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Nota di contenuto	Front cover; Contents; List of Figures; List of Tables; About the Book; Preface; Acknowledgments; Authors; Introduction; Disclaimer; CLV-1: How to Establish a Cleaning Validation Program; Body; CLV-2: Introduction; CLV-3: Scope and Approach; CLV-4: Cleaning Validation Team Membersand Responsibilities; CLV-5: Cleaning Validation Philosophy, Strategies,and Methodology; CLV-6: Planning Phase; CLV-7: Execution Phase; CLV-8: Analytical Testing and Reporting Phase; CLV-9: Equipment Description; CLV-10: Facility Description; CLV-11: Utilities Description: DIW, WFI, Steam,and Compressed Air CLV-12: Utilities Monitoring and Microbiological ControlCLV-13: Equipment Cleaning Materials/DetergentDescription; CLV-14: Microbiological Cleaning of Equipment Surface; CLV-15: Solubility of Active Materials in Water; CLV-16: Toxicity of Active Materials; CLV-17: Cleaning Validation Products Grouping Matrix (Tablets, Capsules, and PPS); CLV-18: Product/Equipment Train Matrix (Tab-Cap-PPS); CLV-19: Worst-Case Products (Tablets, Capsules,and PPS) Matrix; CLV-20: Validation with Corresponding Cleaning Procedures; CLV-20.1: Cleaning Validation Protocol for Fluid Bed Dryer CLV-20.2: Cleaning Validation Protocol for MixerCLV-20.3: Cleaning Validation Protocol for Granulation Machines (Type A); CLV-20.4:

Cleaning Validation Protocol for Powder Bins; CLV-20.5: Cleaning Validation Protocol for Tablet Press; CLV-20.6: Cleaning Validation Protocol for Sieve; CLV-20.7: Cleaning Validation Protocol for Powder-Filling Machine; CLV-20.8: Cleaning Validation Protocol for Encapsulation Machine; CLV-20.9: Cleaning Validation Protocol for Film-Coating Pan; CLV-20.10: Cleaning Validation Protocol for Sugar-Coating Pan
CLV-21: Cleaning Validation Product Grouping Matrix (Syrup)CLV-22: Cleaning Validation Product/Equipment Train (Syrup); CLV-23: Worst-Case Products (Syrup; CLV-24: Cleaning Validation Product Grouping Matrix (Suspension); CLV-25: Product Grouping/Equipment Train Matrix (Suspension); CLV-26: Worst-Case Products (Suspension); CLV-27: Product Grouping Matrix (Drops); CLV-28: Product/Equipment Train (Drops); CLV-29: Worst-Case Products (Drops); CLV-30: Cleaning Validation Product Grouping Matrix (Cream/Ointment); CLV-31: Product/Equipment Train (Cream and Ointment)
CLV-32: Worst-Case Products (Ointment and Cream)CLV-33: Product Grouping Matrix (Suppositories); CLV-34: Cleaning Validation Product/Equipment Train (Suppositories); CLV-35: Worst-Case Products (Suppositories); CLV-36: Cleaning Validation Protocols Products (Suppositories); CLV-36.1 Protocol for Manufacturing Vessel; CLV-36.2 Protocol for Bin-Washing Station; CLV-36.3 Cleaning Validation Protocol for Syrup-Holding Tank; CLV-36.4: Protocol for Filling Station and Filter Assembly; CLV-37: Cleaning Validation Product Grouping Matrix (Sterile)
CLV-38 Cleaning Validation Product/Equipment Train Matrix (Sterile)

Sommario/riassunto

With over 20 easy-to-use template protocols for cleaning validation of extensively used equipments, this book provides technical solutions to assist in fulfilling the training needs of finished pharmaceutical manufacturers. Drawing on the authors more than two decades of experience, the text offers hands-on training based on current approaches and techniques. The manual is organized as a database to train those involved in the development, manufacturing, auditing, and validation of bio-pharmaceuticals on a pilot scale, leading to scaled-up production. It also provides exclusive training guidelines in a CD-ROM to enable the users to amend or adopt them as necessary--Provided by publisher.