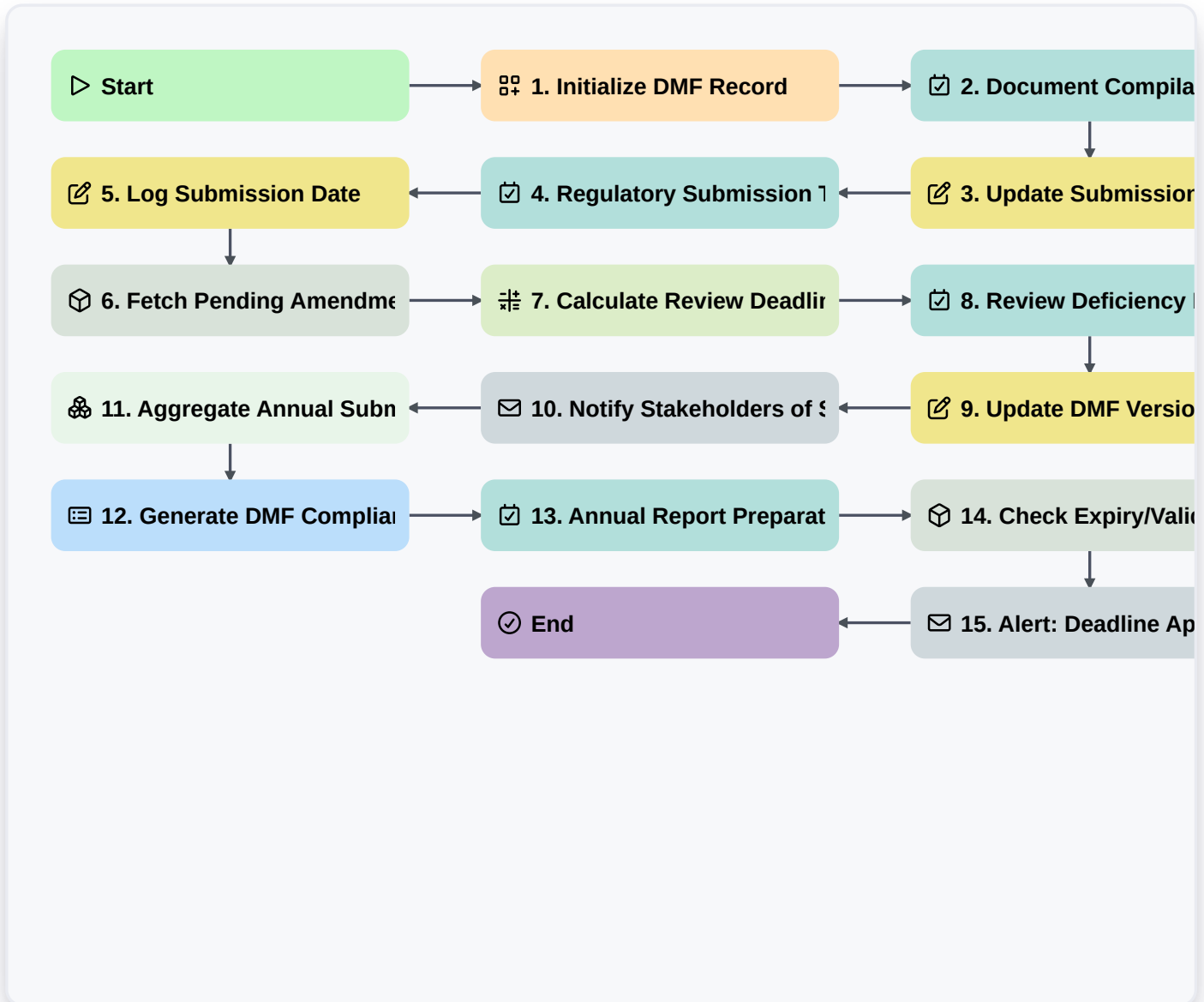


# Drug Master File (DMF) Management Process



## Start

Start of the Workflow/Process.

## 1. Initialize DMF Record

Create a new entry in the DMF Data Model to track the lifecycle of a new Drug Master File.

## 2. Document Compilation Task

Assign a task to the Regulatory Affairs specialist to gather all required technical modules (Module 1-5).

## 3. Update Submission Status

Update the DMF entry status to 'Ready for Submission' once all documents are compiled.

## 4. Regulatory Submission Task

Assign a task to the Submission Lead to upload the dossier to the health authority portal.

## 5. Log Submission Date

Record the actual submission date and receipt number into the DMF Data Model.

## 6. Fetch Pending Amendments

Retrieve all existing entries related to amendments or updates for the specific DMF ID.



## **7. Calculate Review Deadline**

Calculate the regulatory response deadline based on the submission date + standard review period (e.g., 90 days).

## **8. Review Deficiency Letter Task**

If a deficiency is noted, create a task for the Scientific Lead to analyze the regulatory queries.

## **9. Update DMF Version**

Increment the version number in the Data Model when an amendment is processed.

## **10. Notify Stakeholders of Submission**

Send an automated email to the Quality Assurance and Manufacturing teams regarding the new submission.

## **11. Aggregate Annual Submission Count**

Sum the total number of amendments submitted within the last 12 months for regulatory reporting.

## **12. Generate DMF Compliance Report**

Create a summary report showing the current status, upcoming deadlines, and recent changes for all active DMFs.

## **13. Annual Report Preparation**

Create a recurring annual task to prepare and submit the mandatory Annual Report.

## **14. Check Expiry/Validity**

Retrieve data entries of certificates or licenses associated with the DMF to ensure they are valid.

## **15. Alert: Deadline Approaching**

Send an automated email alert to the Regulatory Manager when a review deadline is within 15 days.

## **End**

End of the Workflow/Process.