Validation planning

Validation policies define management intent and commitment
Validation policies

Corporate or site level document that defines the approach to computerized system quality and compliance
Validation policies

Should include at least the following:

- Higher level deliverables
- Standards, templates and procedures for the entire company
- High level process definitions, for example, how to determine if a system is GxP regulated
- Documentation management
Validation planning

- Multi Site
  - Site
    - Department
      - System
  - Validation Policy
    - VMP Level 1
    - VMP Level 2
    - Validation Plan
Validation Planning

• Process owners are responsible for validation plans – in conjunction/delegation with project managers.

• The process owner and a quality unit representative should approve validation plans from a quality and regulatory perspective.
Validation Planning

Validation plan contents should include:

- System overview
- Organisational structure
- Quality risk management
- Validation strategy
- Deliverables, acceptance criteria
Validation Testing

Testing specifications should be adequately developed to match the system design and complexity.

Testing results should be documented against their previously defined acceptance criteria.

Each test result should contain a Pass/Fail statement and a field for the tester’s signature and date of testing.
Validation Reporting

Development of a Validation report (VR) is another user responsibility.

A VR is a summary document that reviews whether all Validation deliverables and activities are met according to the Validation Plan.

A VR requires evidence as verification and conclusions from the testing process.
Validation Reporting

• How will deviations be handled?

• Does the project feature discrete phases such as IQ completion before OQ commencement?

• During IQ testing if changes need to be made to the system what impact will this have on OQ?
Recommend embedding Risk Assessment into existing documents

**User Requirements Specification**

<table>
<thead>
<tr>
<th>Client</th>
<th>Project No.</th>
<th>Department</th>
<th>Template Ref</th>
<th>Document ID</th>
<th>Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Client</td>
<td>Cyyyyy</td>
<td>VAL</td>
<td>VALXXX_R01</td>
<td>VALXXX</td>
<td>01</td>
</tr>
</tbody>
</table>

**Title:** Computer System Name

### 3.2. Data

This subsection shall define the following:

- Data definition e.g. critical parameters identification and valid data ranges and limits
- Capacity requirements
- Data security and integrity, in particular 21 CFR Part 11 requirements

<table>
<thead>
<tr>
<th>Ref. No.</th>
<th>Specification of Requirement</th>
<th>M/D</th>
<th>C/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.12</td>
<td>System shall be compliant with the requirements of 21 CFR Part 11 requirements.</td>
<td>M</td>
<td>C</td>
</tr>
<tr>
<td>U.13</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Traceability and testing

<table>
<thead>
<tr>
<th>Ref. No.</th>
<th>Test Method</th>
<th>Actual Result</th>
<th>PASS / FAIL Initials / Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>F.31.</td>
<td>11.10 (d) Limits system access to authorized individuals.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F.32.</td>
<td>11.10 (e) Creates secure, computer-generated, time-stamped audit trails.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F.33.</td>
<td>11.10 (f) Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Requirements Traceability Matrix

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Design</th>
<th>Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Functional Specification</td>
<td></td>
</tr>
<tr>
<td>U1.1.1</td>
<td>F2.4.1</td>
<td>D2.5</td>
</tr>
<tr>
<td>U1.1.2</td>
<td>F2.4.5</td>
<td>D2.4</td>
</tr>
<tr>
<td>U1.2.1</td>
<td>F3.1</td>
<td>D1.1</td>
</tr>
<tr>
<td>U1.2.2</td>
<td>F3.2</td>
<td>D1.2</td>
</tr>
<tr>
<td>U1.2.3</td>
<td>F3.3</td>
<td>D3.3</td>
</tr>
</tbody>
</table>

Each reference within the matrix, e.g., U1.1.2, F3.1, D1.2, T8.2, could be a reference to a section or subsection within the relevant document, or to a totally separate document.

