Handbook Of Microbiological Quality Control In Pharmaceuticals And Medical Devices Pharmaceutical Science Series

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Biocontamination Control for Pharmaceuticals and Healthcare - Tim Sandle 2018-11-30
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

Handbook of Microbiological Quality Control in Pharmaceuticals and Medical Devices - Rosamund M. Baird 2000-08-17
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 provi

Bacteriological Analytical Manual - United States. Food and Drug Administration. Division of Microbiology 1969

Handbook of Online and Near-real-time Methods in Microbiology - Maximilian Lackner 2017-09-18
Rapid detection and indication of the microbiological quality of liquids is an emerging topic that has high potential for numerous applications in the fields of environmental monitoring, industrial process control and medical surveillance. Latest technologies allow online and near-real-time quantitative or

qualitative microbial measurements with a significantly higher temporal resolution than traditional methods. Such novel developments will significantly enhance quality monitoring of water resources and liquids and have great capability for automation, control and optimization of industrial processes. Therefore, such methods are assumed to have major impacts on scientific research and technical applications in the near future. The book presents cutting edge research on frontiers in microbiological detection from leading experts: Seven chapters containing review articles on emerging and state-of-the-art online and near-real-time methods of microorganism detection and – indication are giving a comprehensive insight into this novel field. A balance between chapters from industry and contributions from academia was aimed for, covering the broad field of microbiological quality of waters and liquids in environmental, industrial and medical systems. This handbook also contains an extensive glossary pointing out and describing relevant terms and definitions. This handbook is the first of its kind and is a timely, comprehensive source of information for researchers and engineers in the areas of biotechnology, environmental sciences, control technology and the process industries.

Handbook of Media for Environmental Microbiology - Ronald M. Atlas 2005-03-29

The second edition of a bestseller, this book provides a comprehensive reference for the cultivation of bacteria, Archaea, and fungi from diverse environments, including extreme habitats. Expanded to include 2,000 media formulations, this book compiles the descriptions of media of relevance for the cultivation of microorganisms from soil, water, an

Handbook of Validation in Pharmaceutical Processes, Fourth Edition - James Agalloco 2021-10-18

Revised to reflect significant advances in pharmaceutical production and regulatory expectations, Handbook of Validation in Pharmaceutical Processes, Fourth Edition examines and blueprints every step of the validation process needed to remain compliant and competitive. This book blends the use of theoretical knowledge with recent technological advancements to achieve applied practical solutions. As the industry's leading source for validation of sterile pharmaceutical processes for more than 10 years, this greatly expanded work is a comprehensive analysis of all the fundamental elements of pharmaceutical and bio-pharmaceutical production processes. Handbook of Validation in Pharmaceutical Processes, Fourth Edition is essential for all global health care manufacturers and pharmaceutical industry professionals. Key Features: Provides an in-depth discussion of recent advances in sterilization Identifies obstacles that may be encountered at any stage of the validation program, and suggests the newest and most advanced solutions Explores distinctive and specific process steps, and identifies critical process control points to reach acceptable results New chapters include disposable systems, combination products, nano-technology, rapid microbial methods, contamination control in non-sterile products, liquid chemical sterilization, and medical device manufacture

Pharmaceutical Manufacturing Handbook - Shayne Cox Gad 2008-04-04

With its coverage of Food and Drug Administration regulations, international regulations, good manufacturing practices, and process analytical technology, this handbook offers complete coverage of the regulations and quality control issues that govern pharmaceutical manufacturing. In addition, the book discusses quality assurance and validation, drug stability, and contamination control, all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines. The team of expert authors offer you advice based on their own firsthand experience in all phases of pharmaceutical manufacturing.

Pharmaceutical Manufacturing Handbook - Shayne Cox Gad 2008-03-21

This handbook features contributions from a team of

expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.

