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

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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 Culture Media for Food Microbiology - Janet E. L. Corry 2003-04-22

This is a completely revised edition, including new material, from 'Culture Media for Food Microbiology' by J.E.L. Corry et al., published in

Progress in Industrial Microbiology, Volume 34, Second Impression 1999. Written by the Working Party on Culture Media, of the International Committee on Food Microbiology and Hygiene, this is a handy reference for microbiologists wanting to know which media to use for the detection of various groups of microbes in food, and how to check their performance. The first part comprises reviews, written by international experts, of the media designed to isolate the major groups of microbes important in food spoilage, food fermentations or food-borne disease. The history and rationale of the selective agents, and the indicator systems are considered, as well as the relative merits of the various media. The second part contains monographs on approximately 90 of the most useful media. The first edition of this book has been frequently quoted in standard methods, especially those published by the International Standards Organisation (ISO) and the European Standards Organisation (CEN), as well as in the manuals of companies manufacturing microbiological media. In this second edition, almost all of the reviews have been completely rewritten, and the remainder revised. Approximately twelve monographs have been added and a few deleted. This book will be useful to anyone working in laboratories examining food - industrial, contract, medical, academic or public analyst, as well as other microbiologists, working in the pharmaceutical, cosmetic and clinical (medical and veterinary) areas - particularly with respect to quality assurance of media and methods in relation to laboratory accreditation.

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

Quality Control Methods for Medicinal Plant Materials - World Health Organization 1998

A collection of test procedures for assessing the identity, purity, and content of medicinal plant materials, including determination of pesticide residues, arsenic and heavy metals. Intended to assist national laboratories engaged in drug quality control, the manual responds to the growing use of medicinal plants, the special quality problems they pose, and the corresponding need for international guidance on reliable methods for quality control. Recommended procedures - whether involving visual inspection or the use of thin-layer chromatography for the qualitative determination of impurities - should also prove useful to the pharmaceutical industry and pharmacists working with these materials.

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.

Biotechnology - Kenneth E. Avis 2020-04-22

Biotechnology: Quality Assurance and Validation provides a practical, detailed discussion of what issues Quality Assurance and Quality Control need to identify for effective control in the preparation of biotechnology products. The book presents a series of topics that define some of the unique challenges facing biotechnology companies in producing biopharmaceutical products. The topics selected address quality and validation issues, starting with the cryopreservation of cell lines through the filling and finishing of the product. It includes a validation guide, a clear presentation of how to use filtration effectively, a synoptic view of cleaning procedures, and much more.

Handbook of Microbiological Quality Control in Pharmaceuticals and Medical Devices - Rosamund M Baird 2019-08-30

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.

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

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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

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.

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.

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

Practical Handbook of Microbiology - Lorrence H Green 2021-05-04

Practical Handbook of Microbiology, 4th edition provides basic, clear and concise knowledge and practical information about working with microorganisms. Useful to anyone interested in microbes, the book is intended to especially benefit four groups: trained microbiologists working within one specific area of microbiology; people with training in other disciplines, and use microorganisms as a tool or "chemical reagent"; business people evaluating investments in microbiology focused companies; and an emerging group, people in occupations and trades that might have limited training in microbiology, but who require specific practical information. Key Features Provides a comprehensive compendium of basic information on microorganisms—from classical microbiology to genomics. Includes coverage of disease-causing bacteria, bacterial viruses (phage), and the use of phage for treating diseases, and added coverage of extremophiles. Features comprehensive coverage of antimicrobial agents, including chapters on anti-fungals and anti-virals. Covers the Microbiome, gene editing with CRISPR, Parasites, Fungi, and Animal Viruses. Adds numerous chapters especially intended for professionals such as healthcare and industrial professionals, environmental scientists and

ecologists, teachers, and businesspeople. Includes comprehensive survey table of Clinical, Commercial, and Research-Model bacteria.

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"--

Quality Systems and Controls for Pharmaceuticals - Dipak Kumar Sarker 2008-07-31

Quality Systems and Control for Pharmaceuticals is an accessible overview of the highly-regulated area of pharmaceutical manufacture, the production of biomedical materials, and biomedical devices. Introducing the subject in a clear and logical manner it enables the reader to grasp the key concepts of the multidisciplinary area of control science and specifically quality control using industrial and theoretical models. Taking a multidisciplinary approach to the subject the reader is guided through key topics such as product safety which takes into account aspects of analytical science, statistics, microbiology, biotechnology, engineering, business practice and optimizing models, the law and safeguarding public health, innovation and inventiveness and contemporary best practice. The author has both industry and academic experience and many ‘best practice’ examples are included throughout the text based on his own industry experience and current practicing industrial pharmacists. This is an invaluable reference for all students of pharmacy who may have little or no familiarity with industrial practice and for those studying BSc chemistry, biomedical sciences, process analytical

chemistry and MSc in Industrial Practice.

