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What's in a Site Master Validation Plan? (Free Template Included)

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The below discussion is adapted from Dr. Paul Pluta's Validation Master Plan series, on "Differences in Terminology, Content, and Applications." The next installment will be included in the April 2018 edition of Journal of Validation Technology.

A Validation Master plan (VMP) can vary in definition from person-to-person. Some view a VMP as a comprehensive site document, while others understand VMP to be the validation approach for a specific project. The VMP should consist of a program description at the site along with chapters or individual validation master plans for each area of validation (e.g., process, equipment, cleaning, computer). Furthermore, it is a "living" document that should be continually updated for regulatory inspections and audits.

A VMP site document is one of the most common types of GMP, comprising of all fundamental validation information about the site. For example, specific sections with describe the facility design, equipment program, HVAC program, cleaning program, manufacturing process program, and so on. All these sections are contained in a single major document or electronic file under the responsibility of the site Validation / Quality function.

A site VMP may be divided into individual chapters such as:

- VMP Introduction, Scope, and Objectives
- Responsibilities
- Site Facility Overview and Design
- General Validation / Qualification Approach
- Facility Heating, Ventilation, and Air Conditioning (HVAC)
- Utilities
- Equipment
- Computer Systems
- Products and Manufacturing Processes
- Cleaning
- Analytical Methods
- Appendix

  * Projects – Current and Completed

  * Facility Heating, Ventilation, and Air Conditioning (HVAC) Qualifications

  * Utilities Qualifications

  * Equipment Qualifications

  * Computer Systems Qualifications

  * Products and Manufacturing Process Validations

  * Cleaning Validations

* Analytical Methods Validation

The site VMP is a critical document and having it up-to-date can set the tone for your entire audit. Most manufacturing sites have a Validation Approval Committee (VAC), who consider themselves surrogate FDA auditors when reviewing validation documents including VMP.

Though there is much that goes into putting together a robust site VMP, you can download a free site validation master template, courtesy of one of our elite speaking faculty members.

REFERENCES

FDA. Guidance for Industry. Process Validation. General Principles and Practices. January 2011.
