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against the criteria can be used to
verify that the overall process is in
control. As the HACCP based
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Microbiological matters continue to exercise considerable influence on product quality. In both the pharmaceutical and medical device industries, products of greater sophistication, along with evolving regulatory requirements, are elevating the challenges related to maintaining microbiological integrity. Updated to reflect technological and regulatory changes, the Guide to Microbiological Control in Pharmaceuticals and Medical Devices, Second Edition covers those principal aspects of microbiology that are relevant to the

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preformulation, formulation, manufacturing, and license application stages involved with the production of pharmaceuticals and medical devices. In recognition of the diverse disciplines involved in pharmaceutical and medical device production, this work provides a brief introduction to microbiology geared towards the nonmicrobiologist.

Covering good manufacturing practice in the control of contamination, the text explores quality control, the preservation of formulations, and principles of sterilization, including microbiological-specific considerations for biotechnological products and other medical devices. It also provides additional materials on package integrity and contamination risks in clean rooms. The editors have produced a companion text, the

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Handbook of Microbiological Quality Control in Pharmaceuticals and Medical Devices (see reverse), which when paired with the Guide offers a complete theoretical and practical treatment of microbiological control. This book provides a comprehensive distillation of information concerning methodology and regulations that would otherwise remain scattered throughout the literature. It allows scientists from many fields to address potential problems in advance and implement suitable strategies at the earliest stages of development.

A handbook to the micro-organism as a contaminant and as a potential growth medium, focusing on the problems of microbiological control in pharmaceutical product design and manufacture. Topics include the

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relative susceptibilities of product types and ingredients and factory hygiene.

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Relying on practical examples from the authors' experience, this book provides a thorough and modern approach to controlling and monitoring microbial contaminations during the manufacturing of non-sterile pharmaceuticals. Offers a comprehensive guidance for non-sterile pharmaceuticals microbiological QA/QC Presents the latest developments in both regulatory expectations and technical advancements Provides guidance on statistical tools for risk assessment and trending of microbiological data Describes strategy and practical examples from the authors' experience in globalized pharmaceutical companies and expert networks Offers a comprehensive guidance for non-sterile pharmaceuticals microbiological

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QA/QC Presents the latest developments in both regulatory expectations and technical advancements Provides guidance on statistical tools for risk assessment and trending of microbiological data Describes strategy and practical examples from the authors ' experience in globalized pharmaceutical companies and expert networks

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

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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

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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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A comprehensive review of the practical issues facing the industrial microbiologist of today including the appreciation of the developing role of rapid methods and the accompanying regulatory requirements.

Making Safe Food is a practical text which focuses on the design and implementation of microbiological practices in the food industry. The book provides food scientists, managers, and technologists, and food studies students with much needed facts in a single, concise, but thorough, source. Making Safe Food embraces the concerns of all those involved in the production, distribution, and sale of food; it is the first book to bridge the gulf between microbiological books that detail laboratory methodologies and quality

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management books written for those with a management and business studies background. The authors are senior lecturers in the food science and technology and microbiology departments at The University of Reading, one of the leading food science research and teaching centers in Europe. [Very short version:--11/6/91 WR] Making Safe Food is a concise, practical text which focuses on the design and implementation of microbiological practices in the food industry. It is the first book to bridge the gulf between microbiological books that detail laboratory methodologies and quality management books written for those with a management and business studies background. Implementing hygiene and microbiological quality in the food factory Designing and

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operating a safe laboratory and critically evaluating microbiological techniques for quality assurance. Installing a quality management system. Seeking certification under ISO 9000 (BS 5750). Legislative aspects. Managers, scientists, and technologists in the food industry; administrators of environmental health, public health, and food quality in local and central government, and students following food studies courses at diploma and degree level will find this book an invaluable guide.

Preservation involves a complex of activities including climate, air-quality, and surface control, as well as microbiological control, which is a key part of preserving and protecting library collections. The Preservation and Protection of Library Collections

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examines microbiological control for preservation of library and archival collections. A supporting tool for conservators, this title should be integrated into conservation and preservation policy. The book comprises nine sections that cover three aspects: microbiology, surveying, and the response required. Chapters in this title cover the nature of the library collections, physical and chemicals factors and their impact on microbiological issues, as well as biological factors and methods of microbiological control of the air and objects. Later chapters examine methods of object disinfection, disaster response, methods of microbiological control and evaluation of collections, and includes a vocabulary guide, appendices, literature information and references.

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Gives an overview of basic biological and environmental facts and their implications for library collections
Informed by practical experience in the library situation Provides guidelines, requirements, procedures, workflow charts, regulations, and case studies

This authoritative reference presents an up-to-date review of the testing methods, emerging technologies, and analytical systems and procedures used to prevent the microbial contamination of pharmaceutical processes, products, and environments. It identifies new tools for sample analysis and evaluation and the impact of these advancements on the continuous supply and manufacturing of pharmaceutical products. With more than 100 tables

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and 430 current references, the book contains a detailed analysis of microbial contamination recalls for nonsterile and sterile pharmaceutical products, demonstrating the distribution of microorganisms worldwide and the identification by geographical regions.

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