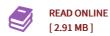




Cleaning Validation: Reference Edition

By Priscilla Browne

CreateSpace Independent Publishing Platform. Paperback. Condition: New. This item is printed on demand. 120 pages. Dimensions: 10.0in. x 8.0in. x 0.3in. This paperback book (Reference Edition) provides an introduction to Cleaning Verification and Validation for pharmaceutical and biological equipment and facilities. It provides a practical framework for the design and execution of cleaning validation. Cleaning Validation is a regulatory requirement as per GMP. There are many organisations and bodies which provide guidance of implementing a Cleaning Program such as PICs ICH, PDA reports, EU GMP V4 to name a few. The key elements to achieving a successful cleaning validation include (1) understanding the sources of residues (soils, excipients, actives, microbes etc) (2) developing a cleaning procedure (3) developing a test method (4) validating the cleaning procedure in respect of the products and equipment to be used in manufacturing. Summary of title index Introduction, What is Cleaning, Why Clean, Verification and Validation Definitions, Regulatory Requirements FDA, EU GMP. ICH Q7, Validation Standards Stages of Validation, Stage 1 Process Design Stage 2 Process Qualification, Stage 3 Continued Process Verification, Validation General Principles and Practices Cleaning Validation Prerequisites to Cleaning Validation Execution Validation Report Clean In Place (CIP) Visibly Clean Soils and their behaviour...



Reviews

This publication is definitely worth buying. It can be loaded with wisdom and knowledge I am easily could possibly get a satisfaction of looking at a composed publication.

-- Rhiannon Steuber

Very helpful to all type of individuals. It really is rally interesting throgh looking at time. Its been designed in an extremely basic way which is just soon after i finished reading this pdf through which basically modified me, change the way i believe.

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