Clinical Microbiology Procedures Handbook - 2020-08-06

In response to the ever-changing needs and responsibilities of the clinical microbiology field, Clinical Microbiology Procedures Handbook, Fourth Edition has been extensively reviewed and updated to present the most prominent procedures in use today. The Clinical Microbiology Procedures Handbook provides step-by-step protocols and descriptions that allow clinical microbiologists and laboratory staff personnel to confidently and accurately perform all analyses, including appropriate quality control recommendations, from the receipt of the specimen through processing, testing, interpretation, presentation of the final report, and subsequent consultation.

Guide to Microbiological Control in Pharmaceuticals and Medical Devices, Second Edition - Stephen P. Denyer 2006-12-26

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.

Occupational Outlook Handbook - United States. Bureau of Labor Statistics 1976

Quality Assurance of Aseptic Preparation Services - Alison M. Beaney 2016

Quality Assurance of Aseptic Preparation Services Standards Handbook (also known as the Yellow Guide) provides standards for unlicensed aseptic preparation in the UK, as well as practical information to aid implementation of the standards. The handbook delivers essential standards in a practical way and in a format that will be useful for pharmacy management, staff working in aseptic preparation units and those whose role it is to audit the services. The accompanying support resources help with understanding the complexities of relevant topics including microbiology, radiopharmaceuticals, advanced therapy medicinal

products, technical (quality) agreements and capacity planning. All the standards have been revised and updated for this 5th edition. The text is produced on behalf of the Royal Pharmaceutical Society (RPS) and the NHS Pharmaceutical Quality Assurance Committee. New in this edition: Replaces the 4th edition standards and forms the basis for an ongoing audit program in the NHS Many new and revised standards Greater emphasis on Pharmaceutical Quality Systems; the responsibilities of pharmacy management, Chief Pharmacists (or equivalent), has been expanded in line with developments in Good Manufacturing Practice Reformatted into 2 parts: standards and support resources. This is a new collaboration between the RPS and NHS. Since the previous edition the RPS has become the professional body for pharmacists and pharmaceutical scientists. RPS launched these standards as part of a library of professional standards and a programme of work to create standards for all areas of pharmacy. The Handbook is essential for pharmacists, hospital pharmacy management and technical services teams, and auditors of unlicensed NHS hospital pharmacy aseptic preparation services in the UK, pharmacists and regulators. The text is used to inform standards used in several other countries.

Quality Control Applications in the Pharmaceutical and Medical Device Manufacturing Industry - Eugenia Gabriela Carrillo-Cedillo 2022

"This book gives the reader an up-to-date overview of the medical device manufacturing process and its influence on current regulations highlighting the importance of quality control in pharmaceutical products and medical devices, which must have very high-quality standards so as not to cause problems to the health of patients"--

Good Manufacturing Practices for Pharmaceuticals, Seventh Edition - Graham P. Bunn 2019-02-04

This book provides insight into the world of pharmaceutical quality systems and the key elements that must be in place to change the business and organizational dynamics from task-oriented procedure-based cultures to truly integrated quality business systems that are self-detecting and correcting. Chapter flow has been changed to adopt a quality systems organization approach, and supporting chapters have been updated based on current hot topics including the impact of the worldwide supply chain complexity and current regulatory trends.

Dairy Microbiology Handbook - Richard K. Robinson 2005-03-11

Throughout the world, milk and milk products are indispensablecomponents of the food chain. Not only do individual consumers useliquid milk for beverages and cooking, but food manufacturers usevast quantities of milk powder, concentrated milks, butter, andcream as raw materials for further processing. Effective qualityassurance in the dairy industry is needed now more than ever. Thiscompletely revised and expanded Third Edition of Dairy MicrobiologyHandbook, comprising both Volume I: Microbiology of Milk and VolumeII: Microbiology of Milk Products, updates the discipline'sauthoritative text with the latest safety research, guidelines, andinformation. Pathogens have become a major issue in dairy manufacturing.Escheria coli is a concern, and milk-borne strains of Mycobacteriumavium sub-sp. paratuberculosis have been identified as a possiblecause of Crohn's disease. Even little-known parasites likeCryptosporidium have caused disease outbreaks. Consequently, ahazard analysis of selected control/critical points (HACCP) in anymanufacturing process has become essential to prevent thecontamination of food. This volume also: -Discusses new diagnostic techniques that allow a pathogen to bedetected in a retail sample in a matter of hours rather thandays -Provides thorough coverage of dairy microbiology principles aswell as practical applications -Includes the latest developments in dairy starter cultures andgenetic engineering techniques -Offers completely updated standards for Good ManufacturingPractice Quality control and product development

