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FLORES WEST

Advances In Pharmaceutical Cell Therapy: Principles Of Cell-based Biopharmaceuticals Butterworth-Heinemann
This book highlights key ideas and factors to coach and guide professionals involved in learning about Sterile Manufacturing and operational requirements. It covers regulations and guidelines instituted by the FDA, ISPE, EMA, MHRA, and ICH, emphasizing good manufacturing practice and inspection requirements in the manufacturing of medicinal products. Additionally, this book provides the fundamentals of aseptic techniques, quality by design, risk assessment, and management in support of sterile operations applications. It creates a link to the implementation of business practices in drug manufacturing and healthcare and forms a correlation between design strategies including a step-by-step process to ensure reliability, safety, and efficacy of healthcare products for human and animal use. The book also provides a connection between drug production and regulated applications by offering a review of the basic elements of sterile processing, and how to remain viable with solid strategic planning. The book is a concise reference for professionals and learners in the field of sterile operations that governs primarily, pharmaceutical and medical device space, but can also extend to food and cosmetics that require clean (aseptic) manufacturing applications. It also helps compounding pharmacists and GMP inspectors and auditors.
Healthcare Sterilisation The Stationery Office
Quality, second edition, provides comprehensive application of regulatory guidelines and quality concepts and methodologies related to pharmaceutical manufacturing. It is an excellent resource for practitioners, those pursuing pharmaceutical related certifications, and for students trying to learn more about pharmaceutical manufacturing. This book provides the background theory, applied descriptions of the guidelines and concepts, plus questions and problems at the end of the chapters that will help provide practice for the reader to apply the concepts. In this book the authors share their combined 60+ years of extensive practical experience in the industry and in process improvement combined with detailed understanding of the needs of the industry and education system. This book provides real-life examples from industry and guidelines for practical application of tools that can be referenced by operators, engineers, and management.This book is fully revised, updated, and expanded with new content in areas such as QbD, Lean, Six Sigma, basic data analysis, and CAPA tools. - Fully revised, updated, and expanded new edition - Features new topics such as QbD, Lean, Six Sigma, basic data analysis, and CAPA tools - Includes end-of-chapter summaries and end-of-chapter question and/or problems - Provides detailed steps and examples for applying the guidelines and quality tools - Written in an accessible style making the content easy to understand and apply
Sterility, Sterilisation and Sterility Assurance for Pharmaceuticals Bentham Science Publishers
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
Validation of Pharmaceutical Processes Elsevier
The most significant changes in isolation technology during the past five years have not been in the technology itself but in its increased acceptance. This acceptance is clearly demonstrated by the series of monographs, guidelines, and standards produced by regulatory bodies to describe best practice in the design and operation of isolators. Thoroughly revised and updated, Isolation Technology: A Practical Guide, Second Edition provides an in-depth overview of new standards and new technology. Here's what's new in the Second Edition: " Descriptions of and comments on new guidelines and standards " Technological advances - such as the new breed of sanitizing gas generators " Updates that reflect current thinking and new information Drawing on his vast experience in this field, the author delineates practical ways to improve product standards, increase operator productivity, efficiency and safety, and cut costs. Carefully designed for easy understanding by readers from multiple fields, the book reviews the how-tos for setting up clean rooms and techniques for maintaining sterility, and includes case studies, resource listings, and numerous photographs. The combination of up-to-date information and the author's clear writing style make this the ideal resource for both experienced and beginning professionals.
Jaypee's Video Atlas of Assisted Reproductive Technologies and Clinical Embryology Smithers Rapra
A single source reference covering every aspect of biotechnology, Biotechnology Fundamentals, Second Edition breaks down the basic fundamentals of this discipline, and highlights both conventional and modern approaches unique to the industry. In addition to recent advances and updates relevant to the first edition, the revised work also covers ethics in biotechnology and discusses career possibilities in this growing field. The book begins with a basic introduction of biotechnology, moves on to more complex topics, and provides relevant examples along the way. Each chapter begins with a brief summary, is illustrated by simple line diagrams, pictures, and tables, and ends with a question session, an assignment, and field trip information. The author also discusses the connection between plant breeding, cheese making, in vitro fertilization, alcohol fermentation, and biotechnology. Comprised of 15 chapters, this seminal work offers in-depth coverage of topics that include: Genes and Genomics Proteins and Proteomics Recombinant DNA Technology Microbial Biotechnology Agricultural Biotechnology Animal Biotechnology Environmental Biotechnology Medical Biotechnology Nanobiotechnology Product Development in Biotechnology Industrial Biotechnology Ethics in Biotechnology Careers in Biotechnology Laboratory Tutorials Biotechnology Fundamentals, Second Edition provides a complete introduction of biotechnology to students taking biotechnology or life science courses and offers a detailed overview of the fundamentals to anyone in need of comprehensive information on the subject.
