Best Practice: Managing Risk Management Plans

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	18-Mar-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 – Impact

2 Contents

1 Revision History 0
2 Contents 2
3 Document Purpose 3
4 Scope 3
5 Use of References 3
6 Risk Management Plan (RMP) 3
6.1.1 Data Administration and Naming Convention Considerations 3
6.1.2 RMP Process 4
6.1.3 Lifecycle Maintenance of an RMP 5
6.1.4 Managing Country Differences 5
6.1.5 Local Annexes 5
6.1.6 Request from Health Authority to submit an RMP 5

3 Document Purpose

The purpose of this document is to provide best practice guidance on the management of Risk Management Plans (RMP) in Calyx RIM for Registrations.

RMPs are submitted for:

- **Initial Applications:** Initial application for a Marketing Authorisation Application (MAA) or New Drug Application (NDA)
- **Changes or Modifications:** Modification to the RMP for pharmacovigilance, risk-minimisation milestones or any significant changes to the benefit-risk profile
- Periodic Submissions or Request from Health Authorities (HA):
- HA Request: EMA or National Competent Authority (NCA)
- Periodic Safety Update Report (PSUR)

Outside of the EU, Regional requirements vary greatly and are increasing. In addition to tracking RMP statuses and dates and the current approved version, it is often important to document the type of RMP template submitted and any local country deviations from the Core or EU RMP.

4 Scope

This document covers the creation and maintenance of References to manage RMPs in Calyx RIM for Registrations.

5 Use of References

References are created to capture information about the RMP and links to supporting documentation. From a Best Practice perspective, standard naming conventions should be defined and documented in operations manuals, allowing for consistency in the creation and tracking of References throughout the system.

6 Risk Management Plan (RMP)

Best Practice for routine tracking of RMPs, both current and historical, is to create a Reference at the Application level.

6.1.1 Data Administration and Naming Convention Considerations

The following Data Administration pick list values should be defined in the system in advance of implementing the RMP Process:

- **Reference Type**: to clearly identify the Reference as a Risk Management Plan.
- **Content**: to further identify the type of RMP submitted e.g. EU, Company Core or Local RMP.
- **Reference Status**: to identify the current status of the RMP e.g. Planned, Approved, Superseded.

For the RMP **Reference Name**, defining a consistent naming convention will ensure that key details, such as the approved version, are recorded.

Best Practice for RMP Naming Conventions are:

- < Product Family Name > < RMP Type > < Version > < Country Name >
- Calyxadone Core RMP v1.0 Brazil
- Calyxadone Core RMP v2.0 Brazil
- Calyxadone Local RMP v1.1 China
- Calyxadone Local RMP v1.1 Russia
- Calyxadone *EU RMP v3.0 and Country Specific Annex Australia*
- Calyxadone EU RMP v5.0 European Union

The **Reference Link** and **Origination Link** fields can be leveraged to link to the RMP content and to related Calyx RIM for Registrations records.

- When creating a Reference, the **Reference Link** field can be used to link directly to the RMP.
- To associate the RMP with its Regulatory Objective (i.e. Event), the Event URL can be copied and pasted in the **Origination Link** field when creating the Reference.

The use of the **Reference Comments** and **Description** fields should also be well defined to ensure that country/regional deviations are captured.

6.1.2 RMP Process

The original RMP **Reference** should be created at the MAA or NDA Application. The Procedure type will determine when the Reference is created:

- EU Centralised Procedures (CP): Reference will be created upon submission to EMA.
- Mutual Recognition Procedure/Decentralised Procedure (MRP/DCP): Reference will be created upon dispatch to the Reference Member State.
- National Application: Reference will be created upon dispatch to country affiliates.

Company defined naming conventions should be followed and the relevant picklist values selected to identify the type of RMP submitted.

A **Reference** should be created within the appropriate Application with the following attributes:

- ***Reference Name***: <follow organisation naming convention>
- ***Reference Type***: <as appropriate>
- ***Content*** : <as appropriate>
- Reference Status: <as default>
- Reference Status Date: <as default>
- Reference Link: <as required>
- Complete other fields as required by your organization.

6.1.3 Lifecycle Maintenance of an RMP

On Approval of the RMP:

- The **Reference Status** is updated.
- The Reference Status Date is updated.
- The **Reference Name** is updated with the approved RMP version number.

When a new RMP version is ready for submission, a new RMP **Reference** is created on approval of subsequent versions of the RMPs:

- The previous RMP **Reference Status** should be updated to Superseded.
- The **Reference Status Date** is updated to reflect the approval date of the latest RMP.

6.1.4 Managing Country Differences

Prior to submission or during the review of nationally approved products, changes may be made to the RMP. These can be introduced prior to submission by the Affiliate or during the review by the Agency. In these cases, a new Local RMP **Reference** is created and the country differences are recorded in the **Reference Comments** field. The Status of the original Reference is updated to Superseded.

6.1.5 Local Annexes

In some non-European markets, the RMP will be submitted with an additional Annex. In these instances, this should be included in the **Reference Name**, as defined by company naming conventions.

6.1.6 Request from Health Authority to submit an RMP

When an RMP is submitted as part of another Regulatory Objective (e.g. MAA, Variation, PSUR) a specific RMP **Event** is not created in Calyx RIM for Registrations. However, when a request is received from the Health Authority (HA Request) to submit the current version of the RMP it is best practice to create a standalone submission. The **Event** should be created within the appropriate **Application** following organisation processes. A **Reference** is created at the Application level with the attributes as described in the RMP Process above.