
Calyx RIM 6.2.8 Upgrade Guidelines

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Calyx RIM 6.2.8 Upgrade Guidelines

Follow the upgrade guidelines to upgrade from version 6.2 CHF 7 to version 6.2.8, along with supporting tools.

Important Notes for this Upgrade

These upgrade guidelines are current as of 20 Jan 2022 and can be used as a reference to upgrade your Calyx RIM.

Regulatory updates introduced in this release will require pre-migration procedures to be completed prior to data migration. Please read and carefully follow these instructions to ensure successful data migration and product upgrade.

There are no updates to Calyx RIM for Analytics 6.2.8. Use Calyx RIM for Analytics 6.2 CHF 7.

Prepare to Upgrade

Please follow these instructions to ensure that your supporting tools are compatible with Calyx RIM 6.2.8.

To configure on Azure AD environment, refer to: [Azure Active Directory Configuration IQ script](#)

Step	Action	Resource
1	Before starting the upgrade procedures, please review the Calyx RIM 6.2 System Support Documentation (SSD) to ensure that all system hardware and software components are compatible with the upgrade.	System Support Documentation
	For general information about this release, see the Calyx RIM 6.2.8 Release Notes.	Calyx RIM 6.2.8 Release Notes
2	Determine the applicable migration path to Calyx RIM 6.2.8 depending on your current installation.	Migration Path
3	Complete all the preceding installation procedures according to your migration path to upgrade your system to Calyx RIM 6.2.8, using appropriate upgrade packages. Refer to the documentation for every release for specific instructions, ensure corresponding pre and post-migration steps, if applicable.	Previous release documentation: <ul style="list-style-type: none"> – Calyx RIM 6.2 Installation Guide – Calyx RIM 6.2 CHF 1 Installation Guide – Calyx RIM 6.2 CHF 2 Installation Guide – Calyx RIM 6.2 CHF 3 Installation Guide – Calyx RIM 6.2 CHF 4 Upgrade Guidelines – Calyx RIM 6.2 CHF 5 Upgrade Guidelines – Calyx RIM 6.2CHF 6 Upgrade Guidelines – Calyx RIM 6.2CHF 7 Upgrade Guidelines

Step	Action	Resource
4	If you use Calyx RIM Linking plug-in (PDF), ensure that you are using Calyx RIM Linking plug-in (PDF) v1.8 CHF 1 with Calyx RIM Linking plug-in (PDF) CHF 1 Hotfix 1.8.1.2 installed.	You must apply Calyx RIM Linking plug-in (PDF) CHF 1 Hotfix 1.8.1.2 to a system running Calyx RIM Linking plug-in (PDF) v1.8 CHF 1. These are available for download at the FTP site.
5	Only the latest version of Calyx RIM Rendering is supported.	You must apply Calyx RIM Rendering 4.4 CHF 2.

Data Migration

Step	Action	Resource
1	Create a backup copy of your database.	N/A
2	Before updating your database, verify that you have read all the Calyx RIM 6.2 CHF 8 Data Migration Document information carefully and have the required level of access to Calyx RIM to complete all the pre-migration tasks listed in the document.	Calyx RIM 6.2. 8 Data Migration Document
3	<p>Apply Calyx RIM 6.2.8 data migration package to your database by following instructions provided in the Calyx RIM 6.2.8 Database Server Installation Qualification script.</p> <p>Notes:</p> <ul style="list-style-type: none"> — Custom database objects in ISM schema are removed during the migration. — Ensure that you are running the Oracle Database installation SQL script on a Windows based computer. If your Oracle Database is hosted by a Unix server, you must run the Oracle Database installation SQL script on a Windows client that can remotely access the database server using Oracle SQL*Plus. — If you have not updated the database before, or if you are unsure how to apply database migration script, contact Technical Support before proceeding. 	Calyx RIM 6.2.8 Database Server Installation Qualification

Application Server

Step	Action	Resource
1	<p>Prepare to install a Calyx RIM 6.2.8 Application Server by completing the following applicable procedures:</p> <ul style="list-style-type: none"> — Save copies of all files that are being replaced to another location, such as a shared network drive. — As a precaution, backup and save all files associated with your Calyx RIM system that you have modified, even if they are not listed in the instructions in the following topics and are not to be replaced during this upgrade. — For any customizable files included with this certified hotfix, such as properties files or template files, compare the new files to your existing files (by performing a diff procedure, for example) to determine whether changes were made that you need to carry forward to the new files. — If you have modified the standard overrides in Calyx RIM, contact Technical Support for assistance with preparing your overrides for this upgrade. XML changes will be required and some functionality may be impacted as a result. 	N/A
2	Install a Calyx RIM 6.2.8 Application Server by following instructions provided in the Calyx RIM 6.2 CHF 7 Application Server Installation Qualification script.	Calyx RIM 6.2.8 Application Server Installation Qualification

Complete the Upgrade

Step	Action	Resource
1	Complete Client Configuration according to the Calyx RIM 6.2.8 Client Installation Qualification script.	Calyx RIM 6.2.8 Client Installation Qualification
2	Complete all post migration tasks listed in the Calyx RIM 6.2.8 Data Migration Document, if applicable.	Calyx RIM 6.2.8 Data Migration Document
3	<p>Post-installation procedures</p> <ul style="list-style-type: none"> — Complete the post-installation tasks. — Create assembly templates from template files. — Ensure the most current versions of DTD files and template files are installed with Calyx RIM 6.2.8. 	<ul style="list-style-type: none"> — Post-installation Tasks — Create Assembly Templates from Template Files — DTD Files — eCTD Template Files

