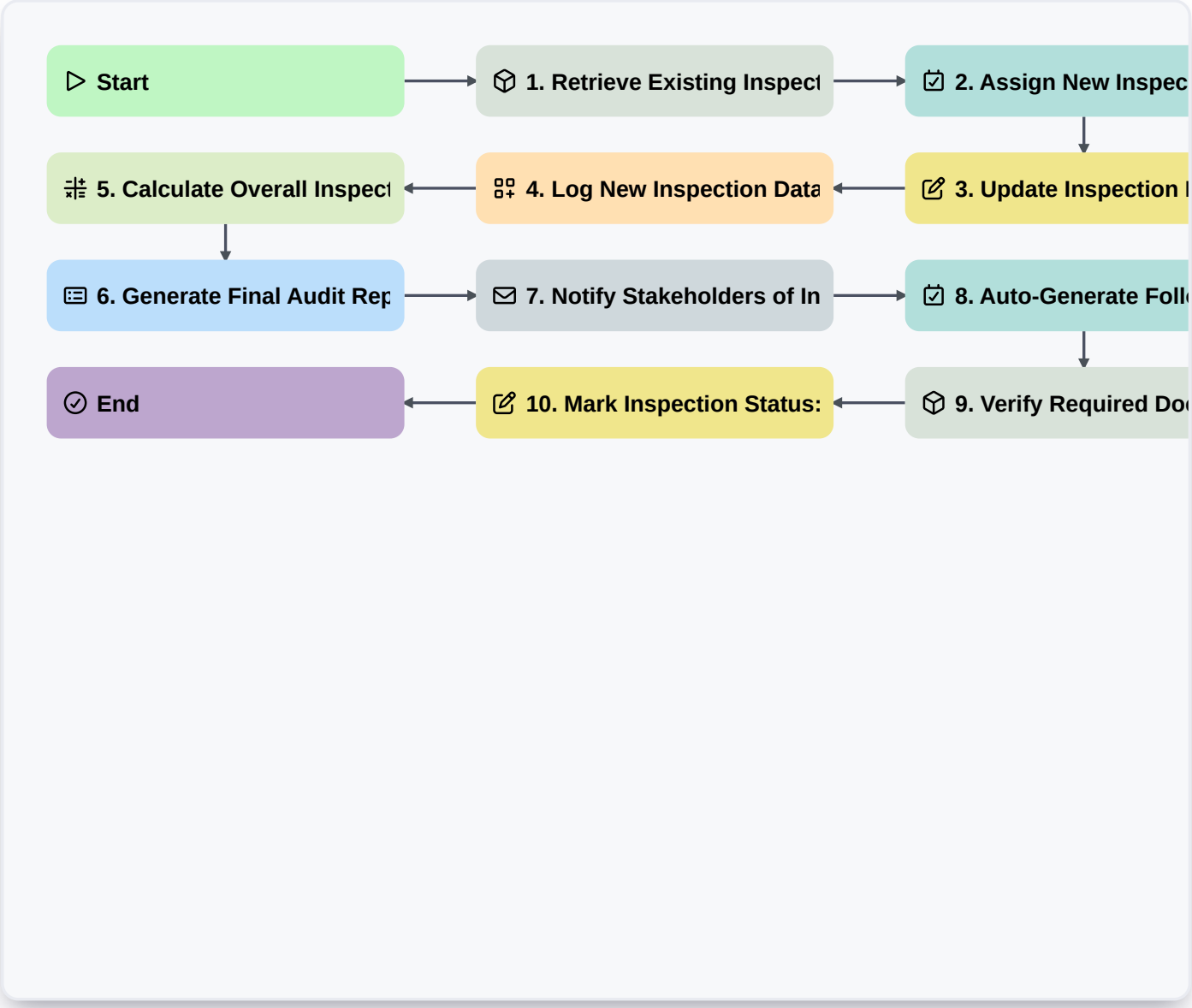
ChecklistGuro

Medical Device Inspection Workflow: Optimized Audit & Quality Management System



Start
Start of the Workflow/Process.

1. Retrieve Existing Inspection Records
Pull historical inspection data for comparative analysis and completeness checks.

2. Assign New Inspection Tasks
Automated creation of inspection tasks for specific devices or sites based on preventative schedules.

3. Update Inspection Findings & Corrective Actions
Allows inspectors to log observations, assign severity, and upload evidence directly into the record.

4. Log New Inspection Data Points
Record real-time data entries for measurements, observations, and checklist items.

5. Calculate Overall Inspection Risk Score
Execute formula based on severity, overdue items, and risk parameters (e.g., Weighting).

6. Generate Final Audit Report
Compile structured, shareable reports detailing all inspection findings, actions, and closure summaries.

7. Notify Stakeholders of Inspection Completion
Automatically email relevant personnel (Manager, QA, Responsible Team) with the inspection outcome and next steps.

8. Auto-Generate Follow-up Action Items
Create subsequent tasks for root cause analysis, corrective and preventative actions (CAPA).

9. Verify Required Documentation Checklist
Check mandatory attachments and forms needed for full audit sign-off.

10. Mark Inspection Status: Passed/Failed
Finalize the inspection record with clear pass/fail status and necessary signatures.

End
Start of the Workflow/Process.