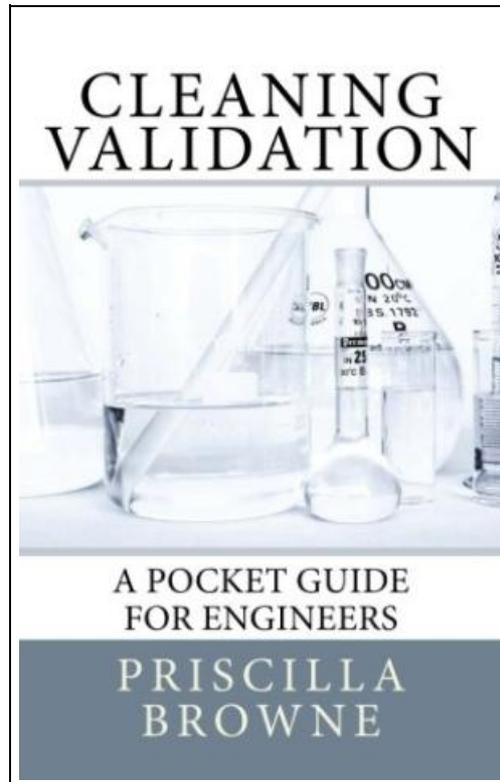# Cleaning Validation: A Pocket Guide for Engineers (Paperback)

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CLEANING VALIDATION: A POCKET GUIDE FOR ENGINEERS (PAPERBACK)

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Createspace Independent Publishing Platform, 2017. Paperback. Condition: New. Language: English . Brand New Book ***** Print on Demand *****.This paperback book 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 PIC/s 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 Detergents Validation Strategies Summary How are Acceptance levels defined? Historical Context of Limits Uses of the term limit PDA Technical Report No. 29 Calculation of MACO MACO for each piece of equipment Cleaning Validation Protocol PIC/S Guidance on Limits Test Methods ICH Q7 Validation of Analytical Methods Definitions Cleaning Process Design Equipment Considerations Cleaning Agent Approval Critical Cleaning Parameters Cleaning Pipes Dead Legs Connections and Tie-ins Valves Materials of Construction Pressure Testing Sampling Direct Sampling Rinse Sampling Sources of Contaminants Utilities Introduction Key Definitions Compressed Air Water Systems Clean Steam Useful References Appendix Precision Cleaning (Medical Devices).

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