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Validation Master Plan (VMP), Part 1: Differences in Terminology, Content, and Applications

By 
Paul L. Pluta

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ABSTRACT

This discussion addresses basic considerations associated with the topic of the Validation Master Plan (VMP). While VMP is a well-known term, its use, structure, and content is not consistent across organizations and in the industry. Organizations may utilize VMP very differently in their respective sites. Further, alternate VMP terminology may be used in organizations.

This discussion identifies four different VMP types commonly used in pharma and related industries. These include site documents, function documents, major project documents, and single project documents. Different terminology, content, and applications in VMPs lead to confusion. Sites should consider developing a procedure that defines VMP and all other terms used at their site with consideration for industry and regulatory standards. Such a procedure will unify terminology used by personnel in the respective areas of the site and help to clarify communications.

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. Whatever structure and content, the site VAC should consider the VMP as their document. The VAC should consider themselves to be a surrogate FDA (or other regulatory agency) 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.