

## DEFINITION

- Generate User requirement Specification (URS)

## PLANNING

- Update Site VMP
- Validation project Plan
- Impact Assessment
- System development Audit Report

## DESIGN

- Functional Specification (FS)
- Design Specifications
- Design Qualification (Traceability report)

## CONSTRUCTION

- Coding and Configuration Standards
- Documented Source Code
- Code Reviews
- Unit and Integration Testing



# VALIDATION LIFECYCLE

## INSTALLATION & CONFIGURATION

- Technical Documents (e.g. installation guides)
- Baseline Hardware and Software Configuration

## TESTING

- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Perfo

## DECOMMISSION

- System Decommission Plan

## RE-VALIDATION

- Periodic Review
- Maintenance

## OPERATIONAL MGT.

- System Recovery Plan
- Standard Operating Procedures (SOPs)
- Training
- Change Management
- Errors and Deviations

## REPORTING

- Final Validation Report



# Quality Management Systems Process Validation Guidance

**Shasha Hu**



## **Quality Management Systems Process Validation Guidance:**

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