Creating DMF
BP_Calyx
RIM_Registrations

CALYX.AI

1 Contents

2 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)
v7.0	11-May-21	Update Best Practice for v7.0 – Impact
N/A	13-Apr-2021	Update Best Practice for Calyx Rebranding – No Impact
v6.2 CHF6	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

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.

US-FDA
In the US, a Drug Master File (DMF) is a submission to the Food and Drug Administration (FDA) that provides confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs. The submission of a DMF is not required by law or FDA regulation. The DMF may be used to support an Investigational New Drug Application (IND), a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), another DMF, an Export Application, or amendments and supplements to any of these.

A DMF is NOT a substitute for an IND, NDA, ANDA, or Export Application. It is not approved or disapproved.

DMF's are generally created to allow a party other than the holder of the DMF to reference material without disclosing to that party the full, confidential contents of the file.

European Union-EMA

The main objective of the Active Substance Master File (ASMF) procedure, formerly known as the European Drug Master File (EDMF) procedure, is to allow valuable confidential intellectual property, or 'know-how', of the manufacturer of the active substance (ASM) to be protected, while at the same time allowing the Applicant or Marketing Authorisation (MA) holder to take full responsibility for the medicinal product and the quality and quality control of the active substance. National Competent Authorities/EMA thus have access to the complete information that is necessary for an evaluation of the suitability of the use of the active substance in the medicinal product.

4 Scope

The document highlights the process for capturing DMF Applications and Events in Calyx RIM for Registrations. For the US, the Applications will be based on DMF Types:

- Type II Drug Substance, Drug Substance Intermediate, and Material Used in Their Preparation; or Drug Product
- Type III Packaging Material
- Type IV Excipient, Colorant, Flavor, Essence, or Material Used in Their Preparation
- Type V FDA-Accepted Reference Information

5 Initial Submission DMF Process (Active Substances)

Each DMF would be captured in a Product Family with marketed Products. 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.

If a Product Family has more than one Active Ingredient, create a DMF Application for each Active Ingredient.

1. An Application should be created for each DMF 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>
    - ***Product***: <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, capture the DMF in Product Family created for the DMF. Such DMFs might be for 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)
- ***Product:*** Add a Product using the appropriate naming convention (e.g. <Substance Type> <Substance Name>) e.g., Excipient - Glucose

2. An Application should be created for each DMF with the following attributes:

- ***Application Code*** :"DMF # XXXXX"
- ***Application Name***: will represent the subject and the type of the DMF (e.g. Manufacture PVC-backed foil for blister DMF Type III)
- Application Type: DMF
- Procedure Type: DMF
- ***Product***: <as appropriate>
- 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 indictacting 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 Calyx RIM processes.