



CALYX™

EAEU-Submissions  
Best Practice Calyx  
RIM Publishing

CALYX.AI



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# 1 Create EAEU Submissions

The following set of procedures provides best practice guidance for creating EAEU submissions. There are several procedures to perform when creating EAEU submissions:

- Create assembly
- Populate extended attributes for assembly leafs
- Publish
- Embed output PDFs into the submission xml

## 1.1 Create an Assembly

1. Run the **Create eCTD** wizard, complete the envelope information and select the sections to add to the submission.
2. Specify the number of repeatable sections and populate the metadata required for some sections.

The screenshot shows the 'Create eCTD' wizard interface. On the left is a navigation pane with options: 'Choose Region', 'Select Attributes', 'Set Application Metadata', 'Select Sections', and 'Select Sets of Submission Metadata' (highlighted with a blue arrow). The main area has a header 'Select the number of sets of assembly metadata to add.' Below this, there are two rows of metadata sets with input fields for their counts:

Sets of Drug Solvent (3.2.A.3 Новые вспомогательные вещества (восстановители, растворители, разбавители, носители))	1
Sets of Drug Substance (2.3.S Общее описание активной фармацевтической субстанции)	1

The screenshot shows the 'Create eCTD' wizard interface at the 'Set Submission Metadata' step. The navigation pane on the left has 'Set Submission Metadata' highlighted with a blue arrow. The main area has a header 'Specify the assembly metadata attributes.' It lists two metadata sets with their respective attributes:

**Drug Solvent(3.2.A.3 Новые вспомогательные вещества (восстановители, растворители, разбавители, носители))**

Set #1  
 Solvent Name : solvent  
 Solvent Manufacturer : solvent\_manufacturer

**Drug Substance(2.3.S Общее описание активной фармацевтической субстанции)**

Set #1  
 Drug Substance Name : \*substance  
 Drug Substance Manufacturer : \*substance\_manufacturer

3. Finish the wizard and navigate to the new assembly.

- Please note that metadata populated in the wizard will be used automatically to update the output folder names for the appropriate folders:

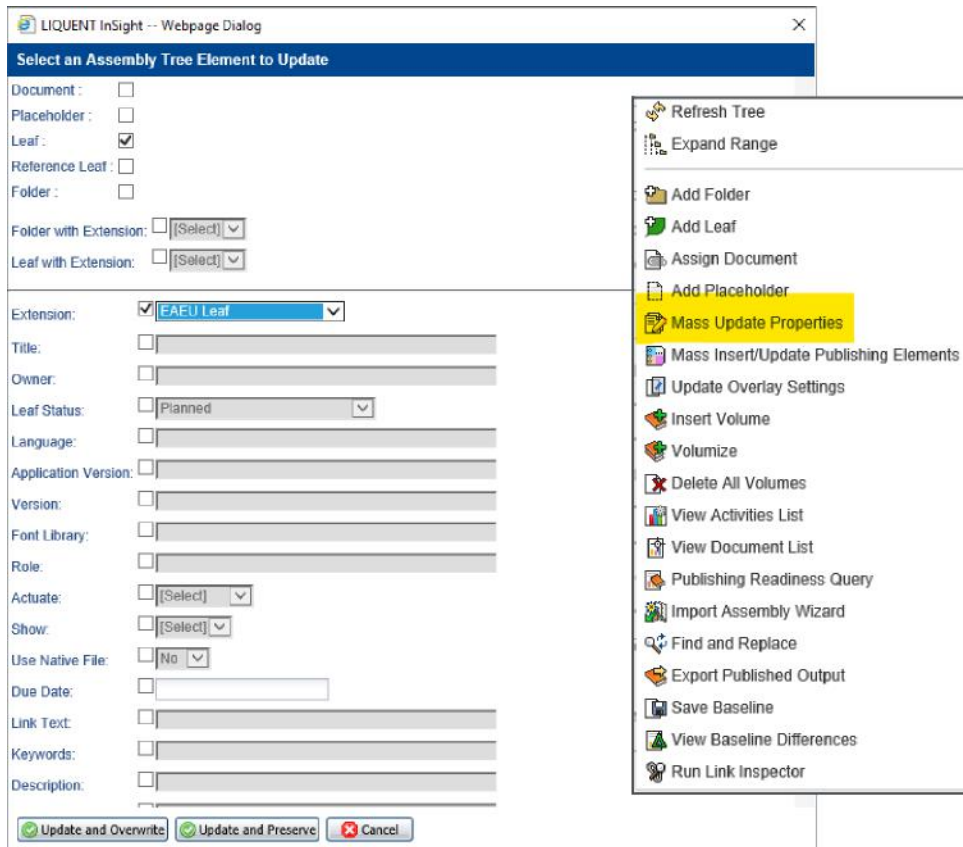
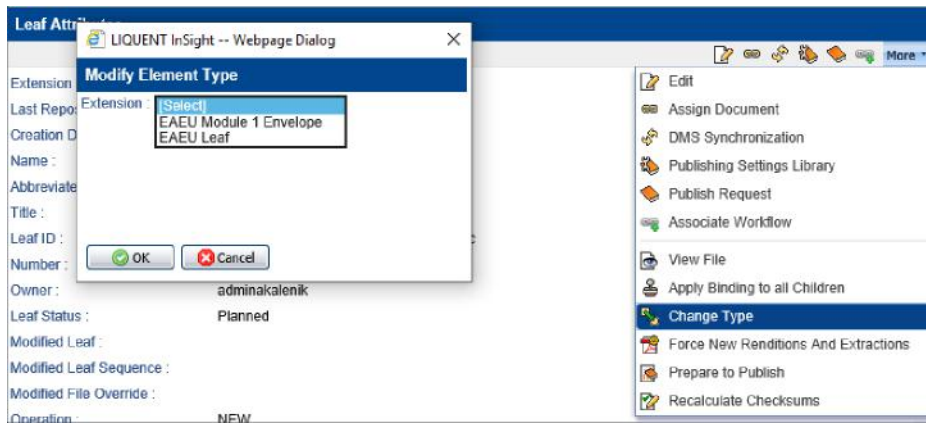
Folder Attributes	
Lock Indicator :	No
Number :	3.2.S
Owner :	adminakalenik
Due Date :	
Keywords :	
Description :	
Creation Date :	14-May-2020
Comments :	
Output Folder :	32s-drug-sub/substance-substance_manufacturer
Division :	
Force New Volume :	No
<hr/>	
Drug Substance Name :	substance
Drug Substance Manufacturer :	substance_manufacturer

Folder Attributes	
Lock Indicator :	No
Number :	3.2.A.3
Owner :	adminakalenik
Due Date :	
Keywords :	
Description :	
Creation Date :	14-May-2020
Comments :	
Output Folder :	solvent-sovent_manufacturer
Division :	MINOR
Force New Volume :	No
<hr/>	
Solvent Name :	solvent
Solvent Manufacturer :	sovent_manufacturer

- Assign documents to the assembly.

## 1.2 Populate Extended Attributes for Assembly Nodes

1. All leafs in the EAEU assembly must have an **EAEU Leaf** extension. If some leafs were auto-created as a result of document assignment, they need to be updated to set the **EAEU Leaf** extension, whether individually by using the **Change Type** menu option, or in bulk using the **Mass Update Properties** functionality. When using the **Mass Update Properties functionality**, be sure to click **Update and Preserve**.