In practice there often is not a simple one-to-one relationship from the requirements through the different design documents. One function may fulfill different requirements or one requirement may require different design elements.
Good Documentation Practice (GDP)

<table>
<thead>
<tr>
<th>GDP should include the following</th>
</tr>
</thead>
<tbody>
<tr>
<td>A consistent documentation format, numbering</td>
</tr>
<tr>
<td>system</td>
</tr>
<tr>
<td>Documentation version control system</td>
</tr>
<tr>
<td>Tracking of document changes and document</td>
</tr>
<tr>
<td>update management</td>
</tr>
<tr>
<td>Documentation security and back up systems</td>
</tr>
<tr>
<td>Documentation review and approval systems</td>
</tr>
<tr>
<td>that are effective and timely</td>
</tr>
</tbody>
</table>
Validation Master Plan (VMP)

A Validation Master Plan is a summary document explaining the validation approach to be used for establishing whether a system is fit for its intended purpose.
Validation Master Plan (VMP) outlines the validation principles

Written program detailing:

- **Areas, systems to be validated**
- **Achieving and maintaining a validated state**
- **Validation program and processes**
Validation characteristics

Multidisciplinary approach
- Collaboration of experts in various disciplines

Time
- As with any project

Costs
- Highly specialised people
Validation characteristics

Good Project Management approach is that many aspects are considered in the validation plan.

› Detail these in the VMP
Validation Master Plan (VMP)

Purpose of the VMP:

- Overview of the entire project
- Organisational structure
- Content
- Planning
Validation Master Plan (VMP)

- As a minimum the VMP must detail a list or inventory of items to be validated
- Large projects may require a separate VMP
The VMP can be used as a management tool where the following are monitored:

- Resources required
- Timeline
- Costs
- Responsibilities
Validation Master Plan (VMP)

The VMP should:

- Be a brief, concise document
- Reference other relevant documents
- Be approved by management
# Validation Master Plan (VMP)

## VMP Contents

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Introduction</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Organisational structure</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Plant/process/product description</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Specific process considerations</strong></td>
<td></td>
</tr>
<tr>
<td><strong>List of all items to be validated</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Key acceptance criteria</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Documentation format</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Required SOPs</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Planning</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Change Control</strong></td>
<td></td>
</tr>
</tbody>
</table>
Validation Master Plan (VMP)

**Introduction**
- Validation policy, rationale

**Organisational structure**
- Who is responsible for what
- Project owners
- Quality Assurance role
An example of a VMP introduction:

The Company will formally commission and qualify equipment which forms the X Project. The equipment will be used in the manufacturing process for product X. The equipment will be designed and constructed to meet the regulatory requirements of Good Manufacturing Practice and in accordance with the Company Quality Management System.

› Global company regulations
Validation Master Plan (VMP)

5. Validation Rationale – Commissioning and Qualification Approach

The purpose of the engineering commissioning and qualification (C&Q) activities within the scope of this document is to demonstrate that the process equipment reliably and reproducibly perform to meet their intended functions. This forms the foundation for process optimisation, development of process control loops and subsequent process validation. The qualification program to be implemented will be consistent with Current Good Manufacturing Practice (cGMP) regulations and guidelines.
Validation Master Plan (VMP)

- Plant, process, product description
  - Overall system description at this stage

- Specific process considerations
  - Specific GMP requirements
  - Knowledge and Subject Matter Experts
  - Key process requirements
Validation Master Plan (VMP)

List of all items to be Validated

- More functional detail regarding each item
- System boundaries must be clearly identified
Validation Master Plan (VMP)

Key acceptance criteria:

- The measures of success for your Validation effort
- Based on scientific knowledge of the process
- Consider “gateways” for example the IQ must be complete before progressing to OQ...
8. **Acceptance Criteria**

All qualification activities will be documented in the respective Qualification Protocols that fully define the acceptance criteria for the equipment, system or component undergoing qualification. If achieved, satisfaction of the acceptance criteria will demonstrate a consistently well controlled process which, in routine production, will provide acceptable quality X Product that will comply with the appropriate specifications.
Validation Master Plan (VMP)

Validation master plans (VMPs) detail the overall plan and validation activities, including:

- The company validation policy
- Organisation of validation activities
- Details of a documentation format and structure
- Change control processes for the project
- GxP criticality assessment processes
Validation Master Plan (VMP)

VMPs must stand up to Management approval and regulatory inspection.

VMPs also feature a Validation hierarchy:
- roles and responsibilities across the Validation life cycle.

Ultimate responsibility rests with user company senior management and QA.
Activity – Audit Checklist

• Using the PIC/S Aide Memoire reference PI006-03, develop an audit checklist

• Section 4 Validation Master Plan

• Work in groups

• Contribute to discussion
Validation Plan (VP)

- Summary of the entire unit operation
- Clearly detail measures for success
- Define the acceptance criteria for the final acceptance of the system
Validation Plan (VP)

VPs should be created for each GxP system clearly identifying:

- What validation activities are required
- The method of validation activities and associated responsibilities
- Outputs of validation
- How the validation status will be maintained through the lifetime of the system
Validation Plan (VP)

- Communication of the VPs to supplier companies will assist with project understanding.

