Cleaning validation, a process to provide evidence that all residues in a manufactory (equipment, facility) are at a predetermined level, play an important role in the pharmaceutical industry. It is not just a regulatory requirement, but a customer requirement as well, and assures the quality of the product. The importance of cleaning validation is reflected by the fact that two volumes on this topic have already been published, and the PDA Technical Report # 49 “Points to Consider for Biotechnology Cleaning Validation” has recently been published as well.

The editor of the book, Paul L. Pluta, a pharmaceutical scientist with immense experience in industrial development, manufacturing and management, compiled material from 21 authors, which resulted in the present book with four sections containing two to eight chapters each.

Volume 1 of this series provides a general introduction to cleaning validation of pharmaceutical and medical devices and associated products. Section 1, Cleaning Validation Basics and Expectations, deals with the basic understanding of cleaning validation. Subjects addressed include policies, regulatory aspects, and quality by design. Chapter 3 is of special interest, describing seven case studies where cleaning problems in the laboratory impacted laboratory results. Chapter 5 is noteworthy, because it describes publicly known failures from the industry including the agencies point of view.

Section two, Cleaning Chemistry and Engineering, and Section three, Residues, describe General Technical Principles. Besides the chemistry of the cleaning reagents and their mechanism, various parameters that affect the cleaning performance are outlined in the two chapters of Section two. In Section three the authors introduce the different aspects of residues, such as microbial and endotoxin residues, residue grouping, visual inspection, to name a few.
The last section, Section four, *Specific Residues for Cleaning – Part 1*, covers the cleaning validation from a more practical point of view in three chapters. Several case studies are described in chapter 17 of this section, whereas the following chapter very interestingly describes in more detail a case study of the implementation of a temperature increase across a purification column. ‘Part 1’ in the title of Section four suggests that a ‘Part 2’ should follow, which is not the case (there is also no ‘Part 2’ in Volume 2 of this series).

The book covers a broad range of interesting aspects of Cleaning Validation in the pharmaceutical industry. It is not only valuable to readers with theoretical interest; the case studies described in several chapters also make it very interesting to hands-on personnel. Each chapter is supplemented with tables and figures, which are of much better quality than those in previous PDA publications. However, in many cases, legends of the figures are often unsatisfactory, and abbreviations are often used without any further explanation. The short summaries at the start of each section form a nice introduction to the different themes. This book is a valuable source for detailed and comprehensive information about many issues regarding Cleaning Process in the pharmaceutical industry and can be recommended.

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