11 Dry Heat Depyrogenation And Sterilization Crcnetbase

Sterile Drug Products: Formulation, Packaging, Manufacturing, and Quality teaches the basic principles of the development and manufacture of high quality sterile dosage forms. The author has 38 years of experience in the development and manufacture of sterile dosage forms including solutions, suspensions, ophthalmics and freeze dried products. This book is based on the courses he has delivered for over three decades, to over 3000 participants, and is intended to remain relevant for the indefinite future even as new technologies and new applications of old technologies become common. This is an ideal reference book for those working directly and indirectly with sterile dosage forms, be it product development (formulation, package, process, analytical), manufacturing, quality control, quality assurance, regulatory, purchasing, or project management. This book is also intended as an educational resource for the pharmaceutical and biopharmaceutical industry and pharmacy schools, providing basic knowledge and principles in four main areas of parenteral science and technology: Product development, including formulation, packaging, and process development. Manufacturing, including basic teaching on all the primary unit operations involved in preparation of sterile products and the underlying importance of contamination control. Quality and regulatory, including the application of good manufacturing practice regulations, aseptic processing guidelines, and unique quality control testing methods for the sterile dosage form Clinical aspects, including administration, potential hazards, and biopharmaceutics of sterile products in a clinical setting.
The field of medical instrumentation is inter-disciplinary, having interest groups both in medical and engineering professions. The number of professionals associated directly with the medical instrumentation field is increasing rapidly due to intensive penetration of medical instruments in the health care sector. In addition, the necessity and desire to know about how instruments work is increasingly apparent. Most dictionaries/encyclopedias do not illustrate properly the details of the bio-medical instruments which can add to the knowledge base of the person on those instruments. Often, the technical terms are not covered in the dictionaries. Unless there is a seamless integration of the physiological bases and engineering principles underlying the working of a wide variety of medical instruments in a publication, the curiosity of the reader will not be satisfied. The purpose of this book is to provide an essential reference which can be used both by the engineering as well as medical communities to understand the technology and applications of a wide range of medical instruments. The book is so designed that each medical instrument/ technology will be assigned one or two pages, and approximately 450 medical instruments are referenced in this edition.
The effective sterilisation of any material or device to be implanted in or used in close contact with the human body is essential for the elimination of harmful agents such as bacteria. Sterilisation of biomaterials and medical devices reviews established and commonly used technologies alongside new and emerging processes. Following an introduction to the key concepts and challenges involved in sterilisation, the sterilisation of biomaterials and medical devices using steam and dry heat, ionising radiation and ethylene oxide is reviewed. A range of non-traditional sterilisation techniques, such as hydrogen peroxide gas plasma, ozone and steam formaldehyde, is then discussed together with research in sterilisation and decontamination of surfaces by plasma discharges. Sterilisation techniques for polymers, drug-device products and tissue allografts are then reviewed, together with antimicrobial coatings for ‘self-sterilisation’ and the challenge presented by prions and endotoxins in the sterilisation of reusable medical devices. The book concludes with a discussion of future trends in the sterilisation of biomaterials and medical devices. With its distinguished editors and expert team of international contributors, Sterilisation of biomaterials and medical devices is an essential reference for all materials scientists, engineers and researchers within the medical devices industry. It also provides a thorough overview for academics and clinicians working in this area. Reviews established and commonly used technologies alongside new and emerging processes Introduces and reviews the key concepts and challenges involved in sterilisation Discusses future trends in the sterilisation of biomaterials and medical devices
This book describes various methods of decontamination and how the methods work. There is a discussion of the various cleaning and disinfection methods utilized, along with details of how to qualify these methods. It also describes new technologies that may be useful in the battle for decontamination across industries. Finally, this book provides a single resource on how one can address contamination issues for a variety of manufacturing processes and industries. Explores new technologies that may be useful in the battle for decontamination Examines various methods of decontamination and how the methods work Addresses contamination issues for a variety of manufacturing processes and industries Describes how to detect contaminants as well as how to deal with contaminants that are present Includes methods for both decontamination (reaction) and preventing contamination (proactive)
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.
Parenteral Medications is an authoritative, comprehensive reference work on the formulation and manufacturing of parenteral dosage forms, effectively balancing theoretical considerations with practical aspects of their development. Previously published as a three-volume set, all volumes have been combined into one comprehensive publication that addresses the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration. Key Features: Provides a comprehensive reference work on the formulation and manufacturing of parenteral dosage forms Addresses changes in the science and advances in the technology associated with parenteral medications and routes of administration Includes 13 new chapters and updated chapters throughout Contains the contributors of leading researchers in the field of parenteral medications Uses full color detailed illustrations, enhancing the learning process
The fourth edition not only reflects enhanced content in all the chapters but also highlights the rapidly advancing formulation, processing, manufacturing parenteral technology including advanced delivery and cell therapies. The book is divided into seven sectionss: Section 1 - Parenteral Drug Administration and Delivery Devices; Section 2 - Formulation Design and Development; Section 3 - Specialized Drug Delivery Systems; Section 4 - Primary Packaging and Container Closure Integrity; Section 5 - Facility Design and Environmental Control; Section 6 - Sterilization and Pharmaceutical Processing; Section 7 - Quality Testing and Regulatory Requirements
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
Sterilisation has always been challenging but sterilisation of healthcare products and polymers, especially together is an even greater challenge - how do you sterilise without adversely affecting the end use or the end user? This book discusses all the sterilisation methods used for polymeric healthcare products both traditional and new.
Presents all the information a pharmacy student needs to understand the purpose and processes of compounding in a logical and

