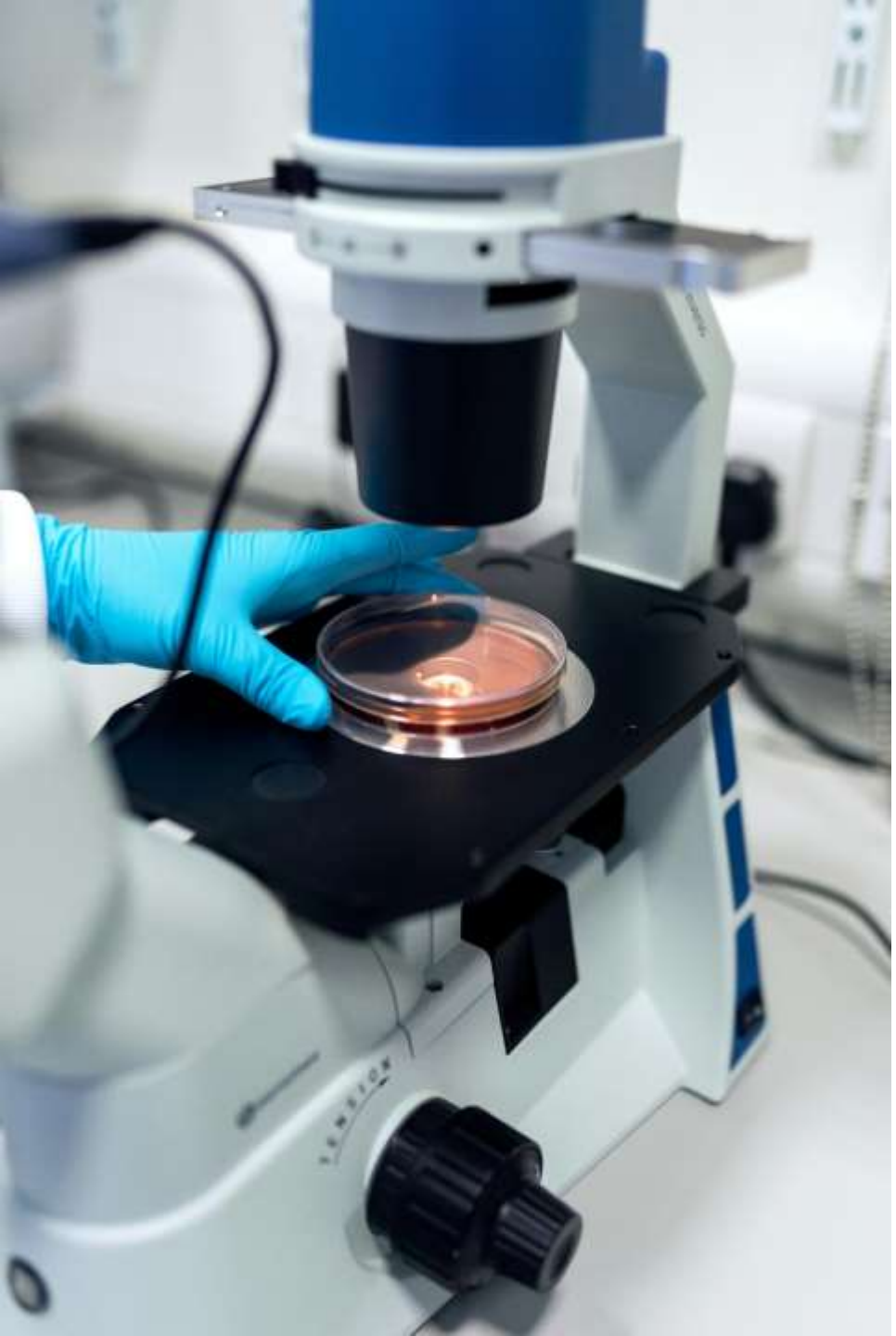

# Validation Master Plan

By: Pharmaguidehub

## *About Document:*

*This Document has been written by Pharmaguidehub based on the ISPE Validation Master Plan.*

***Content Ownership:*** *The actual content of the VMP belongs to the pharmaceutical company. This document provide the outline for philosophy of the company, risk-based approach for determining validation depth, Specify the types of qualification protocols, approach to validation of computer systems, Assign roles and responsibilities for conducting, reviewing, and approving validation activities. Include a schedule for completing the various validation tasks.*

***Final Authority:*** *The pharmaceutical company has ultimate ownership and responsibility for the accuracy of the information within the VMP.*

