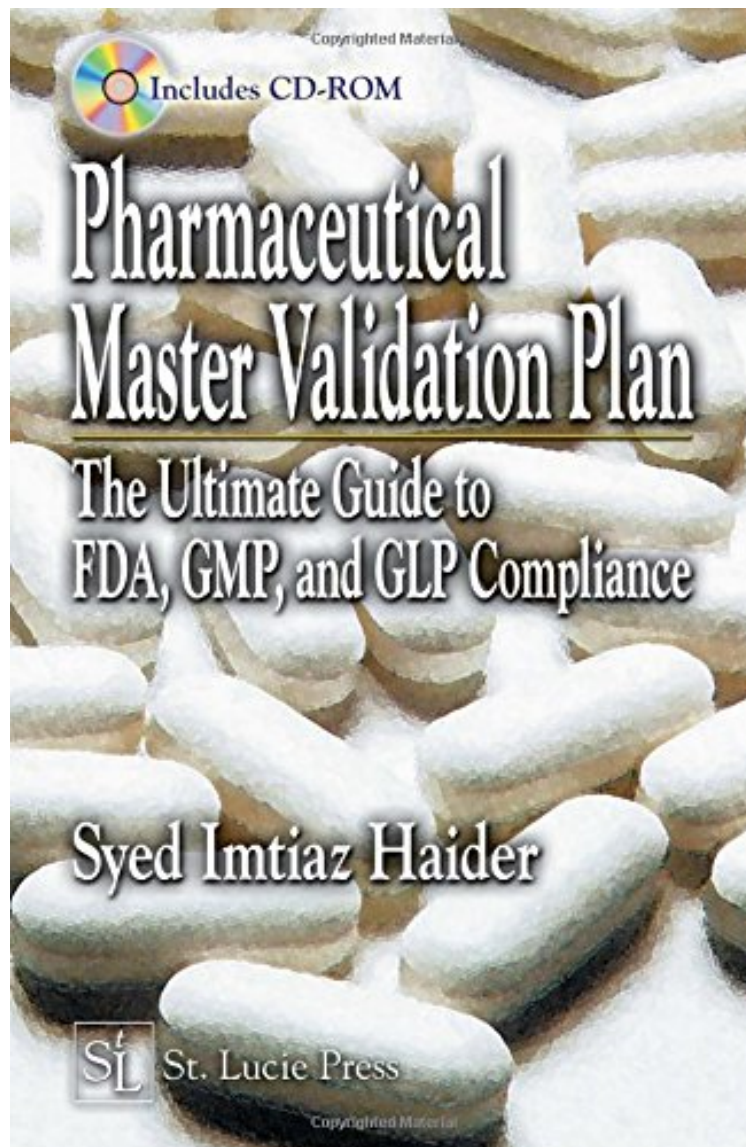


(Download ebook) Pharmaceutical Master Validation Plan: The Ultimate Guide to FDA, GMP, and GLP Compliance

## Pharmaceutical Master Validation Plan: The Ultimate Guide to FDA, GMP, and GLP Compliance

*Syed Imtiaz Haider*

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2 of 5 people found the following review helpful. Master Validation Plan By Bhadresh I have reviewed this excellent book. This book guides you through all process required for validation from FDA. In new edition, the author should give more details and technical guidance for control systems and software validation. Also to help in 21 CFR 11 approval. CD-ROM with the book is a help to cut down all the time wasted in formatting information and make templates for critical forms. Congratulations for writing this excellent book.

6 of 7 people found the following review helpful. BIG WASTE of MONIES and TIME By efila This book may be just as the Author intended, an outline of how to set things in motion. AND, that is all that this is. Don't fool around with this one... you'd be better off going to the FDA site for their guidelines. The CD is a jokingly filled example of templates that waste your time and you have to put more energy into them to configure for your uses. ALSO, there really is NO MASTER VALIDATION PLAN within this. It's a poor example of going about things. It may seem clear, but there is no flow to it whatsoever and it is confusing. I've been in this field of Validation and MVP and medical for years... this is a pure MESS. Soon, I might write a real book.

6 of 7 people found the following review helpful. No actual content By A Customer I'm sorry to report that this book merely presents an outline of steps to take, along with a collection of document templates, neither of which contain any actual "content". In other words, it tells you "what", but not "how". If you're looking for insight and real-world examples, look elsewhere. I couldn't justify a bunch of blank forms and outlines for such a cover-price. I sent mine back and graciously refunded my money.

The Master Validation Plan provides a roadmap to management for on-time start-up of facility operations, and validation of existing facilities, in compliance with GMP requirements. The lack of a comprehensive Master Validation Plan and well-documented validation procedures is the main reason that new drug, medical device, medical equipment, and related product applications are rejected by the FDA. In fact, only about 2% of the applications submitted by foreign pharmaceutical companies are approved each year. This thorough guide provides the needed solutions and guidance for both foreign and U.S. companies to achieve FDA compliance and authorization to market their products in the United States. Pharmaceutical Master Validation Plan: The Ultimate Guide to FDA, GMP, and GLP Compliance will allow you to more easily achieve satisfactory inspections, new medical product approval, minimize non-conformance, reduce rework and rejected lots, and avoid recall lots by developing and managing a Master Validation Plan. The accompanying CD allows users to input the template plan into their computers and tailor it to incorporate additional regulatory requirements specific to individual companies worldwide and print the required documents. Together, the book and CD contain everything required to develop and execute a successful Master Validation Plan based on FDA guidelines for the pharmaceutical industry, and allows the templates to be extended to diagnostic products, medical device, medical equipment, and biotech industry products.