Step	Action	Resource
	<p>To complete the upgrade process, use these links to the optional supporting tools. This is a list of the current, optional supporting tools as of the date this topic was updated. Other versions of these tools may be supported as well. Consult the Calyx RIM SSD for details on these versions.</p>	<ul style="list-style-type: none"> – Liquent SmartLink for PDF 1.8 CHF 1 Installation You must apply Calyx RIM Linking plug-in (PDF) CHF 1 Hotfix 1.8.1.2 to a system running Calyx RIM Linking plug-in (PDF) v1.8 CHF 1. These are available for download at the FTP site. – Liquent InSight Rendering 4.4 CHF 2 Installation. – Liquent SmartLink for Word 1.8 CHF 1 Installation – Liquent Cumulative View Builder 2.3 Installation – Calyx RIM 6.2 CHF 7 Analytics Server Installation and Update Installation Qualification – Liquent InSight Validator 5.1 Installation

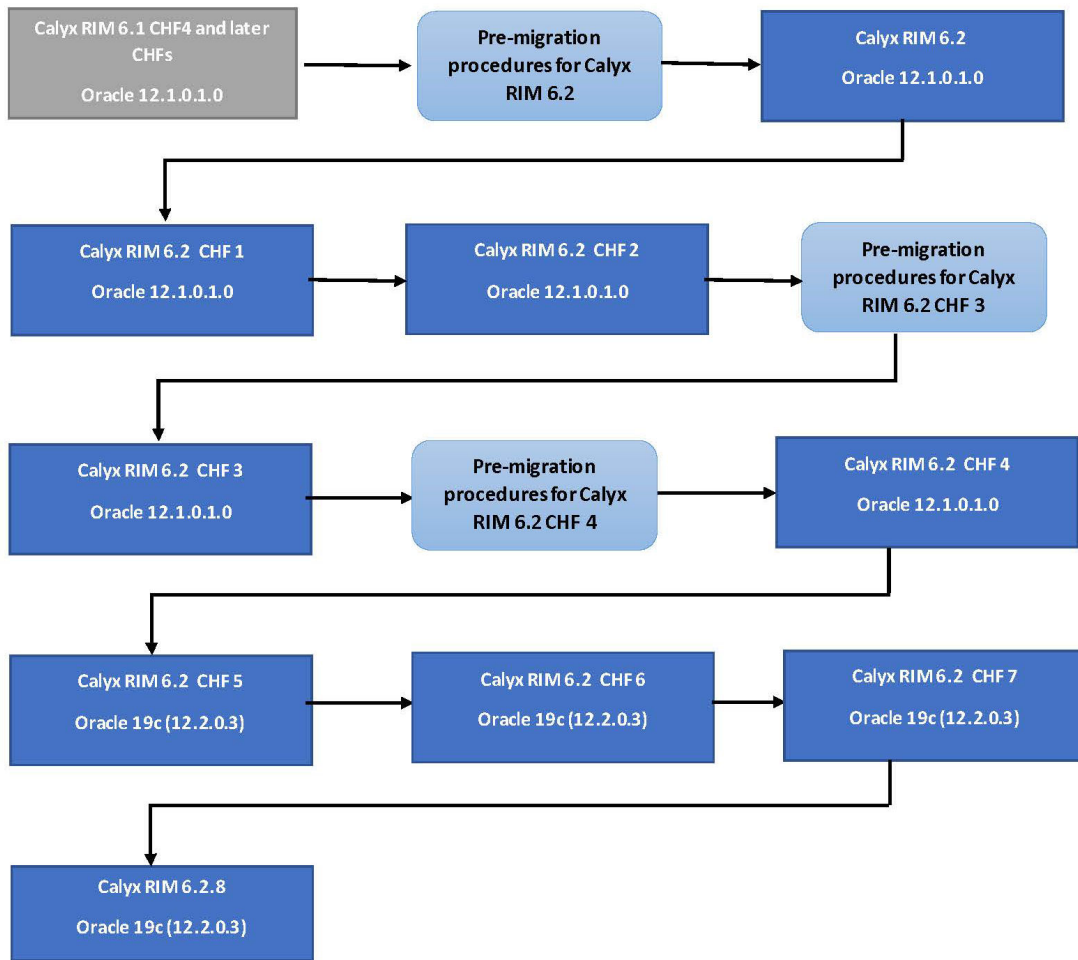
Migration Path

To use the latest version of the Calyx RIM 6.2 certified hotfix, follow the migration path that is applicable to your current version of Calyx RIM

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

Important points about the database migration flow:

- The upgrade to any Calyx RIM 6.2 CHF can only be done from Calyx RIM 6.2. Follow the database migration path from your current version of Calyx RIM 6.2 before proceeding to the database migration for Calyx RIM 6.2 CHF.
- The upgrade to Calyx RIM 6.2 can only be done from the Calyx RIM 6.1 CHF 4 and later CHFs. To upgrade to earlier version of Calyx RIM refer to installation procedures for Calyx RIM 6.1
- When migrating from a previous version of Calyx RIM to a newer, major version of the product, your saved Public and Private queries will not be saved. After your migration is completed, if an error appears when running a query saved in your previous version, use the selected values on the query page to create a new saved query.



