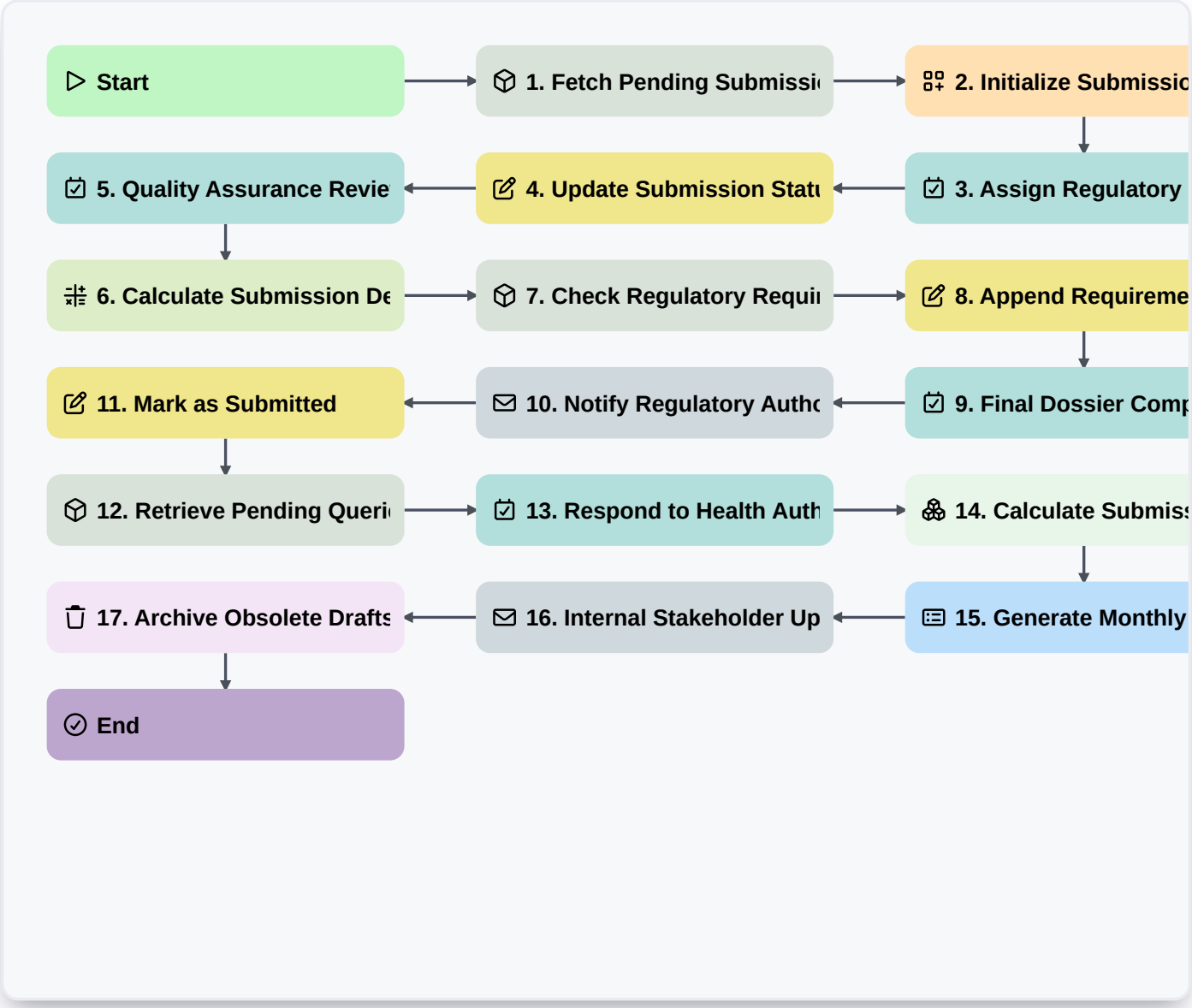
ChecklistGuro

Regulatory Affairs Submission And Tracking Process



Start
Start of the Workflow/Process.

1. Fetch Pending Submissions
Retrieve all active regulatory submission entries that are currently in the 'Draft' or 'Review' stage.

2. Initialize Submission Record
Create a new entry in the Submission Data Model to start the tracking process for a new product/molecule.

3. Assign Regulatory Specialist
Create a task for the assigned Regulatory Affairs Specialist to begin document compilation.

4. Update Submission Status
Update the status of the submission entry to 'In Review' once the dossier is compiled.

5. Quality Assurance Review
Create a task for the QA team to verify the accuracy and completeness of the dossier against the checklist.

6. Calculate Submission Deadline
Calculate the target submission date by adding the required regulatory lead time to the current date.

7. Check Regulatory Requirements
Fetch specific country-level regulatory requirements from the Requirements Data Model based on the target market.

8. Append Requirements to Dossier
Update the Submission entry with the specific requirements retrieved from the requirements model.

9. Final Dossier Compilation
Create a task to assemble all technical documents, certificates, and labels into the final submission package.

10. Notify Regulatory Authority
Send an automated email to the relevant Health Authority contact upon successful submission.

11. Mark as Submitted
Update the Submission entry status to 'Submitted' and record the submission timestamp.

12. Retrieve Pending Queries
Get all 'Request for Information' (RFI) entries related to the current submission.

13. Respond to Health Authority Queries
Create an urgent task for the specialist to address and upload responses to authority queries.

14. Calculate Submission Success Rate
Aggregate all completed submissions in the current year to calculate the percentage of approved vs. rejected submissions.

15. Generate Monthly Compliance Report
Create a comprehensive report summarizing all active, submitted, and approved regulatory submissions for the month.

16. Internal Stakeholder Update
Send an email to the Product Management and Manufacturing teams regarding the submission status change.

17. Archive Obsolete Drafts
Delete or archive redundant draft versions of the dossier from the data model to maintain cleanliness.

End
End of the Workflow/Process.