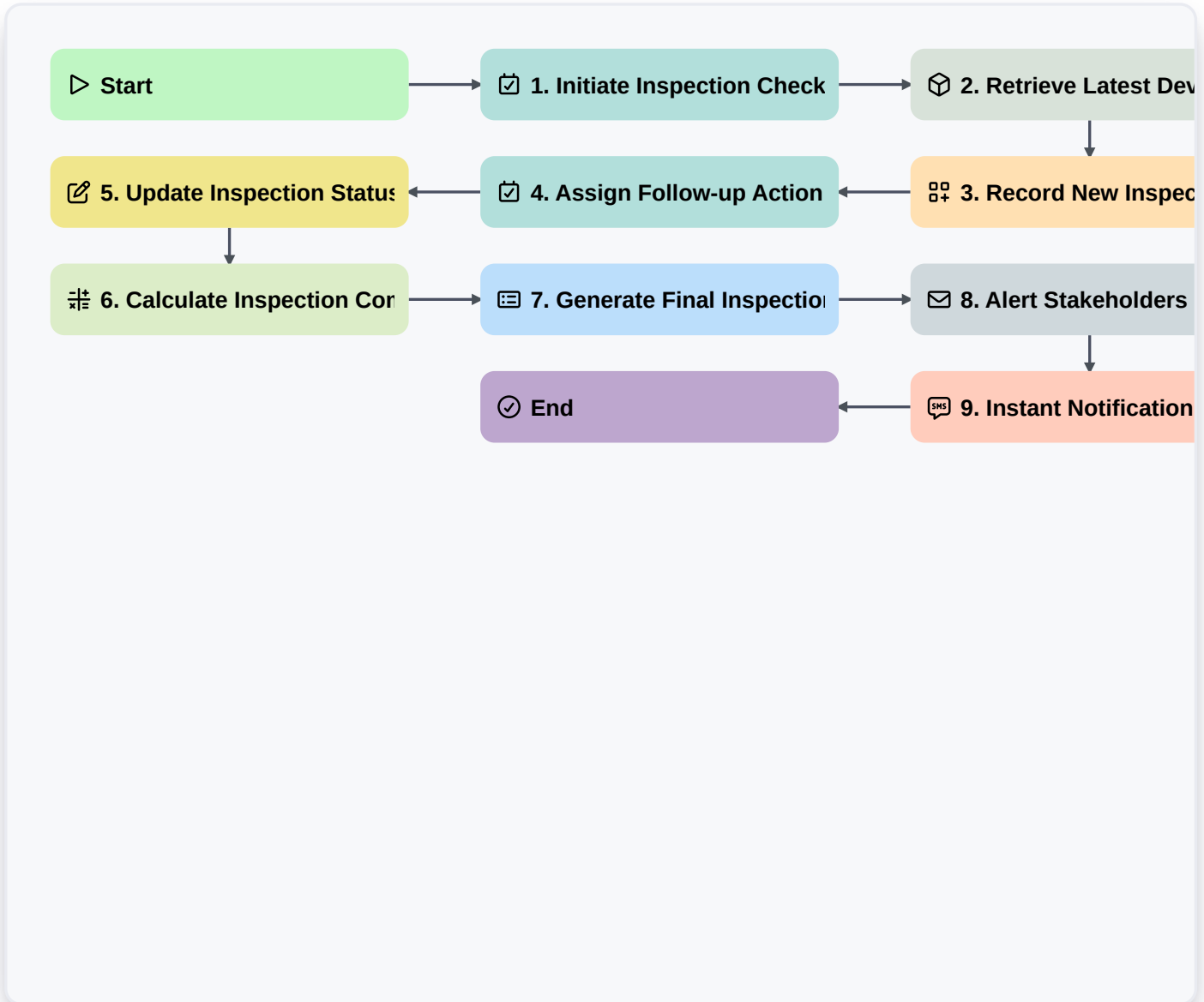


## Medical Device Inspection Workflow: Best Practices For FDA/ISO Audit Management



### ▷ Start

Start of the Workflow/Process.

### ☑ 1. Initiate Inspection Checklist

Creates a new, trackable record for the inspection based on a specific device model or site location.

### 📦 2. Retrieve Latest Device History Records

Pull historical inspection data and associated corrective actions for the specific medical device.

### 📋 3. Record New Inspection Finding/Observation

Allows inspectors to log non-conformities, deviations, or observations with timestamps and evidence.

### ☑ 4. Assign Follow-up Action Items

Automatically generates and assigns tasks to responsible personnel for necessary corrective actions (CAPA).

### ✍ 5. Update Inspection Status (Pass/Fail)

Marks the overall status of the inspection record, triggering next steps or approvals.

## **6. Calculate Inspection Completion Score**

Aggregates data points (e.g., % items checked, overdue tasks) to generate an overall pass/fail score for reporting.

## **7. Generate Final Inspection Summary Report**

Compiles all gathered data, tasks, and findings into a formal, shareable audit report.

## **8. Alert Stakeholders of Critical Non-Conformance**

Automatically notifies relevant department leads or management via email immediately upon logging a critical finding.

## **9. Instant Notification for Failed Critical Checkpoints**

Sends urgent SMS alerts to site managers when immediate corrective action is required during an inspection.

## **End**

Start of the Workflow/Process.