The following flowcharts illustrate the database migration path for Calyx RIM 6.2, the supported Oracle database version, and required pre- and post-migration steps for each Calyx RIM6.2 version.

The following table lists the upgrade packages that need to be used during the migration to the most recent Calyx RIM 6.2 CHF.

Calyx RIM Version	Upgrade Package	Application Server Build
Calyx RIM 6.2	DB_update6_2_0_0000_0200.zip	6.2.0.0.0296
Calyx RIM 6.2 CHF 1	DB_hotfix6_2_0_chf1_0015.zip	6.2.0.1.0004
Calyx RIM 6.2 CHF 2	DB_hotfix6_2_0_chf2_0062.zip	6.2.0.2.0069

Calyx RIM Version	Upgrade Package	Application Server Build
Calyx RIM 6.2 CHF 3	DB_hotfix6_2_0_chf3_0039.zip	6.2.0.3.0062
Calyx RIM 6.2 CHF 4	DB_hotfix6_2_0_chf4_0086.zip	6.2.0.4.0079
Calyx RIM 6.2 CHF 5	DB_hotfix6_2_0_chf5_0027.zip	6.2.0.5.0055
Calyx RIM 6.2 CHF 6	DB_hotfix6_2_0_chf6_0003.zip	6.2.0.6.0007
Calyx RIM 6.2 CHF 7	DB_hotfix6_2_0_chf7_0007.zip	6.2.0.7.0007
Calyx RIM 6.2.8	DB_hotfix6_2_0_chf8_0005.zip	6.2.0.8

Post-Installation Tasks

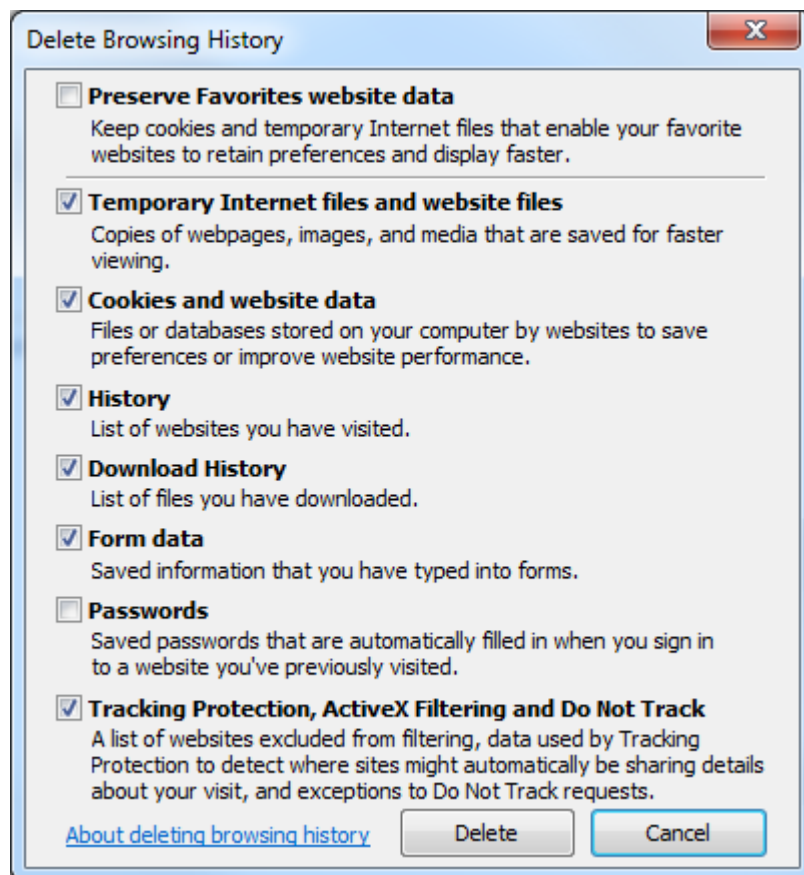
Prerequisites

Before you can use any Calyx RIM 6.2 CHF, you must perform post-installation tasks.

Important: After each Certified Hotfix upgrade, Calyx RIM drops and recreates all views. This affects any custom database objects that have been created and granted rights against any of the Calyx RIM database objects. This also affects each customized report (query) which may need to be recreated. If you have any customization applied, you will need to load them back after the upgrade is completed.

After you install Calyx RIM 6.2 CHF:

1. If you customized any properties files before you installed the CHF and you need to maintain the customizations, add your customizations to the new properties files.
2. Create new assembly templates.
3. If you customized any template files before you installed Calyx RIM 6.2 CHF, and you need to maintain the customizations, add your customizations after the certified hotfix template files are installed.
4. Clear temporary Internet files in Internet Explorer.
 - a) In the Internet Explorer **Tools** menu, select **Internet Options**.
 - b) On the **Internet Options** dialog box, click **Delete**.
 - c) On the **Delete Browsing History** dialog box, select the following options and then click **Delete**:
 - Temporary Internet files and website files
 - Cookies and website data
 - History
 - Download History
 - Form data
 - Tracking Protection, ActiveX Filtering and Do Not Track



5. If you use Veeva, its temporary files accumulate on the application server and remain there until removed. To free up space on the server, delete the files from the temporary directory in the default location (C:\Users\\AppData\Local\Temp) and restart the server.

