Configuring Templates

CALYX.AI

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2 Configuring Templates

After you have installed CALYX RIM, you should perform one-time configuration procedures that enable you to make the most of the templates.
The following eCTD specific templates are provided:

- Regional templates for the AU, CA, CH, EU, GCC, JP, TH, US, and ZA Module 1; these separate templates are provided so that if a specification change focuses just on regional update, only the changed information needs to be provided. This has been done to lessen revalidation efforts.
- A template for the common Modules 2-5.
- A Japanese Module 2-5 template, using Japanese leaf names and the patient listings sections in section 5.3.7 that are specific to Japan.

CALYX RIM includes several Wizards that assist in the creation of the overall assembly.
The eCTD Wizard automatically merges the regional and common portions for the user. The Wizard also allows for the mapping of multiple templates to a given region to allow for different specification versions to be used. When the wizard is executed, users can select from the appropriate Module 1 template to fit the business needs at the time.

In addition to the Module 1 regional configuration, you may want to create separate Module 2-5 templates for each region to customize them for each region's specific needs. The administrator may then configure the Wizard so that for a particular region its Module 2-5 template is used. For example, in the US, Study organization in XML is set to STF creation, while in the EU, this is set to node-extension. This configuration is performed on the server in the file named ectdResources.properties typically located in the RIMManager\server\all\conf\RIM directory. See the Administrator's guide for more detailed information on this configuration. Modification to this file does require a restart of the CALYX RIM Manager Service.

Before making these regional-specific Module 2-5 assemblies, however, you can set common default Publication Settings and attribute mappings in the provided Module 2-5 templates to eliminate having to repeat this process for each region.

2.1 Template Configuration Steps

You can configure templates to reflect your project, including publishing settings and leaf and study reports.

Configuration steps that are recommended for the templates are:

- Publishing to a specific publishing location: Some organizations always publish to a specific publishing location. If this applies to you, you can default the high-level output location (DMS name and publishing cabinet, for example) as part of the Assembly Template Publication Settings. Then upon assembly creation, users only have to drill down to the specific product, for example, rather than navigate through the larger repository.
- Setting overall default leaf and study report DMS mappings and values in Publication Settings to take advantage of leaf and study information attributes captured in your DMS.
- Setting or confirming other publishing settings for paper finishing options: Cover Page Settings, TOC Settings, Overlay Settings, user-defined variables, etc.

Note: The CALYX-provided Templates do have some sample user variables and TOCs configured to enable a quick start. These may be modified to suit your business needs. At a minimum, you will need to specify the location of any definition files and preview locations, for example: the TOC Template file to be used, and the Preview Location.

The EU regional and ICH eCTD v3.2 assembly templates include structure and leaf elements to create TOCs for NeeS (Non-electronic eCTD Submissions) and paper CTD submissions. After updating the TOC profiles in the Publishing Settings Library, the starting ranges for these TOCs can be set in the templates so that users do not need to set the starting range for each assembly created from them. The two TOCs on the Comprehensive Table of Contents leaf in section 1.1 of the EU templates should be set to the assembly root. Each of the Module Table of Contents in the Module 2-5 template and the EU template should be set to its respective Module folder.

Note: If these templates are exported as assembly files and then re-imported, the Range Start setting is not persisted and needs to be redone.

- Setting default mappings for product-specific information if captured as DMS values:
  The templates are configured to capture the additional information required in certain sections of the eCTD through the use of special folders. These special folder types are applied to the following sections within the Assembly:
  - 2.3.S Drug Substance (substance and manufacturer)
  - 2.3.P Drug Product (product name, manufacturer, dosage form)
  - 2.7.3 Summary of Clinical Efficacy (indication)
  - 3.2.S Drug Substance (substance and manufacturer)
  - 3.2.P Drug Product (product name, manufacturer, dosage form)
  - 3.2.P.4 Excipients (excipient name)
  - 3.2.A.1 Facilities and Equipment (manufacturer, substance, dosage form, and product name)
  - 3.2.A.2 Adventitious Agents (manufacturer, substance, dosage form, and product name)
  - 3.2.A.3 Excipients (excipient)

Note: If these templates are exported as assembly files and then re-imported, the Range Start setting is not persisted and needs to be redone.

- 5.3.5 Reports of Efficacy and Safety Studies (indication)

By entering DMS mappings on the extended attributes of these folders, the attributes of the content assigned in these sections will be used to populate the attributes in the published XML as well as build appropriate folder paths when the assembly is created from the template.

Note: If more than one document is included under a section, the attributes of the first document in that section are used to resolve the mapped value.

If this information is not captured in your DMS or you are creating the assembly using the Create eCTD Wizard, you will be prompted for it while executing the Wizard and may adjust it at any point after the assembly is created.

Note: There are some other special folder types applied to sections of the assembly used by the publishing engine that do not have additional attributes, the user does not need to adjust these folders.