progressive format. This comprehensive reference provides practitioners with essential information on establishing, equipping, and operating a compounding facility. Over 200 formulations cover all the dosage forms and delivery systems of modern medications. Written by eminent experts, 25 chapters discuss all aspects of good manufacturing practices, and emphasizes quality control measures for all aspects of compounding medications.

Includes as many case studies as the contributors could identify, with the goal of answering questions that arise as a result of conducting day-to-day sterilization activities. Discussion of the theory of microbial inactivation and the philosophy of sterilization validation is followed by practical information on methods of interest to a broad audience. Chapters on special considerations for ethylene oxide, packaging of sterile products, contract sterilization, and regulations complete the coverage. Annotation copyright by Book News, Inc., Portland, OR

This text lists the necessary steps for meeting compliance requirements during the drug development process. It presents comprehensive approaches for validating analytical methods for pharmaceutical applications.

Freeze-drying is an important preservation technique for heat-sensitive pharmaceuticals and foods. Products are first frozen, then dried in a vacuum at low temperature by sublimation and desorption, rather than by the application of heat. The resulting items can be stored at room temperature for long periods. This informative text addresses both principles and practice in this area. The first chapter introduces freeze-drying. The authors then review the fundamentals of the technique, heat-mass transfer analyses, modelling of the drying process and the equipment employed. Further chapters focus on freeze-drying of food, freeze-drying of pharmaceuticals and the protective agents and additives applied. The final chapter covers the important subjects of disinfection, sterilization and process validation. Freeze-drying of pharmaceutical and food products is an essential reference for food, pharmaceutical and refrigeration engineers and scientists with an interest in preservation techniques. It will also be of use to students in these fields. Addresses the principles and practices used in this important preservation technique Explains the fundamentals of heat-mass transfer analysis, modelling and the equipment used Discusses the importance of disinfection, sterilization and process validation

Drug Delivery Aspects reviews additional features of drug delivery systems, along with the standard formulation development, like preclinical testing, conversion into solid dosage forms, roles of excipients and polymers used on stability and sterile processing. There is a focus on formulation engineering and related large scale (GMP) manufacturing, regulatory, and functional aspects of drug delivery systems. A detailed discussion on biologics and vaccines gives insights to readers on new developments in this direction. The series Expectations and Realities of Multifunctional Drug Delivery Systems examines the fabrication, optimization, biological aspects, regulatory and clinical success of wide range of drug delivery carriers. This series reviews multifunctionality and applications of drug delivery systems, industrial trends, regulatory challenges and in vivo success stories. Throughout the volumes discussions on diverse aspects of drug delivery carriers, such as clinical, engineering, and regulatory, facilitate insight sharing across expertise area and form a link for collaborations between industry-academic scientists and clinical researchers. Expectations and Realities of Multifunctional Drug Delivery Systems connects formulation scientists, regulatory experts, engineers, clinical experts and regulatory stake holders. The wide scope of the book ensures it as a valuable reference resource for researchers in both academia and the pharmaceutical industry who want to learn more about drug delivery systems. Encompasses engineering and large-scale manufacturing of nanocarriers Considers preclinical, regulatory and ethical guidelines on nanoparticles Contains in-depth discussions on delivery of biologics, vaccines and sterilisation Industrial view on solid dispersions, milling techniques

