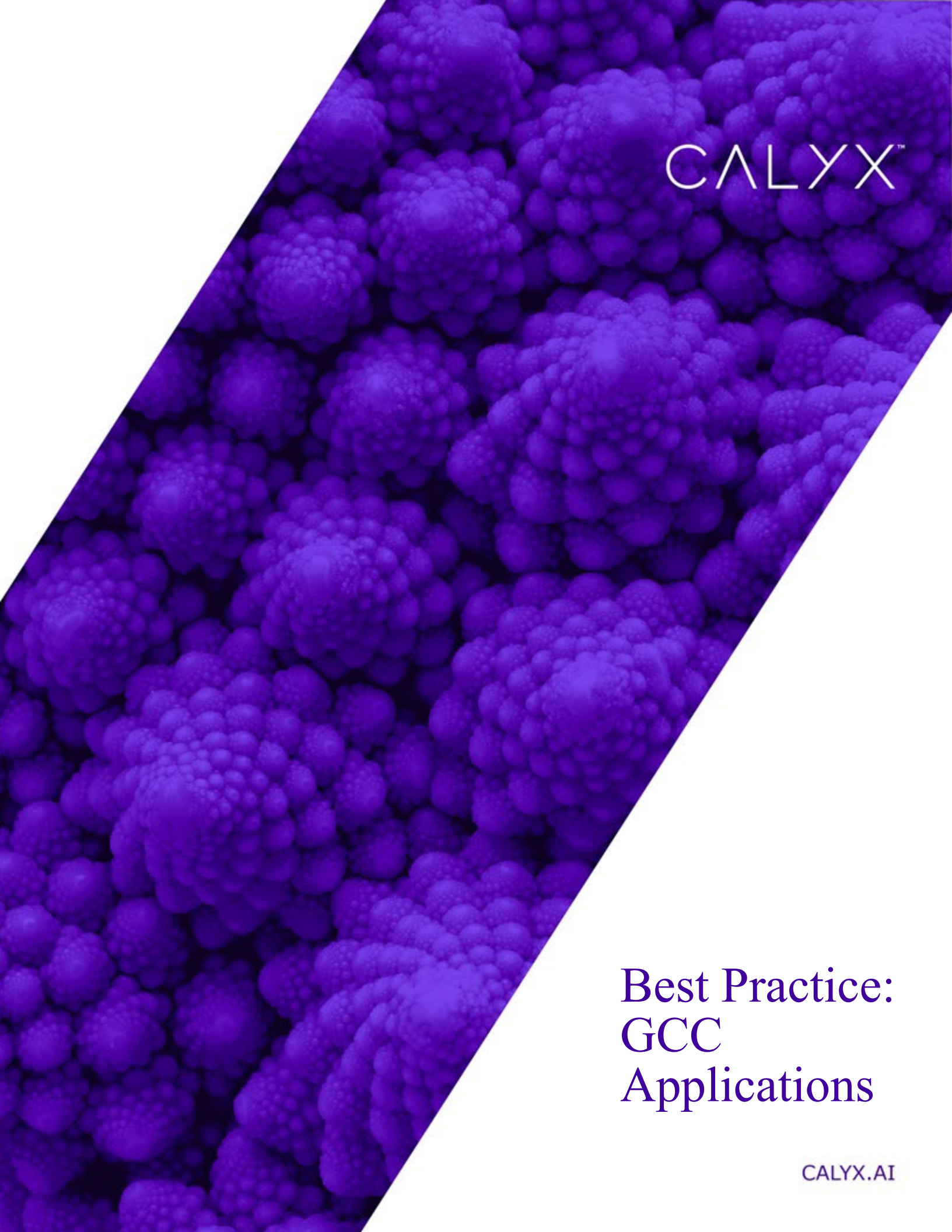

Best Practice: GCC Applications

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)
v7.2	04-Apr-2023	Update Best Practice for v7.2 – No Impact due to system changes, but GCC website address and links to external guidance updated.
v7.1	13-Jan-2022	Update Best Practice for 7.1 – No Impact
v7.0	30-Apr-2021	Update Best Practice for 7.0 - Impact
N/A	01-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

2 Contents

3 Document Purpose

The purpose of this document is to provide Best Practice guidance for tracking Registration data in Calyx RIM for Registrations for the specific Gulf Cooperation Committee Drug Registration (GCC DR) procedure.

4 General Considerations

This section describes the basic process for a drug product registration in the Gulf States; approved by the GCC DR. (For a complete process refer to the Gulf Cooperation Council website: http://gcc-sg.org/en-us/Pages/default.aspx)

4.1 Initial Submission

The approval by the Gulf Cooperation Committee (GCC) is a pre-cursor to a National Approval and the GCC issues a registration certificate which should be maintained as an individual Application. Following the GCC approval a national dossier needs to be submitted following the national requirement of each required Gulf State within one year of the GCC DR approval (Figure 1). The concept of a common dossier does not yet exist and evaluation is nationally independent. For these reasons, each country needs its own Assembly Lifecycle and hence its own Application.

Figure 1: High Level process to complete registration through a GCC DR.

As Best Practice, an individual Application should be created for the Gulf Cooperation Committee evaluation and additional National Applications will be created for each Gulf State with a Reference to link to the GCC DR approval letter.

