# Microbial Quality Assurance In Pharmaceuticals Cosmetics And Toiletries Author R M Baird Published On September 2000





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Microbial Contamination Control in the Pharmaceutical Industry CRC Press
The Microbiological Quality of Food: Foodborne Spoilers specifically addresses the role of spoilers in food technology and how they affect the quality of food. Food spoilers represent a great challenge in food quality, determining the shelf-life of many products as they impact consumer acceptability of taste, texture, aroma, and other perceptions. Divided into four sections, the first section defines microbial spoilage of food, with special emphasis on methods for the evaluation of spoiling phenomena and the status of their regulatory framework, examining both existing regulations and possible gaps. The second section examines spoiling microorganisms, covering a range of common spoilage microorganisms, including pseudomonas, yeasts, and molds and spore formers, as well as less-common spoilers, including lactic acid bacteria and specific spoilage organisms in fish. The third section highlights spoiling phenomena within certain food types. Chapters cover dairy, fish, meat, and vegetables, and other products. The final section investigates emerging topics which point to future trends in the research of food spoilers. There is insight into microorganisms resistant to preservation, the role of biofilms in food quality, and the link between food safety and food spoilage, with a special emphasis on certain spoiling microorganisms which could be opportunistic pathogens. Written by an international team of leading authors, this book provides state-of-the-art coverage of this topic, which is essential to the shelf-life and quality of food. Provides in-depth coverage of the different spoilers which cause the deterioration of foods, including less common spoilers not covered in other publications Includes dedicated chapters covering the spoilage of specific products, making this book ideal for those working in the food industry Presents a framework for future research in the area of foodborne spoilers
*Theory and application of Microbiological Assay* Elsevier
In recent years there has been increased interest in the possibility of rapid microbiological methods offering enhanced potential error detection capabilities. However, these methods raise a number of questions, such as how to validate new methods, will they be accepted by the pharmacopoeias, and, most importantly, how will the regulators respond?
**Microbial Quality Assurance in Pharmaceuticals, Cosmetics, and Toiletries** Taylor & Francis Group
Pharmaceutical Microbiology: Essentials for Quality Assurance and Quality Control presents that latest information on protecting pharmaceutical and healthcare products from spoilage by microorganisms, and protecting patients and consumers. With both sterile and non-sterile products, the effects can range from discoloration to the potential for fatality. The book provides an overview of the function of the pharmaceutical microbiologist and what they need to know, from regulatory filing and GMP, to laboratory design and management, and compendia tests and risk assessment tools and techniques. These key aspects are discussed through a series of dedicated chapters, with topics covering auditing, validation, data analysis, bioburden, toxins, microbial identification, culture media, and contamination control. Contains the applications of pharmaceutical microbiology in sterile and non-sterile products Presents the practical aspects of pharmaceutical microbiology testing Provides contamination control risks and remediation strategies, along with rapid microbiological methods Includes bioburden, endotoxin, and specific microbial risks Highlights relevant case studies and risk assessment scenarios
**Quality Control in the Pharmaceutical Industry** CRC Press
The use of drugs in food animal production has resulted in benefits throughout the food industry; however, their use has also raised public health safety concerns. The Use of Drugs in Food Animals provides an overview of why and how drugs are used in the major food-producing animal industries--poultry, dairy, beef, swine, and aquaculture. The volume discusses the prevalence of human pathogens in foods of animal origin. It also addresses the transfer of resistance in animal microbes to human pathogens and the resulting risk of human disease. The committee offers analysis and insight into these areas Monitoring of drug residues. The book provides a brief overview of how the FDA and USDA monitor drug residues in foods of animal origin and describes quality assurance programs initiated by the poultry, dairy, beef, and swine industries. Antibiotic resistance. The committee reports what is known about this controversial problem and its potential effect on human health. The volume also looks at how drug use may be minimized with new approaches in genetics, nutrition, and animal management. November
Benefits and Risks CRC Press
This authoritative two-volume reference provides valuable, necessary information on the principles underlying the production of microbiologically safe and stable foods. The work begins with an overview and then addresses four major areas: 'Principles and application of food preservation techniques' covers the specific techniques that defeat growth of harmful microorganisms, how those techniques work, how they are used, and how their effectiveness is measured. 'Microbial ecology of different types of food' provides a food-by-food accounting of food composition, naturally occurring microflora, effects of processing, how spoiling can occur, and preservation. 'Foodborne pathogens' profiles the most important and the most dangerous microorganisms that can be found in foods, including bacteria, viruses, parasites, mycotoxins, and 'mad cow disease.' The section also looks at the economic aspects and long-term consequences of foodborne disease. 'Assurance of the microbiological safety and quality of foods' scrutinizes all aspects of quality assurance, including HACCP, hygienic factory design, methods of detecting organisms, risk assessment, legislation, and the design and accreditation of food microbiology laboratories. Tables, photographs, illustrations, chapter-by-chapter references, and a thorough index complete each volume. This reference is of value to all academic, research, industrial and laboratory libraries supporting food programs; and all institutions involved in food safety, microbiology and food microbiology, quality assurance and assessment, food legislation, and generally food science and technology.
