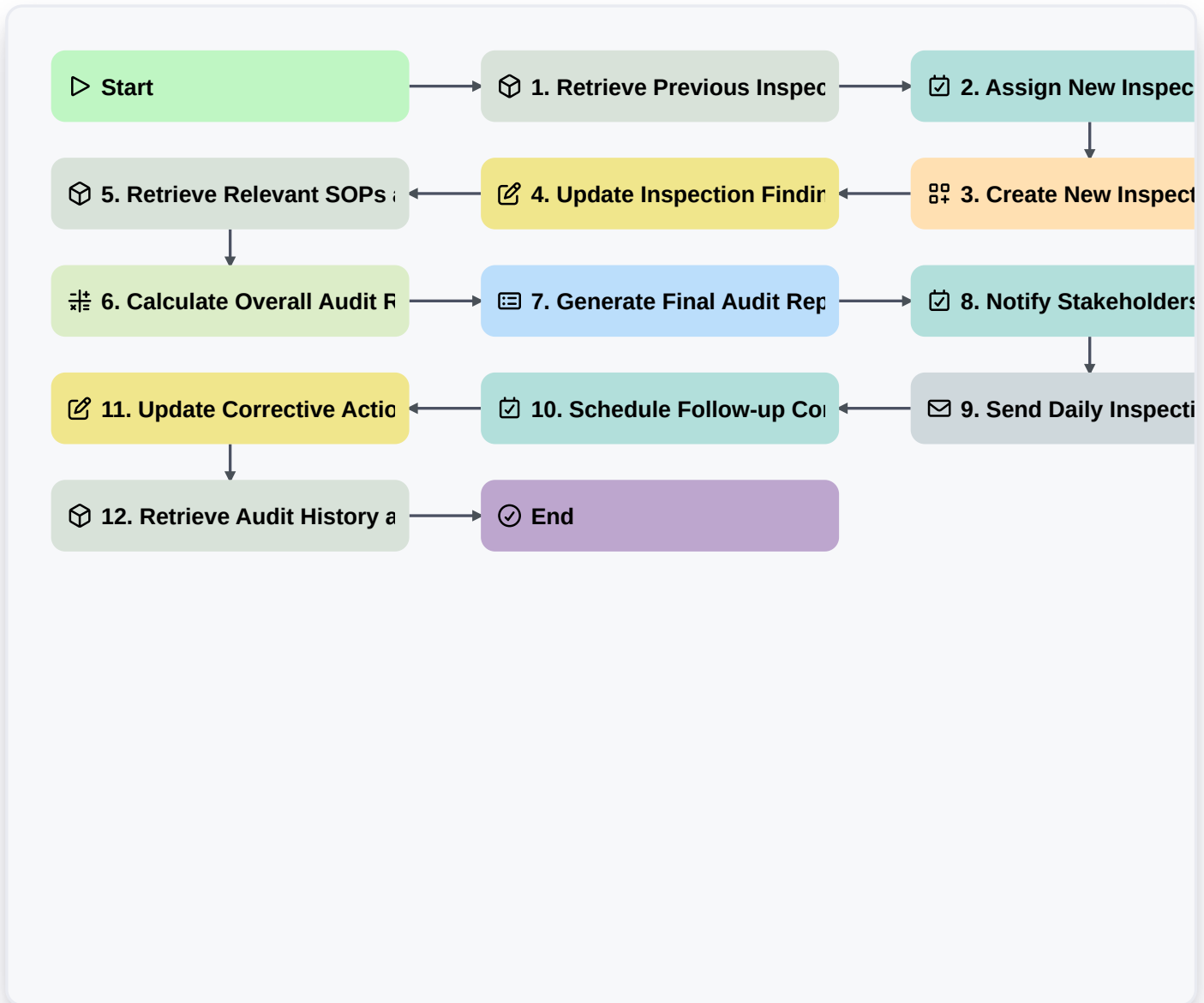


# Medical Device Inspection Workflow: Audit Readiness & Quality Management System



▷ **Start**

Start of the Workflow/Process.

 **1. Retrieve Previous Inspection Records**

Fetch historical inspection data for site comparison and trend analysis.

 **2. Assign New Inspection Tasks to Auditor**

Automatically create and assign necessary inspection tasks to the designated auditor upon initiation.

 **3. Create New Inspection Checklist Instance**

Generate a new, standardized inspection record for the specific site or device being audited.

 **4. Update Inspection Findings and Observations**

Allow auditors to input real-time findings, deviations, and corrective actions against the checklist items.

 **5. Retrieve Relevant SOPs and Guidelines**

Fetch and display current Standard Operating Procedures (SOPs) pertinent to the inspected area or device.

## ⚙️ **6. Calculate Overall Audit Risk Score**

Execute formulas combining finding severity, closure rate, and risk factors for a comprehensive risk score.

## 📄 **7. Generate Final Audit Report**

Compile all inspection data, findings, and necessary documentation into a final, structured report.

## 📧 **8. Notify Stakeholders of Inspection Completion**

Automatically assign follow-up tasks to management and relevant department heads upon submission.

## ✉️ **9. Send Daily Inspection Progress Summary Email**

Distribute summary reports to project managers and stakeholders daily.

## 📅 **10. Schedule Follow-up Corrective Action Task**

Create a follow-up task for required corrective actions after the initial inspection report is filed.

## ✍️ **11. Update Corrective Action Tracker Status**

Modify the status of open non-conformances (e.g., from 'Open' to 'In Progress' or 'Closed').

## 📦 **12. Retrieve Audit History and Findings**

Access past inspection reports to identify recurring non-conformances and process improvements.

## 🏁 **End**

Start of the Workflow/Process.