The Quality Management Sourcebook - Christine Avery 2002-09-11

The concept of Quality Management began in the manufacturing sector, but a growing concern with quality in other areas of the economy has led to its wider application in service industries, government, education, and other not-for-profit agencies. A great quantity of material related to quality management has been produced in recent years, much of it by small presses, professional and trade associations, and consultants. The Quality Management Sourcebook is the first in-depth, international guide to the most useful material and sources of information. The book begins with the origins of quality management, explains how it evolved, examines its current situation, and explores the future. The book is divided into five main sections: * Introduction: General sources for information * Applications of total quality management * Focus on specific aspects of quality management * Quality in the future * Resource materials The Quality Management Sourcebook is an essential reference for everybody involved in either the theory or practice of quality management: in manufacturing, retail, banking, and insurance, the utilities industry, the transportation industry, health, education and other public services. Over 900 citations cover books, journal articles, technical reports, video training materials and software. Each is followed by a descriptive annotation. Resource materials include strategies for locating additional information; training materials; organizations; and consultants. The book concludes with a glossary of quality management terms, a name index, a title index, and a detailed subject index.

Microbiology and Sterility Assurance in Pharmaceuticals and Medical Devices - 2011

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

of Microbiology 1969

Clinical Microbiology Procedures Handbook - 2016-05-02

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.

Cleanroom Microbiology for the Non-Microbiologist - David M. Carlberg 2004-10-28

Written for the professional who has an immediate need for the information but has little or no training in the subject, Cleanroom Microbiology for the Non-Microbiologist, Second Edition introduces principles of microbiology. It explains the consequences of microbiological contamination, what contamination is all about, how microorganisms grow, and how they can be controlled. The author introduces the vocabulary of microbiology and the types, sources, control, and elimination of organisms encountered in the manufacture of sterile products. Beginning with a discussion of the various types of organisms, the text then covers applications for bacterial detection, avoidance of contamination, cleanroom design considerations, and validation of disinfection methods. New topics covered include: International cleanroom standards Application of rapid, automated methods for detecting and identifying microbial contaminants In-depth examination of the role of biofilms in pure water systems Increased coverage of production of therapeutic products derived from

live tissues and cells

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

Risk Management and Risk Assessment for Pharmaceutical Manufacturing Dr Tim Sandle 2013-06-01

This book presents an overview of risk management and risk assessment for those working in the pharmaceutical and healthcare sectors. An understanding of risk management and risk assessment is today becoming a prerequisite for those working in quality control and quality assurance, and for those active in pharmaceuticals and medical devices, Quality Risk Management it is a mandatory requirement. The book expands upon this subject through a series of case studies, utilizing tools like HACCP

and FMEA.

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.

Microbiological Methods for Environment, Food and Pharmaceutical Analysis Abhishek Chauhan 2020-09-18

This book provides a broad account of various applied aspects of microbiology for quality and safety evaluations in food, water, soil, environment and pharmaceutical sciences. The work is timely, as the safety and quality of various commodities such as water and wastewater, food, pharmaceutical medications and medical devices are of paramount concern in developing countries globally for improved public health quality in areas ranging from food security to disease exposure. The book offers an introduction to basic concepts of biosafety and related microbiological practices and applies these methodologies to a multitude of disciplines in subject-focused chapters. Each chapter offers experiments and exercises pertaining to the specific area of interest in microbiological research, which will allow readers to apply the knowledge gained in a laboratory or classroom setting to see the microbiological methods discussed in practice. The book will be useful for industrialists, researchers, academics and undergraduate/graduate students of microbiology, biotechnology, botany and pharmaceutical sciences. The text aims to be a significant contribution in effectively guiding scientists, analysts, lab technicians and quality managers working with microbiology in industrial and commercial fields.

