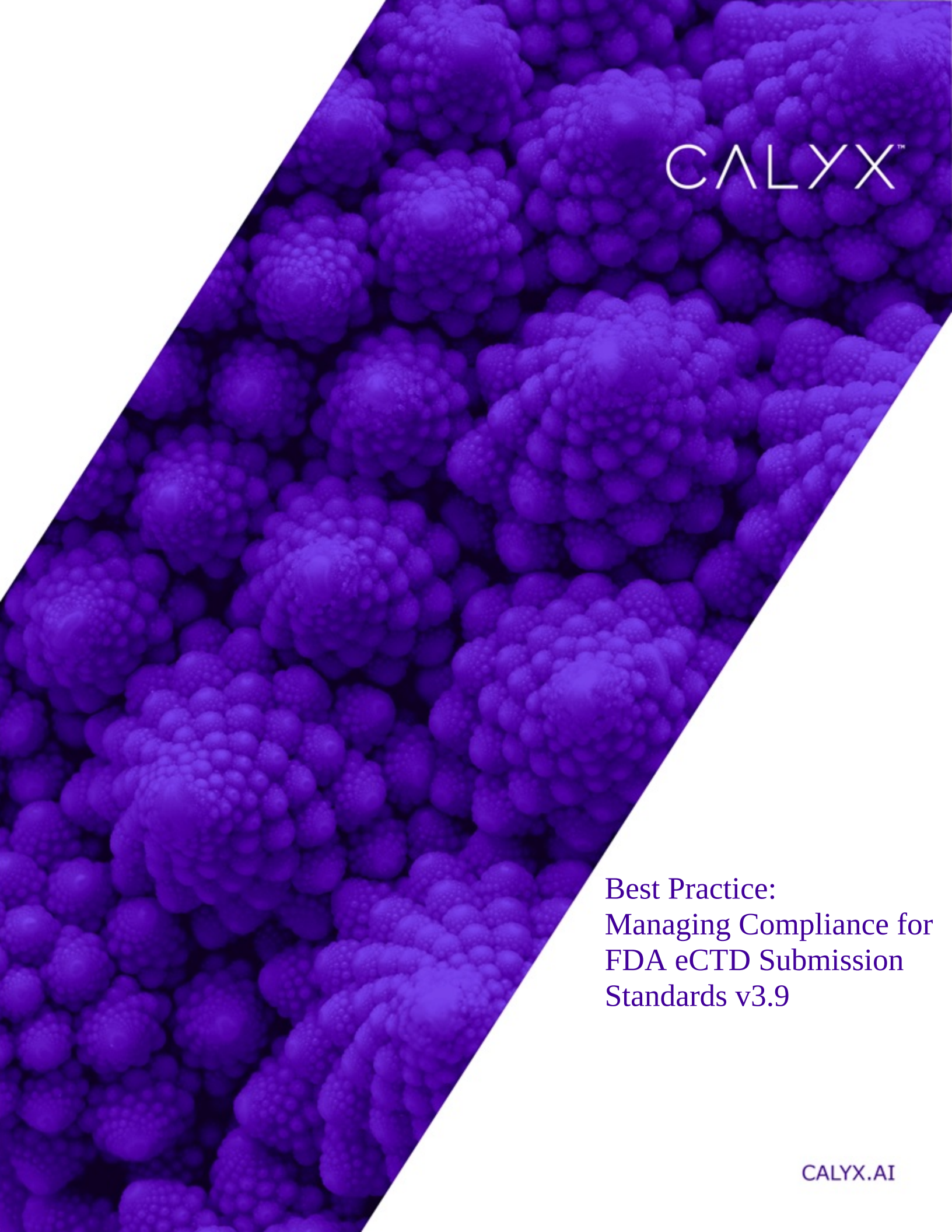


Best Practice: Managing Compliance for FDA eCTD Submission Standards v3.9

CALYX.AI

1 Revision History

When Parexel releases a new version of Calyx RIM, they issue Release Notes which explain the new features and updates. Parexel reviews the Release Notes against each Best Practice to determine any impact to the document:

- Impact = Release Notes change this Best Practice
- No Impact = Release Notes do not change this Best Practice

When Release Notes impact Best Practice documentation, Parexel 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)
N/A	29-Apr-2021	Best Practice created to reflect the latest updates from US FDA

2 Contents

2.1 Document Purpose

On 15 March 2021, the US FDA published eCTD Validation Criteria version 3.9 and eCTD Submission Standards version 3.9. As part of the change, Form FDA 3938: Drug Master File has been introduced. The additional form-type.xml needs to be included for the relevant submission. The purpose of this document is to provide a best practice to comply with FDA's latest updates, to ensure the following form-type.xml are available for user:

- <code-display code="fdaft10" display="Form FDA 3988: Transmittal of PMR/PMC Submissions for Drugs and Biologics" status="active"/>
- <code-display code="fdaft11" display="Form FDA 3938: Drug Master File" status="active"/>

2.2 Scope

This document will guide users through Data Administration to add the following:

- Form FDA 3988: Transmittal of PMR/PMC Submission for Drugs and Biologics
- Form FDA 3938: Drug Master File
- REMS Supplement as a Submission Type

Additionally, this document will guide users to add the new forms to the US eCTD Module 1 v3.3 Assembly Template.