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.

Completely revised and updated to reflect the significant advances in pharmaceutical production and regulatory expectations, this third edition of Validation of Pharmaceutical Processes examines and blueprints every step of the validation process needed to remain compliant and competitive. The many chapters added to the prior compilation examine va

The Future of Pharmaceutical Product Development and Research examines the latest developments in the pharmaceutical sciences, also highlighting key developments, research and future opportunities. Written by experts in the field, this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of the product development phase of drug discovery and drug development. Each chapter covers fundamental principles, advanced methodologies and technologies employed by pharmaceutical scientists, researchers and the pharmaceutical industry. The book focuses on excipients, radiopharmaceuticals, and how manufacturing should be conducted in an environment that follows Good Manufacturing Practice (GMP) guidelines. Researchers and students will find this book to be a comprehensive resource for those working in, and studying, pharmaceuticals, cosmetics, biotechnology, foods and related industries. Provides an overview of practical information for clinical trials Outlines how to ensure an environment that follows Good Manufacturing Practice (GMP) Examines recent developments and suggests future directions for drug production methods and techniques

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

This three-volume set of Pharmaceutical Dosage Forms: Parenteral Medications is an authoritative, comprehensive reference work on the formulation and manufacture of parenteral dosage forms, effectively balancing theoretical considerations with the practical aspects of their development. As such, it is recommended for scientists and engineers in the pharmaceutical industry and academia, and will also serve as an excellent reference and training tool for regulatory scientists and quality assurance professionals. First published in 1984 (as two volumes)

and then last revised in 1993 (when it grew to three volumes), this latest revision will address the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration. The third edition of this book maintains the features that made the last edition so popular but comprises several brand new chapters, revisions to all other chapters, as well as high quality illustrations. Volume two presents: • Chapters on aseptic facility design, environmental monitoring, and cleanroom operations. • A comprehensive chapter on pharmaceutical water systems. • A discussion of quality attributes of sterile dosage forms, including particulate matter, endotoxin, and sterility testing. • A detailed chapter on processing of parenteral drug products (SVPs and LVPs). • Presentations on widely used sterilization technologies – steam, gas / chemical, radiation, filtration and dry heat. • An in-depth chapter on lyophilization.

The ways of sterilisation begin as far back as biblical and roman times, from early beginnings to standardization. Sterilisation evolution has gone through a series of trials and wizardry before it achieved the status of science. And even with a scientific approach, some of its modalities frequently has been referred to as an art (an imaginary focus), while most have achieved a certain scientific standardization. This book provides a drawbridge between history, terminology, environmental and fundamentals of sterilisation that beginners to sterilisation should recognize, but continues with advancements, which supervisors and managers should know and apply. So while providing historical and current sterilisation information, the book also provides interfacial areas with design practices, development, environmental control, material compatibility, microbiology, packaging, process selection, statistics, technical information and validation. This book consists of two volumes (Healthcare Sterilisation, Introduction and Standard Practices: Volume 1, and Healthcare Sterilisation, Challenging Practices: Volume 2). Volume 1 provides an introduction, and an overview of sterilisation on early and classical sterilisation principles such as absolutism and overkill, and steadfast and standard methods. It will help answer some healthcare sterilisation queries such as: what are the origins and evolution of sterilisation? How does environmental control and microbiology affect sterilisation? What are some of the classical as well as standard sterilisation methods? What are the most consistent and reliable sterilisation methods? Is sterilisation in your future? An ounce of prevention is worth a pound of cure. Without sterilisation, infectious disease and contamination would run rampant. Consequently, sterilisation has tremendous value and disease control, and this book provides a three dimensional view of it.