Handbook of Banana Production, Postharvest Science, Processing Technology, and Nutrition - Muhammad Siddiq 2020-07-17

A comprehensive guide that covers the banana's full value chain – from production to consumption The banana is the world's fourth major fruit crop. Offering a unique and in-depth overview of the fruit's entire value chain, this important new handbook charts its progression from production through to harvest, postharvest, processing, and consumption. The most up-to-date data and best practices are drawn together to present guidelines on innovative storage, processing, and packaging technologies, while

fresh approaches to quality management and the value-added utilization of banana byproducts are also explained. Additionally, the book examines the banana's physiology, nutritional significance, and potential diseases and pests. The book also Edited by noted experts in the field of food science, this essential text: Provides a new examination of the world's fourth major fruit crop Covers the fruit's entire value chain Offers dedicated chapters on bioactive and phytochemical compounds found in bananas and the potential of processing byproducts Gives insight into bananas' antioxidant content and other nutritional properties Identifies and explains present and possible effects of bioactive and phytochemical compounds Handbook of Banana Production, Postharvest Science, Processing Technology, and Nutrition offers the most far-reaching overview of the banana currently available. It will be of great benefit to food industry professionals specializing in fruit processing, packaging, and manufacturing banana-based products. The book is also an excellent resource for those studying or researching food technology, food science, food engineering, food packaging, applied nutrition, biotechnology, and more.

Handbook of Validation in Pharmaceutical Processes, Fourth Edition - James Agalloco 2021-10-28

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

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.

Microbiology - Nina Parker 2016-05-30

"Microbiology covers the scope and sequence requirements for a single-semester microbiology course for non-majors. The book presents the core concepts of microbiology with a focus on applications for careers in allied health. The pedagogical features of the text make the material interesting and accessible while maintaining the career-application focus and scientific rigor inherent in the subject matter. Microbiology's art program enhances students' understanding of concepts through clear and effective illustrations, diagrams, and photographs. Microbiology is produced through a collaborative publishing agreement between OpenStax and the American Society for Microbiology Press. The book aligns with the curriculum guidelines of the American Society for Microbiology."--BC Campus website.

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.

Microbial Quality of Water Supply in Distribution Systems - Edwin E. Geldreich 1996-01-18

Hidden problems, buried deep in the pipe networks of water distribution systems, are very serious potential threats to water quality. Microbial Quality of Water Supply in Distribution Systems outlines the processes and issues related to the degradation of water quality upon passage through networks of pipes, storage reservoirs, and standpipes on its way to the consumer. The risks associated with biofilm accumulation, bacteria, and other contaminants are discussed in great detail. In addition to its excellent microbiological coverage of organisms in drinking water and biofilms in distribution systems, Microbial Quality of Water Supply in Distribution Systems provides clear treatments of the technical and public communication issues

most commonly affecting the quality of water and water supply systems. The inclusion of numerous case histories in this new book makes it a complete reference source for anyone concerned with water quality and water distribution systems.

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

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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

Pharmaceutical Computer Systems Validation - Guy Wingate 2016-04-19

Thoroughly revised to include the latest industry developments, the Second Edition presents a comprehensive overview of computer validation and verification principles and how to put them into practice. To provide the current best practice and guidance on identifying and implementing improvements for computer systems, the text extensively reviews r

Cleaning Validation Manual - Syed Imtiaz Haider 2010-05-24

During the past decades, enormous progress and enhancement of pharmaceutical manufacturing equipment and its use have been made. And while there are support documents, books, articles, and online resources available on the

principles of cleaning and associated processing techniques, none of them provides a single database with convenient, ready-to-

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

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.

Laboratory Methods in Microbiology W. F. Harrigan 2014-06-28

Laboratory Methods in Microbiology is a laboratory manual based on the experience of the authors over several years in devising and organizing practical classes in microbiology to meet the requirements of students following courses in microbiology at the West of Scotland Agricultural College. The primary object of the

manual is to provide a laboratory handbook for use by students following food science, dairying, agriculture and allied courses to degree and diploma level, in addition to being of value to students reading microbiology or general bacteriology. It is hoped that laboratory workers in the food manufacturing and dairying industries will find the book useful in the microbiological aspects of quality control and production development. The book is organized into two parts. Part I is concerned with basic methods in microbiology and would normally form the basis of a first year course. Abbreviated recipes and formulations for a number of typical media and reagents are included where appropriate, so that the principles involved are more readily apparent. Part II consists of an extension of these basic methods into microbiology as applied in the food manufacturing, dairying and allied industries. In this part, the methods in current use are given in addition to, or in place of, the ""classical"" or conventional techniques.

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 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.