

Best Practice

Validation Master Plan

**for Equipment, Computer Systems, Networked Systems
and Spreadsheet Applications**



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1. Purpose and scope of this plan

Provides a framework and practices for validation and qualification of equipment, computer systems and networked systems for laboratories and manufacturing. It also is applicable to the validation of Macros and Spreadsheet applications. The Validation Master plan should ensure that validations and qualifications are done efficiently and consistently throughout the organization and meet regulatory, quality and business requirements. The plan should ensure that the company's validation procedures are followed. The company validation master plan is the basis of individual project validation plans, sometimes also called master validation plan.

2. Introduction

This is the most important part of a validation plan. It summarizes what the project is all about and what you are trying to accomplish with it and with validation. It summarizes

- The purpose of project
- Brief description of the system
- Validation approach
- The name and location of the facility where the equipment or system is located
- Timeline