Microbiological Best Laboratory Practices Usp

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

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.

Maintaining the high standard set by the previous bestselling editions, Fundamental Food Microbiology, Fourth Edition presents the most up-to-date information in this rapidly growing and highly dynamic field. Revised and expanded to reflect recent advances, this edition broadens coverage of foodborne diseases to include many new and emerging pathogens, as well as descriptions of the mechanism of pathogenesis. An entirely new chapter on detection methods appears with evaluations of advanced rapid detection techniques using biosensors and nanotechnology. With the inclusion of many more easy-to-follow figures and illustrations, this text provides a comprehensive introductory source for undergraduates, as well as a valuable reference for graduate level and working professionals in food microbiology or food safety. Each chapter within the text's seven sections contains an introduction as well as a conclusion, references, and questions. Beginning with the history and development of the field, Part I discusses the characteristics and sources of predominant food microorgasnisms and their significance. Part II introduces microbial foodborne diseases, their growth and influencing factors, metabolism, and sporulation. The third Part explains the beneficial uses of microorganisms in starter cultures, biopreservation, bioprocessing, and probiotics. Part IV deals with food spoilage and methods of detection, followed by a discussion in Part V of foodborne pathogens associated with intoxication, infections, and toxicoinfections. Part VI reviews control methods with chapters on control of microbial access and removal by heat, organic acids, physical means, and combinations of methods. The final section is an in-depth look at advanced and traditional methods of microbial detection and food safety. Four appendices provide additional details on food equipment and surfaces, predictive modeling, regulatory agencies, and hazard analysis critical control points.

Good Laboratory Practice Regulations Management Briefings

Introduction to Wine Laboratory Practices and Procedures

Practical Guide for Non-Sterile Manufacturing

Post Conference Report

Regulations and Quality

Guidance for the Validation of Analytical Methodology and Calibration of Equipment Used for Testing of Illicit Drugs in Seized Materials and Biological Specimens

Analytical Microbiology focuses on the processes, methodologies, developments, and approaches involved in analytical microbiology, including microbiological, antibiotic, and amino acid assays and dilution methods. The selection first offers information on the theory of antibiotic inhibition zones, microbiological assay using large plate methods, and dilution methods of antibiotic assays. Discussions focus on serial dilution assay, requirements for accurate assay, microbiological assay of riboflavin, laws of adsorption and partition, mechanisms of antibiotic action, and biological considerations affecting the use of statistical methods. The text then ponders on the elements of photometric assaying and automation of microbiological assays. The manuscript elaborates on antibiotic substances, vitamins, and amino acids. Topics include assay organisms, validity, specificity, reliability, and calculation of results of amino acid assays, bacitracin, chloramphenicol, dihydrostreptomycin, erythromycin, neomycin, and streptomycin. The selection is a dependable reference for researchers interested in analytical microbiology.

¿Biosafety in Microbiological & Biomedical Labs.¿ quickly became the cornerstone of biosafety practice & policy upon first pub. in 1984. The info. is advisory in nature even though legislation & regn., in some circumstances, have overtaken it & made compliance with the guidance mandatory. This rev. contains these add¿l. chap.: Occupat¿l. med. & immunization; Decontam. & sterilization; Lab. biosecurity & risk assess.; Biosafety Level 3 (Ag.) labs.; Agent summary state. for some ag. pathogens; & Biological toxins. Also, chapters on the principles & practices of biosafety & on risk assess. were expanded; all agent summary state. & append. were rev.; & efforts were made to harmonize recommend. with reg¿s. promulgated by other fed. agencies.

The Laboratory Mouse, Second Edition is a comprehensive book written by international experts. With inclusions of the newly revised European standards on laboratory animals, this will be the most current, global authority on the care of mice in laboratory research. This well-illustrated edition offers new and updated chapters including immunology, viruses and parasites, behavior, enrichment and care standards of laboratory mice across the life sciences, medical and veterinary fields. Features four-color illustrations with complete instruction on mouse surgery, anatomy, behavior and care of the mouse in laboratory research Offers additional chapters on new mouse strains, phenotyping of strains, bacteria and parasites, and immunology Includes the newly revised EU standards on care, as well as, comparisons to standards and regulations in the US and other countries

Cosmetic Microbiology

Pharmaceutical Quality Control Microbiology

Good Quality Control Laboratory Practice (GQCLP)

Handbook of Stability Testing in Pharmaceutical Development

Manual of Microbiological Culture Media

NF 27

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.