**Biocontamination Control for Pharmaceuticals and Healthcare** Pharmaceutical Microbiological Quality Assurance and ControlPractical Guide for Non-Sterile Manufacturing
In recent years, the field of pharmaceutical microbiology has experienced numerous technological advances, accompanied by the publication of new and harmonized compendial methods. It is therefore imperative for those who are responsible for monitoring the microbial quality of pharmaceutical/biopharmaceutical products to keep abreast of the latest changes. Microbial Limit and Bioburden Tests: Validation Approaches and Global Requirements guides readers through the various microbiological methods listed in the compendia with easy-to-follow diagrams and approaches to validations of such test methodologies. Includes New and Updated Material Now in its second edition, this work is the culmination of research and discussions with technical experts, as well as USP and FDA representatives on various topics of interest to the pharmaceutical microbiologist and those responsible for the microbial quality of products, materials, equipment, and manufacturing facilities. New in this edition is an entire chapter dedicated to the topic of biofilms and their impact on pharmaceutical and biopharmaceutical operations. The subject of rapid methods in microbiology has been expanded and includes a discussion on the validation of alternative microbiological methods and a case study on microbial identification in support of a product contamination investigation.

Substantially updated and revised, this book assists readers in understanding the fundamental issues associated with pharmaceutical microbiology and provides them with tools to create effective microbial contamination control and microbial testing programs for the areas under their responsibility.
**Pharmaceutical Microbiology Manual** Elsevier
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.
*Pharmaceutical Quality by Design* Academic Press
This book contains essential knowledge on the preparation, control, logistics, dispensing and use of medicines. It features chapters written by experienced pharmacists working in hospitals and academia throughout Europe, complete with practical examples as well as information on current EU-legislation. From prescription to production, from usage instructions to procurement and the impact of medicines on the environment, the book provides step-by-step coverage that will help a wide range of readers. It offers product knowledge for all pharmacists working directly with patients and it will enable them to make the appropriate medicine available, to store medicines properly, to adapt medicines if necessary and to dispense medicines with the appropriate information to inform patients and caregivers about product care and how to maintain their quality. This basic knowledge will also be of help to industrial pharmacists to remind and focus them on the application of the medicines manufactured. The basic and practical knowledge on the design, preparation and quality management of medicines can directly be applied by the pharmacists whose main duty is production in community and hospital pharmacies and industries. Undergraduate as well as graduate pharmacy students will find knowledge and backgrounds in a fully coherent way and fully supported with examples.
**Quality Assurance in Bacteriology and Immunology** Academic Press
Biocontamination Control for Pharmaceuticals and Healthcare outlines a biocontamination strategy that tracks bio-burden control and reduction at each transition in classified areas of a facility. This key part of controlling risk escalation can lead to the contamination of medicinal products, hence necessary tracking precautions are essential. Regulatory authorities have challenged pharmaceutical companies, healthcare providers, and those in manufacturing practice to adopt a holistic approach to contamination control. New technologies are needed to introduce barriers between personnel and the environment, and to provide a rapid and more accurate assessment of risk. This book offers guidance on building a complete biocontamination strategy. Provides the information necessary for a facility to build a complete biocontamination strategy Helps facilities understand the main biocontamination risks to medicinal products Assists the reader in navigating regulatory requirements Provides insight into developing an environmental monitoring program Covers the types of rapid microbiological monitoring methods now available, as well as current legislation
Practical Guide for Non-Sterile Manufacturing Springer
Standards for unlicensed aseptic preparation in the UK, as well as practical information for implementing the standards.
