Parenteral Quality Control

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Pharmaceutical Microbiological Quality Assurance and Control Academic Press
Completely updated and enlarged to three volumes (originally published as two volumes), the Second Edition of Pharmaceutical Dosage Forms: Parenteral Medications examines every important aspect of sterile drug products. This volume (3) offers comprehensive coverage of medical devices, quality assurance and regulatory issues.;This in-depth reference and text: discusses regulatory requirements in record-keeping based on the US Food and Drug Administration's (FDA) Current Good Manufacturing Practices; places special emphasis on methods of detecting, counting and sizing particles; offers new perspectives on contemporary validation concepts and how they affect the validation process; explains current FDA enforcement activities, the voluntary compliance policy, select court cases, and how these relate to parenterals; provides recent materials on the use of audits as a means of verifying the efficacy of manufacturing control systems; highlights new US regulations for medical devices; and examines quality assurance, including new information on biological control tests for medical device materials.;With the contributions of leading experts, volume 3 of Pharmaceutical Dosage Forms: Parenteral Medications is intended as a day-to-day reference for pharmacists, medical device manufacturers, quality control and regulatory personnel, chemists and drug patent and litigation attorneys, as well as a text for upper-level undergraduate, graduate and continuing-education students in the pharmaceutical sciences.
Compounding Sterile Preparations CRC Press
Malnutrition and obesity are both common among Americans over age 65. There are also a host of other medical conditions from which older people and other Medicare beneficiaries suffer that could be improved with appropriate nutritional intervention. Despite that, access to a nutrition professional is very limited. Do nutrition services benefit older people in terms of morbidity, mortality, or quality of life? Which health professionals are best qualified to provide such services? What would be the cost to Medicare of such services? Would the cost be offset by reduced illness in this population? This book addresses these questions, provides recommendations for nutrition services for the elderly, and considers how the coverage policy should be approached and practiced. The book discusses the role of nutrition therapy in the management of a number of diseases. It also examines what the elderly receive in the way of nutrition services along the continuum of care settings and addresses the areas of expertise needed by health professionals to provide appropriate nutrition services and therapy.
Requirements and Quality Control Regarding "particulate Matter in Parenteral Solutions" CRC Press
Completely updated and enlarged to three volumes (originally published as two volumes), the Second Edition of Pharmaceutical Dosage Forms: Parenteral Medications examines every important aspect of sterile drug products. This volume (3) offers comprehensive coverage of medical devices, quality assurance and regulatory issues.;This in-depth reference and text: discusses regulatory requirements in record-keeping based on the US Food and Drug Administration's (FDA) Current Good Manufacturing Practices; places special emphasis on methods of detecting, counting and sizing particles; offers new perspectives on contemporary validation concepts and how they affect the validation process; explains current FDA enforcement activities, the voluntary compliance policy, select court cases, and how these relate to parenterals; provides recent materials on the use of audits as a means of verifying the efficacy of manufacturing control systems; highlights new US regulations for medical devices; and examines quality assurance, including new information on biological control tests for medical device materials.;With the contributions of leading experts, volume 3 of Pharmaceutical Dosage Forms: Parenteral Medications is intended as a day-to-day reference for pharmacists, medical device manufacturers, quality control and regulatory personnel, chemists and drug patent and litigation attorneys, as well as a text for upper-level undergraduate, graduate and continuing-education students in the pharmaceutical sciences.
The Role of Nutrition in Maintaining Health in the Nation's Elderly CRC Press
It is therefore obvious that good patient management necessitates the use of an alternative route of nutritional support in patients unable to eat or absorb an oral diet. This alternative is parenteral nutrition, which is the subject of this book. While there are many texts on the subject of parenteral nutrition, very few if any are directed to the practical details of organizing the delivery of parenteral nutrition from a multidisciplinary point of view. In this publication we present the practice of parenteral nutrition as viewed by a team of a physician, nurse, and pharmacist.
Pharmaceutical Dosage Forms World Health Organization
Nuclear medicine is an ever changing subject, and the emphasis and utility of one type of study is often abruptly supplanted by another. In this unstable environment, there is a set of circumstances that offers a basic unifying structure to the activities encountered in nuclear medicine. The pivotal importance of radio pharmaceuticals in these activities makes a thorough understanding of them paramount for all who would

