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Martin C. Easter

**Parenteral Medications, Fourth Edition** Sandeep Nema, John D. Ludwig, 2019-07-19 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 sections: 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

*Handbook of Validation in Pharmaceutical Processes, Fourth Edition* James Agalloco, Phil DeSantis, Anthony Grilli, Anthony Pavell, 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

**Process Scale Purification of Antibodies** Uwe Gottschalk, 2017-04-03 Promoting a continued and much-needed renaissance in biopharmaceutical manufacturing, this book covers the different strategies and assembles top-tier technology experts to address the challenges of antibody purification. • Updates existing topics and adds new ones that include purification of antibodies produced in novel production systems, novel separation technologies, novel antibody formats and alternative scaffolds, and strategies for ton-scale manufacturing • Presents new and updated discussions of different purification technologies, focusing on how they can address the capacity crunch in antibody purification • Emphasizes antibodies and innovative chromatography methods for processing

*Biotechnology from Idea to Market* Fred Mermelstein, Richard Prince, Carl Novina, 2019-08

**Spray-Freeze-Drying of Foods and Bioproducts** S. Padma Ishwarya, 2022-04-08 Spray-freeze-drying

(SFD) is a synergistic drying technology that imbibes in it the merits of both spray drying and freeze-drying, whilst overcoming the limitations of these predecessor technologies. SFD produces uniquely powdered food and pharmaceutical products with porous microstructure and superior quality attributes. Owing to its atomization step and ultra-low-temperature operation, SFD is a competent drying technique for the production of valuable but sensitive bioactive components. Despite the costs and complexities involved, SFD has a competitive edge over the conventional drying techniques in providing distinctive product attributes. The applications of spray-freeze-drying in the area of food and bioproducts span across the product categories of instant food powders, dry flavors, active pharmaceutical ingredients, poorly water-soluble drugs, probiotics, proteins, enzymes and vaccines. *Spray-Freeze-Drying of Foods and Bioproducts: Theory, Applications and Perspectives* is the first exclusive title on this interesting drying technique. It provides a comprehensive understanding of the fundamentals of SFD and its food and pharmaceutical applications. The scope of this book, comprising 12 chapters, has been organized under four major headings: fundamentals of process-stages, applications with case-studies, recent advancements and the processing bottlenecks and solutions. **Key Features** Provides examples and case studies of nuances and intricacies associated with each stage of the spray-freeze-drying process Highlights the applications of spray-freeze-drying in the production of food products including soluble coffee, dairy powders, probiotics and flavors Serves as a ready-reckoner of characterization methods for spray-freeze-dried products Contains 200+ illustrations and tabulations The contents of this book are organized to cater to the knowledge needs of students, academicians, researchers and professionals in the food and pharmaceutical industry.

**Consults in Obstetric Anesthesiology** Suzanne K. W. Mankowitz, 2018-11-15 This text addresses the need for a book specifically aimed at obstetric anesthesia and covers topics such as pulmonary, cardiac renal, hepatic, hematologic, neurologic, endocrine and other diseases. The real anesthetic challenge arises when patients present to Labor and Delivery with unusual or complicated medical problems and, in recent years, a few of the larger institutions have developed an Obstetric Anesthesiology Consultation Service to prepare for the management of these patients. While most pregnant women who present to Labor and Delivery require anesthetic intervention, they typically meet the anesthesiologist for the first time in labor. Since the majority of laboring women are healthy without significant comorbidities, this does not present much of a challenge to the anesthesiologist and the anesthetic management tends to be straight-forward with favorable outcomes. However, using this new model, the anesthesiologist has the opportunity to discuss the various treatment modalities and potentially suggest diagnostic testing to be performed prior to delivery, similar to the pre-operative testing that is done in other surgical environments.

**Nursing and Clinical Informatics: Socio-Technical Approaches** Staudinger, Bettina, H[un] á, Victoria, Ostermann, Herwig, 2009-02-28 This book gives a general overview of the current state of nursing informatics giving particular attention to social, socio-technical, and political basic conditions--Provided by publisher.

**Biocontamination Control for Pharmaceuticals and Healthcare** Tim Sandle, 2024-02-09 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. The first edition of the book covered many of the aspects of the strategy, but the new official guidance signals that a roadmap is required to fully comply with its requirements. Completely updated with the newest version of the EU-GPM (EN17141) the new edition expands the coverage of quality risk management and new complete examples to help professionals bridge the gap between regulation and implementation. Biocontamination Control for Pharmaceuticals and Healthcare offers professionals in pharma quality control and related areas guidance on

building a complete biocontamination strategy. Includes the most current regulations Contains three new chapters, including Application of Quality Risk Management and its Application in Biocontamination Control, Designing an Environmental Monitoring Programme, and Synthesis: An Anatomy of a Contamination Control Strategy Offers practical guidance on building a complete biocontamination strategy

*Filtration and Purification in the Biopharmaceutical Industry, Third Edition* Maik W.

