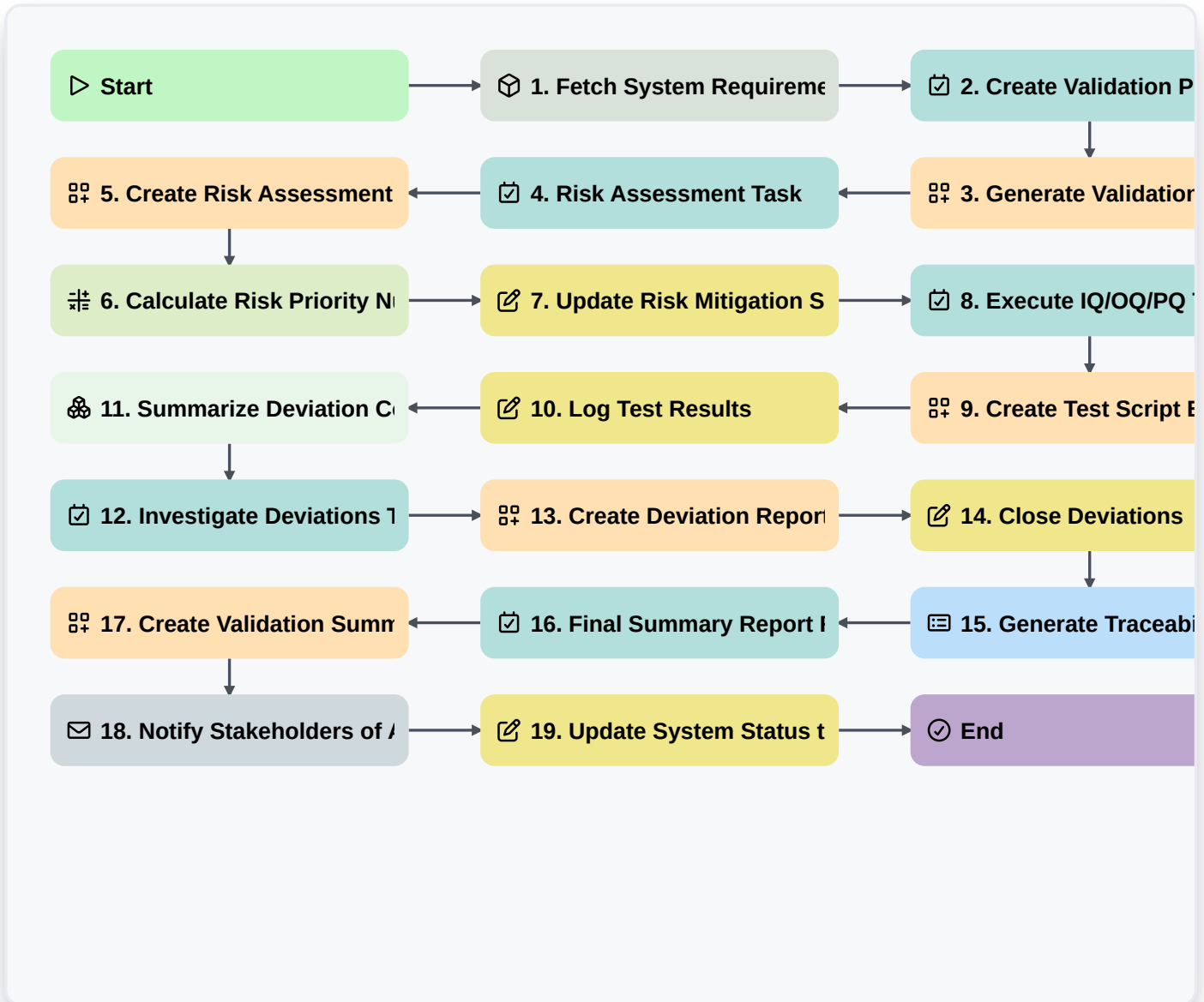


# Computer System Validation (CSV) Workflow



## ▷ Start

Start of the Workflow/Process.

## 📦 1. Fetch System Requirements

Retrieve all User Requirements (URS) entries from the Requirements Data Model to initiate the validation scope.

## ✅ 2. Create Validation Plan Task

Assign a task to the QA Lead to draft the Validation Plan based on the identified system scope.

## 📋 3. Generate Validation Plan Entry

Create a new entry in the Validation Plan data model containing the scope, strategy, and testing approach.

## ✅ 4. Risk Assessment Task

Assign a task to the Subject Matter Expert (SME) to perform a GAMP5-based risk assessment.

## 📋 5. Create Risk Assessment Record

Create an entry in the Risk Management data model to document identified hazards and mitigation strategies.

## 🔢 6. Calculate Risk Priority Number (RPN)

Execute formula (Severity \* Occurrence \* Detectability) to determine the critical level of each risk.



## **7. Update Risk Mitigation Status**

Update the Risk Assessment entry to reflect that mitigation controls have been implemented.

## **8. Execute IQ/OQ/PQ Testing**

Assign testing tasks to Validation Engineers to execute Installation, Operational, and Performance Qualifications.

## **9. Create Test Script Entry**

Create a record in the Test Script data model for each protocol being executed.

## **10. Log Test Results**

Update the Test Script entry with pass/fail results and evidence links after execution.

## **11. Summarize Deviation Count**

Aggregate the number of 'Fail' statuses from all Test Script entries to determine total deviations.

## **12. Investigate Deviations Task**

Create a task for the Quality Engineer if the Deviation Count is greater than zero.

## **13. Create Deviation Report**

Create an entry in the Deviation Data Model for every failed test case identified.

## **14. Close Deviations**

Update the Deviation entries to 'Closed' once corrective actions are verified.

## **15. Generate Traceability Matrix Report**

Create a report linking Requirements  $\rightarrow$  Risks  $\rightarrow$  Test Scripts to ensure full coverage.

## **16. Final Summary Report Review**

Assign a task to the Quality Manager to review the final Validation Summary Report (VSR).

## **17. Create Validation Summary Report**

Create the final record in the Validation Summary data model summarizing the entire process outcome.

## **18. Notify Stakeholders of Approval**

Send an email to the Project Sponsor and IT Department once the VSR is approved and the system is released for production.

## **19. Update System Status to 'Validated'**

Update the Computer System entry in the Inventory Data Model to 'Validated' status.

## **End**

End of the Workflow/Process.