prescribe, dispense, or in any way utilize such materials. In this volume, the author has distilled an awesome body of literature on nuclear pharmacy into a concise and readily understandable textbook. It is written from the viewpoint of one who not only has broad experience and knowledge in nuclear pharmacy, who daily guides and instructs a variety of students in the discipline, but who also directs a clinical nuclear medicine radiopharmacy program. In this book he has avoided the esoteric and maintained an emphasis on the practical. The approach is not encyclopedic in nature, as adequate references refer the more interested reader to appropriate sources of detailed information, but one which ensures that the students will be able to absorb the essentials of nuclear pharmacy and practice it effectively with a broad understanding of the subject. At the end of each chapter a set of questions provokes the reader to assess the sufficiency of the knowledge gained.

Parenteral Quality Control National Academies Press

Parenteral Products: The Preparation and Quality Control of Products for Injection deals with modern pharmaceutical practice in the preparation, quality control, and storage of injectable drug solutions. The book gives a basic background of parenteral solutions, the routes of administration, the effects of the different administrations of injection solutions, and the formulation of these products. The text discusses the theories of filtration, the different methods used, such as screen filters, depth filters, and the possible choices of filtration to capture any preselected unwanted particle size. Developments on sterilization of the product are given attention, citing techniques and equipment. The working and preparation conditions are discussed, since the sterile intravenous solutions, whether in large or small quantities, are done in quite the same procedures, with the similar equipment, and same organization. Equally important in the discussion are the monitoring and control of contamination by particulates through the application of standards known as the Coulter principle and the light-blockage method. The pharmaceutical problems encountered during the administration of large volume drip solutions are analyzed. This book is helpful for pharmacists, pharmaceutical students and professors, and those working in the pharmaceutical industry and hospital/health sector.

Pharmaceutical Dosage Forms Elsevier

A detailed guide to the operation and quality assurance of UK hospital aseptic preparation services This new edition of Quality Assurance of Aseptic Preparation Services provides information and up to date national guidance on unlicensed aseptic preparation. Although it is primarily intended for the use of non-licensed UK hospital pharmacies, it will also be of use in licensed units and other countries and institutions. Aseptic services include the preparation of parenteral nutrition solutions (PN), cytotoxics, radiopharmaceuticals, additives for parenteral administration and intrathecals Since the publication of the Breckenridge report in 1976, which recommended that drug additions to intravenous (IV) infusions should be made in hospital pharmacy departments and not on wards, there has been a substantial increase in hospital pharmacy departments providing aseptic preparation services

Visible and Subvisible Particles in Parenteral Products CRC Press

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.

Quality Assurance of Aseptic Preparation Services Pergamon

Asceptic Pharmaceutical Manufacturing II explores the sophisticated technology, developments, and applications that allow aseptic processing to approach the sterility levels achieved with terminal sterilization. Written by experts in sterile manufacturing, this book covers aseptic technology, developments, and applications and makes a valuable contribution to understanding the issues involved in aseptic manufacture. Topics include the processing of biopharmaceuticals, lyophilization, personnel training, radiopharmaceuticals, hydrogen peroxide vapor sterilization, regulatory requirements, validation, and quality systems.