Pharmaceutical Quality Control Microbiology Ellis Horwood Limited
With the help of leading Quality Assurance (QA) and Quality Control (QC) microbiology specialists in Europe, a complete set of guidelines on how to start and implement a quality system in a microbiological laboratory has been prepared, supported by the European Commission through the Measurement and Testing Programme. The working group included food and water microbiologists from various testing laboratories, universities and industry, as well as statisticians and QA and QC specialists in chemistry. This book contains the outcome of their work. It has been written with the express objective of using simple but accurate wording so as to be accessible to all microbiology laboratory staff. To facilitate reading, the more specialized items, in particular some statistical treatments, have been added as an annex to the book. All QA and QC tools mentioned within these guidelines have been developed and applied by the authors in their own laboratories. All aspects dealing with reference materials and interlaboratory studies have been taken in a large part from the projects conducted within the BCR and Measurement and Testing Programmes of the European Commission. With so many different quality control procedures, their introduction in a laboratory would appear to be a formidable task. The authors recognize that each laboratory manager will choose the most appropriate procedures, depending on the type and size of the laboratory in question. Accreditation bodies will not expect the introduction of all measures, only those that are appropriate for a particular laboratory. Features of this book: • Gives all quality assurance and control measures to be taken, from sampling to expression of results • Provides practical aspects of quality control to be applied both for the analyst and top management • Describes the use of reference materials for statistical control of methods and use of certified reference materials (including statistical tools).
**Microbial Quality Assurance of Pharmaceutical Manufacturing Water** World Health Organization
The importance of quality assurance in the production, storage and use of manufactured preparations is widely recognized. This book encapsulates the issues involved in the manufacture of non-steriles, such as creams, ointments, herbal remedies, shampoos, soaps and toiletry products (as opposed to sterile drugs and injectible products). Knowledge of the microbial limits is expanded, new standards are included, and coverage of the preservation issues of dosage forms is widened to include semi-solids and liquid preparations. This edition also contains new regulations regarding preservative efficacy testing and covers pharmacopoeial and industry regulations and guidelines. Rapid methods are also discussed, now more common in cosmetic and toiletry practice, in their pharmaceutical capacity.
An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients Elsevier
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 relative susceptibilities of product types and ingredients and factory hygiene.
*Rapid Microbiological Methods in the Pharmaceutical Industry* John Wiley & Sons
Pharmaceutical Microbiology: Essentials for Quality Assurance and Quality Control presents that latest information on protecting pharmaceutical and healthcare products from spoilage by microorganisms, and protecting patients and consumers. With both sterile and non-sterile products, the effects can range from discoloration to the potential for fatality. The book provides an overview of the function of the pharmaceutical microbiologist and what they need to know, from regulatory filing and GMP, to laboratory design and management, and compendia tests and risk assessment tools and techniques. These key aspects are discussed through a series of dedicated chapters, with topics covering auditing, validation, data analysis, bioburden, toxins, microbial identification, culture media, and contamination control. Contains the applications of pharmaceutical microbiology in sterile and non-sterile products Presents the practical aspects of pharmaceutical microbiology testing Provides contamination control risks and remediation strategies, along with rapid microbiological methods Includes bioburden, endotoxin, and specific microbial risks Highlights relevant case studies and risk assessment scenarios
**Microbiological Safety and Quality of Food** CRC Press
Completely revised and updated Pharmaceutical Microbiologycontinues to provide the essential resource for the 21st centurypharmaceutical microbiologist "....a valuable resource for junior pharmacists graspingan appreciation of microbiology, microbiologists entering thepharmaceutical field, and undergraduate pharmacy students." Journal of Antimicrobial Chemotherapy ".....highly readable. The content is comprehensive, withwell-produced tables, diagrams and photographs, and is accessiblethrough the extensive index." Journal of Medical Microbiology WHY BUY THIS BOOK? Completely revised and updated to reflect the rapid pace ofchange in the teaching and practice of pharmaceuticalmicrobiology Expanded coverage of modern biotechnology, including genomicsand recombinant DNA technology Updated information on newer antimicrobial agents and theirmode of action Highly illustrated with structural formulas of organiccompounds and flow diagrams of biochemical processes