- Method for reporting Validation Plan outputs.

- Responsibility for VPs rests with the system owner and project manager where applicable.
# Validation, Quality and Project Planning

<table>
<thead>
<tr>
<th>Validation plan</th>
<th>Quality plan</th>
<th>Project plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Created by the user to define the Validation activities, responsibilities and procedures</td>
<td>• Agreed to between the user and supplier, defining actions, deliverables, responsibilities and satisfying the user’s quality and Validation requirements</td>
<td>• Agreed to between the user and supplier</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Detail planning and execution deliverables,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Responsibilities, problem resolution,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• System delivery and user requirements.</td>
</tr>
</tbody>
</table>
Validation planning and reporting

The user should provide the supplier with a validation plan and a URS.

- The technical and regulatory requirements can be assessed by the supplier and later form the basis of a GMP/technical agreement.
Validation planning and reporting

Validation plans should include:

- GxP criticality assessment
- Validation strategy
- Validation deliverables, acceptance criteria
- Change management
- Standard operating procedures
- Training requirements and deliverables
- Documentation management
- How to maintain a validated state
User involvement in quality planning

Specific user responsibilities include the review and approval of the quality and project plan to ensure it meets quality, compliance and business requirements throughout the project.
Activity – Validation Master Plan

- Read and review the contents of the VMP template
- Highlight the key information
- Work in groups
- Contribute to discussion
User Requirements Specifications

- User Requirements Specifications (URS) are supposed to describe what the system is intended for, as written by the user.
- URS may be used as part of the process for vendor selection – tender document.
User Requirements Specifications

- URSs should include all **musts** that users require and include a list of **wants** that are also desirable.

- URS if not written by the users, should be reviewed and approved by the user’s representatives and a Quality Assurance representative.
User Requirements Specifications

The top-down approach

- Product and process understanding
- CQAs, regulatory requirements
- Quality by Design
User Requirements Specifications

URS Content should include the following requirements:

- Operational
- Functional
- Technical
- Interface (data)
- Performance
- Availability
- Security
- Maintenance
- Regulatory
- Constraints
- Life cycle
Quality critical requirements:

- Directly reference GxP regulatory requirements

Particular emphasis on the requirements that are critical to:

- Patient safety
- Product quality
- Data integrity
- Business needs
User Requirements Specifications

Some URS feature priorities on requirements:

**Mandatory**
- No negotiation
- Absolutely must have

**Beneficial**
- For useability
- Ideal system operation

**Nice to have**
- Can be negotiated
- Flexible in approach
User Requirements Specifications

URS introduction:

- Contractual status of the document
- Who produced the document, scope of the document
- Overview
User Requirements Specifications

URS entire system overview:

- System goals
- System limits, boundaries
- Key objectives and benefits
- GxP, regulatory requirements
User Requirements Specifications

Operational requirements:

- Functions
- Data
- Technical requirements
- Interfaces
- Environment
User Requirements Specifications

System constraints that may be detailed in the URS:

- Compatibility of systems
- Reliability
- Downtime allowable for maintenance and servicing
- User skill levels
- Expansion capability and anticipated lifetime
- Ongoing system support
User Requirements Specifications

Life Cycle requirements
- Any specific requirements that might impact on the supplier’s development lifecycle and verification activities

- Minimum standards of development and design
- Factory acceptance testing (FAT)
- Documentation deliverables of the supplier
- Training
- Support/maintenance
User Requirements Specifications

Out of scope topics:

- System configuration details
- Implementation details
- Timelines
- Cost
- Organisational details
User Requirements Specifications

What to watch out for:

- Misunderstanding of requirements between parties
- Not all business levels contributing to the requirements capture
- Ambiguous requirements
- Functionality that will not be used
- Shifting goalposts
Activity – URS

• Using the URS template, develop a User Requirement Specification for a tablet press machine.
• Work in groups
• Contribute to discussion
Summary

- Documented evidence of validation planning and reporting
- Validation Master Plan
- User Requirement Specification
Thank you for your time. Questions?

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