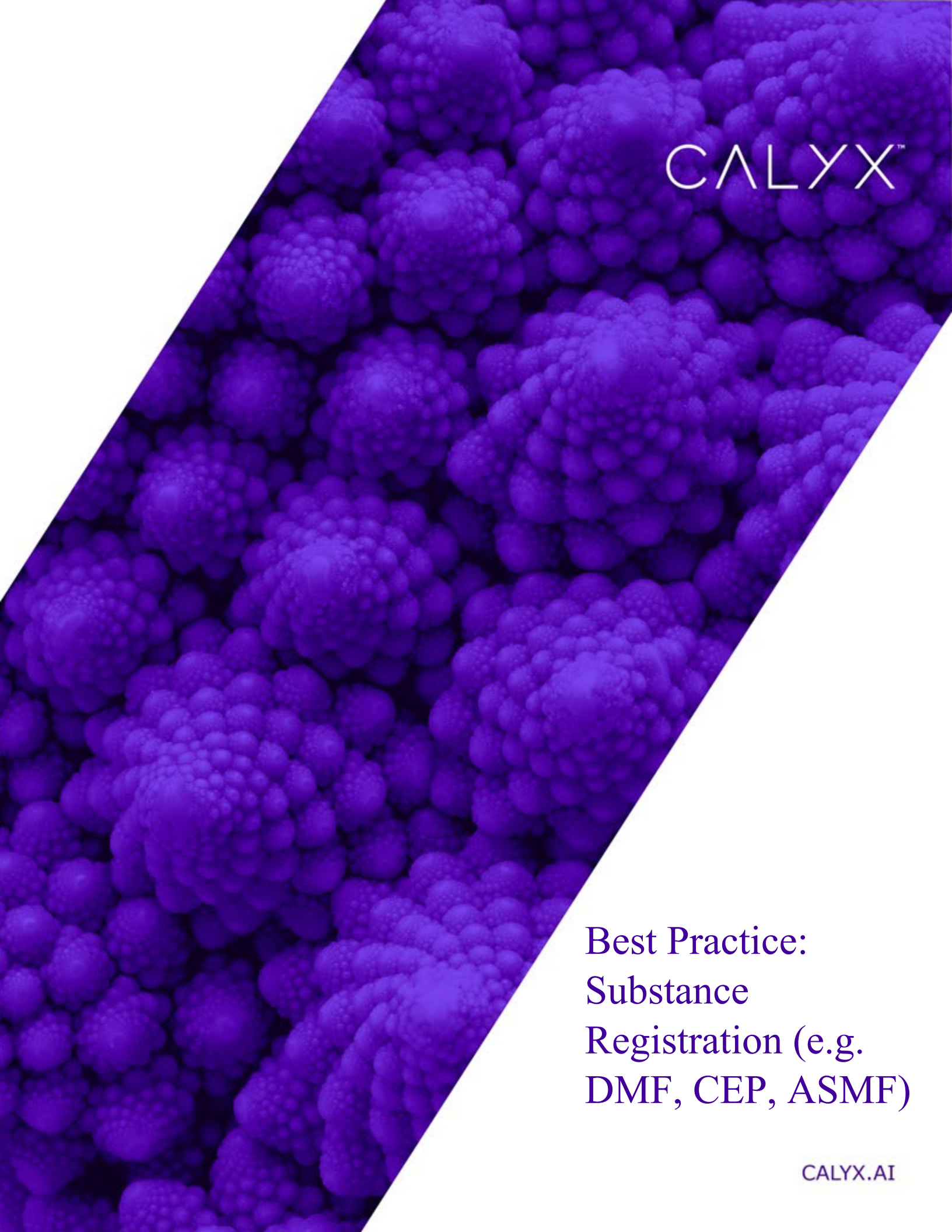

Best Practice: Substance Registration (e.g. DMF, CEP, ASMF)

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. The Calyx RIM Business Consulting team 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)
v7.2	04-Apr-2023	Update Best Practice for v7.2 – No Impact
v7.1	13-Jan-2022	Update Best Practice for v7.1 – No Impact
v7.0	30-Apr-2021	Update Best Practice for v7.0 – No Impact
N/A	22-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

2 Contents

3 Document Purpose

The purpose of this document is to provide a Best Practice guide defining the process of capturing Substance Registrations such as Drug Master File (DMF) Applications, Active Pharmaceutical Ingredient (API) Application, Certificate of Suitability to the Monographs of the European Pharmacopoeia (CEP) Application and other substance registration processes specific for each Country.