4.2 Lifecycle Submissions

Similar to the initial submission, the evaluation of renewals or variations must be approved by the GCC. Following the GCC evaluation, a national dossier should be submitted following the national requirement of each required Gulf State (Figure 2). All Events for GCC and Gulf States have independent lifecycles. As a Best Practice, Events are created for GCC and each Gulf States through a Project.

Figure 2: High Level process for Variation / Renewal evaluation

Since a Gulf State(s) evaluation is dependent on the initial review and approval of the Gulf Cooperation Committee, as a best Practice the GCC DR evaluation Event URL is associated as a Reference to each Gulf State Events in order to easily refer to the GCC dossier submission and approval.

► Note: ensure that only GCC submission/approval dates are tracked under its own application and that only Gulf State National submission / approval dates are tracked under the respective National Application.

5 Data Administration Activities

5.1 Country

A new Country should be created named Gulf Cooperation Council with the country code of GCC.

5.2 Region

If a Gulf Cooperation Council Region does not exist then it should be created and the Gulf Cooperation Council Country as well as the individual Gulf Countries added to it.

5.3 Application Type

Add Gulf Cooperation Council to the GCC Marketing Authorisation Application Type.

5.4 Procedure Type

Add Gulf Cooperation Council to GCC Procedure.

5.5 Filing Type

Add or update appropriate Filling type to include ‘Gulf Cooperation Council’ as necessary.

5.6 Assembly DTD/Schema Type

Add Gulf Cooperation Council to GC-1-5.

5.7 Timeline / Event Plan Values

Add or update appropriate Event Plan to include Gulf Cooperation Committee timeline.

6 GCC Application Process

6.1 GCC Initial Evaluation

1. An Application should be created to track the Committee’s approval:
    a. ***Application Name***: follow organization naming conventions (e.g. <Product Family Name> GCC DR Evaluation)

b. ***Application Type***: GCC Marketing Authorisation.
c. ***Procedure Type***: GCC.
d. **Reviewing Country:** Gulf Cooperation Council.
e. ***Countries:*** <all Gulf States that plan to submit a National registration following GCC DR approval>.
f. ***Product(s):*** <associate as required>
g. Complete other fields as required by your organization.

Note: The association of Gulf States to the GCC application will provide clarity as to which Gulf States are included in the process. However Gulf States will not be associated with Events or PDS under the GCC application as National details are tracked under a National application.

2. Create an Event with the following attributes:
   a. ***Event Name*:** follow organization naming convention (e.g. GCC Initial Evaluation).
   b. Complete other fields as required by your organization.
3. Create a PDS as required by your organization.
4. Create a Sequence as required by your organization.
5. Create an Assembly as required by your organization.

Note: only the Gulf Cooperation Committee will be associated as a country to the Event, Sequence and PDS.

6. Following the initial approval, a Registration is created.
7. Create a Reference on the Initial Event and Application for the approval letter as required by your organization.

Note: A PDS template may be created from the approved GCC PDS to be assigned to the National Gulf State Applications.

6.2 Individual Gulf State Applications

1. An Application should be created for each Gulf State:
   a. ***Application Name***: follow organization naming conventions (e.g. <Product Family Name> GCC National <country code>).
   b. ***Application Type***: GCC Marketing Authorization
   c. ***Procedure Type***: GCC National
   d. ***Reviewing Country***: <as appropriate>
   e. ***Product(s)***: <associate as required>
   f. Complete other fields as required by your organization.
2. Create an Event with the following attributes:
   a. ***Event Name*:** follow organisation naming convention.
   b. Complete other fields as required by your organization.
3. Create a PDS as required by your organisation (from the GCC PDS template).
4. Create a Sequence as required by your organization.

5. Create an Assembly as required by your organization.
6. Create a Reference on Each Event to capture the initial GCC Event URL.
7. Following approval, a Registration is created.
8. Create a Reference on the Event and the Application for the approval letter as required by your organization.

Note: When Calyx RIM Publisher is used; it is possible to create the individual Gulf State Assemblies from the approved or submitted view of the GCC DR Assembly. For additional information please refer to Best Practices: Publishing with Calyx RIM.

7 Lifecycle management process

The process to maintain or renew an approval for a pharmaceutical product under the GCC procedure is always initiated with an evaluation by the Gulf Cooperation Committee. This would follow the same process as above, with an Event created under the GCC DR Application and after approval an Event under each National Application.

8 References

- BYLAWS FOR REGISTRATION OF PHARMACEUTICAL COMPANIES AND THEIR PRODUCTS https://taawon-ghc.com/esop/ksa-ghc-host/public/attached/pharmaceuticals/rules_and_regulations/regulations/BYLAWS%20FOR%20REGISTRATION%20OF%20PHARMACEUTICAL%20COMPANIES%20AND%20THEIR%20PRODUCTS.pdf
- Cortellis database: Title - 'Authorities / Organizations: GCC', Feb 2014, Regulatory Summary, Gulf Cooperation Council, IDRAC Number – 102296
- TARIUS database: Guidelines / Guidances / Notes, Registration By-Laws of Pharmaceutical Companies and their Products, 31 Mar 2016