



CALYX™

Best Practice: Withdrawing Products

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)
v7.0	30-Apr-2021	Update Best Practice for 7.0 - No 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 Best Practice guidance for withdrawing approved Products and Package Sets from an Approved Application. Any consequential actions on Registration records are also documented. Calyx recommends using the features of the Global Project Plan (Withdraw Product Package Set Registrations) where possible to perform withdraw actions, since the wizard will perform many consequential actions on appropriate entities.

4 Scope

This document covers the following withdrawal scenarios:

1. Withdraw Products from Applications and consequential actions on Application and Registration(s) through one of the following withdrawal actions:
 - Withdraw all approved Products
 - Withdraw one of a number of approved Products
2. Withdraw one or more approved Package Sets from an approved Product under an active Application and any impacted Registrations.

5 Withdraw Approved Products from an Application

The Project should include all Products in all Applications that need to be withdrawn. A Project can also be used to withdraw Products from just one Application, since it will simplify the process of updating entities when the Event is approved.

1. Follow the steps in the *Withdraw Product Package Set Registration GPP* flow as required to:
 - Select the Appropriate Application(s) and Product(s) to be withdrawn.
 - Create Event(s).
 - Create Sequence(s) as required by your organization.
2. Use the GPP *Update Project Event Country Status* wizard or the *Update Status* wizard to capture the Approval of the Event(s).
3. When the Event is updated to the *Approved* status, the following actions will be performed automatically:
 - Change the *Application Status* to *Withdrawn* when all approved Product(s) are withdrawn.
 - Leave the *Application Status* as *Active* when it still contains other active Products.
 - Change the Event-Country status to *Approved* (approval of the Withdrawal request).
 - Set the *Product Detail Set* status to *Withdrawn*.
 - Set the *Registration(s)* status to *Withdrawn*.

- Set the *Registration Package Set(s)* status to *Withdrawn* when all, the last or the only approved Product Detail Set(s) are withdrawn.
 - Leave the *Registration Attributes* status to *Active* when at least one Approved Product Detail Set is still associated with the Registration.
4. Navigate to the *Registration Package Set-Country Attributes* screen to update marketing status information if required.

Please note:

- The Product status is not set to *Withdrawn* since the Product may be actively marketed in other countries. When the Product is withdrawn from the last Country where it is marketed, navigate to the Product Attributes screen and update the status to *Withdrawn* with the appropriate Withdrawal Date.
- The individual PDS details – including Package Sets – are not marked as *Withdrawn* because the status of the entire PDS is set as *Withdrawn*.

6 Withdraw one or more Approved Package Sets from a Product

Global Project Planning (GPP) does not feature a flow for Package Set withdrawal. However, *Update Product Detail Set* Project functionality can create Events and Sequences, and associate PDSs under multiple Applications, saving substantial time by mass producing records critical to withdrawal activities.

1. Follow the steps in the *Update Product Detail Set* GPP flow as required to:
 - a. Select the Appropriate Application(s) and Product(s) in which the pack set should be withdrawn.
 - b. Create Event(s).
 - c. Associate the PDS to the Event.
 - d. Create Sequence(s) as required by your organization.
2. Navigate to each Event's associated Product Detail Set(s).
3. Right-click on each Package Set to be withdrawn and select *Withdraw*.
 - The Status of the Package Set is marked as *Pending Withdrawal*.
4. Use the GPP *Update Project Event Country Status* wizard or the *Update Status* wizard to capture the Approval of the Event.
5. When the Withdrawal Event is updated to the *Approved* status, the following actions will be performed automatically:
 - Change the Event-Country status to *Approved* (approval of the Withdrawal request).
 - Change the status of each *Pending Withdraw* Package Set detail to *Withdrawn*.
6. If all Package Sets associated with the Registration have been withdrawn, navigate to the Registration entity and update the status to *Withdrawn*.
7. Navigate to the *Registration Package Set-Country Attributes* screen to update marketing status information if required.

Please note:

- Removing all package sets from a Product has the effect of withdrawing the entire Product.
- The *Update Product Detail Set* project should not be used to withdraw all Package Sets because it does not contain withdrawal functionality that operates on the Application, Registration and Product Detail Set Attributes screens.
- To remove all Package Sets from a Product, use the *GPP Withdraw Product Package Set Registration* project type as described earlier in this Best Practice document.