managers,microbiologists, dairy scientists, engineers, and graduate studentswill find the Third Edition of Dairy Microbiology Handbook to be avital resource.

Guide to Microbiological Control in Pharmaceuticals - S. P. Denyer 1990

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.

Pharmaceutical Microbiology - Ashutosh 2007

Microbiological Quality Assurance - M.R.W. Brown 2018-01-18

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.

Microbiological Contamination Control in Pharmaceutical Clean Rooms - Nigel Halls 2016-04-19

Contamination control in pharmaceutical clean rooms has developed from a jumble of science and engineering, knowledge of what has worked well or badly in the past, dependent upon the technology available at the time the clean room was built and subsequent technological developments. Surrounding it all is a blanket of regulations. Taking a multidisc

Pharmaceutical Microbiology Manual - United States Food and Drug Administration 2017-09-21

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.

Aulton's Pharmaceutics - Michael E. Aulton 2013
"Pharmaceutics is the art of pharmaceutical preparations. It encompasses design of drugs, their manufacture and the elimination of micro-organisms from the products. This book encompasses all of these areas."--Provided by publisher.

Bad Bug Book - Mark Walderhaug 2014-01-14
The Bad Bug Book 2nd Edition, released in 2012, provides current information about the major known agents that cause foodborne illness.Each chapter in this book is about a pathogen—a bacterium, virus, or parasite—or a natural toxin that can contaminate food and cause illness. The book contains scientific and technical information about the major pathogens that cause these kinds of illnesses.A separate “consumer box” in each chapter provides non-technical information, in everyday language. The boxes describe plainly what can make you sick and, more important, how to prevent it.The information provided in this handbook is abbreviated and general in nature, and is intended for practical use. It is not intended to be a comprehensive scientific or clinical reference.The Bad Bug Book is published by the Center for Food Safety and Applied Nutrition (CFSAN) of the Food and Drug Administration (FDA), U.S. Department of Health and Human Services.

Microbial Limit and Bioburden Tests - Lucia Clontz 2008-10-14
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.

Microbial Contamination and Food Degradation - Alexandru Mihai Grumezescu 2017-11-03
Microbial Contamination and Food Degradation, Volume 10 in the Handbook of Food Bioengineering series, provides an understanding of the most common microbial agents involved in food contamination and spoilage, and highlights the main detection techniques to help pinpoint the cause of contamination. Microorganisms may cause health-threatening conditions directly by being ingested together with contaminated food, or indirectly by producing harmful toxins and factors that can cause food borne illness. This resource discusses the potential sources of contamination, the latest advances in contamination research and strategies to prevent contamination using key methods of

analysis and evaluation. Presents modern alternatives for avoiding microbial spoilage and food degradation using preventative and intervention technologies Provides key methods for addressing microbial contamination and preventing food borne illness through research and risk assessment analysis Includes detailed information on bacterial contamination problems in different environmental environments and the methodologies to help solve those problems

Pharmaceutical Microbiology - Tim Sandle 2015-10-09

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

Sterility, Sterilisation and Sterility Assurance for Pharmaceuticals - Tim Sandle 2013-10-31

