Orphan Drug Designation BP Calyx RIM Registrations

CALYX.AI

1 Best Practice 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)
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

2 Contents

3 Document Purpose

The purpose of this document is to provide a Best Practice defining the process of managing Orphan Drug Designation (ODD) Application in Calyx RIM.

3.1 Scope

The tracking and maintenance of Orphan Drug Designation submission to health authorities by creating appropriate Applications and Events and other entities in Calyx RIM for Registrations.

4 Data Administration Activities

4.1 Application Category

A new Application Category should be created and named Orphan Drug Designation (ODD).

4.2 Application Type

A new Application Type should be created named Orphan Drug Designation, this should be mapped to the Default Application Type (Entity XML Type) and to the Orphan Drug Designation Application Category; countries assigned should be all countries appropriate for the ODD submission.

4.3 Product Family

Product Family should follow standard Calyx RIM Best Practice.

4.4 Product and Component

Product and Component should follow standard Calyx RIM Best Practice.

5 Orphan Drug Application Process

1. An Application should be created within the appropriate Product Family with the following attributes:
    - Reviewing Country: <as appropriate>
    - Application Code: <as appropriate>
    - Application Name: <Product Family Name> ODD <Country or EU procedure> <RMS / Rapp (if appropriate)>
    - Application Type: Orphan Drug Designation (ODD)
    - Procedure Type: <as appropriate>
    - Registration Type: Package Set Registration
    - Associated Products: (select the Products associated to this application)
    - Countries: (Only For EU CP procedure Type)

- Select all of the appropriate countries. Ensure that European Union is selected from the Reference country list.

- Complete other fields as required by your organization.
- Note: All activity relating to this submission will then be added underneath the application as events (i.e. one event for initial submission, one event for Annual report submission etc.)

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2. Create an Event with the following attributes:
   - **Event Name**: follow organisation naming convention (Eg: Initial ODD Application)
   - Complete other fields as required by your organization.
3. Create a PDS as required by your organization.
4. Create a Sequence as required by your organization.
5. Create an Assembly as required by your organization.
6. Once approval is received:
   - Verify PDS detail as required by your organization.
   - Close and Approve the Initial Event.
   - Create Reference as required by your organization.
   - Create Registration as required by your organization.

Planning and Tracking activities will follow standard Calyx RIM processes.