# *About us:*

- *In the continuously developing world of pharmaceuticals, ensuring compliance and quality can feel awesome. **Pharmaguidehub** steps in as your trusted partner, navigating the complex web of regulations. We specialize in creating customized pharmaceutical documents that meet the industry's strictest standards.*

- *Our team of **expert's** develop SOPs (Standard Operating Procedures), Qualification, risk assessment, compliance, dossier, cleaning validation and a comprehensive range of other documents tailored to your specific needs. We don't offer generic templates – we take the time to understand your processes and create documents that consistently integrate with your existing quality system.*

- ***Pharmaguidehub** goes beyond document creation. We help you implement these documents effectively, leading to a more robust and efficient quality system. By bridging the gap between regulations and practical application, we empower you to achieve and maintain the highest quality standards. Let **Pharmaguidehub** be your guide to pharmaceutical excellence.*

# Our Knowledge Sharing Platform:

*To get regular updates on Pharmaceutical industry you can join us at our following knowledge sharing platforms:*

- *Web address: www.pharmaguidehub.com*
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- *Twitter Link: https://x.com/pharmaguidehub*
- *WhatsApp Group Link: https://chat.whatsapp.com/HY09XT4iEL07oCE4Am3JUW*

# What is Validation Master Plan?

- *The VMP serves as the validation roadmap, setting the course, justifying the strategy, outlining the preliminary test and acceptance criteria, and documenting the necessary programs that ensure a continuing state of validation.*

# *Which Guideline follow for preparat of VMP?*

- *A Guide to the Validation Master Plan (VMP) from the International Society for Pharmaceutical Engineering (ISPE) [ISPE Validation Master Plan]*

*https://pharmaguidehub.com/validation-master-plan-ispe/*

- *Validation Master Plans (VMP) from Ofni Systems [Ofni VMP]*

# About VMP:

*This document define the goals of the VMP, which is typically to demonstrate compliance with Good Manufacturing Practice (GMP) regulations. Outline the breadth of the validation activities covered in VMP. It encompass equipment, facilities, processes, cleaning procedures, and analytical methods.*

# Validation Program tell us:

# Validation Master Plan (VMP)

- The VMP serves as the validation roadmap, setting the course, justifying the strategy, out lining the preliminary test and acceptance criteria, and documenting the necessary programs that ensure a continuing state of validation.

# Qualification

- The Qualification phase provides documentation that equipment and utility systems were installed properly through an Installation Qualification (IQ), operate correctly through an Operational Qualification (OQ), and perform effectively through a Performance Qualification (PQ).

# Process Validation

- Building on the data generated from the Qualification phase, the Process Validation (PV) phase focuses on the reproducibility of the systems used and the resulting product quality. This program challenges the ability of the systems used (methods, equipment, and operators) to meet the pre-approved design intent.

# Final Reports

- Final Reports (FR) compare the conclusions of data gathered to the acceptance criteria out lined in the Qualification and Validation phases. They determine the pass/fail status and address the resolution of any deviations. They also can be referred to as Summary Reports.

# Compliance Programs

- The Validation program must ensure policies and procedures comply with current Good Manufacturing Practices (cGMP). Systems such as calibration, preventative maintenance, change control, and revalidation contribute to a continuous state of validation.

# Content of VMP

| Typical VMP Contents |
| --- |
| 1. Introduction |
| 2. Scope |
| 3. Facility Description |
| 4. Commissioning |
| 5. Qualification |
| 6. Process Validation |
| 7. Computer System Validation |
| 8. List of Required Protocols and Procedures |
| 9. List of Required Standard Operating Procedures |
| 10. Equipment and Utility System Descriptions |
| 11. Computer System Description |
| 12. Other cGMP Programs |
| 13. References |

# Validation Requirements

**Process Equipment/Other Systems**

| EQUIPMENT | Comm. | IQ | OQ | PQ | PV |
|---|---|---|---|---|---|
| Reactor System Series 100 | ✓ | ✓ | ✓ | ✓ | ✓ |
| Centrifuge | ✓ | ✓ | ✓ | ✓ | ✓ |
| Catch Tank | ✓ | | | | |
| Solvent Storage and Distribution | ✓ | ✓ | ✓ | ✓ | ✓ |
| Glass Lined Mix Tank and TCU | ✓ | ✓ | ✓ | ✓ | ✓ |

**Utility Systems**

| UTILITY SYSTEM | Comm. | IQ | OQ | PQ | PV |
|---|---|---|---|---|---|
| Fire Water System | ✓ | | | | |
| Breathing Air System | ✓ | | | | |
| Cold Glycol System | ✓ | | | | |
| USP Water System | ✓ | ✓ | ✓ | ✓ | ✓ |
| HVAC | ✓ | ✓ | ✓ | ✓ | ✓ |

**Legend**

Comm.: Commissioning
IQ: Installation Qualification
OQ: Operational Qualification
PQ: Performance Qualification
PV: Process Validation
Not Applicable

# Introduction of VMP

- This section should include the company name, location, division or subsidiary name (if applicable) and business sector served. A short overview of the project provides the reader with the necessary background from a macro standpoint. A cross reference to the relevant company Quality Assurance Policy is appropriate here.

