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

This book offers a guide, drawing upon 'real world' examples, for the review and assessment of microbiological data. The book includes examples drawn from water monitoring, bioburden assessment, and environmental monitoring. The book serves as a guide for quality control microbiologists, quality assurance personnel, students, and those with an interest in data, graphs and statistics in general.

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.

Biocontamination control concerns the risks to medicinal products from microorganisms, microbial by-products, and particulates. The risks of biocontamination in a well-designed facility stem from transfer on people and material surfaces, airborne contamination, and via utilities and interfaces. Biocontamination Control for Pharmaceutical and Healthcare outlines elements in a biocontamination strategy that tracks through a facility with bio-burden control and reduction at each transition in classified areas; this is a key part of controlling risk escalation to contaminating medicinal products. Regulatory authorities have challenged pharmaceutical and healthcare sectors, and those involved in Good Manufacturing Practice (GMP), to adopt a holistic approach to contamination control. Established ways of assessing contamination are limited, and therefore risk-based approaches are required. As well as using risk to assess types of contamination and where contamination can arise, 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 an up to date and complete biocontamination strategy. Provides the information for a facility to build a complete biocontamination strategy Allows a facility to understand the main biocontamination risks to medicinal products Assists the reader in navigating regulatory requirements and reducing process risks Provides insight into developing an environmental monitoring programme Covers the types of rapid microbiological monitoring methods now available, as well as current legislation

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.

Pharmaceutics is one of the most diverse subject areas in all of pharmaceutical science. In brief, it is concerned with the scientific and technological aspects of the design and manufacture of dosage forms or medicines. An understanding of pharmaceutics is therefore vital for all pharmacists and those pharmaceutical scientists who are involved with converting a drug or a potential drug into a medicine that can be delivered safely, effectively and conveniently to the patient. Now in its fourth edition, this best-selling textbook in pharmaceutics has been brought completely up to date to reflect the rapid advances in delivery methodologies by eye and injection, advances in drug formulations and delivery methods for special groups (such as children and the elderly), nanomedicine, and pharmacognosy. At the same time the editors have striven to maintain the accessibility of the text for students of pharmacy, preserving the balance between being a suitably pitched introductory text and a clear reflection of the state of the art. provides a logical, comprehensive account of drug design and manufacture includes the science of formulation and drug delivery designed and written for newcomers to the design of dosage forms New to this edition New editor: Kevin Taylor, Professor of Clinical Pharmaceutics, School of Pharmacy, University of London. Twenty-two new contributors. Six new chapters covering parenteral and ocular delivery; design and administration of medicines for the children and elderly; the latest in plant medicines; nanotechnology and nanomedicines, and the delivery of biopharmaceuticals. Thoroughly revised and updated throughout.

A detailed guide to the operation and quality assurance of UK hospital aseptic preparation services This new edition of Quality Assurance of Aseptic Preparation Services provides information and up to date national guidance on unlicensed aseptic preparation. Although it is primarily intended for the use of non-licensed UK hospital pharmacies, it will also be of use in licensed units and other countries and institutions. Aseptic services include the preparation of parenteral nutrition solutions (PN), cytotoxics, radiopharmaceuticals, additives for parenteral administration and intrathecals Since the publication of the Breckenridge report in 1976, which recommended that drug additions to intravenous (IV) infusions should be made in hospital pharmacy departments and not on wards, there has been a substantial increase in hospital pharmacy departments providing aseptic preparation services

This reference surveys emerging trends, concepts, and procedures used in the characterization and control of contaminants; the sterile production of traditional drugs and biologics; the design, construction, and validation of new parenteral facilities; and the monitoring of clean environments-vividly illustrating the routes by which products, proce

