Best Practice: EAEU Procedures

CALYX.AI

1 Revision History

When Calyx releases a new version of InSight, 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) (Refer to Release Notes for Full Description)
v6.2 CHF6	01-Apr-2021	Update Best Practice for Calyx Rebranding – No Impact
v6.2 CHF6	21-Oct-2020	Update Best Practice for v6.2 CHF5 – 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 Best Practice guidance for tracking Registration data in Calyx RIM for the specific Eurasian Economic Union procedures.

3.1 Scope

Eurasian Economic Union adopted the model of European Union procedures for the drug product registration by Mutual Recognition procedure or Decentralised procedure (for a complete process refer to the Eurasian Economic Commission website: http://www.eurasiancommission.org, http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/LS1/Pages/regist_proc_infogr.aspx). This document describes how to set up the Procedure Type in Data Administration and how to set up the Application and related entities for the Eurasian Economic Union procedures.

4 Data Administration Activities

4.1 Procedure Type

Create New Procedure Types for EAEU MRP and EAEU DCP, using the internal procedure code MRP, and associate Eurasian Economic Union countries as deemed necessary.

4.2 Timeline / Event Plan Values

Add or update appropriate Event Plan to include EAEU MRP and EAEU DCP timeline.

5 Initial Application Process

5.1 Mutual Recognition Procedure

5.1.1 Converting Applications to MRP Applications

1. Update the National Application for the country that will act as the RMS
    a. ***Application Name***: follow organisation naming conventions (e.g. <Product Family Name> MRP <RMS>)
    b. ***Procedure Type:*** EAEU MRP
    c. Complete other fields as required by your organisation
    d. Associate the Application Countries that are part of the Procedure
2. Create an Event with the following attributes
    a. ***Event Name*:** follow organisation naming convention (e.g. Conversion from National to MRP)
    b. ***Countries***: Select Countries that are part of the Procedure.
    c. Complete other fields as required by your organisation

3. Associate a PDS as required by your organization
4. Ensure that the additional countries are added to the country node of the PDS
5. Create a Sequence as required by your organisation
6. Create an Assembly as required by your organisation
7. Following the first Concerned Member State approval close the event and its associations as approved but do not close the Event Status schedule as this will allow the other CMSs to record their approval dates
8. Create the country Registration
9. Create a Reference on the Initial Event or Application for the approval letter as required by your organization
10. Following the CMS approval ensure that the previous national application and registration statuses are updated so that it is clear that the product(s) are now managed under an MRP Application

5.2 Decentralised Procedure

1. An Application should be created with the following Attributes:
    a. ***Application Name***: follow organisation naming conventions (e.g. <Product Family Name> DCP <RMS CC>)
    b. ***Application Type***: New Drug Application
    c. ***Procedure Type:*** EAEU DCP
    d. ***Reviewing Country:*** *Reference Member States*
    e. ***Countries:*** Associate Countries part of the Procedure
    f. Complete other fields as required by your organisation
2. Create an Event with the following attributes
    a. ***Event Name*****:** follow organisation naming convention (e.g. Reference Member State initial Approval)
    b. ***Countries*****:** Associate Countries part of the Procedure
    c. Complete other fields as required by your organisation
3. Create a PDS as required by your organisation
4. Create a Sequence as required by your organisation
5. Create an Assembly as required by your organisation
6. Following the first Country approval close the event and its associations as approved but do not close the Event Status schedule as this will allow the other markets to record their approval dates
7. Create the country Registration Create a Reference on the Initial Event and Application for the approval letter as required by your organization

6 Maintenance process

The process to maintain or renew an approval for mutual and decentralised procedure will follow standard Calyx RIM processes.