Best Practice: Consumer Product Applications

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 Date	Summary of Change(s) (Refer to Release Notes for Full Description)
v6.2 CHF6	22-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 – No Impact

2 Contents

3 Document Purpose

The purpose of this document is to provide a Best Practice guide defining the process of capturing Consumer and Cosmetic Products in Calyx RIM.

3.1 Scope

The scope of the proposed document is the process for defining the details required for Consumer and Cosmetic Products Applications in Registrations Component of Calyx RIM.

3.2 Consumer Products

Consumer Products are products that are bought by individuals or households for personal use.

Over-the-Counter (OTC), or nonprescription, drug products are those drugs that are available to consumers without a prescription. Non-prescription medicinal products are subject to the same rules, regulations and requirements as prescription medicinal products, as far as concerns data to be submitted and procedures to be followed for clinical trials, marketing authorisation and medicinal products maintenance.

4 Application

4.1 Consumer/Over-The-Counter Application

Create Application, from the Product Family:

1. ***Application Name***: follow organisation naming conventions (e.g. <Product Family Name> <Consumer><NDA><US>).
2. ***Application Type***: New Drug Application.
3. ***Procedure Type:*** Select appropriate procedure type e.g. National.
4. ***Reviewing Country:*** *Select Country.*
5. ***Product:***. Select appropriate Product
6. Complete other fields as required by your organization.
    a. Complete other fields as required by your organisation
7. Create a ***Sequence*** as required by your organization.
8. Create an ***Assembly*** as required by your organization.
9. Once approval is received:
    a. Verify PDS detail as required by your organization.
    b. Close and Approve the Initial Event.
    c. Create ***Reference*** as required by your organization.
    d. Create ***Registration*** as required by your organization.