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Validation Master Plan (VMP), Part 3: Validation Project Master Plans

By Paul L. Pluta Oct 22, 2018 11:37 am PDT

ABSTRACT

This discussion continues a series of discussions on types of Validation Master Plans (1). The previous discussion addressed overview VMPs (2). The present discussion addresses project VMPs. The general topic of VMP terminology is a source of confusion in industry meetings and has been requested for further discussion by several validation and quality managers.

Project VMPs described in the present discussion include the following:

- VMP -- Major Project Document. This VMP document comprises all information about a specific major validation project at the site such as a new facility addition requiring multiple validation protocols. For example, a major project VMP would describe validations such as HVAC, Purified Water, equipment, manufacturing, cleaning, and other requirements for validation of the new facility and its future use.
- VMP -- Single Project Document. This VMP document comprises all information about a specific individual validation project at the site. This document is one of the sections in the above-described VMP major project document for an individual validation / qualification.

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 VAC approves all documents in the above-described VMPs. The VAC must consider the VMP as "their" document. Members of the VAC should consider themselves to be a surrogate FDA or other regulatory auditor when they are reviewing the above VMP documents.

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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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