Federal Register CRC Press

Pharmaceutical Quality by Design: Principles and Applications discusses the Quality by Design (QbD) concept implemented by regulatory agencies to ensure the development of a consistent and high-quality pharmaceutical product that safely provides the maximum therapeutic benefit to patients. The book walks readers through the QbD framework by covering the fundamental principles of QbD, the current regulatory requirements, and the applications of QbD at various stages of pharmaceutical product development, including drug substance and excipient development, analytical development, formulation development, dissolution testing, manufacturing, stability studies, bioequivalence testing, risk and assessment, and clinical trials. Contributions from global leaders in QbD provide specific insight in its application in a diversity of pharmaceutical products, including nanopharmaceuticals, biopharmaceuticals, and vaccines. The inclusion of illustrations, practical examples, and case studies makes this book a useful reference guide to pharmaceutical scientists and researchers who are engaged in the formulation of various delivery systems and the analysis of pharmaceutical product development and drug manufacturing process. Discusses vital QbD precepts and fundamental aspects of QbD implementation in the pharma, biopharma and biotechnology industries Provides helpful illustrations, practical examples and research case studies to explain QbD concepts to readers Includes contributions from global leaders and experts from academia, industry and regulatory agencies

Fundamentals of Nuclear Pharmacy Springer Science & Business

Media
This up-to-the-minute reference delineates-in a systematic fashion-the appropriate, sequential steps for the formulation of safe, effective, stable, and marketable liquid parenteral biopharmaceutical products-covering fundamentals and essential pathways for each phase as well as its purpose, function, and relation to other stages in the product development process. Written by experts currently involved in state-of-the-art advances in the pharmaceutical drug industry, Development of Biopharmaceutical Parenteral Dosage Forms details biopharmaceuticals that are licensed or undergoing clinical development, including genetically engineered cell and engineered vectors in the fermentation process describes purification and characterization techniques for rDNA therapeutics, discussing several types of unit operations for isolation, purification, and characterization considers preformulation and formulation requirements, such as physicochemical properties, drug delivery, stability studies programs, deactivation/denaturation routes, selection of compatible excipients, and regulatory compliance elucidates basics of analytical techniques, methods development, separation methods using chromatographic and electrophoretic techniques, and bioactivity methods covering bioassays and immunoassays for quantifying the stability of biological activity shows how to select the appropriate filter for maximizing compatibility and minimizing adsorption and inactivation, examining topics from basic filtration theories to future trends reviews the selection process for compatible elastomeric closures, analyzing physical, chemical, toxicological properties, protein adsorption on elastomeric surfaces, strategies to reduce/eliminate adsorption, and specialized containers for biotechnological applications and more! Furnished with helpful references, tables, and drawings, this practical guide is indispensable for pharmaceutical, medicinal, and protein chemists; molecular biologists; process engineers; purification scientists; biopharmaceutical and pharmaceutical formulators and product developers; quality control, quality assurance, and regulatory compliance personnel; and upper-level undergraduate and graduate students in these disciplines.
Quality Control in the Manufacture of Parenteral Solutions Pharmaceutical Press