In recent years, the field of pharmaceutical microbiology has experienced numerous technological advances, accompanied by the publication of new and harmonized compendial methods. It is therefore imperative for those who are responsible for monitoring the microbial quality of pharmaceutical/biopharmaceutical products to keep abreast of the latest changes. Microbial Limit and Bioburden Tests: Validation Approaches and Global Requirements guides readers through the various microbiological methods listed in the compendia with easy-to-follow diagrams and approaches to validations of such test methodologies. Includes New and Updated Material Now in its second edition, this work is the culmination of research and discussions with technical experts, as well as USP and FDA representatives on various topics of interest to the pharmaceutical microbiologist and those responsible for the microbial quality of products, materials, equipment, and manufacturing facilities. New in this edition is an entire chapter dedicated to the topic of biofilms and their impact on pharmaceutical and biopharmaceutical operations. The subject of rapid methods in microbiology has been expanded and includes a discussion on the validation of alternative microbiological methods and a case study on microbial identification in support of a product contamination investigation. Substantially updated and revised, this book assists readers in understanding the fundamental issues associated with pharmaceutical microbiology and provides them with tools to create effective microbial contamination control and microbial testing programs for the areas under their responsibility.

Pharmaceutical Microbiology: 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

U. S. Pharmacopoeia National Formulary

Laboratory Biosafety Manual

Supplement

Practical Fermentation Technology

Microbial Limit and Bioburden Tests

USP 33 NF 28

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‚Äìfrom 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.

Data integrity is the hottest topic in the pharmaceutical industry. Global regulatory agencies have issued guidance, after guidance after guidance in the past few years, most of which does not offer practical advice on how to implement policies, procedures and processes to ensure integrity. These guidances state what but not how. Additionally, key stages of analysis that impact data integrity are omitted entirely. The aim of this book is to provide practical and detailed help on how to implement data integrity and data governance for regulated analytical laboratories working in or for the pharmaceutical industry. It provides clarification of the regulatory issues and trends, and gives practical methods for meeting regulatory requirements and guidance. Using a data integrity model as a basis, the principles of data integrity and data governance are expanded into practical steps for regulated laboratories to implement. The author uses case study examples to illustrate his points and provides instructions for applying the principles of data integrity and data governance to individual laboratory needs. This book is a useful reference for analytical chemists and scientists, management and senior management working in regulated laboratories requiring either an understanding about data integrity or help in implementing practical solutions. Consultants will also benefit from the practical guidance provided.

The definitive and essential source of reference for all laboratories involved in the analysis of human semen.

Microbiological Methods for Environment, Food and Pharmaceutical Analysis

Technology, Validation and Current Regulations

Anthrax in Humans and Animals

USP, NF.

The Laboratory Mouse

Validation Approaches and Global Requirements,Second Edition

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.

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

The validation of analytical methods and the calibration of equipment are important aspects of quality assurance in the laboratory. This manual deals with both of these within the context of testing of illicit drugs in seized materials and biological specimens. It provides an introduction and practical guidance to national authorities and analysts in the implementation of method validation and verification, and also in the calibration/performance verification of laboratory instrumentation and equipment within their existing internal quality assurance programmes. The procedures described represent a synthesis of the experience of scientists from several reputable laboratories around the world.

Pharmaceutical Microbiological Quality Assurance and Control

Regulations, Methodologies, and Best Practices

Pharmaceutical Manufacturing Handbook

170 Years of USP

Sterility, Sterilisation and Sterility Assurance for Pharmaceuticals

A Practical Approach

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

In the beginning, for me, winemaking was a romanticized notion of putting grape juice into a barrel and allowing time to perform its magic as you sat on the veranda watching the sunset on a Tuscan landscape. For some small wineries, this notion might still ring true, but for the majority of wineries commercially producing quality wines, the reality of winemaking is far more complex. The persistent evolution of the wine industry demands continual advan- ments in technology and education to sustain and promote quality winem- ing. The sciences of viticulture, enology, and wine chemistry are becoming more intricate and sophisticated each year. Wine laboratories have become an integral part of the winemaking process, necessitating a knowledgeable staff possessing a multitude of skills. Science incorporates the tools that new-age winemakers are utilizing to produce some of the best wines ever made in this multibillion dollar trade. A novice to enology and wine chemistry can find these subjects daunting and intimidating. Whether you are a home winemaker, a new winemaker, an enology student, or a beginning-to-intermediate laboratory technician, p- ting all the pieces together can take time. As a winemaker friend once told me, "winemaking is a moving target." Introduction to Wine Laboratory Practices and Procedures was written for the multitude of people entering the wine industry and those that wish to learn about wine chemistry and enology.

The USP-NF is a combination of two official compendia, the United States Pharmacopeia (USP) and the National Formulary (NF). It contains standards for medicines, dosage forms, drug substances, excipients, biologics, compounded preparations, medical devices, dietary supplements, and other therapeutics. USP-NF standards are enforceable by the U.S. Food and Drug Administration for medicines manufactured and marketed in the United States. Learn more about USP-NF. Highlights & Features: * More than 4,500 monographs with specifications for identity, strength, quality, purity, packaging, and labeling for substances and dosage forms. View a sample USP-NF monograph (100KB). * Over 230 General Chapters providing clear, step-by-step guidance for assays, tests, and procedures * Focus-specific charts and a combined index helps you find the information you need * Helpful sections on reagents, indicators, and solutions, plus reference tables * Published annually in an official English edition (print, CD, and new USB flash drive formats) and an official Spanish edition (print).