# Scope of VMP

- This section defines the breadth and reach of the validation effort covered by the VMP. A brief description of the installation, whether single- or multi-product, and a breakdown of installed equipment as new or existing should be included here.

# Facility Description

- Whether the project is a new building, extension, or remodeling of a current building, the facility characteristics are listed here. The number of floors, the inter-connectivity of process and utility systems, isolation means, and the design product and personnel flow used to minimize cross-contamination are identified. Be sure to note any room classification (cleanroom certification levels) and specialty surfaces and finishes integral to achieving the required product quality. Process Flow Diagrams (PFDs) are useful here, depicting the anticipated personnel, raw material, process, and waste material flow. The emphasis here is on design considerations to eliminate cross contamination of material.

# Commissioning

- Document here the selection criteria governing what equipment and utility systems will undergo Commissioning. As Commissioning is not part of the Validation Program and is not regulated by the FDA, people often wonder why they should include this section at all. The reason is the FDA is just as interested in the rationale behind why one system is not validated while another is. The VMP needs to answer that question, identifying support utilities that do not need to be validated because they do not directly affect product quality. It also demonstrates thoroughness, showing the FDA that all systems have been examined for product quality impact. To maximize the usefulness of commissioning, the system should be tested within the anticipated operating range of the respective OQ

# Qualification

- The selection criteria governing what equipment and utility systems will undergo Qualification is discussed here. Individual definitions of IQ, OQ, and PQ, may be included. Company policies, regulatory references, and published guidelines used in this selection process should be addressed. This discussion may include considerations such as product contacting surfaces, critical/non-critical instrumentation, direct and indirect systems, and downstream processing, among others. A discussion of protocol and final report formats may be included here, with either a reference to existing protocol development procedures, or a description of the format to be utilized. Final Reports may be generated as attachments to the protocols themselves, or as separate documents.

# Process Validation

- This section addresses the selection criteria governing what equipment and utility systems need to undergo Process Validation. Company policies, regulatory references, and published guidelines utilized in the selection process should be addressed. One such criteria is if the "results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated…." Also included is a discussion on the appropriate Cleaning Validations (CV) required to verify inter- and intra-campaign cleaning methods. If this is to be a finished product, Packaging and Sterility validation needs to be addressed.

# Computer System Validation

- A separate section should be devoted to the discussion of Computer Validation, whether that is in the form of a Programmable Logic Controller (PLC) or a Distributed Control System (DCS). Computer Validation criteria also should be discussed, and whether the installed control system is to be 21 CFR 11 compliant, i.e., secure audit trails, authority checks, etc.

# List of Required Protocols and Procedures

- Include here a tabular representation of the equipment and utility systems, and the required protocols and procedures associated with each – Validation requirement table. This is the essence of the VMP because it defines the validation requirements for the project, and can be used to determine resource loading. This table can subsequently be used as a "Deliverables List" if the validation effort is contracted outside of the organization.

# List of Required Standard Operating Procedures (SOPs)

- This should take the form of a tabular representation of the installed equipment and utility systems and the required SOP associated with each, similar to the List of Required Protocols and Procedures. This will help identify the level of SOP generation necessary to complete validation activities. These will generally take the form of Operation, Maintenance, and Cleaning SOPs.

# Equipment and Utility System Descriptions

- An overview of the particular system should be given, aligned with the Basis of Design documentation. A listing of proposed Qualification tests (IQ/OQ/PQ) should be identified with a brief description of the procedure and how the associated Acceptance Criteria will be determined. As the VMP should be developed early in the planning stage, many system specifics will be in the draft phase and subject to change. To avoid duplication of effort and unnecessary revisions, do not assign numeric-specific Acceptance Criteria in the VMP. Those details will be fully delineated in the respective Qualification and Validation protocols that will follow. Keep in mind the intent of the VMP as a scope and guidance document. System specific acceptance criteria fall under the auspices of the individual protocols.

# Additional cGMP Programs

- Document/Change Control
- Standard Operating Procedures
- Calibration
- Preventative Maintenance
- Revalidation
- Operator Training

# References

- All company policies and procedures, as well as any applicable local, state and federal regulations, and industry standards referenced should be listed.

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