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Master Validation Plan SOP and Approval Template

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The Validation Master Plan (VMP) is a universally known term and universally required document in regulated manufacturing industries. Essentially all pharmaceutical, medical device, and related healthcare manufacturing industries have some type of VMP in their facility. The VMP is often the first document requested in a regulatory audit.

Despite widespread awareness of VMP, there is great diversity regarding its structure, content, understanding, and application -- the VMP to certain individuals is not the same as the VMP to others. Validation managers comment about frustration with inconsistent terms used in VMP between industries, between companies, between various functional groups within the same organization. VMP is widely known in general, but specifics are not universally consistent.

The attached comprises three documents providing fundamental aspects of the VMP. These include an overview description of VMP and applications implemented by various organizations, an actual VMP form that would be approved by relevant groups in the organization, and an SOP providing directions to create the VMP.

Validation Master Plan (VMP), Part 1. Differences in Terminology, Content, and Applications provides basic considerations associated with the topic of the Validation Master Plan (VMP). 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. Additional VMP documents are planned for publication in the Journal of Validation Technology.

Master Validation Plan Approval Form provides an example structured VMP document that would be approved by all key functions in an organization. The VMP provides basic physical plant information, manufacturing process flow, validation approach, and other site information. The sections of the example VMP include Manufacturing, Engineering, R&D, QA, and other relevant organizations. Components of these sections are described.

Master Validation Plan SOP Form provides an example SOP for development of the VMP. This document describes each functional element of the VMP to be used by functional areas in the organization. Additional basic elements such as the signature list, roles and responsibilities, revision history, and other sections are described. The Master Validation SOP is a prerequisite for creation and development of the Master Validation Plan.

Tags:

Protocols & SOPs, GMP - Compliance & Regulations
