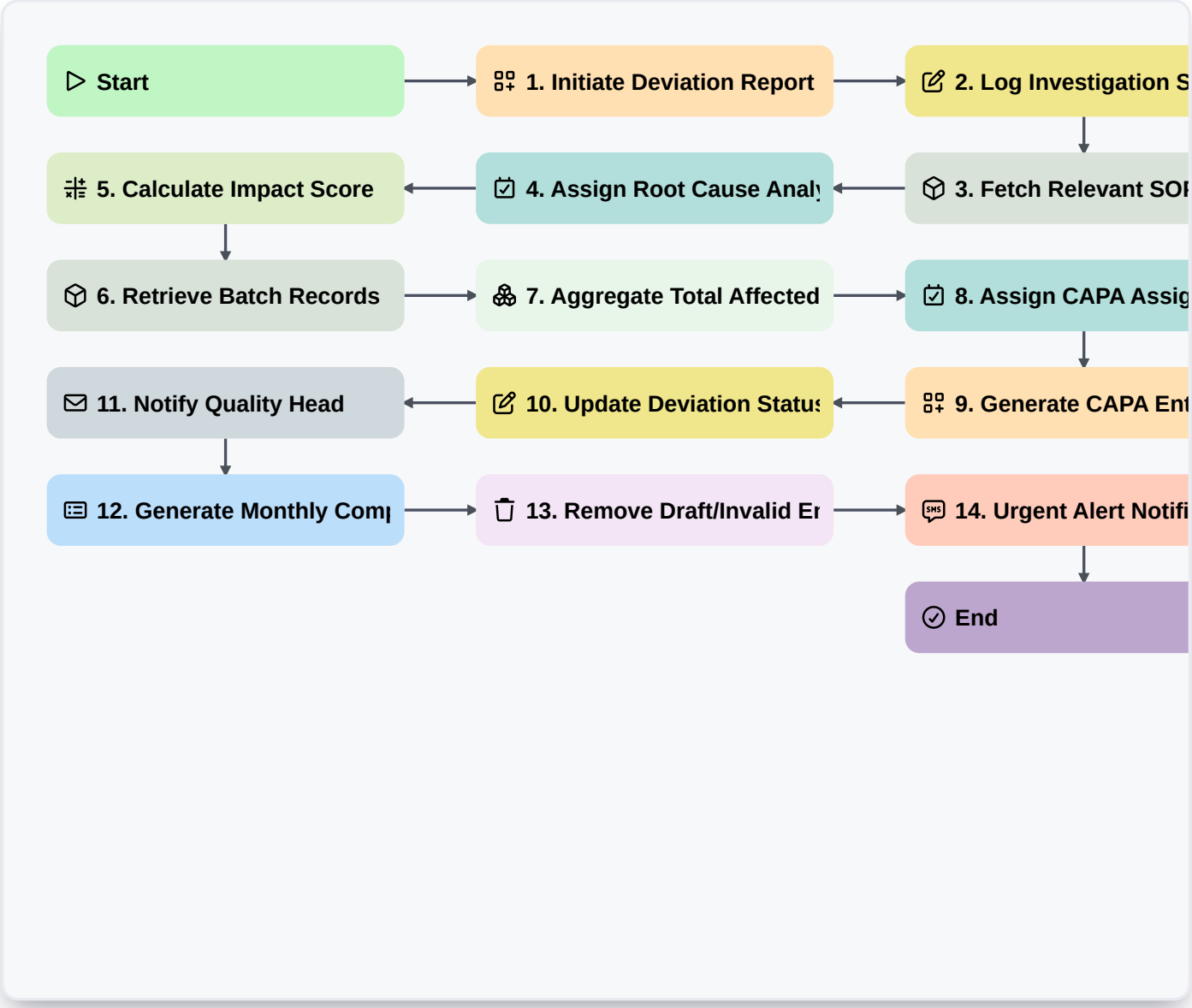
ChecklistGuro

Good Manufacturing Practice (GMP) Compliance Workflow



Start
Start of the Workflow/Process.

1. Initiate Deviation Report
Create a new entry in the Deviation Data Model to document a non-compliance event.

2. Log Investigation Start
Update the Deviation entry with the current timestamp and 'In Investigation' status.

3. Fetch Relevant SOPs
Retrieve all Standard Operating Procedures (SOPs) related to the specific manufacturing area involved in the deviation.

4. Assign Root Cause Analysis (RCA)
Create a task for the Quality Assurance specialist to perform the RCA using the 5-Whys or Fishbone method.

5. Calculate Impact Score
Calculate a risk score based on product criticality, batch volume, and regulatory impact variables.

6. Retrieve Batch Records
Fetch all batch entries associated with the affected production lot.

7. Aggregate Total Affected Units
Sum the quantity field from all retrieved batch entries to determine the total volume of potentially impacted product.

8. Assign CAPA Assignment
Create a task for the Production Manager to define Corrective and Preventive Actions (CAPA).

9. Generate CAPA Entry
Create a new entry in the CAPA Data Model linked to the original Deviation entry.

10. Update Deviation Status to 'Closed'
Update the original Deviation entry status to 'Closed' once all investigations are complete.

11. Notify Quality Head
Send an email notification to the Head of Quality containing the summary of the closed deviation.

12. Generate Monthly Compliance Summary
Generate a periodic report summarizing all deviations and CAPAs closed during the current month.

13. Remove Draft/Invalid Entries
Delete any duplicate or incorrectly filed deviation drafts that do not meet minimum data requirements.

14. Urgent Alert Notification
Send an SMS to the On-call Supervisor if the deviation is flagged as 'Critical' during the calculation phase.

End
End of the Workflow/Process.