



CALYX™

# Best Practice: Site Registrations and Site Master Files

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) (Refer to Release Notes for Full Description)
v7.0	30-Apr-2021	Update Best Practice for 7.0 - Impact
N/A	02-Apr-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

The purpose of this document is to provide a Best Practice defining the process of managing Site Registrations and Site Master Files. This approach addresses the regulatory need of countries that require the manufacturing site be registered prior to Products being manufactured.

Beginning in v7.0, you may pull Products from multiple Product Families into your Site Registration Application.

### 4 Scope

Creating the appropriate Applications and Events in Registrations Component of Calyx RIM to track activities relating to site registrations and site master files.

## 5 Data Administration Activities

### 5.1 Application Category

A new Application Category should be created named Site Registration.

### 5.2 Application Type

A new Application Type should be created named Site Registration. This should be mapped to the Default Application Type (Entity XML Type) and to the Site Registration Application Category. Countries associated with this Application Type are those that require Site Registrations (typically, but not exclusively Middle Eastern Markets).

## 6 Site Registration Process

1. An Application should be created with the following attributes:
  - **Application Name:** <Type of Application> <Manufacturing Site> <Country/Region> (e.g. Site Registration CalyxPharm BH, or Site Master File CalyxPharm BH)
  - **Application Type:** Site Registration
  - **Procedure Type:** <as appropriate>
  - **Reviewing Country:** <as appropriate>\*
  - **Associate Product(s):** <as appropriate>
  - Complete other fields as required by your organization.
2. Create an Event with the following attributes:
  - **Event Name:** follow organisation naming convention (e.g. New Site Registration)

- **Associate Product(s):** <as appropriate>
  - Complete other fields as required by your organization.
3. Create a Sequence as required by your organization.
  4. Create an Assembly as required by your organization.

**Note:**

- Planning and Tracking activities will follow standard Calyx RIM processes.
- \* For EU Site Master Files, the Country, European Union, could be used.