist — ORA-04043: object GET_DIRLIST does not exist — ORA-00904: "SUB_TO_ADD_MONITOR_CODE": invalid identifier — ORA-00904: "ORPHAN_DRUG_FLAG": invalid identifier 	Ignore
6.1 CHF 2 to 6.1 CHF 3	ORA-02298: cannot validate (MGR.T_1671) - parent keys not found	Ignore
6.1 CHF 2 to 6.1 CHF 3 to 6.1 CHF 4	ORA-02298: cannot validate (MGR.T_1671) - parent keys not found	Ignore
6.1 CHF 2 to 6.1 CHF 3	<ul style="list-style-type: none"> — ORA-00001: unique constraint (MGR.AK0BROAD_INDC_COUNTRY) violated — ORA-00955: name is already used by an existing object 	Ignore. These errors can be ignored if the migration path contained Calyx RIM 6.0 CHF 6 or Calyx RIM 6.0 CHF 7.
6.1 CHF 3 to 6.1 CHF 4	<ul style="list-style-type: none"> — ORA-00001: unique constraint (MGR.UX1REGULATORY_ACT_LEAD) violated — ORA-00001: unique constraint (MGR.UX1SEQ_DESCR_TYPE) violated 	Ignore. These errors can be ignored if the migration path contained Calyx RIM 6.0 CHF 6 or Calyx RIM 6.0 CHF 7.
6.1 to 6.2	ORA-01418: specified index does not exist	Ignore

Upgrade path	Error	Description/Resolution
6.1 CHF 4 to 6.2 CHF 1	<ul style="list-style-type: none"> - ORA-24344: success with compilation error - Any errors for the PACKAGE BODY ISM.PRODUCT_FAMILY_COPY: - ORA-02298: cannot validate (MGR.T_1671) - parent keys not found 	Ignore
6.2 (new installation only)	<pre>drop table d_date * ERROR at line 1: ORA-00942: table or view does not exist</pre>	<p>Ignore</p> <p>This error does not appear during the migration from the previous Calyx RIM versions to Calyx RIM 6.2. It may be seen only if you install a new Calyx RIM 6.2 database. If you see this error, you can ignore it.</p>
6.2 CHF 1 to 6.2 CHF 2	<ul style="list-style-type: none"> - drop table dbcommon.role *ERROR at line 1:ORA-00942: table or view does not exist - drop table dbcommon.entity_type *ERROR at line 1:ORA-00942: table or view does not exist 	Ignore.

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

Upgrade path	Error	Description/Resolution
6.2 CHF 4 to 6.2 CHF 5	<ul style="list-style-type: none"> - drop table dbcommon.role * ERROR at line 1: ORA-00942: table or view does not exist - drop table dbcommon.entity_type * ERROR at line 1: ORA-00942: table or view does not exist 	Ignore
6.2 CHF 5 to 6.2 CHF 6	<ul style="list-style-type: none"> - drop table dbcommon.role * ERROR at line 1: ORA-00942: table or view does not exist - drop table dbcommon.entity_type * ERROR at line 1: ORA-00942: table or view does not exist 	Ignore
6.2 CHF 6 to 7.0	<ul style="list-style-type: none"> - ORA-02443: Cannot drop constraint - nonexistent constraint - ORA-01418: specified index does not exist 	Ignore

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

Table 2: Common Errors

Error	Description
SP2-0310: unable to open file "define.passwords"	Ignore
SP2-0310: unable to open file "define.application"	Ignore
ORA-02264: name already used by an existing constraint	DO NOT IGNORE. Call Technical Support

Errors Message - Example

Errors for PACKAGE BODY ISM.PRODUCT_FAMILY_COPY

LINE/COL ERROR

```
-----  
971/11 PL/SQL: SQL Statement ignored  
973/21 PL/SQL: ORA-00942: table or view does not exist  
977/9 PLS-00364: loop index variable 'IREC' use is invalid  
977/9 PL/SQL: Statement ignored  
978/9 PLS-00364: loop index variable 'IREC' use is invalid  
978/9 PL/SQL: Statement ignored  
979/9 PLS-00364: loop index variable 'IREC' use is invalid  
979/9 PL/SQL: Statement ignored  
980/9 PLS-00364: loop index variable 'IREC' use is invalid  
980/9 PL/SQL: Statement ignored  
982/9 PL/SQL: SQL Statement ignored  
LINE/COL ERROR
```

```
-----  
991/35 PL/SQL: ORA-00904: "IREC"."PRODUCT_ID": invalid identifier  
993/9 PL/SQL: SQL Statement ignored  
993/25 PL/SQL: ORA-00942: table or view does not exist  
1004/11 PL/SQL: SQL Statement ignored  
1006/21 PL/SQL: ORA-00942: table or view does not exist  
1010/9 PLS-00364: loop index variable 'IREC' use is invalid
```

```
1010/9 PL/SQL: Statement ignored
```

```
1011/9 PLS-00364: loop index variable 'IREC' use is invalid
```

```
991/35 PLS-00364: loop index variable 'IREC' use is invalid
```

Index

D

Data Migration 1, 2, 4–8, 10–13, 16, 20, 22, 30–33, 35, 36, 47