2.3 Data Administration Activities

To add the FDA Forms to Data Administration:

1. Select **Go To>Data Administration**. The list of value groups appears.
2. Navigate to **Submission Maintenance** and select **Application Form Type Values**.
3. Click **Create** and fill in the required information for Form FDA 3938: Drug Master File.

Field	**Value**
Region	United States
Regulatory Code	fdaft11
Application Form Type	Form FDA 3938: Drug Master File

4. Click **Save**.

Note: In case you have not added Form FDA 3988: Transmittal PMR/PMC Submissions for Drugs and Biologics to the 'Application Form Type Values' list, follow Step #5 below:

5. Repeat **Steps #2 and #3** to add Form FDA 3988: Transmittal PMR/PMC Submissions for Drugs and Biologics. Enter the following information required for Form FDA 3988:

Field	Value
Region	United States
Regulatory Code	fdaft10
Application Form Type	Form FDA 3988: Transmittal PMR/PMC Submissions for Drugs and Biologics

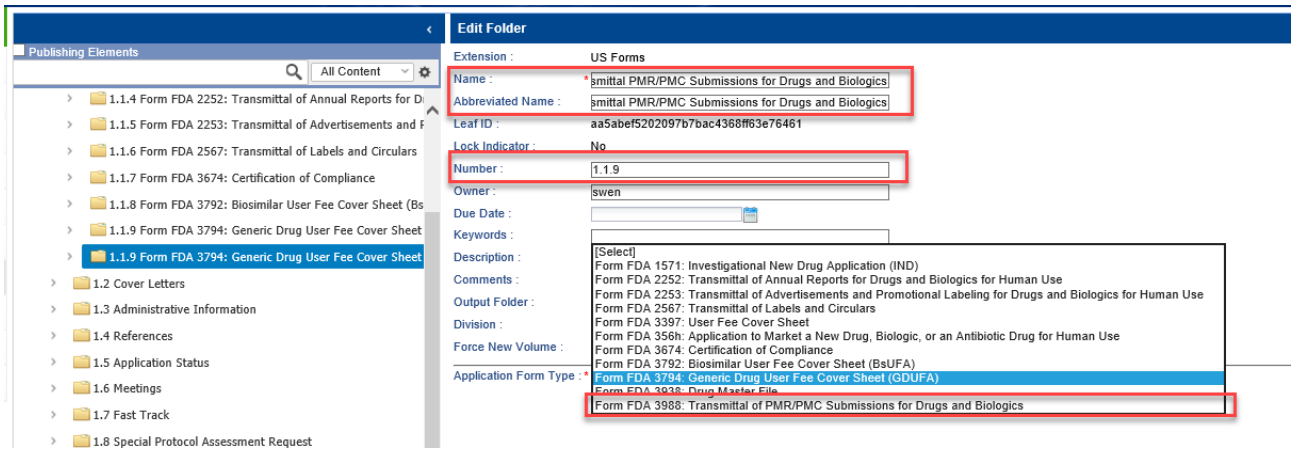
6. Click **Save.**

2.4 Assembly Template

Following the addition of the FDA Forms to Data Admin. The forms also need to be added to the US eCTD Module 1 v3.3 Assembly Template.

1. From the **Home Page**, navigate to the **Assembly Templates** from the **Entity List**.
2. Search and select the US eCTD Module 1 v3.3 Assembly Template.
3. In the Assembly Template, right click on the last form folder and select **Duplicate.**
4. Revise the following fields in newly created folder:

