

Validation Planning



CONCEPT
HEIDELBERG

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Validation Planning

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Computerized Systems Validation
Dr. Guenter Generlich

Planning 1

Why Planning

- Moves us from activity centered to results-oriented
- Eliminates unnecessary activities
- Keeps everyone in the loop
- Provides sense of direction and purpose
- Structures control and coordination
- Serves as a roadmap to success
- Key topic for regulatory bodies

*The words
from the sage:
to fail to plan is
to plan to fail*

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Planning 2

CSV Planning Outline

For **all** systems:

- Inventory and Master Planning

For a **specific** system:

- Validation planning for specific project / system
- Project life cycle
- Multidisciplinary team / responsibility matrix

Tips, tricks, and pitfalls

Create Validation Inventory

- Identify systems
- Create Inventory
- Determine Validation need
- Prioritize systems
- Create master plan
- Maintain Inventory



Validation Planning

Systems Inventory

Division / Area / Department:				Date	
System Name	Location	Owner	Current Validation Status	Date Validation Completed	Date Next Review
			N/A in progress validated retired		

Create CSV Master Plan (VMP)

- The VMP describes the areas of the company within which validation is to take place
- Define policy and guidelines (high level procedures)
 - overall structure of CSV activities
 - priority criteria
- Create an overall implementation schedule for **all** systems and their actual validation status

Validation Planning

The VMP - A Summary Document

- Company Validation Policy
- Organization for Validation
 - major roles and responsibilities involved
 - controlling body / steering committee / individual
- Summary of facilities, **systems**, equipment, or processes to be validated
- Documentation structure, format, basic contents
- Change control process
- Planning and scheduling
 - overall structure of CSV activities
 - priority criteria
 - validation date for systems

Implementation Schedule

Division / Area / Department:				Date	
System Name	Location	Priority	Planned Completion Date	Date Validation Plan Approved	Date Validation Report Approved
		A, B, C or I, II, III			

Validation Planning

Validation Plan

- A Validation Plan should be established individually for each application/project
- This Validation Plan is a multidisciplinary strategy from which each phase of validation for a specific project/application/system is planned, implemented, and documented



General Guidelines for CSV Planning and Reporting

- Assemble Validation team
- Clarify roles & responsibilities
- Specify Validation activities
- Define deliverables - content of Validation Registry
- Schedule ongoing reviews
- Prepare, review & approve Validation Plan
- Plan for archiving
- Prepare, review & approve Validation Report (based on Validation Plan)

Validation Planning

Validation Plan Contents

- Purpose, scope, background
- System / environment description / limitations
- Organizational structure, roles & responsibilities
 - owner, vendor, developer, validator, user
- Detailed sequence of activities, incl.
 - quality procedures / associated tasks
 - GxP criticality assessment
 - description of life cycle activities
 - acceptance criteria, risk management, traceability matrix
 - supplier assessment(s) & audits
 - maintaining the validated state
- Glossary
- Documentation list (intended validation baseline registry)
 - detailed description of collected, used and delivered docs

Roles and Responsibilities

- Project Sponsor / Application Owner
- (Business) Project Leader
- Developer
- CSV Expert
- Quality Assurance
- others . . .



All stakeholders have different and changing tasks during the validation exercise

Validation Planning

Documentation List

Generic Name of Document	Actual Name of Document	Location	Document Owner	Created		Approved	
				By	Date	By	Date

Validation Report Contents

- Clear statement that the system is validated and released for operational use
- Identification of possible restrictions
- Confirmation that all activities according to the plan have been performed
- Summary evaluation of test results and confirmation of meeting the acceptance criteria
- Action list (if appropriate)
- Planned activities for maintaining the validated state
- Updated and completed documentation list / validation registry

Validation Planning

CSV Planning Tips

- One person to co-ordinate CSV
- Get appropriate representation in the team
- Start with CSV planning during Specify & Design
- Clarify responsibilities: who, what, when
- Apply change management to the plan also
- Organize documentation
- The Plan is a living document