Laboratory Methods in Anaerobic Bacteriology

Pharmaceutical Microbiology

Data Integrity and Data Governance

United States Pharmacopeia [and] National Formulary. Reissue. Supplement 2.a

Quality Control Systems for the Microbiology Laboratory

Bacteriological Analytical Manual

This fourth edition of the anthrax guidelines encompasses a systematic review of the extensive new scientific literature and relevant publications up to end 2007 including all the new information that emerged in the 3-4 years after the anthrax letter events. This updated edition provides information on the disease and its importance, its etiology and ecology, and offers guidance on the detection, diagnostic, epidemiology, disinfection and decontamination, treatment and prophylaxis procedures, as well as control and surveillance processes for anthrax in humans and animals. With two rounds of a rigorous peer-review process, it is a relevant source of information for the management of anthrax in humans and animals.

This updated edition provides research scientists, microbiologists, process engineers, and plant managers with an authoritative resource on basic microbiology, manufacturing hygiene, and product preservation. It offers a contemporary global perspective on the dynamics affecting the industry, including concerns about preservatives, natural ingredients, small manufacturing, resistant microbes, and susceptible populations. Professional researchers in the cosmetic as well as the pharmaceutical industry will find this an indispensable textbook for in-house training that improves the delivery of information essential to the development and manufacturing of safe high-quality products

A collection of recommended procedures for analysis and specifications for the determination of pharmaceutical substances, excipients and dosage forms intended to serve as source material for reference by any WHO member state.

CDC Laboratory Manual

Third Edition

Pearson Etext Microbiology Access Card

Analytical Microbiology

Biosafety in Microbiological and Biomedical Laboratories

A Commitment to Quality and Continuous Improvement

This handbook is the first to cover all aspects of stability testing in pharmaceutical development. Written by a group of international experts, the book presents a scientific understanding of regulations and balances methodologies and best practices.

A hands-on book which begins by setting the context;- defining 'fermentation' and the possible uses of fermenters, and setting the scope for the book. It then proceeds in a methodical manner to cover the equipment for research scale fermentation labs, the different types of fermenters available, their uses and modes of operation. Once the lab is equipped, the issues of fermentation media, preservation strains and strain improvement strategies are documented, along with the use of mathematical modelling as a method for prediction and control. Broader questions such as scale-up and scale down, process monitoring and data logging and acquisition are discussed before separate chapters on animal cell culture systems and plant cell culture systems. The final chapter documents the way forward for fermenters and how they can be used for non-manufacturing purposes. A glossary of terms at the back of the book (along with a subject index) will prove invaluable for quick reference.Edited by academic consultants who have years of experience in fermentation technology, each chapter is authored by experts from both industry and academia. Industry authors come from GSK (UK), DSM (Netherlands), Eli Lilly (USA) and Broadley James (UK-USA).

This is the third edition of this manual which contains updated practical guidance on biosafety techniques in laboratories at all levels. It is organised into nine sections and issues covered include: microbiological risk assessment; lab design and facilities; biosecurity concepts; safety equipment; contingency planning; disinfection and sterilisation; the transport of infectious substances; biosafety and the safe use of recombinant DNA technology; chemical, fire and electrical safety aspects; safety organisation and training programmes; and the safety checklist.

USP35 NF30, 2012

Compounding Sterile Preparations

Basic and Clinical Principles

A Guidebook to the Basics

The International Pharmacopoeia

WHO Laboratory Manual for the Examination of Human Semen and Sperm-Cervical Mucus Interaction

Empower your staff to improve safety, quality and compliance with the help of new guidelines and standards. We've updated every chapter of this popular review of the fundamentals of preparing sterile products in hospital, home-care, and community pharmacy settings to reflect the most recent revisions to USP . Included are the latest guidelines for the compounding process, quality assurance methods, and comprehensive coverage of all aspects of the dispensing process. Comprehensive documentation for the guidelines is included in the appendices.Chapters new to this edition focus on: Gap analysis and action plans Safe use of automatic compounding devices Cleaning and disinfecting Radiopharmaceuticals as CSPs Allergen extracts as CSPs.

Handbook of Microbiological Quality Control in Pharmaceuticals and Medical Devices

Essentials for Quality Assurance and Quality Control

Practical Implementation in Regulated Laboratories

Fundamental Food Microbiology

Difco and BBL Manual

The End of the Beginning : Proceedings of the United States Pharmacopeial Convention, Inc. : Quinquennial Meetings of the Convention, March 22-24, 1985 : March 8-10, 1990