

Medical Device Inspection Workflow: SaaS Solution For FDA & ISO Compliance Audits



▶ Start

Start of the Workflow/Process.

☑ 1. Generate New Inspection Record

Creates the initial record for a specific inspection event.

📦 2. Retrieve Device Information

Fetches existing asset/device data (e.g., Serial Number, Model) for the inspection scope.

☑ 3. Assign Inspection Tasks to Personnel

Assigns specific checklists or actions to relevant team members (e.g., Mechanical, Electrical, Software).

✍ 4. Update Inspection Findings and Non-Conformances (NCs)

Allows inspectors to log observations, severity, and necessary corrective actions.

📦 5. Retrieve Historical Inspection Data

Accesses previous inspection results and corrective actions for trend analysis.

⚙️ 6. Calculate Risk Score from Observations

Automated calculation to prioritize findings based on severity and potential impact (Risk Matrix).

📝 7. Generate Corrective Action Request (CAR)

Automatically creates tasks for root cause analysis and preventative measures based on failed inspections.

📄 8. Generate Final Audit Report

Compiles all inspection data, checklists, and action items into a standardized, client-ready report format.

✉️ 9. Submit Inspection Results Notification

Sends automated email summary to stakeholders (Management, QA) upon completion.

📱 10. Urgent Safety Alert Notification

Sends real-time SMS alerts for critical safety findings or immediate hazards.

✅ End

Start of the Workflow/Process.