Jornitz, 2019-06-26 Since sterile filtration and purification steps are becoming more prevalent and critical within medicinal drug manufacturing, the third edition of *Filtration and Purification in the Biopharmaceutical Industry* greatly expands its focus with extensive new material on the critical role of purification and advances in filtration science and technology. It provides state-of-the-science information on all aspects of bioprocessing including the current methods, processes, technologies and equipment. It also covers industry standards and regulatory requirements for the pharmaceutical and biopharmaceutical industries. The book is an essential, comprehensive source for all involved in filtration and purification practices, training and compliance. It describes such technologies as viral retentive filters, membrane chromatography, downstream processing, cell harvesting, and sterile filtration. Features: Addresses recent biotechnology-related processes and advanced technologies such as viral retentive filters, membrane chromatography, downstream processing, cell harvesting, and sterile filtration of medium, buffer and end product Presents detailed updates on the latest FDA and EMA regulatory requirements involving filtration and purification practices, as well as discussions on best practises in filter integrity testing Describes current industry quality standards and validation requirements and provides guidance for compliance, not just from an end-user perspective, but also supplier requirement It discusses the advantages of single-use process technologies and the qualification needs Sterilizing grade filtration qualification and process validation is presented in detail to gain the understanding of the regulatory needs The book has been compiled by highly experienced contributors in the field of pharmaceutical and biopharmaceutical processing. Each specific topic has been thoroughly examined by a subject matter expert.

*Organic Pollutants Ten Years After the Stockholm Convention* Tomasz Puzyn, Aleksandra

Mostrag, 2012-02-24 Ten years after coming into force of the Stockholm Convention on Persistent Organic Pollutants (POPs), a wide range of organic chemicals (industrial formulations, plant protection products, pharmaceuticals and personal care products, etc.) still poses the highest priority environmental hazard. The broadening of knowledge of organic pollutants (OPs) environmental fate and effects, as well as the decontamination techniques, is accompanied by an increase in significance of certain pollution sources (e.g. sewage sludge and dredged sediments application, textile industry), associated with a potential generation of new dangers for humans and natural ecosystems. The present book addresses these aspects, especially in the light of Organic Pollutants risk assessment as well as the practical application of novel analytical methods and techniques for removing OPs from the environment. Providing analytical and environmental update, this contribution can be particularly valuable for engineers and environmental scientists.

Sources of Contamination in Medicinal Products and Medical Devices Denise Bohrer, 2012-11-19

The first one-volume guide to sources of contamination in pharmaceuticals and medical devices Most books dealing with contaminants in medicinal products often focus on analytical methods for detecting nonspecific impurities. Key to the work of the pharmaceutical chemist, this unique reference helps identify the sources of contamination in medicinal and pharmaceutical products and medical devices. Divided into three parts, *Sources of Contamination in Medicinal Products and Medical Devices* covers chemical, microbiological, and physical (particulate matter) contamination, including those originating from sterilization procedures. As compelling as a medical documentary, the book sheds light on how impurities

and contaminants can enter the human body transported via a specific product or treatment. Focusing on only those medicinal products and medical devices that may lead to exposure to contaminants harmful to human health, the book offers a comprehensive, systematic look at the entire universe of medical contamination: Chemical contaminants including residual solvents, catalyst residuals, and genotoxic impurities in active pharmaceutical ingredients (APIs) Diagnostic imaging agents (i.e., radiopharmaceuticals and contrast agents) Microbiological and endotoxin contamination involving single and multiple dose products, medical devices, and biofilms Contamination from sterilization procedures, residuals from radiation sterilization, ionizing radiation on packaging materials and medical devices Medicinal gases and volatile anesthetics Biopharmaceuticals including recombinant DNA technology products Extractables and leachables from containers made of glass, plastics, and metal Each section of the book contains information on what contaminants could be expected in a particular product, and how they were generated and reached that product. With up-to-date regulatory guidelines for determining contamination, as well as methods for assessing, quantifying, avoiding and removing contaminants, *Sources of Contamination in Medicinal Products and Medical Devices* is essential to fully understanding the specific threats that undermine the safety of medicines and medical devices.