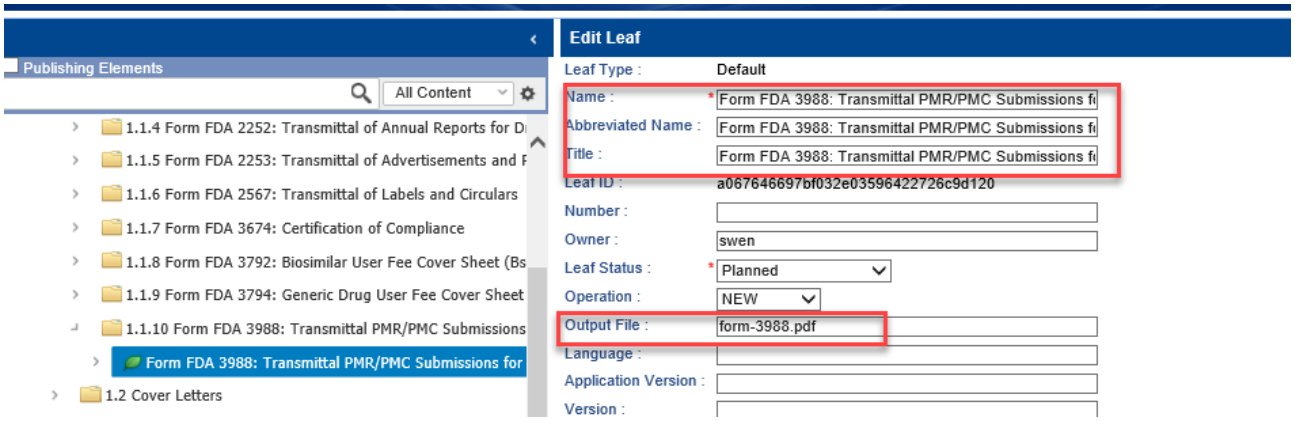
Field	Value
Name	Form FDA 3988: Transmittal PMR/PMC Submissions for Drugs and Biologics
Abbreviated Name	Form FDA 3988: Transmittal PMR/PMC Submissions for Drugs and Biologics
Number	1.1.10
Application Form Type	Form FDA 3988: Transmittal PMR/PMC Submissions for Drugs and Biologics



- Click **Save.**

5. Navigate to the leaf under the new **1.1.10 Form FDA 3988 Folder** and select the leaf.
6. Select **Edit** to change the Leaf Attributes to the following:

Field	Value
Name	Form FDA 3988: Transmittal PMR/PMC Submissions for Drugs and Biologics
Abbreviated Name	Form FDA 3988: Transmittal PMR/PMC Submissions for Drugs and Biologics
Title	Form FDA 3988: Transmittal PMR/PMC Submissions for Drugs and Biologics
Output File	form-3988.pdf



   - Click **Save**.

7. Repeat Steps #4-6 to add 1.1.11 Form FDA 3938: Drug Master File folder and leaf to the Assembly Template

2.5 Adding REMS Supplement

This section is for users who have not included submission type REMS Supplement in the 'Filing Type' since this requirement was introduced in Module 1 Specification v2.4. This section provides guidance on updating D**ata Administration** values for compliance with FDA submission-type.xml v1-3 and FDA eCTD Module 1 specification v2.4

2.5.1 Update Filing Type Values

To update the Filing Type Values:

1. Select **Go To > Data Administration.** The list of value groups appears.
2. Under Sequence Maintenance, select Filing Type Values.

3. Make sure that the **REMS Supplement** value exists and is associated with the United States. To add REMS Supplement value:
    - Click **Create**.
    - On the **Filing Types Values** window, set the following values:

Field Name	Value
Filing Type	REMS Supplement
Display Name	REMS Supplement
Countries	United States

4. Click **Save.**

2.5.2 Update Filing Type eCTD Code

1. Under **Sequence Maintenance**, select **Filing Type Values**.

2. Select **REMS Supplement**. 3. Make sure it is associated with **fdast11** Filing Type eCTD code. To add eCTD Code for **REMS Supplement**:
    - On the **Filing Type eCTD Code** tab, click Create.
    - On the **Filing Types Values** window, set the following values:

Field Name	Value
Applicable DTD/Schema	us-3-3
eCTD Code	fdast11
Available for Application Types	Abbreviated New Drug Application, New Drug Application, Biologic License Application
Types Valid for Grouped Submissions	Abbreviated New Drug Application, New Drug Application, Biologic License Application

    - Click **Save**
4. Click **Return to menu**.

2.5.3 Update Sub Filing Type Values

1. Under **Submission Maintenance,** select **Sub Filing Type Values**.
2. Make sure that **Amendment, Application**, and **Resubmission** values are associated with **REMS Supplement**. To associate values to **REMS Supplement**:
    - Select the corresponding Sub Filing Type
    - Open the **us-3-3** record on the **Sub Filing Type eCTD Code** tab for editing.

- Add **REMS Supplement** to **Selected** in **Available for Filing Types**.
- **Save**.
- Click **Back**.

3. Click **Return to menu**.

2.5.4 Update Supplement Effective Date Type Values

1. Under **Submission Maintenance**, select **Supplement Effective Date Type Values**.
2. Make sure that **Changes Being Effected-30 (CBE-30)** and **Prior Approval Supplement (PAS)** values are associated with **REMS Supplement**. To associate values to **REMS Supplement**:
   - Select the corresponding Supplement Effective Date Type**.**
   - Open the **us-3-3** record on the **Supplement Effective Date Type eCTD Code** tab for editing.
   - Add **REMS Supplement** to **Selected** in **Available for Filing Types**.
   - Save.
   - Click **Back**.
3. Click **Return to menu**.