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Validation Master Plan (VMP), Part 2: Site and Function Validation Master Plans

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ABSTRACT

This discussion addresses two of four VMP approaches experienced by the author in presentations and discussions at pharma meetings and in written submissions to the Journal. These include the following:

- VMP – Site document. This document comprises all fundamental information about the site and the site validation program. It includes specific individual sections about all functions at the site. It also includes a compilation of approved validations.
- VMP – Function document. This document comprises all fundamental information about a specific function at the site. A VMP function document is an individual section in the above-described VMP site document. Some organizations prefer to have specific stand-alone function VMPs controlled by each individual site function. It also includes a compilation of approved validations for each specific function.

The above two categories may be considered validation overview documents describing the general validation program at a site. Both the site VMP or the function VMP must be consistent with higher level policies / procedures for the site and corporation.

The Site VMP comprises the following key sections:

- Table of contents
- Site approvals and document effective date
- Validation overview. This includes fundamental validation information such as scope, objectives, approach, responsibilities, templates, and related information.
- Site facility overview. This includes the site facility design and related information.
- Site functions. This includes individual sections for HVAC, utilities, equipment, cleaning, and so on.
- Revision history
- Appendix. This includes a reference list of validations / qualifications and a list of current improvement projects.

The site Validation Approval Committee (VAC) has a vital responsibility to the manufacturing site and is critical to the success of the site validation program. The site VAC should consider the VMP as “their” document. The VAC should consider themselves to be a surrogate FDA or other auditor when they are reviewing VMP. Clarifying and unifying VMP terminology used at a site should be a joint responsibility of the VMP and the site validation function. The terminology, content, and applications of VMP should be consistent with industry and regulatory norms and expectations.

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Paul Pluta, Ph.D, has extensive pharmaceutical industry and university academic experience, and has been involved with the Journal of Validation Technology and Journal of GXP Compliance as a writer and editor-in-chief...
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