

Cleaning and Cleaning Validation (Volume 1)

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"Cleaning and Cleaning Validation" is a series of volumes containing current knowledge and approaches to cleaning and cleaning validation of pharmaceutical, medical devices, and associated products. Information provided will be consistent with current regulatory documents and expectations. Volumes will provide increasingly specific and detailed information, beginning with validation basics and culminating with a discussion of various topics in the lifecycle approach to cleaning process validation. Practical information and case studies presented throughout the volumes will supplement the basic information with useful experiences. Volume one in this series, "Basics, Expectations, and Principles," provides general information applicable to the entirety of cleaning and cleaning validation. This includes process validation basics and expectations, including cleaning validation basics, regulatory guidelines and industry standards. Volume one also includes discussions of basic chemistry and engineering technical principles relevant to cleaning and cleaning validation. Technical principles applicable to residue to be cleaned are also discussed. Specific topics include residue chemistry, microbial considerations, residue pharmacology and toxicology, residue grouping strategies for pharmaceutical and biotechnology products, and visual cleanliness including personnel training. Discussion of specific residues is initiated including biotech residues and manual cleaning. This volume provides the baseline general understanding of topics in advance of the more specific technical information discussed in subsequent volumes.



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