Failure to adequately control any microbial challenge associated within process or product by robust sterilisation will result in a contaminated marketed product, with potential harm to the patient. Sterilisation is therefore of great importance to healthcare and the manufacturers of medical devices and pharmaceuticals. Sterility, sterilisation and sterility assurance for pharmaceuticals examines different means of rendering a product sterile by providing an overview of sterilisation methods including heat, radiation and filtration. The book outlines and discusses sterilisation technology and the biopharmaceutical manufacturing process, including aseptic filling, as well as aspects of the design of containers and packaging, as well as addressing the cleanroom environments in which products are prepared. Consisting of 18 chapters, the book comprehensively covers sterility, sterilisation and microorganisms; pyrogenicity and bacterial endotoxins; regulatory requirements and good manufacturing practices; and gamma radiation. Later chapters discuss e-beam; dry heat sterilisation; steam sterilisation; sterilisation by gas; vapour sterilisation; and sterile filtration, before final chapters analyse depyrogenation; cleanrooms; aseptic processing; media simulation; biological indicators; sterility testing; auditing; and new sterilisation techniques. Covers the main sterilisation methods of physical removal, physical alteration and inactivation Includes discussion of medical devices, aseptically filled products and terminally sterilised products Describes bacterial, pyrogenic, and endotoxin risks to devices and products

Handbook of Hygiene Control in the Food Industry - H. L. M. Lelieveld 2005-10-30

Developments such as the demand for minimally-processed foods have placed a renewed emphasis on good hygienic practices in the food industry. As a result there has been a wealth of new research in this area. Complementing Woodhead's best-selling Hygiene in the food industry, which reviews current best practice in hygienic design and operation, Handbook of hygiene control in the food industry provides a comprehensive summary of the key trends and issues in food hygiene research. Developments go fast: results of the R&D meanwhile have been applied or are being

implemented as this book goes to print. Part one reviews research on the range of contamination risks faced by food processors. Building on this foundation, Part two discusses current trends in the design both of buildings and types of food processing equipment, from heating and packaging equipment to valves, pipes and sensors. Key issues in effective hygiene management are then covered in part three, from risk analysis, good manufacturing practice and standard operating procedures (SOPs) to improving cleaning and decontamination techniques. The final part of the book reviews developments in ways of monitoring the effectiveness of hygiene operations, from testing surface cleanability to sampling techniques and hygiene auditing. Like Hygiene in the food industry, this book is a standard reference for the food industry in ensuring the highest standards of hygiene in food production. Standard reference on high hygiene standards for the food industry Provides a comprehensive summary of the key trends in food hygiene research Effective hygiene management strategies are explored

Quality Assurance of Pharmaceuticals - World Health Organization 2007

Quality assurance of pharmaceutical products is a continuing concern of WHO. Despite efforts made around the world to ensure a supply of quality and effective medicines, substandard, spurious and counterfeit products still compromise health care delivery in many countries. To respond to the global need for adequate quality assurance of pharmaceuticals, WHO's Expert Committee on Specifications for Pharmaceutical Preparations has over the years made numerous recommendations to establish standards and guidelines and to promote the effective functioning of national regulatory and control systems and the implementation of internationally agreed standards by trained personnel. Many of the relevant documents endorsed by the Committee are reproduced in this volume providing guidance covering all aspects of good manufacturing practices (GMP). Important texts on inspection are also included. Most of the material has been published separately in the Expert Committee's reports. This compendium brings it together to make it more accessible and of greater practical value to those working in faculties of pharmacy, in medicines regulation and control and in the pharmaceutical industry. This is the second updated edition of the compendium and includes texts published in 2005 and 2006 in the WHO Technical Report Series.