Journal of the Medical Association of Thailand ,2008-10 The journal of Medical Association of Thailand publishes original and review articles including case report that relate to the study or research on diseases, epidemiology, drug or vaccine that have the influence on clinical course, treatment and prevention of human illness

Continuous Manufacturing of Pharmaceuticals Peter Kleinebudde,Johannes Khinast,Jukka Rantanen,2017-07-14 A comprehensive look at existing technologies and processes for continuous manufacturing of pharmaceuticals As rising costs outpace new drug development, the pharmaceutical industry has come under intense pressure to improve the efficiency of its manufacturing processes. Continuous process manufacturing provides a proven solution. Among its many benefits are: minimized waste, energy consumption, and raw material use; the accelerated introduction of new drugs; the use of smaller production facilities with lower building and capital costs; the ability to monitor drug quality on a continuous basis; and enhanced process reliability and flexibility. *Continuous Manufacturing of Pharmaceuticals* prepares professionals to take advantage of that exciting new approach to improving drug manufacturing efficiency. This book covers key aspects of the continuous manufacturing of pharmaceuticals. The first part provides an overview of key chemical engineering principles and the current regulatory environment. The second covers existing technologies for manufacturing both small-molecule-based products and protein/peptide products. The following section is devoted to process analytical tools for continuously operating manufacturing environments. The final two sections treat the integration of several individual parts of processing into fully operating continuous process systems and summarize state-of-art approaches for innovative new manufacturing principles. Brings together the essential know-how for anyone working in drug manufacturing, as well as chemical, food, and pharmaceutical scientists working on continuous processing Covers chemical engineering principles, regulatory aspects, primary and secondary manufacturing, process analytical technology and quality-by-design Contains contributions from researchers in leading pharmaceutical companies, the FDA, and academic institutions Offers an extremely well-informed look at the most promising future approaches to continuous manufacturing of innovative pharmaceutical products Timely, comprehensive, and authoritative, *Continuous Manufacturing of Pharmaceuticals* is an important professional resource for researchers in industry and academe working in the fields of pharmaceuticals development and manufacturing.

User Centered Design for Medical Visualization Dong, Feng, Ghinea, Gheorghita, Chen, Sherry Y., 2008-05-30 This book features a comprehensive review of advances in medical visualization and human-computer interaction. It investigates the human roles during a visualization process, specifically motivation-based design, user-based design, and perception-and-cognitive-based design. It also provides real-world examples and insight into the analytical and architectural aspects of user centered design--Provided by publisher.

Rapid Microbiological Methods in the Pharmaceutical Industry Martin C. Easter, 2003-03-19 In recent years there has been increased interest in the possibility of rapid microbiological methods offering enhanced potential error detection capabilities. However, these methods raise a number of questions, such as how to validate new methods, will they be accepted by the pharmacopoeias, and, most importantly, how will the regulators respond?

**Clinical Technologies: Concepts, Methodologies, Tools and Applications** Management Association, Information Resources, 2011-05-31 This multi-volume book delves into the many applications of information technology ranging from digitizing patient records to high-performance computing, to medical imaging and diagnostic technologies, and much more--

Russell, Hugo & Ayliffe's Principles and Practice of Disinfection, Preservation and Sterilization Adam P. Fraise, Peter A. Lambert, Jean-Yves Maillard, 2008-04-15 Highly respected, established text – a definitive reference in its field – covering in detail many methods of the elimination or prevention of microbial growth highly recommended to hospital and research personnel, especially to clinical microbiologists, infection control and environmental-safety specialists, pharmacists, and dieticians. New England Journal of Medicine WHY BUY THIS BOOK? Completely revised and updated to reflect the rapid pace of change in this area Updated material on new and emerging technologies, focusing on special problems in hospitals, dentistry and pharmaceutical practice Gives practical advice on problems of disinfection and antiseptics in hospitals Discusses increasing problems of natural and acquired resistance to antibiotics New contributors give a fresh approach to the subject and ensure international coverage Systematic review of sterilization methods, with uses and advantages outlined for each Evaluation of disinfectants and their mechanisms of action

Biopolymer Nanostructures for Food Encapsulation Purposes Seid Mahdi Jafari, 2019-06-14 Biopolymer Nanostructures for Food Encapsulation Purposes, a volume in the Nanoencapsulation in the Food Industry series, guides readers on how to fabricate and apply nanostructures from different proteins, carbohydrates and chemical sources for food encapsulation purposes. This book covers recent and applied research in all disciplines of bioactive and nutrient delivery. Chapters emphasize original results relating to experimental, theoretical, formulations and/or applications of nano-structured biopolymers. Includes updated applications of biopolymer nanostructures from different protein, carbohydrate and chemical sources Discloses the current knowledge and potential of biopolymer nanostructures Brings the novel applications of biopolymer nanostructures for the development of bioactive delivery systems together

*Handbook of Drying for Dairy Products* C. Anandharamakrishnan, 2017-05-01 Handbook of Drying for Dairy Products is a complete guide to the field's principles and applications, with an emphasis on best practices for the creation and preservation of dairy-based food ingredients. Details the techniques and results of drum drying, spray drying, freeze drying, spray-freeze drying, and hybrid drying Contains the most up-to-date research for optimizing the drying of dairy, as well as computer modelling options Addresses the effect of different drying techniques on the nutritional profile of dairy products Provides essential information for dairy science academics as well as technologists active in the dairy industry

J.P.C.,2009-12-31 This reference set provides a complete understanding of the development of applications and concepts in clinical, patient, and hospital information systems--Provided by publisher.

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