Create Assembly Templates from Template Files

Prerequisites

After you install the new Calyx RIM 6.2 CHF, create assembly templates from the template files that you import.

To create an assembly template from a template file:

1. From a Calyx RIM Web client workstation, log on to Calyx RIM.
2. If a version of the template file already exists in Calyx RIM, delete or rename the existing template file.
 - To delete the existing template - On the Calyx RIM home page, select the **Assembly Templates** tab, then choose the template. On the **More** menu, select **Delete** and then confirm the deletion.
 - To rename the existing template - On the Calyx RIM home page, select the **Assembly Templates** tab, then choose the template. Click the **Edit** icon, update the **Name** field, and click **Save**.
3. Navigate to the **Assembly Templates** tab, and then in the menu bar, click **New > Template**.
The *Create Template* page appears.
4. Select **Assembly File**, browse to the location where you saved your new templates, and then choose the assembly template file.
5. Set **Use Source Assembly Publishing Settings Library** to **Yes**.
6. Set the **Import Publishing Elements** to **Yes**.
7. Click **Next**. The *Assembly Attributes* page appears for the template you created.

DTD Files

To conform to the current submission specifications, you must update the DTD files to the latest version.

To make sure that you have the current version of each listed DTD file on your system, refer to the **Last Modified Build** column in the table. This column displays the product build number in which the file was introduced or updated.

Component	Customizable	Last Modified Build
\\DTDs\\au-0-90.zip	No	6.2.0.0.0296
\\DTDs\\au-0-90-ectd.zip	No	6.2.0.0.0296
\\DTDs\\au-3-0.zip	No	6.2.0.0.0296
\\DTDs\\au-3-0-ectd.zip	No	6.2.0.0.0296
\\DTDs\\au-3-1.zip	No	6.2.0.0.0296
\\DTDs\\au-3-1-ectd.zip	No	6.2.0.0.0296
\\DTDs\\au-nees-2-0.zip	No	6.2.0.0.0296
\\DTDs\\au-nees-2-0-ectd.zip	No	6.2.0.0.0296
\\DTDs\\ca-1-0.zip	No	6.2.0.0.0296
\\DTDs\\ca-1-0-ectd.zip	No	6.2.0.0.0296
\\DTDs\\ca-2-2.zip	No	6.2.0.0.0296
\\DTDs\\ca-2-2-ectd.zip	No	6.2.0.0.0296
\\DTDs\\ch-1-0-1.zip	No	6.2.0.0.0296
\\DTDs\\ch-1-0-1-ectd.zip	No	6.2.0.0.0296
\\DTDs\\ch-1-1.zip	No	6.2.0.0.0296
\\DTDs\\ch-1-1-ectd.zip	No	6.2.0.0.0296
\\DTDs\\ch-1-2.zip	No	6.2.0.0.0296
\\DTDs\\ch-1-2-ectd.zip	No	6.2.0.0.0296
\\DTDs\\ch-1-3.zip	No	6.2.0.0.0296
\\DTDs\\ch-1-3-ectd.zip	No	6.2.0.0.0296
\\DTDs\\ch-1-4.zip	No	6.2.0.2.0069
\\DTDs\\ch-1-4-ectd.zip	No	6.2.0.2.0069
\\DTDs\\ch-1-5.zip	No	6.2.0.5.0055

Component	Customizable	Last Modified Build
\DTDs\ch-1-5-ectd.zip	No	6.2.0.5.0055
\DTDs\cn-1-0.zip	No	6.2.0.8
\DTDs\cn-1-0-ectd.zip	No	6.2.0.8
\DTDs\ea-1-0.zip	No	6.2.0.6.0007
\DTDs\ea-1-0-ectd.zip	No	6.2.0.6.0007
\DTDs\eu-1-0.zip	No	6.2.0.0.0296
\DTDs\eu-1-0-ectd.zip	No	6.2.0.0.0296
\DTDs\eu-1-1.zip	No	6.2.0.0.0296
\DTDs\eu-1-1-ectd.zip	No	6.2.0.0.0296
\DTDs\eu-1-2-1.zip	No	6.2.0.0.0296
\DTDs\eu-1-2-1-ectd.zip	No	6.2.0.0.0296
\DTDs\eu-1-3.zip	No	6.2.0.0.0296
\DTDs\eu-1-3-ectd.zip	No	6.2.0.0.0296
\DTDs\eu-1-4.zip	No	6.2.0.0.0296
\DTDs\eu-1-4-ectd.zip	No	6.2.0.0.0296
\DTDs\eu-2-0.zip	No	6.2.0.0.0296
\DTDs\eu-2-0-ectd.zip	No	6.2.0.0.0296
\DTDs\eu-3-0.zip	No	6.2.0.0.0296
\DTDs\eu-3-0-1.zip	No	6.2.0.4.0079
\DTDs\eu-3-0-1-ectd.zip	No	6.2.0.4.0079
\DTDs\eu-3-0-ectd.zip	No	6.2.0.0.0296
\DTDs\form-1-1.zip	No	6.2.0.0.0296
\DTDs\form-1-1-ectd.zip	No	6.2.0.0.0296
\DTDs\gc-1-2.zip	No	6.2.0.0.0296
\DTDs\gc-1-2-ectd.zip	No	6.2.0.0.0296
\DTDs\gc-1-5.zip	No	6.2.0.4.0079
\DTDs\gc-1-5-ectd.zip	No	6.2.0.4.0079
\DTDs\hr-1-4.zip	No	6.2.0.0.0296
\DTDs\hr-1-4-ectd.zip	No	6.2.0.0.0296
\DTDs\ich-3-2.zip	No	6.2.0.0.0296

