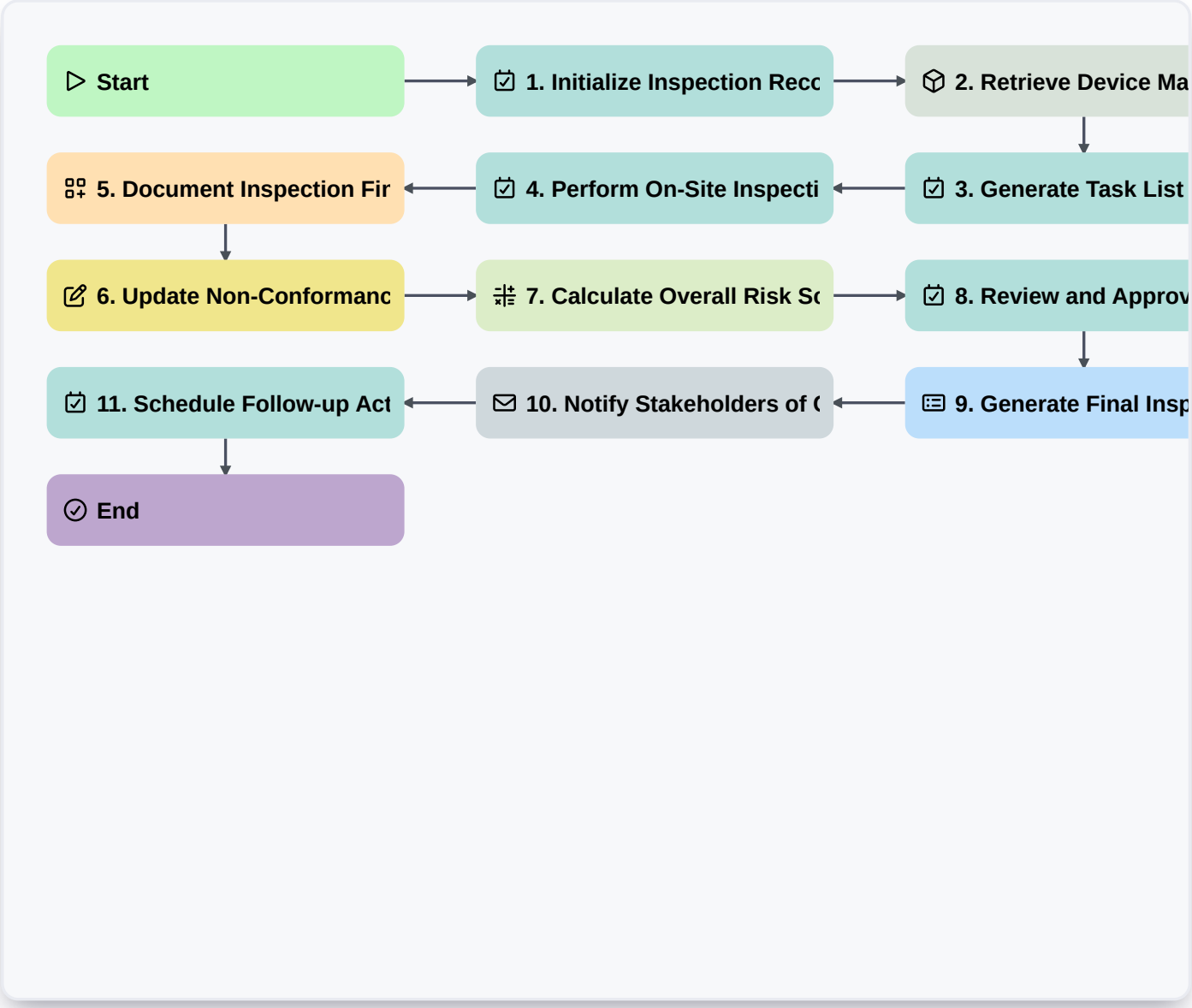
ChecklistGuro

Medical Device Inspection Workflow: Streamlined Audit & Compliance Management



Start
Start of the Workflow/Process.

1. Initialize Inspection Record
Creates a new inspection record, capturing essential details like inspection date, device ID, and assigned inspector.

2. Retrieve Device Master Data
Fetches necessary background information (e.g., Model Number, Calibration Schedule) for the specific medical device being inspected.

3. Generate Task List & Assign Inspectors
Automatically generates the required inspection checklist tasks and assigns them to relevant team members.

4. Perform On-Site Inspection Steps
Guides the inspector through standardized, sequential physical inspection steps using interactive checklists.

5. Document Inspection Findings & Observations
Allows inspectors to record detailed observations, including pass/fail status, non-conformances, and corrective actions directly on the device record.

6. Update Non-Conformance Details
Updates the severity, root cause, and proposed corrective actions for identified defects or non-conformances.

7. Calculate Overall Risk Score
Executes a formula based on collected data (e.g., weighted average of failure points) to determine the overall risk level of the device.

8. Review and Approve Inspection Report
Creates a final review task assigned to the Quality Manager for official sign-off.

9. Generate Final Inspection Report
Compiles all collected data, tasks completed, and identified non-conformances into a comprehensive, traceable final report.

10. Notify Stakeholders of Completion
Automatically emails the final report and next steps to relevant parties (e.g., Engineering, Quality, Management).

11. Schedule Follow-up Actions
Generates follow-up tasks and due dates for necessary Corrective and Preventive Actions (CAPA).

End
Start of the Workflow/Process.