

## 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

**Roseann B. Termini**



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

## Whispering the Techniques of Language: An Psychological Quest through **Quality Management Systems Process Validation Guidance**

In a digitally-driven earth where screens reign supreme and quick interaction drowns out the subtleties of language, the profound strategies and psychological nuances hidden within words often move unheard. However, nestled within the pages of **Quality Management Systems Process Validation Guidance** a interesting fictional prize pulsating with fresh feelings, lies a fantastic quest waiting to be undertaken. Published by a skilled wordsmith, that wonderful opus encourages visitors on an introspective journey, lightly unraveling the veiled truths and profound affect resonating within the very fabric of each and every word. Within the psychological depths of the moving review, we can embark upon a genuine exploration of the book is key subjects, dissect their charming publishing type, and succumb to the effective resonance it evokes heavy within the recesses of readers hearts.

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