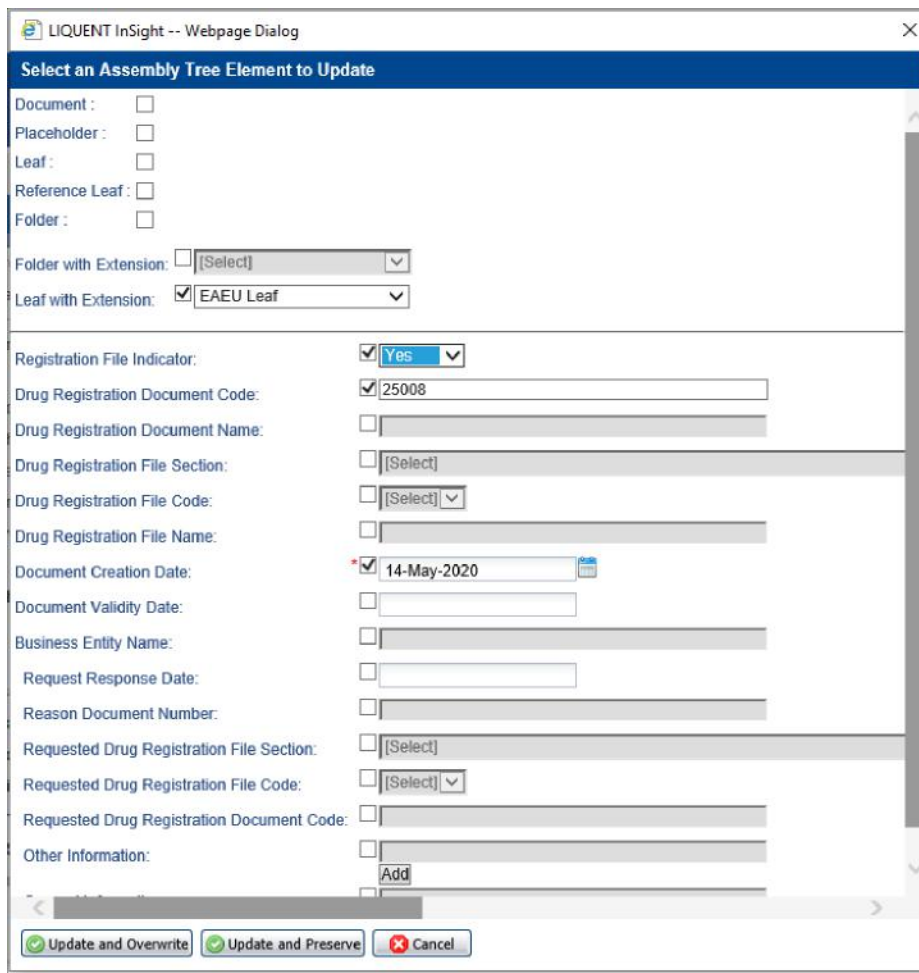


2. All leafs in an EAEU assembly must have the following extended attributes populated:

- Registration File Indicator
- Drug Registration Document Code
- Document Creation Date

Although the **Registration File Indicator** and **Drug Registration Document Code** values are populated for the leafs created from the template, leafs auto-created as a result of document assignment will not have those values populated.

Values must be populated, whether individually on each leaf by using the **Edit** menu option, or in bulk using the **Mass Update Properties** functionality.



**Note:** Please make sure you select the correct option, **Update and Overwrite** or **Update and Preserve**, depending on if you want previously populated values to be preserved or overridden.

If Drug Registration Code is not specified, you should specify Drug Registration Document Name.

### 1.3 Publish

Publishing EAEU submissions consists of 2 separate phases:

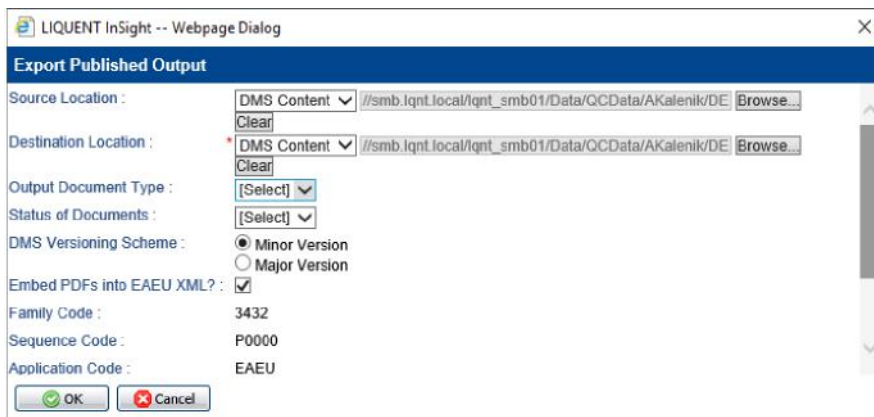
- Generate file/folder structure with the submission xml.
- Embed content of PDF documents into submission xml.

The first phase is the same as publishing any ICH eCTD submission. Once the file/folder structure and submission xml are generated, all post-publishing activities, like linking and QCing the submission, should be done against this output.

Only after the submission is finalized and ready to be sent to the agency, proceed to the phase of embedding PDF documents into the submission xml.