3.1 Scope

The scope of the proposed is the process for defining the details required for Substance Applications in Calyx RIM for Registrations.

4 Data Administration Activities

4.1 Application Category

Applications for substance registration will use the existing standard Application Category: DMF.

4.2 Application Type

New Application Types should be created as applicable. This should be mapped to the Drug Master File (DMF) Entity XML Type and to the DMF Application Category. Countries assigned should be all countries appropriate for each Application Type.

Example 1

- ***Application Type***: CEP
- ***Name***: Certificate of Suitability to the Monographs of the European Pharmacopoeia
- ***Display Name***: CEP
- ***Entity XML Type Name***: Drug Master File (DMF)
- ***Application Category***: DMF
- ***Countries***: EDQM

For more information on Publishing eCTD for CEP submissions, please refer to help.liquent.com: *Updating Data Administration for Publishing Specifications*.

Example 2

- ***Application Type***: API
- ***Name***: Active Pharmaceutical Ingredient
- ***Display Name***: Active Pharmaceutical Ingredient
- ***Entity XML Type Name***: Drug Master File(DMF)
- ***Application Category***: DMF
- ***Countries***: Russia, China, Brazil, India, …

5 Product Family

In case a substance registration Application is required for an Active Ingredient, it should be captured in the appropriate Product Family. The Product Family should reflect the single Active Ingredient to which the substance registration Application relates. If no Product Family exists for the single Active Ingredient, one should be created following standard best practices.

In cases where a substance registration Application is required for a non-active substance, one Product Family should be created in which all non-active substance registration Applications should be captured. Such Applications might be for Drug Substance Intermediates, Packaging Materials, Excipients etc.

Product Family Name*:* Use an appropriate naming convention (e.g. Non-Active Substance Registration)

6 Product and Component

Product and Component should be created for each Product Family which requires a Substance Registration with the following Attributes:

- ***Product Name***: [Product Family Name] Substance
- ***Component Name***: Substance

Note: leave the Product Dosage Form and Component Form blank

For Active Ingredient Substance Registration Component Active ingredient will be created with the following attributes:

- ***Component Active Ingredient Name***: Select Active Ingredient substance
- ***Concentration Measure Type***: Equal
- ***Low Amount Numerator Value***: 100
- ***Low Amount Numerator Unit***: Percent

7 Initial Submission for Substance Registration Process

Each Substance Registration should be captured in the appropriate Product Family.

1. An Application should be created for each Substance with the following attributes:
   - ***Application Code***: as required by your organization (e.g. DMF # XXXXX", CEP123..)
   - ***Application Name***: as required by your organization – will represent the Substance Name, the subject and application type

Note: For Non-Active Substance Registration, one Application is created per individual Non-Active Substance. Application Name will indicate the specific Substance Name, if required PDS details could be created as required by your organization. e.g. pvc backed foil for blister DMF Type III

   - ***Application Type***: DMF, or API or CEP
   - ***Procedure Type***: National
   - ***Reviewing Country***: <as appropriate>
   - ***Product***: <as appropriate>
   - Complete other fields as required by your organization.
2. Create an Event with the following attributes:
   - ***Event Name***: follow organization naming convention.
   - Complete other fields as required by your organization.
3. Create a Sequence as required by your organization.
4. Create a PDS as required by your organization.
5. Create a Reference on the Application for:

   a) Each Letter of Authorization (LOA) issued to an Authorized Party.

   b) Initial communication with Health Authority.
6. Create a Publishing Assembly as required by your organization

Note: Create Assembly as per country requirements. (e.g., European Union Countries create assembly with separate sections identifying the open and closed portion of the DMF/ASMF.)

7. After approval is received:

   a) Verify PDS detail as required by your organization.

   b) Close and Approve the Initial Event.

   c) Create Registration (if required).

Planning and Tracking activities will follow standard Calyx RIM processes.