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The master validation plan: A vision of things to come

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The master validation plan (MVP, and also called validation master plan) can be one of the more mysterious documents in the life sciences organization. It is not technically required by the FDA, but they routinely ask to see it. Certain European regulatory standards require it. So, what exactly is it? Why do you need one? How do you create a MVP? In this session we will answer these questions, and many more. Risk assessment is a critical component of MVP design & effectivity and will be discussed as well. Inspectional observations regarding the MVP will be reviewed and lessons learned will be presented. For this presentation, the definition of MVP is your overall comprehensive validation program, while the VP will address planning for specific projects.

The MVP is a critical document identifying and providing the complete overview of your validation program and intentions in your organization. With the need for highly strategic business planning and to reduce costs while providing highly compliant, high quality validations, a MVP is critical to communicate to senior management, manufacturing, and all stakeholders on the value of creating and maintaining a MVP.

This presentation will show you a practical approach to creating MVPs for your company. You will leave with the knowledge of how to write your draft MVP and how to use it to get your organization in alignment with your validation programs.

Biography

Steven Mattos is a quality systems consultant with over 20 years experience in Quality and Regulatory Compliance, including extensive experience in Process and Computer Systems Validation. He has worked with multiple start-ups, as well as major organizations such as Becton Dickinson, Abbott, Merck, Unilever, and Thermo Fisher. Currently he is a consultant with ALKU Quality, a consulting firm in Andover, MA. Steven holds a B.S in Biological Sciences and an M.S in Bioscience Regulatory Affairs from the Johns Hopkins University.

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