Follow these steps to embed PDF documents into the submission xml:

1. Select assembly. In the **Publishing** view, right-click on the assembly root.
2. Select **Export Published Output**.
3. In the Export Published Output window, provide the valid values for the **Source Location** and **Destination Location** fields. For **Source Location**, a folder containing the index-r-022.xml file must be specified.
4. Select **Embed PDFs into EAEU XML?**. Click **OK**. The confirmation message appears: “The export request was successfully sent. Choose Go To | Job Requests to check the status of your request.”
5. Click **OK**.



6. Go to the **Job Requests** page and view the **Job Message** for details. Verify that everything was exported successfully. Only the index-r-022.xml file is created in the **Destination Location** selected previously in the wizard.

## 2 Import EAEU Submissions into Calyx RIM

To import EAEU submissions that do not have PDFs embedded in the submission xml and are just a file/folder structure with the submission xml, please follow the same procedures for importing any ICH eCTD submission:

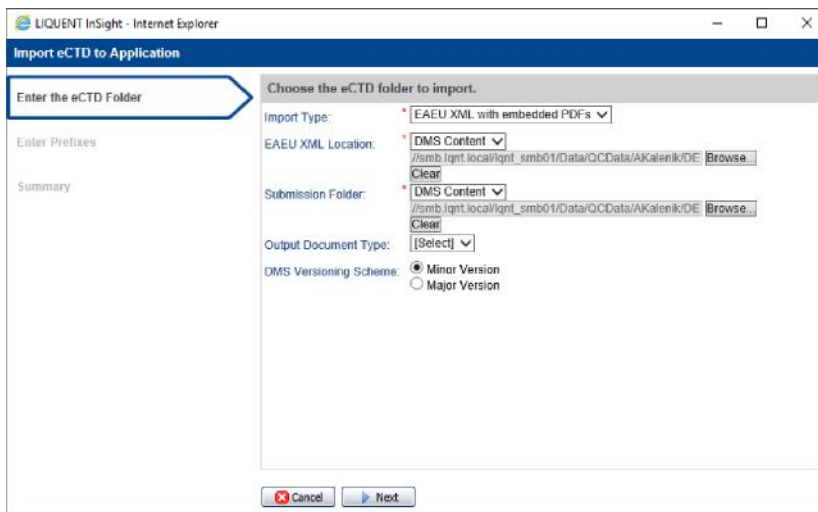
- Run the **Import eCTD** wizard.
- In the **Import Type** drop-down field, select **eCTD**.
- Finish the wizard.

Perform the following steps to import an EAEU submission xml with embedded PDFs:

- Run the **Import eCTD** wizard.
- In the **Import Type** drop-down field, select **EAEU XML with embedded PDFs**.

If you select **EAEU XML with embedded PDFs**, the following fields appear:

- **EAEU XML Location:** Required field. Select the application level folder (the folder that contains subfolders **0000**, **0001**, etc.). Each of these subfolders should contain only one .xml file.
- **Submission Folder:** Required field. The selected location must be a folder.



Note: If the same path as the EAEU XML Location is indicated, the .xml file is replaced after import. All PDFs are extracted to the Submission Folder location, where you can perform further import by selecting eCTD as the Import type. One of the following names for the xml file must be defined: index-r-022.xml or index.xml.

- To create each subsequent leaf, the system searches for *DrugRegistrationDocCode* and creates the same structure as the one in the assembly template. If more than one folder corresponds to this code, the random folder is taken.

- To create the assembly structure, the system searches for *DrugRegistrationDocCode*. If it is absent, the leaf is created under the assembly root.
  - **Output Document type:** This field is specified only when the Submission Folder field indicates the DMS location. Otherwise, a message prompts you to: “Select an output doc type.”
  - **DMS Versioning Scheme:** Select the appropriate version. By default, Minor Version is selected.
- After all valid values are provided for the EAEU XML Location and Submission Folder fields, please proceed and finish the wizard.
- Go to the **Job Requests** page and check the **Job Message** for any details. Verify that everything has been imported successfully. For the EAEU XML with embedded PDFs import type, one Job info for each sequence (Preparing for EAEU Submission Import) and one general Job information Import) is generated.

Note: Each PDF file created by extracting PDF content from the xml is named based on the output file name in the XML section. The value is taken from the attribute DocName. Files with identical output names have an additional timecode added to the output name. Example:  
2837712746383400common-info.pdf