Microbiology and Sterility Assurance in Pharmaceuticals and Medical Devices - 2011

Hugo and Russell's Pharmaceutical Microbiology - Brendan F. Gilmore 2023-04-10

Hugo & Russell's Pharmaceutical Microbiology Discover the very latest developments in pharmaceutical microbiology in the 9th edition of this popular textbook Microbiology is one of the essential pharmaceutical sciences upon which the study and practice of pharmacy is built. It has a bearing on all aspects of the manufacture of medicines and sterile products, from their design and development to their delivery as quality products. Few interventions are more central to modern medicine than the treatment of infection, where antibiosis, vaccination and hygienic practices have essential roles to play. The COVID-19 pandemic, the appearance of new pathogens and the rise of antibiotic resistance have demonstrated most completely the need for pharmaceutical practitioners, researchers and industrial scientists to be fully conversant with this field. The 9th edition of Hugo and Russell's Pharmaceutical Microbiology has been updated to meet this need. Having long served as the sole comprehensive textbook covering this subject, it has now been adapted to a critical new period in the advancement of medical and pharmaceutical research and development. Its experienced editors have incorporated contributions from subject experts and created a text which will serve the next generation of pharmacy students, pharmaceutical industry scientists and researchers.

In this ninth edition of Hugo and Russell's Pharmaceutical Microbiology, readers will find: A mix of established and new authors bringing practical and research experience to their chapters Material covering the fundamentals of microbiology, microbial behavior and laboratory investigation Revised chapters incorporating new material on microbe-host interactions, antibiotic resistance, emerging pathogens, public health microbiology, healthcare-associated infection and pharmaceutical manufacture Emerging understandings from the COVID-19 pandemic on infection prevention and control and vaccine development Practitioners providing their insights on clinical practice and pharmaceutical production An accompanying website incorporating teaching resources Hugo and Russell's Pharmaceutical Microbiology, 9th edition promises to remain the essential text for pharmacy and medical students, as well as researchers and industry professionals.

Handbook of Water and Wastewater Microbiology - Duncan Mara 2003-08-07

"Access to safe water is a fundamental human need and therefore a basic human right" --Kofi Annan, United Nations Secretary General Edited by two world-renowned scientists in the field, The Handbook of Water and Wastewater Microbiology provides a definitive and comprehensive coverage of water and wastewater microbiology. With contributions from experts from around the world, this book gives a global perspective on the important issues faced in the provision of safe drinking water, the problems of dealing with aquatic pollution and the processes involved in wastewater management. Starting with an introductory chapter of basic microbiological principles, The Handbook of Water and Wastewater Microbiology develops these principles further, ensuring that this is the essential text for process engineers with little microbiological experience and specialist microbiologists alike. Comprehensive selection of reviews dealing with drinking water and aquatic pollution Provides an understading of basic microbiology and how it is applied to engineering process solutions Suitable for all levels of knowledge in microbiology -from those with no background to specialists who require the depth of information

Handbook of Water Purity and Quality - Satinder Ahuja 2009-07-17

This work provides those involved in water purification research and administration with a comprehensive resource of methods for analyzing water to assure its safety from contaminants, both natural and human caused. The book first provides an overview of major water-related issues in developing and developed countries, followed by a review of issues of sampling for water analysis, regulatory considerations and forensics in water quality and purity investigations. The subsequent chapters cover microbial as well chemical contaminations from inorganic compounds, radionuclides, volatile and semi-volatile compounds, disinfectants, herbicides, and pharmaceuticals, including endocrine disruptors, as well as potential terrorist-related contamination. The last chapter describes the Grainger prize-winning filter that can remove arsenic from water sources and sufficiently protect the health of a large number of people. - Covers the scope of water contamination problems on a worldwide scale - Provides a rich source of methods for analyzing water to assure its safety from natural and deliberate contaminants - Describes the filter that won the $1 million Grainger prize and thereby highlighting an important approach to remediation

Microbiology Laboratory Guidebook - United States. Food Safety and Inspection Service. Microbiology Division 1998