This book provides a wide ranging overview of key themes and technologies used in Biotechnology. It is written from an engineers perspective and focuses on understanding the key subject areas including facility requirements, clean utilities, equipment validation, aseptic processes, Chapter 1: Facilities Introduction Contamination Control Material Flow Material Transfer Disinfection and Cleaning Agents GMP Zoning Environmental Grade A (Aseptic) Environmental Grade B Environmental Grade C Environmental Grade D Chapter 2: Clean Utilities Compressed Air Water Systems Water for Injection Clean Steam HVAC Chapter 3: Sterile Manufacturing Operations Unit Operations Raw materials Upstream Processing Filling Operations Container Closure Integrity Isolator Barrier Systems Decontamination Agents Containment Steam Sterilisers Chapter 4: Depyrogenation What is Depyrogenation? Pyrogens Endotoxins and Depyrogenation Biological Indicators for Dry Heat Control of Materials In-Process Controls Cooling Failure of Depyrogenation Chapter 5: Cleaning and Disinfection Cleaning Validation PICS/s Guidance on limit Test Methods Cleaning Process Design Piping Utilities Chapter 6: Process Development Vial Washers Depyrogenation Tunnels Isolators Chapter 7: Physical Processes Fluid Flow Classification of Fluids Mixing Vessel Geometry Heat Transfer Chapter 8: Equipment Validation Depyrogenation Tunnels (Equipment Validation) Isolators (Equipment Validation) Steam Sterilisers (Equipment Qualification) Chapter 9: Performance Qualification Depyrogenation Isolators Steam Sterilisers Chapter 10: Data Integrity The Lifecycle of Data System Categorisation Chapter 11: Test Method Validation Basics Chapter 12: Ethylene Oxide Sterilisation Sterilisation and Parametric Release Sterilisation Conditions Packaging Systems Pure ethylene oxide sterilizers Ethylene Oxide Sterilisation Cycles Biological indicator (BI) placement Chapter 13: Single Use Technology Introduction Extractables and Leachables Biocompatibility Chapter:14 Extractables and Leachables Introduction Extractables Explained Leachables Explained

Provides basic guidelines concerning quality assurance and its responsibilities for biopharmaceuticals manufactured by either recombinant, monoclonal antibody or other biotechnological methodologies. Discusses what systems are needed along with a description of each system and its functions. Leading authorities in the biotechnology industry offer insight and suggestions in order to assure the safety, purity and efficacy of products produced.

A textbook which is both comprehensive and comprehensible and that offers easy but scientifically sound reading to both students and professionals Now in its 12th edition in its native German, Voigt's Pharmaceutical Technology is an interdisciplinary textbook covering the fundamental principles of pharmaceutical technology. Available for the first time in English, this edition is produced in full colour throughout, with a concise, clear structure developed after consultation with students, instructors and researchers. This book: Features clear chapter layouts and easily digestible content Presents novel trends, devices and processes Discusses classical and modern manufacturing processes Covers all formulation principles including tablets, ointments, capsules, nanosystems and biopharmaceutics Takes account of legal requirements for both qualitative and quantitative composition Addresses quality assurance considerations Uniquely relates contrasting international pharmacopeia from EU, US and Japan to formulation principles Includes examples and text boxes for quicker data assimilation Written for both students studying pharmacy and industry professionals in the field as well as toxicologists, biochemists, medical lab technicians, Voigt’s Pharmaceutical Technology is the essential resource for understanding the various aspects of pharmaceutical technology.

For more than 100 years, this textbook has been the definitive reference for all aspects of the science and practice of pharmacy, and is used for pharmaceutics, therapeutics and pharmacy practice courses in primary curricula. Since the first edition was published, pharmacists have used this book as a key one-stop reference. This updated edition covers many education and practice issues, from the history of pharmacy and ethics, to industrial pharmacy and pharmacy practice. New to the edition are expanded sections on pharmacy administration and patient care, which include new topics such as: nutrition in pharmacy practice; self care and home diagnostic products; health care delivery systems and interdisciplinary care; and home health patient care. Also, information has been condensed into one volume for greater portability and convenience.

