



Handbook of Microbiological Quality Control in Pharmaceuticals and Medical Devices (Pharmaceutical Science Series)

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Microbiologists working in both the pharmaceutical and medical device industries, face considerable challenges in keeping abreast of the myriad microbiological references available to them, and the continuously evolving regulatory requirements. The Handbook of Microbiological Quality Control provides a unique distillation of such material, by providing a wealth of microbiological information not only on the practical issues facing the company microbiologist today, but also the underlying principles of microbiological quality assurance. All the chapters have been written by leading experts in this field. The Handbook of Microbiological Quality Control provides guidance on safe microbiological practices, including laboratory design and sampling techniques. The design storage, use and quality control of microbiological culture is considered in depth. Principles of enumeration and identification of micro-organisms, using both traditional and rapid methods as well as the pharmacopoeial methods for the detection of specified organisms, are elaborated in detail. Guidance is given on laboratory methods supporting the sterility assurance system: sterility testing, bioburden testing, the use of biological indicators and environmental monitoring methods, as well as methods for detecting and quantifying endotoxins. Pharmacopoeial methods for microbiological assay and preservative efficacy testing are reviewed. Problems for those involved in disinfection and cleansing techniques and microbiological audit are discussed from a practical viewpoint. Finally, a number of pertinent case studies and worked examples illustrate problems highlighted in the text. The Handbook of Microbiological Quality Control is the essential reference source for the professional microbiologist.

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