Spon's Architects' and Builders' Price Book 2022 World Scientific
Pharmaceutical manufacturing can be viewed as a supply chain which spans from the production and purchase of the starting and packaging materials through the manufacture of dosage forms until the safe reception of the finished product by the patient. The entire chain comprises of several processes: auditing, materials purchase (procurement), production, storage, distribution, quality control, and quality assurance. The quality standard for pharmaceutical production is ‘current good manufacturing practice (CGMP)’‘, which is applied within the frame of a pharmaceutical quality system (PQS). This implementation, however, requires a scientific approach and has to take into account several elements such as risk assessment, life cycle,

patient protection, among other factors. Hence, pharmaceutical manufacturing is a complex subject in terms of regulation, given the technical and managerial requirements. This comprehensive handbook describes CGMP for new professionals who want to understand and apply the elements which build up pharmaceutical quality assurance. The book gives details about basic quality control requirements (such as risk management, quality hazards and management systems, documentation, clean environments, personnel training) and gives guidelines on regulatory aspects. This is an ideal handbook for undergraduates studying pharmaceutical or industrial manufacturing and supply chains as well for entrepreneurs and quality control professionals seeking to learn about CGMP standards and implementing quality assurance systems in the pharmaceutical sector.
Metric Handbook CRC Press
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.
Trends on the Role of PET in Drug Development John Wiley & Sons
For each building type, the book gives basic design requirements, principal dimensional data and details of relevant building regulations. The book also contains information on broader aspects of design applicable to all building types, such as materials, acoustics and lighting, and data on human dimensions and space requirements. Significantly updated, the new edition of this work focuses on sustainable design practice to make projects competitive within a green market.
Reinraumtechnik Elsevier
This book offers practical applications addressing the specifics of contamination, including particle origination, characterization, identification, and elimination, with a special focus on quality considerations. Written by an industry expert, this material offers a clear and concise understanding of particle populations and their control in stability, efficacy, and predictability in the manufacture of healthcare products. Complete with a full-color insert of micrographs illustrating commonly encountered particulate matter and over eighty figures, tables, and charts. Features
Spon's Architects' and Builders' Price Book 2023 Springer
Advances in food safety knowledge, combined with the continuing rapid development of new food products, have had an impact on the need for improved hygiene in the food manufacturing infrastructure. This has created a need for the second edition of Hygienic Design of Food Factories, which expands all existing chapters and includes new topics, such as cold storage and the control of air in food refrigeration facilities. Additionally, chapters explore the prevention of food contamination when building during production, the risk assessment of which is becoming important globally, and hygienic building design regulations in Russia and Brazil. Divided into 6 parts, the book is now thoroughly updated and expanded. Part one reviews the implications of hygiene and construction regulation in various countries on food factory design, while taking into account retailer requirements as well. Part two describes site selection, factory layout and the associated issue of airflow. Parts three through four and five then address the hygienic design of the essential parts of a food factory. These include walls, ceilings, floors, selected utility and process support systems, entry and exit points, storage areas and changing rooms. Lastly part six covers the management of building work and factory inspection when commissioning the plant. With its distinguished editors and international team of contributors, Hygienic Design of Food Factories, 2nd edition, continues to be an essential reference for managers of food factories, food plant engineers and all those with an academic research interest in the field. - Presents an authoritative overview of hygiene control in the design, construction and renovation of food factories - Examines the implications of hygiene and construction regulation in various countries on food factory design - Describes site selection, factory layout and associated issues of service provision
The Sustainable Laboratory Handbook Pharmaceutical Press
20 interactive DVDs featuring over 130 videos providing a comprehensive overview of Assisted Reproductive Technologies (ART). Accompanying book covers In Vitro Fertilisation (IVF).
Handbook for Critical Cleaning: Applications, processes, and controls CRC Press
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.
Fast Track Surgery in Hip and Knee Arthroplasty World Scientific
Drug development is very expensive and a fight against time. PET offers possibilities to speed up this process by adding unique in vivo information on pharmacokinetics/dynamics of a drug at an early stage. This information can help decision makers to move the drug in the drug development process or to decide to stop further developments. This unique and complete book highlights the different ways PET can be used and describes the latest trends in the various disciplines within nuclear medicine to further improve methodologies and increase the number of tools to accelerate drug development. Various topics within tracer development, instrumentation, data analysis and many clinical and preclinical topics are described by leading scientists from industry and academia.