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questions, such as how to validate new methods, will they be accepted by the pharmacopoeias, and, most importantly, how will the regulators respond?
The fourth volume in the series covers the techniques and technologies involved in the preparation of semisolid products such as ointments, creams, gels, suppositories, and special topical dosage forms.
Drug manufacturers need a thorough understanding of the specific requirements that regulatory agencies impose on the formulation and efficacy deter
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 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
These first-person accounts demonstrate how students, including nonscience majors, can learn to do science as it is done in the real world—through hypothesis building, observation, and experimental design.
Highly respected, established text – a definitive reference in its field – covering in detail many methods of the elimination or prevention of microbial growth "highly recommended to hospital and research personnel, especially to clinical microbiologists, infectioncontrol and environmental-safety specialists, pharmacists, and dieticians." New England Journal of Medicine WHY BUY THIS BOOK? Completely revised and updated to reflect the rapid pace of change in this area Updated material on new and emerging technologies, focusing on special problems in hospitals, dentistry and pharmaceutical practice Gives practical advise on problems of disinfection and antiseptics in hospitals Discusses increasing problems of natural and acquired resistance to antibiotics New contributors give a fresh approach to the subject and ensure international coverage Systematic review of sterilization methods, with uses and advantages outlined for each Evaluation of disinfectants and their mechanisms of action
The Quality Control of Medicines documents the proceedings of the 35th International Congress of Pharmaceutical Sciences, organized by the Pharmaceutical Society of Ireland on behalf of the Federation Internationale Pharmaceutique, held in Dublin, on 1-5 September 1975. The theme chosen for the Congress was ""the basis for the quality control of medicines"", because of the importance and relevance of quality control in the production and distribution of medicines at national and international levels. This volume is arranged according to the manner in which the theme of the Congress was developed by the eminent invited speakers. Following the inaugural address a main symposium was held where five speakers presented a review of the quality control of medicines under the general headings of (i) chemical and physical aspects; (ii) biological aspects; (iii) control of drug delivery systems; (iv) storage problems; and (v) problems of international control. Certain aspects of the content of the main symposium were then developed in greater depth in parallel symposia. In the first parallel symposium some novel physicochemical aspects of the quality control of medicines were treated under the headings of spectrofluorimetry, mass spectrometry, detection in gas chromatography, and automation in pharmaceutical analysis. The second parallel symposium developed certain microbiological aspects of quality control under the headings of sterility testing and microbiological control of non-sterile products and ophthalmic preparations. The final symposium on submissions to regulatory bodies and international aspects of drug control covered aspects of politics in submissions, regulatory problems in small countries, and various pharmacopoeial problems.
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.
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.
Pharmaceutical Microbiology encompasses those aspects of Microbiology which impact directly upon the development, production and use of pharmaceutical compounds. It is a part of industrial microbiology, which is concerned with the production of various drugs for various diseases. All drugs must undergo microbiology testing for the detection of contamination especially before packing. The purpose of this book is to understand the various issues that relate to the establishment, maintenance and control of the microbiological quality of the controlled environment. In this book, I have compiled the various experiments which are performed to check the microbial contamination of pharmaceutical products, pharmaceutical water and environment monitoring of the plant.
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

This new edition is a comprehensive, practical reference on contemporary methods of disinfection, sterlization, and preservation and their medical, surgical, and public health applications. New topics covered include recently identified pathogens, microbial biofilms, use of antibiotics as antiseptics, synergism between chemical microbicides, pulsed-light sterilization of pharmaceuticals, and new methods for medical waste management. (Midwest).

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.

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 thoseprincipal aspects of microbiology that arerelevant to the 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 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.

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

The Beta-3 Adrenoreceptor plays an important role in regulating human fat storage and variants of this receptor are thought to be relevant to diabetes. In addition to the major interest in obesity and diabetes expressed by the pharmaceutical industry, increasing numbers of academic groups are attracted by this general research area. This renewed

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? Rapid Microbiological Methods in the Pharmaceutical Industry answers these questions and more. Martin Easter and his panel of experts: § Describe the range of rapid microbiological methods and their applications, including practical tips, and their status regarding validation, established use, and regulatory acceptance § Explore the origins of current methods and the current issues facing the requirements of microbiology and its associated test methods § Delineate the challenges involved in seeking better and more pragmatic methods for the assessment of microbial hazards and risks to ensure product and consumer safety The book assists you in applying an effective system to assess the real microbiological hazards and, hence, quantify realistic risks. Additionally, it provides monitoring methods that will deliver meaningful, useful data for effective decision making in manufacturing, quality assurance, and product safety. The expert and authoritative information in Rapid Microbiological Methods in the Pharmaceutical Industry will help you find better solutions to ensuring the microbiological safety of pharmaceutical products. Features

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.