



# BEST PRACTICE: CONSUMER PRODUCT APPLICATIONS

# 1 Contents

|     |  |   |
|-----|--|---|
| 1   | Contents .....                             | 1 |
| 2   | Revision History .....                     | 2 |
| 3   | Document Purpose.....                      | 3 |
| 3.1 | Scope.....                                 | 3 |
| 4   | Consumer Products.....                     | 4 |
| 5   | Application.....                           | 5 |
| 5.1 | Consumer/Over-The-Counter Application..... | 5 |

## 2 Revision History

When Ennov releases a new version of Ennov InSight, they issue Release Notes which explain the new features and updates. The Ennov 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, Ennov 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)  |
|------------------|------------------------|---|
| v7.3.1           | 28-Jun-2024            | Update Best Practice for Ennov rebranding & for v7.3.1 – No Impact  |
| v7.3             | 01-Mar-2024            | Update Best Practice for v7.3 – No Impact (minor reformatting only) |
| v7.2             | 04-Apr-2023            | Update Best Practice for v7.2 – No Impact                           |
| v7.1             | 11-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                      |

## 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 Ennov InSight.

### 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 Ennov InSight.

## 4 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 authorization and medicinal products maintenance.

## 5 Application

### 5.1 Consumer/Over-The-Counter Application

Create Application, from the Product Family:

1. **Application Name:** follow organization 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. **Countries:** <as appropriate>
5. **Products:** <as appropriate>
6. Complete other fields as required by your organization.
7. Create an **Event** as required by your organization.
8. Create a **Sequence** as required by your organization.
9. Create an **Assembly** as required by your organization.
10. 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.