After the Module 2-5 template has been configured to take advantage of the options above, the regional Module 2-5 templates can be created for each region by creating a new template using the provided template as the starting point, making appropriate adjustments and configuring the Wizard settings to use the appropriate template for each region.

The following Module 2-5 configuration steps may prove useful:

1. Ensure all relevant XML Definition files are active. By default the templates are shipped with these defined, but as their location will change in each environment, this screen should be accessed and the choices re-applied. The extended types available for folders and leafs are driven by the active XML Definition files. If an expected type is not available, verify that the corresponding Definition file is active.
2. Set the Module 4 and Module 5 Study Organization settings to appropriate values for each region. This option improves assembly reuse potential across regions as well as improves Study Report processing overall. The user can set how all Studies in each Module should be organized in the index.xml (STF, node-extension, leaf only) as well as in the directory structure (whether an additional folder should be created at the end of the default directory path to hold all study documents – this uses the assembly folder's name). All Study Reports in the assembly should be organized into Study Report folders to take advantage of this option, which if you use the Study Report Wizard to create, will be the default setting. The Module Studies extension also has a Subject Matter attribute, that can be inherited by all leafs under the study report folders, for example, on the Module 4 folder, this can be set to nonclinical-data or pre-clinical-study-report, and all study report leafs may be left as Default leafs and will inherit the Module value. For any exceptions, the exception leafs can be explicitly set to Study Report Leafs and the subject matter value selected from the Advanced list.
3. For each region where STFs will be provided, since only specific study types require additional category information, such as species, route of administration, etc., users may want to develop

separate Study Report Assembly structures for those sections and set values for those specific study types. These types and the requested attributes are as follows:

- Section 4.2.3.1 Single Dose Toxicity Studies should include species and route of administration
- Section 4.2.3.2 Repeat Dose Toxicity Studies should include species, route of administration, and duration
- Section 4.2.3.4.1 Long Term Carcinogenicity Studies should include species
- Section 5.3.5.1 Controlled Clinical Studies Pertinent to the Indication should include type of control
- The Assembly templates include comments on the folders listed above that describe the requested attribute as an additional tip to the user. The other study types do not require this additional information, although these attributes are available for all study reports to allow for any special requests and/or agreements with regulatory authorities. If the values listed above are captured in the DMS, users can set the mappings for the necessary attributes for each study type, and later use the duplicate folder functionality for other studies within that section to take advantage of the templated mappings. These different assembly templates can be associated with their appropriate sections through configuration of the "StudyReportResources.properties" file on the Server to ensure the Wizard uses these samples when adding new study reports to the desired sections. See the Administrator's guide for more detail on this configuration option. Modification to this file does require a restart of the CALYX RIM Manager Service.

4. If STFs will be provided in the EU, Canada and/or Japan, users should select Module 4 folder and reset the subject matter value to "pre-clinical-study-report" as the default value, "nonclinical-data" is a US-specific value.
5. If node-extensions will be used for the EU and/or Canada, change the setting for Study Organization in XML on the Module 4 and 5 folders to node-extension. The setting on the Module folder dictates how Study Report folders in these modules will be processed.

Note: Instead of requiring the user to change the type of Study Report folders for different regions, they always should be of type Study Report and the setting on the Module folder dictates how they are processed during publishing: STF, node-extensions, leaf-only.

6. In the EU and Canadian templates, remove the sample ISS and ISE folders from section 5.3.5.3.
7. Adjust Paper options as necessary. The templates do include default variables for tabs and TOCs and samples are applied in the templates. If these require adjustment for regional needs, these should be done here. The default tab text includes the CTD number and the abbreviated leaf name. For leaf elements in Study Reports, the default has been overridden to use the Study Report folder abbreviated name and the leaf abbreviated name, since the Study Report folders are not numbered. To take advantage of this, when creating study reports, it will be most beneficial to populate the folder abbreviated name with just the study number to ensure information fits on the tabs.
8. Adjust abbreviations on leaf elements to your desired values. The templates provided did not truncate values in the abbreviated folder or leaf names as different customers have different rules for abbreviating values. The template administrator should review the templates to determine folder and file names that exceed acceptable corporate guidelines and abbreviate appropriately.
9. Ensure that other leaf element attributes are set appropriately. Attributes such as 'font library', 'role', 'actuate', and 'show' are unused in regional and ICH specifications. Attributes such as 'modified

leaf, ‘modified leaf sequence’, ‘operation’, and ‘leaf ID’ are reserved by CALYX RIM and will always be appropriately populated in the final, published XML. The following attributes are optional and don’t have to be populated at all to be valid:

- **Version** - Should be used to record the internal DMS document version number but again is not required, EXCEPT in the case of sending STF files and in this case must be set to ‘STF Version 2.2’ which CALYX RIM will do automatically at publish time.
- **Application Version** - Should be used to record the product and version used to create the document, for example ‘PDF 1.4’, ‘Word 2003’, or ‘SPL v2’, etc.
- **Font Library** - Should be used to indicate the set of fonts necessary to correctly view the document; is generally not needed as all fonts should be embedded if possible in the output format.