Handbook of Biocide and Preservative Use - H.W. Rossmoore 2012-12-06

My professional interest in antimicrobial agents and contamination control goes back 50 years to my tour as a microbiologist in a field hospital in Europe during World War II. With no experience and

relying solely on a military handbook, I prepared thermometer trays with jars of blue bichloride of mercury and pink isopropyl alcohol. A preliminary typhoid diagnosis of one of our cooks resulted in the need for lab testing. His stool specimen and its subsequent disposal was my problem. My handbook said bum it. So burn it T did, in a five-gallon can with gasoline. Flames shot up almost six feet, and my next mistake was to extinguish them with carbon tetrachloride. This resulted in the production of lethal phosgene gas. The hospital had a near disaster. I could say that at that moment I vowed to write a how-to book so that such stupidities could be avoided. Nevertheless, when I was offered the opportunity to edit this book I thought back on the need for a real, practical treatment of my subject. This book, then, is a practical handbook for technical service personnel and scientists who are not necessarily specialists in microbiology. It provides information on suitable antimicrobial agents appropriate to their particular problem-solving needs and information on the microbial groups contributing to the specific problem, their ecologies, and strategies for controlling their access to the area or material of interest.

Pharmaceutical Microbiological Quality Assurance and Control - David Roesti 2020-01-02

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

Quality Management and Accreditation in Hematopoietic Stem Cell Transplantation and Cellular Therapy - Mahmoud Aljurf 2021-02-19

This open access book provides a concise yet comprehensive overview on how to build a quality management program for hematopoietic stem cell transplantation (HSCT) and cellular therapy. The text reviews all the essential steps and elements necessary for establishing a quality management program and achieving accreditation in HSCT and cellular therapy. Specific areas of focus include document development and implementation, audits and validation, performance measurement, writing a quality management plan, the accreditation process, data management, and maintaining a quality management program. Written by experts in the field, Quality Management and Accreditation in Hematopoietic Stem Cell Transplantation and Cellular Therapy: A Practical Guide is a valuable resource for physicians, healthcare professionals, and laboratory staff involved in the creation and maintenance of a state-of-the-art HSCT and cellular therapy program.

Microbial Quality Assurance in Pharmaceuticals, Cosmetics, and Toiletries - R. Baird 2017-12-14

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.

Culture Media for Food Microbiology - J.E.L. Corry 1996-04-23

This publication deals in depth with a limited number of culture media used in Food Science laboratories. It is basically divided into two main sections: 1) Data on the composition, preparation, mode of use and quality control of various culture media used for the detection of food borne microbes. 2) Reviews of several of these media, considering their selectivity and productivity and comparative performance of alternative media. Microbiologists specializing in food and related areas will find this book particularly useful.

The Handbook of Microbiological Media for the Examination of Food - Ronald M. Atlas 2006-01-13

Responding to an estimated 14 million cases of food-borne disease that occur every year in the United States alone, the Food and Drug Administration and US Department of Agriculture have begun implementing new regulations and guidance for the microbial testing of foods. Similarly, Europe and other regions are implementing stricter oversight, as foodborne pathogens that cause deadly diseases such as e. coli 0157:H7 have raised the stakes everywhere. Food safety scientists have acted on this growing public health risk by developing improved media for the cultivation of bacteria, fungi, and viruses, much of it geared toward specific rapid detection. Reflecting the development of these new media and the latest FDA recommendations, the second edition of the Handbook of Microbiological Media for the Examination of Foodprovides an essential resource for anyone involved with the monitoring of both food production and post-production quality control. Organized alphabetically by medium, the expanded edition of this highly respected handbookincludes – · Descriptions of nearly 1,400 media including those recommended by the FDA, as well as media used elsewhere in the world · Concise and lucid instructions for the preparation and uses of each of the media · Cross-referenced indexing that allows the media to be found by name or specific microorganism of interest · Descriptions of expected results as they apply to microorganisms of importance for the examination of foods · Common synonyms for the various media and listings of compositions, so that alternate media an be effectively employed when needed Compiled by Ronald M. Atlas, a world-renowned researcher and author known for his pioneering work in pathogen detection, the Handbook of Microbiological Media for the Examination of Food, Second Edition, provides microbiologists with an essential tool for safeguarding public health.

Hugo and Russell's Pharmaceutical Microbiology - Stephen P. Denyer 2008-04-15

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