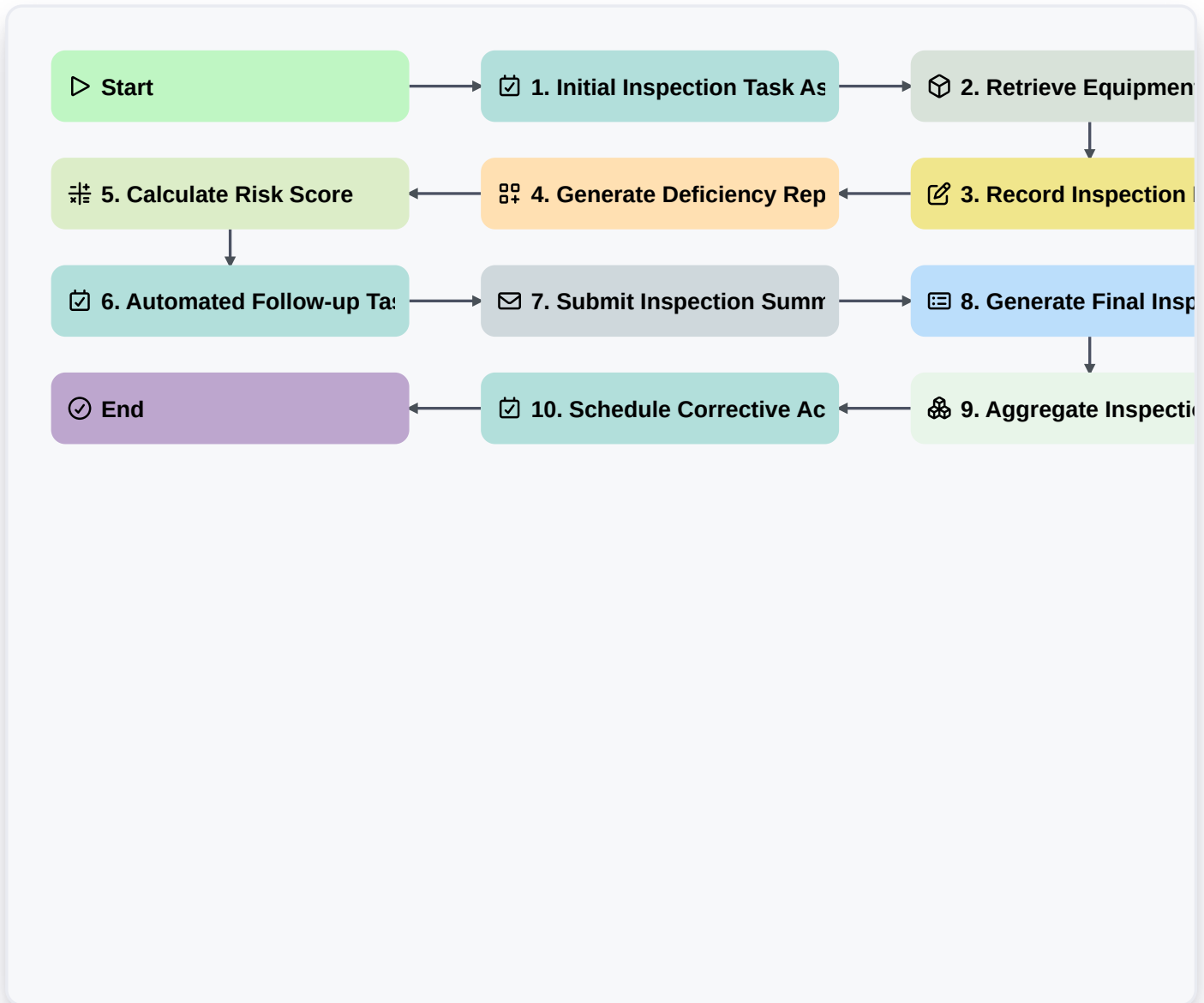


Medical Device Inspection Workflow: FDA & Quality Compliance Tracking



▷ Start

Start of the Workflow/Process.

☑ 1. Initial Inspection Task Assignment

Creates the initial inspection task for the assigned team member based on facility location or device type.

📦 2. Retrieve Equipment Details

Fetches specific details (e.g., Serial Number, Model, Calibration Date) from the Equipment Inventory Data Model.

📝 3. Record Inspection Findings

Allows inspectors to document observations, pass/fail status, and corrective actions for specific inspection checklist items.

📄 4. Generate Deficiency Report Entry

Creates a formal record of non-conformances found during the inspection process.

5. Calculate Risk Score

Executes a formula to determine the overall risk level based on aggregated findings (e.g., assigning weights to severity).

6. Automated Follow-up Task Generation

Creates subsequent tasks for necessary follow-up actions based on critical findings (e.g., 'Immediate Remediation Required').

7. Submit Inspection Summary Email

Sends a summary report via email to Quality Assurance and Management upon completion.

8. Generate Final Inspection Report

Compiles all data (findings, actions, status) into a final, signed-off, auditable PDF report.

9. Aggregate Inspection Results

Aggregates all findings to calculate overall pass/fail metrics and trend analysis.

10. Schedule Corrective Action Meeting

Automatically schedules a review meeting task for stakeholders to discuss necessary remediation steps.

End

Start of the Workflow/Process.