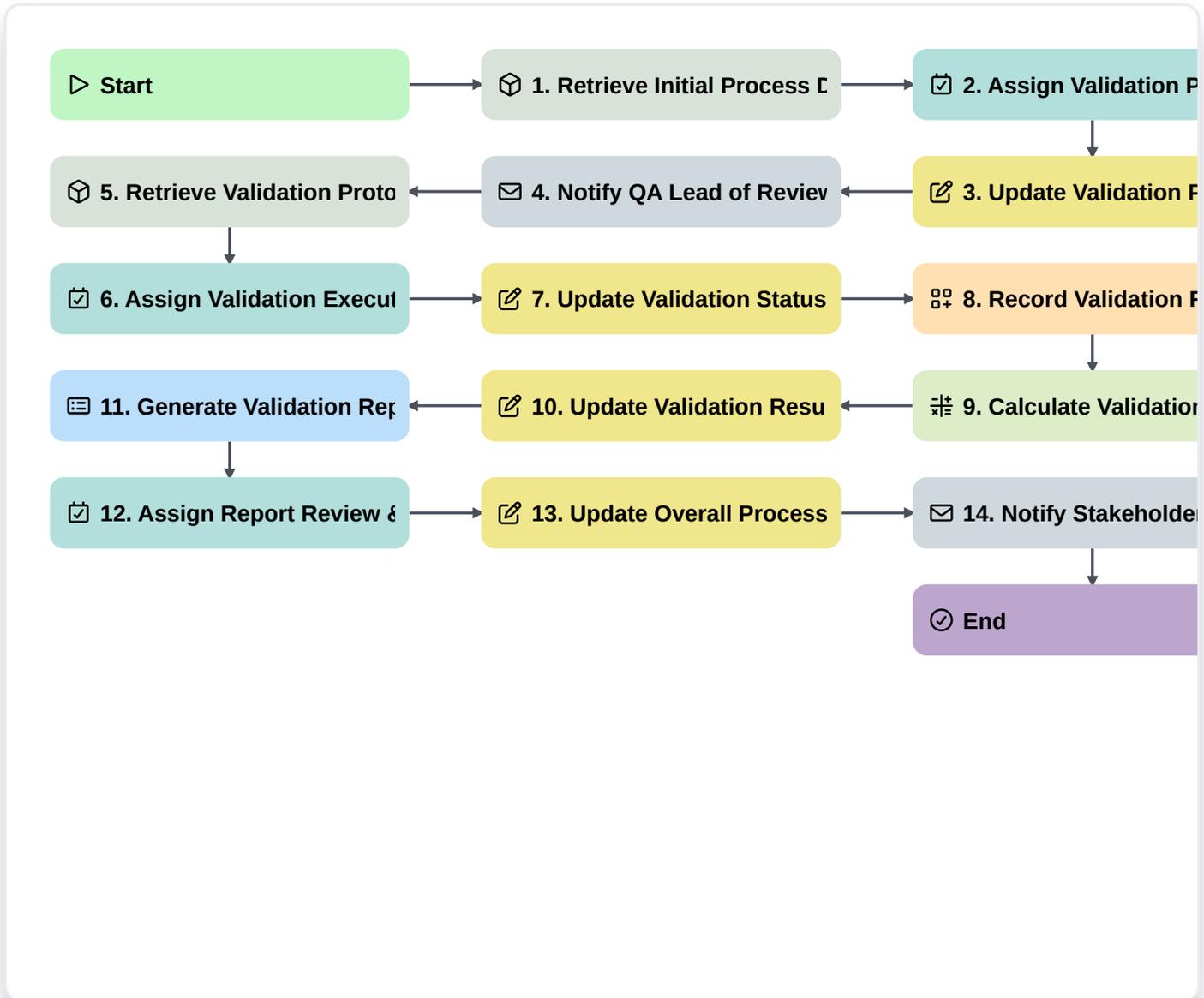


# Manufacturing Process Validation Workflow



## Start

Start of the Workflow/Process.

## 1. Retrieve Initial Process Data

Fetch initial process parameters and specifications from the Process Data Model.

## 2. Assign Validation Plan Review

Create a task to assign the process validation plan for review by the Quality Assurance team.

## 3. Update Validation Plan Status

Update the process validation plan status to 'Under Review' in the Process Data Model.

## 4. Notify QA Lead of Review

Send an email to the QA Lead notifying them of the validation plan review.

## 5. Retrieve Validation Protocol

Retrieve the validation protocol from the Validation Protocol Data Model.

## 6. Assign Validation Execution

Create a task to assign the execution of the validation protocol to the designated team.

### **7. Update Validation Status to 'Executing'**

Update the validation status in the Process Data Model to 'Executing'.

### **8. Record Validation Results**

Create new entries to record actual validation results, including data points, observations, and any deviations.

### **9. Calculate Validation Success Criteria**

Calculate whether the validation results meet the defined acceptance criteria based on recorded data.

### **10. Update Validation Result Status**

Update the validation result status to 'Pass' or 'Fail' based on calculated success criteria.

### **11. Generate Validation Report**

Create a comprehensive validation report detailing the entire process, results, and conclusions.

### **12. Assign Report Review & Approval**

Create a task to assign the validation report for review and approval by stakeholders.

### **13. Update Overall Process Validation Status**

Update the overall process validation status in the Process Data Model to 'Validated' or 'Rejected'.

### **14. Notify Stakeholders of Validation Outcome**

Send an email notification to relevant stakeholders (e.g., Engineering, Production) regarding the validation outcome.

### **End**

Start of the Workflow/Process.