Component	Customizable	Last Modified Build
\DTDs\ich-3-2-ectd.zip	No	6.2.0.0.0296
\DTDs\jo-1-0.zip	No	6.2.0.4.0079
\DTDs\jo-1-0-ectd.zip	No	6.2.0.4.0079
\DTDs\jo-1-1.zip	No	6.2.0.6.0007
\DTDs\jo-1-1-ectd.zip	No	6.2.0.6.0007
\DTDs\jp-1-0.zip	No	6.2.0.0.0296
\DTDs\jp-1-0-ectd.zip	No	6.2.0.0.0296
\DTDs\pim-2-1.zip	No	6.2.0.0.0296
\DTDs\pim-2-1-ectd.zip	No	6.2.0.0.0296
\DTDs\schema.properties	Yes	6.2.0.7.0006
\DTDs\stf-2-2.zip	No	6.2.0.0.0296
\DTDs\stf-2-2-3-0.zip	No	6.2.0.0.0296
\DTDs\stf-2-2-3-0-ectd.zip	No	6.2.0.0.0296
\DTDs\stf-2-2-5-0.zip	No	6.2.0.2.0069
\DTDs\stf-2-2-5-0-ectd.zip	No	6.2.0.2.0069
\DTDs\stf-2-2-ectd.zip	No	6.2.0.0.0296
\DTDs\th-0-92.zip	No	6.2.0.0.0296
\DTDs\th-0-92-ectd.zip	No	6.2.0.0.0296
\DTDs\th-1-0.zip	No	6.2.0.0.0296
\DTDs\th-1-0-ectd.zip	No	6.2.0.0.0296
\DTDs\tw-1-0.zip	No	6.2.0.7.0006
\DTDs\tw-1-0-ectd.zip	No	6.2.0.7.0006
\DTDs\us-2-01.zip	No	6.2.0.0.0296
\DTDs\us-2-01-ectd.zip	No	6.2.0.0.0296
\DTDs\us-2-01-ectd-folder.zip	No	6.2.0.0.0296
\DTDs\us-3-3.zip	No	6.2.0.0.0296
\DTDs\us-3-3-ectd.zip	No	6.2.0.0.0296
\DTDs\za-1-0.zip	No	6.2.0.0.0296
\DTDs\za-1-0-ectd.zip	No	6.2.0.0.0296
\DTDs\za-2-1.zip	No	6.2.0.0.0296

Component	Customizable	Last Modified Build
\DTDs\za-2-1-ectd.zip	No	6.2.0.0.0296

eCTD Template Files

Calyx RIM includes ICH-compliant eCTD templates with preconfigured folder types to capture the metadata for the specific headings in the eCTD that require additional information: drug substance, drug product, excipient, clinical indication, and regional administrative information.

To ensure that you have the current version of each listed template file on your system, refer to the **Modified/Introduced in Version** column in the **Template Files** table. This column contains information about the template status for every version in the Calyx RIM6.2 branch:

- **No** - template was not updated
- **Yes** - template was updated
- **New** - template introduced or updated
- **N/A** - template did not exist for the release

Template	Modified/Introduced in Version								
	6.2	6.2 CHF 1	6.2 CHF 2	6.2 CHF 3	6.2 CHF 4	6.2 CHF 5	6.2 CHF 6	6.2 CHF 7	6.2.8
	Build 6.2.0.0.0296	Build 6.2.0.1.0004	Build 6.2.0.2.0069	Build 6.2.0.3.0039	Build 6.2.0.4.0079	Build 6.2.0.5.0055	Build 6.2.0.6.0007	Build 6.2.0.7.0006	Build 6.2.0.8
templates \510k Template (Sep 2019).xml	N/A	N/A	N/A	N/A	New	No	No	No	No
\templates \510k template.xml	No	No	No	No	No	No	No	No	No
\templates \A4SampleTOCTemplate.docx	No	No	No	No	No	No	No	No	No
\templates \ASEAN ACTD-NeeS.xml	No	No	No	No	No	No	No	No	No
\templates\AU eCTD Module 1 v0.90.xml	No	No	No	No	No	No	No	No	No
\templates\AU eCTD Module 1 v3.0.xml	No	No	No	No	No	No	No	No	No

