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# Three Tiers of Medical Device Process Validation Plans

By Yeong-Lin Chen Dec 20, 2018 7:57 am PST

**Abstract**

Based on the characteristics of medical device process validation plans, this article presents three tiers of medical device process validation plans structure (including Site Validation Master Plan (SVMP) - Tier I, Validation Master Plan (VMP) - Tier II, and Individual Validation Plan (VP) - Tier III), explains the rationale of the plan structure, and provides the key content for each validation plan.

**Introduction**

In the medical device industry, though not directly called out as requirement by the Food and Drug Administration's (FDA) Quality System Regulation (21 CFR 820) and ISO 13485 (Medical Devices - Quality Management Systems QMS), GHTF Study Group 3 - Quality Management Systems - Process Validation Guidance mentions that a good Validation Master Plan (VMP) identifies the processes to be validated, the schedule for validations, interrelationships between processes requiring validation and timing for revalidations, which are critical to executing a successful process validation program. A Validation Master Plan (or equivalent document) provides medical device manufacturers with a roadmap by outlining the process validation requirements and providing justification for these requirements. Therefore, medical device manufacturers should understand what makes a good Validation Master Plan. The VMP allows companies to agree upon and document an overall validation strategy, which can be provided to regulators and auditors to serve as clear justification for the validation effort. The VMP allows medical device manufacturers to show that they are in control of their quality system and produce devices with a focus on product quality.

However, the VMP content and structure can vary widely in the medical device industry, and organizations may utilize VMP very differently at their respective sites. Further, alternate VMP terminology may be used in each organization. For example, an individual validation plan is another tool that is widely used to support the planning for more complex projects or site. In addition, while compared to pharmaceutical industry, medical device companies could face different product customers (e.g. pharmaceutical companies as customers for combination products), and therefore more levels of validation plans could be needed. This article proposes a three-tier process for a validation plan structure (including Site Validation Master Plans (SVMP) as tier I, Validation Master Plans (VMP) as Tier II, and Individual Validation Plans (VP) as Tier III) that will provide a well-organized and structured validation program or approach to cope with the needs of the medical device industry. These needs include product diversity, process complexity, multi-customer situation, and validation plan documentation flexibility. Once the process validation plans are completed (or approved), their corresponding protocol preparation can be started in accordance with the process validation plans' requirements.



Tags:
Regulatory & Industry Guidance

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