Creating DMF

CALYX.AI

1 Revision History

When Calyx releases a new version of Calyx RIM, they issue Release Notes which explain the new features and updates. Calyx reviews the Release Notes against each Best Practice to determine any impact to the document:

- Impact = Release notes-documented upgrade changes this Best Practice
- No Impact = Release notes-documented upgrade changes do not affect this Best Practice

When Release Notes impact Best Practice documentation, Calyx recommends that clients review the entire Release Notes for a full understanding of all changes associated with this Best Practice documentation.

Software Version	Release/Revision Date	Summary of Change(s)
v6.2 CHF6	25-May-2021	Update Best Practice for Calyx Rebranding – No Impact
	21-Oct-2020	Update Best Practice for v6.2 CHF6 – No Impact
v6.2 CHF5	03-Aug-2020	Update Best Practice for v6.2 CHF5 – No Impact
v6.2 CHF4	28-Feb-2020	Update Best Practice for v6.2 CHF4 – No Impact
v6.2 CHF3	27-Jun-2019	Update Best Practice for v6.2 CHF3 – No Impact
v6.2 CHF2	15-Feb-2019	Update Best Practice for v6.2 CHF2 – No Impact

2 Contents

3 Document Purpose

The purpose of this document is to provide a Best Practice guide defining the process of capturing Drug Master File (DMF) Applications and Events. Drug Master Files also include Active Substance Master Files (ASMF) in Europe.

4 Scope

The scope of the proposed is the process for capturing DMF Applications and Events in LIQUENT Calyx RIM for Registrations.

5 Initial Submission DMF Process (Active Substances)

Each DMF should be captured in the appropriate Product Family. The Product Family should reflect the single Active Ingredient to which the DMF relates. If no Product Family exists for the single Active Ingredient, one should be created.

1. An Application should be created for each DMF within the appropriate Product Family with the following attributes:
    - ***Application Code*** :"DMF # XXXXX"
    - ***Application Name*** : will represent the subject and could include type of the DMF, if applicable (e.g. Morphine Sulphate DMF Type II)
    - Application Type: DMF
    - Procedure Type: National
    - ***Reviewing Country***: <as appropriate>
    - Complete other fields as required by your organisation
2. Create an Event with the following attributes:
    - Event Name: follow organisation naming convention
    - Complete other fields as required by your organisation
3. Create a Sequence as required by your organisation
4. Create a reference on the application for :
    - Each Letter of Authorization (LOA) issued to an Authorized Party
    - Initial communication with Health Authority
5. Create a Publishing Assembly as required by your organisation
    - **Please note**: Create Assembly as per country requirements. (e.g. European Union Countries create
    - assembly with separate sections indicating the open and closed portion of the DMF/ASMF.)

6 Initial Submission DMF Process (Non-Active Substances)

In cases where a DMF is required for a non-active substance a specific Product Family may be created in which the DMF should be captured. Such DMFs might be for Manufacturing Sites, Drug Substance Intermediates, Packaging Materials, Excipients etc.

1. A Product Family should be created with the following attributes:
    - ***Product Family Name:*** Use an appropriate naming convention (e.g. Non-Active Substance DMF)
    - Complete other fields as required by your organisation
2. An Application should be created for each DMF within the appropriate Product Family with the following attributes:

- ***Application Code*** :"DMF # XXXXX"
- ***Application Name***: will represent the subject and the type of the DMF (e.g. pvc backed foil for blister DMF Type III)
- Application Type: DMF
- Procedure Type: DMF
- Complete other fields as required by your organisation

3. Create an Event with the following attributes:
    - Event Name: follow organisation naming convention
    - Complete other fields as required by your organisation
4. Create a Sequence as required by your organisation
5. Create a reference on the application for :
    - Each Letter of Authorization (LOA) issued to an Authorized Party
    - Initial communication with Health Authority
6. Create a Publishing Assembly as required by your organisation
    - **Please note**: Create Assembly as per country requirements. (e.g. European Union Countries create
    - assembly with separate sections indicating the open and closed portion of the DMF/ASMF.)

7 DMF Maintenance

In the event that a Health Authority initiates any correspondence or changes to the DMF, this should be captured under the Initial Application.

1. Create an Event with the following attributes:
    - Event Name: (i.e amendment) follow organisation naming convention
    - Complete other fields as required by your organisation
2. Create a Sequence as required by your organisation
3. Create a Reference on the Event for :
    - Written correspondence with all Authorized Parties with reference to the DMF informing of any additions, changes or deletion of information.
    - All communication with Health Authorities (i.e correspondence, amendment)
4. Create a Publishing Assembly as required by your organisation
    - Lifecycle maintenance : Add new/replace documents
    - **Please note**: Create Assembly as per country requirements. (e.g. European Union Countries create assembly with separate sections indicating the open and closed portions of the DMF/ASMF.)

Planning and Tracking activities will follow standard LIQUENT Calyx RIM processes.