Template	Modified/Introduced in Version								
	6.2	6.2 CHF 1	6.2 CHF 2	6.2 CHF 3	6.2 CHF 4	6.2 CHF 5	6.2 CHF 6	6.2 CHF 7	6.2.8
	Build 6.2.0.0.0296	Build 6.2.0.1.0004	Build 6.2.0.2.0069	Build 6.2.0.3.0039	Build 6.2.0.4.0079	Build 6.2.0.5.0055	Build 6.2.0.6.0007	Build 6.2.0.7.0006	Build 6.2.0.8
\\templates\AUS Module 1 CTD v2.1.xml	No	No	No	No	No	No	No	No	No
\\templates\AUS Module 1 CTD-NeeS v2.0 2011.xml	No	No	No	No	No	No	No	No	No
\\templates\AU Module 1 eCTD v3.1.xml	New	No	No	No	No	No	No	No	No
\\templates\AU Module 1 NeeS v2.0.xml	New	No	No	No	No	No	No	No	No
\\templates\Canadian eCTD Module 1 v1.0.xml	No	No	No	No	No	No	No	No	No
\\templates\Canadian eCTD Module 1 v2.2.xml	No	No	No	No	No	No	No	No	No
\\templates\Canadian electronic CTA CTA-A-29-May-2013.xml	No	No	No	No	No	No	No	No	No
\\templates\Canadian electronic CTA.xml	No	No	No	No	No	No	No	No	No
\\templates\CH eCTD Module 1 v1.0.1.xml	No	No	No	No	No	No	No	No	No

Template	Modified/Introduced in Version								
	6.2	6.2 CHF 1	6.2 CHF 2	6.2 CHF 3	6.2 CHF 4	6.2 CHF 5	6.2 CHF 6	6.2 CHF 7	6.2.8
	Build 6.2.0.0.0296	Build 6.2.0.1.0004	Build 6.2.0.2.0069	Build 6.2.0.3.0039	Build 6.2.0.4.0079	Build 6.2.0.5.0055	Build 6.2.0.6.0007	Build 6.2.0.7.0006	Build 6.2.0.8
\\templates\CH eCTD Module 1 v1.1.xml	No	No	No	No	No	No	No	No	No
\\templates\CH eCTD Module 1 v1.2.xml	No	No	No	No	No	No	No	No	No
\\templates\CH eCTD Module 1 v1.3.xml	No	No	No	No	No	No	No	No	No
\\templates\CH eCTD Module 1 v1.4.xml	N/A	N/A	New	Yes	No	No	No	No	No
\\templates\CH eCTD Module 1 v1.5.xml	N/A	N/A	N/A	N/A	N/A	New	No	No	No
\\templates\CN eCTD Module 1 v1.0.xml	N/A	N/A	N/A	N/A	New	No	No	No	Yes
\\templates\CN eCTD ICH Module 2-5 v3.2.xml	N/A	N/A	N/A	N/A	New	No	No	No	Yes
\\templates\CN Clinical Study Report (VV5-0).xml	N/A	N/A	N/A	N/A	New	No	No	No	Yes
\\templates\CN Nonclinical Study Report (SEND Dataset).xml	N/A	N/A	N/A	N/A	New	No	No	No	No

Template	Modified/Introduced in Version								
	6.2	6.2 CHF 1	6.2 CHF 2	6.2 CHF 3	6.2 CHF 4	6.2 CHF 5	6.2 CHF 6	6.2 CHF 7	6.2.8
	Build 6.2.0.0.0296	Build 6.2.0.1.0004	Build 6.2.0.2.0069	Build 6.2.0.3.0039	Build 6.2.0.4.0079	Build 6.2.0.5.0055	Build 6.2.0.6.0007	Build 6.2.0.7.0006	Build 6.2.0.8
\\templates\CN Nonclinical Study Report.xml	N/A	N/A	N/A	N/A	New	No	No	No	No
\\templates\ eCTD ICH Module 2-5 v3.2.xml	No	No	Yes	No	No	No	No	No	No
\\templates\ \EAEU Template v1.0.xml	N/A	N/A	N/A	N/A	New	Yes	Yes	No	No
\\templates\EU CTA.xml	No	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v1.0 - CP.xml	No	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v1.0 - MRP-DCP.xml	No	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v1.0 - NP.xml	No	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v1.1 - CP.xml	No	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v1.1 - MRP-DCP.xml	No	No	No	No	No	No	No	No	No

Template	Modified/Introduced in Version								
	6.2	6.2 CHF 1	6.2 CHF 2	6.2 CHF 3	6.2 CHF 4	6.2 CHF 5	6.2 CHF 6	6.2 CHF 7	6.2.8
	Build 6.2.0.0.0296	Build 6.2.0.1.0004	Build 6.2.0.2.0069	Build 6.2.0.3.0039	Build 6.2.0.4.0079	Build 6.2.0.5.0055	Build 6.2.0.6.0007	Build 6.2.0.7.0006	Build 6.2.0.8
\\templates\EU eCTD Module 1 v1.1 - NP.xml	No	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v1.2.1 - CP.xml	No	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v1.2.1 - MRP-DCP.xml	No	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v1.2.1 - NP.xml	No	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v1.3 - CP.xml	No	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v1.3 - MRP-DCP.xml	No	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v1.3 - NP.xml	No	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v1.4 - CP.xml	No	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v1.4 - MRP-DCP.xml	No	No	No	No	No	No	No	No	No

Template	Modified/Introduced in Version								
	6.2	6.2 CHF 1	6.2 CHF 2	6.2 CHF 3	6.2 CHF 4	6.2 CHF 5	6.2 CHF 6	6.2 CHF 7	6.2.8
	Build 6.2.0.0.0296	Build 6.2.0.1.0004	Build 6.2.0.2.0069	Build 6.2.0.3.0039	Build 6.2.0.4.0079	Build 6.2.0.5.0055	Build 6.2.0.6.0007	Build 6.2.0.7.0006	Build 6.2.0.8
\\templates\EU eCTD Module 1 v1.4 - NP.xml	No	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v2.0 - CP.xml	No	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v2.0 - MRP-DCP.xml	No	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v2.0 - NP.xml	No	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v3.0 - CP.xml	No	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v3.0 - MRP-DCP.xml	No	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v3.0 - NP.xml	No	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v3.0.1 - CP.xml	No	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v3.0.1 - MRP-DCP.xml	No	No	No	No	No	No	No	No	No