**The Microbiological Quality of Food** Woodhead Publishing Limited
Papers of a conference held at the University of London, April 1987. Contributors address control of microbial contamination and formulation and preservation of products to ensure microbial quality during storage and use. They also review guidelines, official and unofficial, for microbial quality. Annotation copyrighted by Book News, Inc., Portland, OR
*Practical Guide for Non-Sterile Manufacturing* CRC Press
There is an increasing dependence on clinical and public health laboratories for better patient management and also for preventing the spread of emerging pathogens. With rapid and significant growth of laboratories at all levels of health care, it has become mandatory to check results to make them reliable and cost-effective, as well as comparable with those obtained by international laboratories. The International Standards Organization (ISO) has provided several guidelines and standards for achieving quality in laboratory results. These guidelines dwell upon the basic concepts of quality assurance in microbiology and also describe essential practices and steps of ensuring quality in various activities that a microbiology laboratory is expected to undertake in its support to primary health care system in a biosafe environment and in accordance with ISO. Following these guidelines will help in delivery of reliable, cost-effective and timely laboratory results and support clinical and public health actions.
Guide to Microbiological Control in Pharmaceuticals and Medical Devices, Second Edition CRC Press
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 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.
**Pharmaceutical Microbiology** Createspace Independent Publishing Platform
Microbiological Quality Assurance: A Guide Towards Relevance and Reproducibility of Inocula sheds light on the difficulties of obtaining results in the test tube that will be reproducible and relevant for a wide variety of tests. This book explores the current state of research in this area and troubleshoots the problems that may be encountered in setting up appropriate cultures. The text divides naturally into three sections-growth conditions, post-growth conditions, and applications. This book serves as a valuable resource for clinical microbiologists, pharmacologists, and anyone doing in vitro experiments.
**Validation Approaches and Global Requirements,Second Edition** Parenteral Drug Association
Manual and is a supplement to the United States Pharmacopeia (USP) for pharmaceutical microbiology testing, including antimicrobial effectiveness testing, microbial examination of non-sterile products, sterility testing, bacterial endotoxin testing, particulate matter, device bioburden and environmental monitoring testing. The goal of this manual is to provide an ORA/CDER harmonized framework on the knowledge, methods and tools needed, and to apply the appropriate scientific standards required to assess the safety and efficacy of medical products within FDA testing laboratories. The PMM has expanded to include some rapid screening techniques along with a new section that covers inspectional guidance for microbiologists that conduct team inspections. This manual was developed by members of the Pharmaceutical Microbiology Workgroup and includes individuals with specialized experience and training. The instructions in this document are guidelines for FDA analysts. When available, analysts should use procedures and worksheets that are standardized and harmonized across all ORA field labs, along with the PMM, when performing analyses related to product testing of pharmaceuticals and medical devices. When changes or deviations are necessary, documentation should be completed per the laboratory's Quality Management System. Generally, these changes should originate from situations such as new products, unusual products, or unique situations. This manual was written to reduce compendia method ambiguity and increase standardization between FDA field laboratories. By providing clearer instructions to FDA ORA labs, greater transparency can be provided to both industry and the public. However, it should be emphasized that this manual is a supplement, and does not replace any information in USP or applicable FDA official guidance references. The PMM does not relieve any person or laboratory from the responsibility of ensuring that the methods being employed from the manual are fit for use, and that all testing is validated and/or verified by the user. The PMM will continually be revised as newer products, platforms and technologies emerge or any significant scientific gaps are identified with product testing. Reference to any commercial materials, equipment, or process in the PMM does not in any way constitute approval, endorsement, or recommendation by the U.S. Food and Drug Administration.