



CALYX™

Best Practice:
MRP and DCP
Variations
Approvals

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)
v7.0	30-Apr-2021	Update Best Practice for 7.0 - No Impact
N/A	18-Mar-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

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3 Document Purpose

This document is intended to summarise the process for capturing Procedure Closure and Country Approvals for variations within the Mutual Recognition Procedure (MRP) and the Decentralised Procedure (DCP).

4 Background

Multi-Country MRP / DCP Events which impact the Registered Details in Product Detail Sets require specific management to ensure that the details are approved at the Close of the Procedure, or where appropriate when the National Competent Authority Approval is received.

4.1 Management of Change

It is recommended best practice to create a Change and Change Detail(s) and associate with each Variation Event.

4.2 Creation of MRP /DCP Variation Event

To create an MRP / DCP variation Event:

1. Create an Event in Calyx RIM, completing the system and business mandatory fields as defined in organisational documentation. Ensure that the required Product(s) are selected to allow the Product Detail Set to be associated.
2. Associate the Product Detail Set, and update to include all common changes across all Markets.
3. Associate the Change Details.
4. Update the Event Country Status for each Country on Submission to the National Competent Authority (NCA) using the Change Submittal Status Wizard for the first country to submit and the Update Status Wizard for all other Countries.

4.3 Procedure Closure

When the RMS confirms a positive outcome at the end of the Procedure:

1. Update the PDS common details as appropriate, where Labels are managed in the PDS ensure that the link to the approved English Language Label is associated in the Label Details Node.
2. Using the Update Status Wizard, Update the Event Status to 'Procedure Approved' for all Countries associated with the MRP / DCP Event.
3. On the Enter values to update Entities page:
 - a. **Procedure Closure Date** = <RMS Procedure Approval Date>
4. On the Enter Event Country Status page:
 - a. **Event-Country Status** = 'Procedure Approved'
 - b. **Status Date** = <RMS Procedure Approval Date>
 - c. **Close Event?** = Yes
 - d. **Event Closed Date** = <RMS Procedure Approval Date>
 - e. **Event Closed As** = APPROVED

Where there are Change Details associated to the Event, the Event-Change Detail Status will be updated to Approved and the Event is Closed as Approved. Where there are pending changes to PDS, the PDS node will be updated to Approved at the Procedure Approved.

4.4 National Approvals

If the National Competent Authority confirms a positive outcome after the end of the Procedure

1. Using the Update Status Wizard update the Event-Country Status:
 - a. **Event-Country Status:** Approved
 - b. **Status Date :** <Country Approval Date>

4.5 National Approvals with impact on local details on the PDS

If National Competent Authority has an impact on local registered detail (PDS) in addition of updating the event to Approved then do the following:

1. Create an Administrative Event for the corresponding country with appropriate information relative to parents Event(s).
2. Update PDS with appropriate Label Details and/or Country Details, and or Indication/intended Use Details (Countries field).
3. Using the Update Status Wizard update the Event-Country Status:
 - a. **Event-Country Status** = Approved
 - b. **Status Date** = <Country Approval Date>
 - c. **Lock the Event-Country Schedule?** = Yes
 - d. **Close Event?** = Yes

4.6 Not Approved Process

The Event would be updated to Not Approved Status and the Status Schedule Locked for all associated Markets and Closed as Not Approved when the RMS provides notification of a negative outcome.

1. Using the Update Status Wizard update the Event-Country Status for all Countries associated with the MRP / DCP Event.
2. At the Enter values to update Entities screen populate:
 - a. **Procedure Closure Date** = <RMS Procedure Closure Date>
3. At the Enter Event Country Status screen:
 - a. **Event-Country Status** = 'NOT APPROVED'
 - b. **Status Date** = <RMS Procedure Closure Date>
 - c. **Lock the Event-Country Schedule?** = Yes
 - d. **Close Event?** = Yes
 - e. **Event Closed Date** = <RMS Procedure Closure Date>
 - f. **Event Closed As** = NOT APPROVED

5 References

Calyx RIM Best Practice on Management of Change

Calyx RIM Best Practice on the use of Event Closed As Functionality