Template	Modified/Introduced in Version								
	6.2	6.2 CHF 1	6.2 CHF 2	6.2 CHF 3	6.2 CHF 4	6.2 CHF 5	6.2 CHF 6	6.2 CHF 7	6.2.8
	Build 6.2.0.0.0296	Build 6.2.0.1.0004	Build 6.2.0.2.0069	Build 6.2.0.3.0039	Build 6.2.0.4.0079	Build 6.2.0.5.0055	Build 6.2.0.6.0007	Build 6.2.0.7.0006	Build 6.2.0.8
\\templates\EU eCTD Module 1 v3.0.1 - NP.xml	No	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v3.0.3 - CP.xml	New	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v3.0.3 - MRP-DCP.xml	New	No	No	No	No	No	No	No	No
\\templates\EU eCTD Module 1 v3.0.3 - NP.xml	New	No	No	No	No	No	No	No	No
\\templates\EU IMPD template.xml	No	No	No	No	No	No	No	No	No
\\templates\EU PMF Submission in eCTD.xml	No	No	No	No	No	No	No	No	No
\\templates\EU VNees - Immunologica l.xml	No	No	No	No	No	No	No	No	No
\\templates\EU VNees - Pharmaceutical.xml	No	No	No	No	No	No	No	No	No

Template	Modified/Introduced in Version								
	6.2	6.2 CHF 1	6.2 CHF 2	6.2 CHF 3	6.2 CHF 4	6.2 CHF 5	6.2 CHF 6	6.2 CHF 7	6.2.8
	Build 6.2.0.0.0296	Build 6.2.0.1.0004	Build 6.2.0.2.0069	Build 6.2.0.3.0039	Build 6.2.0.4.0079	Build 6.2.0.5.0055	Build 6.2.0.6.0007	Build 6.2.0.7.0006	Build 6.2.0.8
\\templates\EU VNeedS v2.2 - Immunological.xml	No	No	No	No	No	No	No	No	No
\\templates\EU VNeedS v2.2 - MRL Maximum Residue Limits.xml	No	No	No	No	No	No	No	No	No
\\templates\EU VNeedS v2.2- Pharmaceutical.xml	No	No	No	No	No	No	No	No	No
\\templates\EU VNeedS v2.3 - Immunological.xml	No	No	No	No	No	No	No	No	No
\\templates\EU VNeedS v2.3 - MRL Maximum Residue Limits.xml	No	No	No	No	No	No	No	No	No
\\templates\EU VNeedS v2.3- Pharmaceutical.xml	No	No	No	No	No	No	No	No	No
\\templates \GCC eCTD Module 1 v1.2 - GCC.xml	No	No	No	No	No	No	No	No	No
\\templates \GCC eCTD Module 1 v1.2 - NP.xml	No	No	No	No	No	No	No	No	No

Template	Modified/Introduced in Version								
	6.2	6.2 CHF 1	6.2 CHF 2	6.2 CHF 3	6.2 CHF 4	6.2 CHF 5	6.2 CHF 6	6.2 CHF 7	6.2.8
	Build 6.2.0.0.0296	Build 6.2.0.1.0004	Build 6.2.0.2.0069	Build 6.2.0.3.0039	Build 6.2.0.4.0079	Build 6.2.0.5.0055	Build 6.2.0.6.0007	Build 6.2.0.7.0006	Build 6.2.0.8
\\templates\GCC eCTD Module 1 v1.5 - GCC.xml	No	No	No	No	No	No	No	No	No
\\templates\GCC eCTD Module 1 v1.5 - NP.xml	No	No	No	No	No	No	No	No	No
\\templates\HR eCTD Module 1 v1.4 - NP.xml	No	No	No	No	No	No	No	No	No
\\templates\ICH E3 Clinical Study Report (VV2-2).xml	No	No	No	No	No	No	No	No	No
\\templates\ICH E3 Clinical Study Report (VV3-0).xml	No	No	No	No	No	No	No	No	No
\\templates\ICH E3 Clinical Study Report (VV5-0).xml	N/A	N/A	New	No	No	No	No	No	No
\\templates\JO eCTD Module 1 v1.0.xml	N/A	N/A	N/A	New	No	No	No	No	No
\\templates\JO eCTD Module 1 v1.1.xml	N/A	N/A	N/A	N/A	N/A	N/A	New	No	No