Presenting authoritative and engaging articles on all aspects of drug development, dosage, manufacturing, and regulation, this Third Edition enables the pharmaceutical specialist and novice alike to keep abreast of developments in this rapidly evolving and highly competitive field. A dependable reference tool and constant companion for years to com

Environmental Management System ISO 14001:2004 provides the information and practical know-how required to facilitate a smooth adoption and incorporation of the latest revisions and enhancements put forth by the International Organization for Standardization. This unique work shows how to adopt or transition to the documentation procedures required

The new edition of this established and highly respected text isTHE definitive reference in its field. It details methods for

theelimination or prevention/control of microbial growth, andfeatures: New chapters on bioterrorism and community healthcare New chapters on microbicide regulations in the EU, USA andCanada Latest material on microbial resistance to microbicides Updated material on new and emerging technologies, focusing onspecial problems in hospitals, dentistry and pharmaceuticalpractice Practical advice on problems of disinfection and antiseptics inhealthcare A systematic review of sterilization methods, with uses andadvantages outlined for each Evaluation of disinfectants and their mechanisms of action withrespect to current regulations The differences between European and North American regulationsare highlighted throughout, making this a truly global work, idealfor worldwide healthcare professionals working in infectiousdiseases and infection control.

For over 100 years, Remington has been the definitive textbook and reference on the science and practice of pharmacy. This Twenty-First Edition keeps pace with recent changes in the pharmacy curriculum and professional pharmacy practice. More than 95 new contributors and 5 new section editors provide fresh perspectives on the field. New chapters include pharmacogenomics, application of ethical principles to practice dilemmas, technology and automation, professional communication, medication errors, re-engineering pharmacy practice, management of special risk medicines, specialization in pharmacy practice, disease state management, emergency patient care, and wound care. Purchasers of this textbook are entitled to a new, fully indexed Bonus CD-ROM, affording instant access to the full content of Remington in a convenient and portable format.

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

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 Dosage Forms - Parenteral MedicationsVolume 2: Facility Design, Sterilization and ProcessingCRC Press

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.

Endotoxin detection and control is a dynamic area of applied science that touches a vast number of complex subjects. The intersection of test activities includes the use of an ancient blood system from an odd “living fossil” (Limulus). It is used to detect remnants of the most primitive and destructive forms of life (prokaryotes) as contaminants of complex modern systems (mammalian and Pharma). Recent challenges in the field include those associated with the application of traditional methods to new types of molecules and manufacturing processes. The advent of “at will” production of

biologics in lieu of harvesting animal proteins has revolutionized the treatment of disease. While the fruits of the biotechnology revolution are widely acknowledged, the realization of the differences in the means of production and changes in the manner of control of potential impurities and contaminants in regard to the new versus the old are less widely appreciated. Endotoxin as an ancient, dynamic interface between lifeforms, provides a singular perspective from which to view the parallel development of ancient and modern organisms as well as the progress of man in deciphering the complexity of their interactions in his efforts to overcome disease.

This comprehensive book encompasses various facets of sterile product development. Key concepts relevant to the successful development of sterile products are illustrated through case studies and are covered under three sections in this book: • Formulation approaches that discuss a variety of dosage forms including protein therapeutics, lipid-based controlled delivery systems, PEGylated biotherapeutics, nasal dosage form, and vaccines • Process, container closure and delivery considerations including freeze-thaw process challenges, best practices for technology transfer to enable commercial product development, innovations and advancement in aseptic fill-finish operations, approaches to manufacturing lyophilized parenteral products, pen / auto-injector delivery devices, and associated container closure integrity testing hurdles for sterile product closures • Regulatory and quality aspects in the areas of particulate matter and appearance evaluation, sterile filtration, admixture compatibility considerations, sterilization process considerations, microbial contamination investigations and validation of rapid microbiological methods, and dry and moist heat sterilizers This book is a useful resource to scientists and researchers in both industry and academia, and it gives process and product development engineers insight into current industry practices and evolving regulatory expectations for sterile product development.

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.