ChecklistGuro

Medical Device Inspection Workflow: FDA/ISO Audit Management And Quality Control

Start
Start of the Workflow/Process.

1. Retrieve Device Registration Details
Fetch existing medical device ID, model number, and last inspection dates from the master inventory model.

2. Create New Inspection Record
Generate a new primary record for the inspection, linking it to the specific device model and location.

3. Assign Inspection Tasks to Technicians
Automatically create inspection tasks (e.g., Visual Check, Functionality Test, Documentation Review) for assigned personnel.

4. Schedule Follow-up Actions
Create follow-up tasks for corrective actions and necessary next inspections based on current findings.

5. Update Inspection Status and Findings
Update the central record with inspection results, pass/fail status, and detailed findings.

6. Get Current Regulatory Requirements
Retrieve the latest FDA/ISO standards applicable to the inspected device category.

7. Calculate Inspection Score & Risk Level
Compute overall compliance score based on multiple task results (e.g., calculating the % pass rate).

8. Send Inspection Summary to Stakeholders
Email automated summary report and required approvals to management and relevant teams.

9. Alert Technician of Immediate Safety Hazard
Send critical SMS alerts for immediate safety violations identified during the physical inspection.

10. Generate Comprehensive Audit Report
Compile final, sign-off report containing all findings, evidence, and action plans for submission.

End
Start of the Workflow/Process.