Template	Modified/Introduced in Version								
	6.2	6.2 CHF 1	6.2 CHF 2	6.2 CHF 3	6.2 CHF 4	6.2 CHF 5	6.2 CHF 6	6.2 CHF 7	6.2.8
	Build 6.2.0.0.0296	Build 6.2.0.1.0004	Build 6.2.0.2.0069	Build 6.2.0.3.0039	Build 6.2.0.4.0079	Build 6.2.0.5.0055	Build 6.2.0.6.0007	Build 6.2.0.7.0006	Build 6.2.0.8
\\templates\JP eCTD Module 1 v1.0.xml	N/A	N/A	Yes	No	No	No	No	No	No
\\templates\JP eCTD Module 2-5 v3.2.xml	No	No	No	No	No	No	No	No	No
\\templates \MD - IMDRF (HC) IVD Template.xml	N/A	N/A	N/A	N/A	New	No	No	No	No
\\templates \MD - IMDRF nIVD Template.xml	N/A	N/A	N/A	N/A	New	No	No	No	No
\\templates \Nonclinical Study Report (SEND Dataset).xml	No	No	No	No	No	No	No	No	No
\\templates \Nonclinical Study Report.xml	No	No	No	No	No	No	No	No	No
\\templates \PMA Template (Feb 2019).xml	N/A	N/A	N/A	N/A	New	No	No	No	No
\\templates \PMA Template.xml	No	No	No	No	No	No	No	No	No
\\templates \ROW CTD Module 1.xml	No	No	No	No	No	No	No	No	No

Template	Modified/Introduced in Version								
	6.2	6.2 CHF 1	6.2 CHF 2	6.2 CHF 3	6.2 CHF 4	6.2 CHF 5	6.2 CHF 6	6.2 CHF 7	6.2.8
	Build 6.2.0.0.0296	Build 6.2.0.1.0004	Build 6.2.0.2.0069	Build 6.2.0.3.0039	Build 6.2.0.4.0079	Build 6.2.0.5.0055	Build 6.2.0.6.0007	Build 6.2.0.7.0006	Build 6.2.0.8
\\templates\SampleCoverPageTemplate.docx	No	No	No	No	No	No	No	No	No
\\templates\SampleOverlayTemplate.docx	No	No	No	No	No	No	No	No	No
\\templates\SampleTOCTemplate.docx	No	No	No	No	No	No	No	No	No
\\templates\Saudi Arabia CTD Module 1 v1.0.xml	No	No	No	No	No	No	No	No	No
\\templates\THECTD Module 1 v0.92.xml	No	No	No	No	No	No	No	No	No
\\templates\THECTD Module 1 v1.0.xml	No	No	No	No	No	No	No	No	No
\\templates\TW eCTD Module 1 v1.0.xml	N/A	N/A	N/A	N/A	N/A	N/A	N/A	New	No
\\templates\UCSampleCoverPageTemplate.docx	No	No	No	No	No	No	No	No	No
\\templates\UCSampleOverlayTemplate.docx	No	No	No	No	No	No	No	No	No

Template	Modified/Introduced in Version								
	6.2	6.2 CHF 1	6.2 CHF 2	6.2 CHF 3	6.2 CHF 4	6.2 CHF 5	6.2 CHF 6	6.2 CHF 7	6.2.8
	Build 6.2.0.0.0296	Build 6.2.0.1.0004	Build 6.2.0.2.0069	Build 6.2.0.3.0039	Build 6.2.0.4.0079	Build 6.2.0.5.0055	Build 6.2.0.6.0007	Build 6.2.0.7.0006	Build 6.2.0.8
\\templates\UCSampleTOCTemplate.docx	No	No	No	No	No	No	No	No	No
\\templates\USECTD Module 1 v2.01.xml	No	No	No	No	No	No	No	No	No
\\templates\USECTD Module 1 v3.3.xml	No	No	Yes	No	No	No	No	Yes	No
\\templates\ZAECTD Module 1 v1.0.xml	No	No	No	No	No	No	No	No	No
\\templates\ZAECTD Module 1 v2.1.xml	No	No	No	No	No	No	No	No	No

Sample Templates

Calyx RIM includes additional assembly templates to enable the creation of reports or other electronic submission types. The following templates are samples for the publishing finishing options for overlays, Tables of Contents (TOC), and cover pages. Unicode (UC) templates for TOC, cover pages, and overlays are available (for A4 paper size).

- A4SampleTOCTemplate.docx
- SampleCoverPageTemplate.docx
- SampleOverlayTemplate.docx
- SampleTOCTemplate.docx
- UCSampleCoverPageTemplate.docx
- UCSampleOverlayTemplate.docx
- UCSampleTOCTemplate.docx

Calyx RIM 6.2.8 IQ Scripts

PDF copies of the Calyx RIM 6.2.8 Installation Qualification (IQ) scripts are provided for guidance in performing your installation or upgrade of Calyx RIM.

These PDF copies of the Calyx RIM 6.2.8 Installation Qualification (IQ) scripts are intended for use in conjunction with the other reference information provided in the [Upgrade Installation Guidelines](#) topic.

- [Calyx RIM 6.2.8 Application Server Installation Qualification](#)
- [Calyx RIM 6.2.8 Database Server Installation Qualification](#)
- [Calyx RIM 6.2.8 Client Installation Qualification](#)
- [Calyx RIM 6.2 CHF 7 Analytics Server Installation and Update Installation Qualification](#)
- [Calyx RIM 6.2 CHF 5 Analytics Server Upgrade Installation Qualification](#)
- [Calyx RIM 6.2 CHF 5 Analytics Server Upgrade Verification Installation Qualification](#)

To configure on Azure AD environment, refer to: [Azure Active Directory Configuration IQ script](#)

***Note:** To obtain Installation Qualification scripts (IQ) in Word file format, please contact your Business Development Representative.*

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