Handbook of Filter Media The Stationery Office
Almost half of the total energy produced in the developed world is inefficiently used to heat, cool, ventilate and control humidity in buildings, to meet the increasingly high thermal comfort levels demanded by occupants. The utilisation of advanced materials and passive technologies in buildings would substantially reduce the energy demand and improve the environmental impact and carbon footprint of building stock worldwide.Materials for energy efficiency and thermal comfort in buildings critically reviews the advanced building materials applicable for improving the built environment. Part one reviews both fundamental building physics and occupant comfort in buildings, from heat and mass transport, hygrothermal behaviour, and ventilation, on to thermal comfort and health and safety requirements.Part two details the development of advanced materials and sustainable technologies for application in buildings, beginning with a review of lifecycle assessment and environmental profiling of materials. The section moves on to review thermal insulation materials, materials for heat and moisture control, and heat energy storage and passive cooling technologies. Part two concludes with coverage of modern methods of construction, roofing design and technology, and benchmarking of façades for optimised building thermal performance.Finally, Part three reviews the application of advanced materials, design and technologies in a range of existing and new building types, including domestic, commercial and high-performance buildings, and buildings in hot and tropical climates.This book is of particular use to, mechanical, electrical and HVAC engineers, architects and low-energy building practitioners worldwide, as well as to academics and researchers in the fields of building physics, civil and building engineering, and materials science. - Explores improving energy efficiency and thermal comfort through material selection and sustainable technologies - Documents the development of advanced materials and sustainable technologies for applications in building design and construction - Examines fundamental building physics and occupant comfort in buildings featuring heat and mass transport, hygrothermal behaviour and ventilation
Sterile Processing of Pharmaceutical Products iSmithers Rapra Publishing
Compiled by AECOM, the 2024 edition has been updated with the latest pricing information to help you manage your projects over the next 12 months through this challenging period of high inflation and financial uncertainty. It includes 20,000 prices for the most frequently specified construction items, the majority with labour constants and detailed build-ups. All prices have been updated via comprehensive supplier engagement combined with AECOM’s market intelligence and a short-term inflationary forecast to ensure you have the most accurate cost data available. Activity descriptions and build ups have been updated to reflect changes to standard specifications, Building Regulation changes, emerging practices, and changing outputs. Although it suits a wide range of project sizes, this is the only price book which sets out a detailed cost base for contracts exceeding £4,000,000 in value. All the standard features you have come to expect from SPON's are also included: Hundreds of alternative materials prices for the more unusual items Detailed guidance on wage rates, daywork, cost limits and allowances, property insurance and professional fees, plus useful formulae, design criteria and trade association addresses Included within the inside front cover of every book is a VitalSource® eBook redemption code giving one user access to the content digitally until the end of December 2024.
Good Quality Practice (GQP) in Pharmaceutical Manufacturing: A Handbook Woodhead Publishing
This work considers the basic concepts, definitions, and standards necessary in the design, construction, commissioning, maintenance, and use of pharmaceutical isolators.
Hygienic Design of Food Factories Routledge
Provides guidance to help health planners, estates and facilities managers, sterile services managers and capital planning and design teams to plan and design a sterile services department. It discusses the objectives of a sterile services department (SSD) and service requirements, particularly focusing on: raising standards in decontamination services by optimising the built environment: service requirements strategy: calculating the optimum capacity of an SSD to eradicate bottlenecks: determining the most appropriate location of an SSD. Design guidance based on the above service objectives is outlined. Finally, the finer details of the individual spaces within an SSD are discussed.
Spon's Architects' and Builders' Price Book 2025 CRC Press
A central resource of technology and methods for environments where the control of contamination is critical.
Reinraumtechnik Routledge
This document gives best practice advice on the design and layout of cancer facilities within acute hospitals, primarily chemotherapy and radiotherapy facilities. Although it is aimed at new builds, the recommendations should be applied, where possible, when existing facilities are being upgraded. It describes a chemotherapy unit for the delivery of intravenous and intrathecal chemotherapy, and a radiotherapy unit for the delivery of external beam radiotherapy (teletherapy), as well as facilities for undertaking unsealed source radiotherapy and sealed source radiotherapy (brachytherapy). It also describes a dedicated out-patients unit (OPU) for cancer patients, although it is acknowledged that some trusts will use a shared out-patients facility. Reference is made to facilities that are not used exclusively by people with cancer but have a particular relevance.
Exposure to Microbiological Agents in Indoor and Occupational Environments CRC Press
The first comprehensive guide to modern laboratory planning in ten years to address both construction and operating aspects. Many of the 30 authors are affiliated with the European Association for Sustainable Laboratory Technologies (EGNATON), which has also endorsed this ready reference. This expert team covers the entire lifecycle of a laboratory facility, starting with the site layout and the planning of the building, followed by the planning of such areas as housing for laboratory animals, clean rooms and production facilities. The next section of the book deals with the installation of laboratory equipment, including storage and emergency facilities, while the final parts address safety and sustainability standards applicable to laboratories, as well as facility management and optimization during normal laboratory operation. The relevant norms and standards are cited throughout, and examples from recent construction sites are also presented. Hundreds of photographs and drawings, many in full color, provide visual examples of the design and building concepts. As a result, readers will learn how to construct and maintain efficient and long-serving laboratory spaces with a minimum of maintenance costs and a maximum of safety. An invaluable, practical guide for planners, builders and managers of chemical, biological and medical research laboratories of any size.

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