It is therefore obvious that good patient management necessitates the use of an alternative route of nutritional support in patients unable to eat or absorb an oral diet. This alternative is parenteral nutrition, which is the subject of this book. While there are many texts on the subject of parenteral nutrition, very few if any are directed to the practical details of organizing the delivery of parenteral nutrition from a multidisciplinary point of view. In this publication we present the practice of parenteral nutrition as viewed by a team of a physician, nurse, and pharmacist.
Quality Assurance of Pharmaceuticals Food & Agriculture Org.
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 stabi
Parenteral Products CRC Press
Parenteral Products: The Preparation and Quality Control of Products for Injection deals with modern pharmaceutical practice in the preparation, quality control, and storage of injectable drug solutions. The book gives a basic background of parenteral solutions, the routes of administration, the effects of the different administrations of injection solutions, and the formulation of these products.
Parenteral Quality Control CRC Press
In this era of biotechnology there have been many books covering the fundamentals of recombinant DNA technology and protein chemistry. However, not many sources are available for the pharmaceutical develop ment scientist and other personnel responsible for the commercialization of the finished dosage forms of these new biopharmaceuticals and other products from biotechnology. This text will help to fill this gap. Once active biopharmaceutical molecules are candidates for clinical trial investigation and subsequent commercialization, a number of other activities must take place while research and development on these molecules continues. The active ingredient itself must be formulated into a finished dosage form that can be conveniently used by health care professionals and patients. Properties of the biopharmaceutical molecule must be clearly understood so that the appropriate finished product formulation can be developed. Finished product formulation development includes not only the chemical formulation, but also the packaging system, the manufacturing process, and appropriate control strategies to assure such good manufacturing practice attributes as safety, identity, strength, purity, and quality.
Quality Control of Veterinary Vaccines in Developing Countries Lippincott Williams & Wilkins
Quality assurance of pharmaceutical products is a continuing concern of WHO. Despite efforts made around the world to ensure a supply of quality and effective medicines, substandard, spurious and counterfeit products still compromise health care delivery in many countries. To respond to the global need for adequate quality assurance of pharmaceuticals, WHO's Expert Committee on Specifications for Pharmaceutical Preparations has over the years made numerous recommendations to establish standards and guidelines and to promote the effective functioning of national regulatory and control systems and the implementation of internationally agreed standards by trained personnel. Many of the relevant documents endorsed by the Committee are reproduced in this volume providing guidance covering all aspects of good manufacturing practices (GMP). Important texts on inspection are also included. Most of the material has been published separately in the Expert Committee's reports. This compendium brings it together to make it more accessible and of greater practical value to those working in faculties of pharmacy, in medicines regulation and control and in the pharmaceutical industry. This is the second updated edition of the compendium and includes texts published in 2005 and 2006 in the WHO Technical Report Series.
A Protocol for the Quality Control (tests and Assays) of Selected Toronto General Hospital Manufactured Parenteral Products CRC Press
Concepts in Sterile Preparations and Aseptic Technique examines the current standards and best practices for sterile compounding, along with the fundamentals of aseptic technique, in a manner accessible to pharmacy and pharmacy technician students and professionals. Beginning with a review of foundational calculations and microbiological considerations, this resource reviews compatibility, stability, engineering controls, and quality assurance and control, with pertinent information from USP Chapter incorporated throughout. With engaging case studies, tips, alerts, and accompanying video tutorials, this text facilitates

student learning through a robust companion website for students as well as helpful instructor resources. Video Tutorial Topics and Procedures: HLFW Cleaning, Hand Washing, Garbing, Sterile Glove, Attaching Needle to Syringe, Accessing a Vial, Equal Pressure (Milking), Equal Pressure (Reverse Milking), Removal of Air Bubbles, Ampule Breaking, Using a Filter Needle, Using a Filter Straw, Reconstituting a Vial, Uncapping and Recapping a Needle, Capping a Syringe, Priming Infusion Set, Positive Pressure, Negative Pressure, Workflow, Incompatibility, Fingertip Testing Instructor Resources: Instructor's Manual including Lab Activities and Supply List, Answer Key for Review Questions and Case Studies, PowerPoint Presentations with 375 slides, Test Bank with 189 Multiple Choice, Fill-in-the-Blank, and Short Answer questions. Student Resources: Navigate Companion Website, including: Videos, Quizzes, Interactive Glossary, Interactive Flashcards, Crossword Puzzles, Matching Exercises, Web Links Each new text includes an online access code to the Navigate Companion Website. Electronic and eBook formats may not include access to the Navigate Companion Website. Access may also be purchased separately.

Aseptic Pharmaceutical Manufacturing II CRC Press

Pharmaceutical Dosage Forms: Parenteral Medications explores the administration of medications through other than the enteral route. First published in 1984 (as two volumes) and then last revised in 1993, this three-volume set presents the plethora of changes in the science and considerable advances in the technology associated with these products

Development and Manufacture of Protein Pharmaceuticals CRC Press

Quality Assurance of Aseptic Preparation Services Standards Handbook (also known as the Yellow Guide) provides standards for unlicensed aseptic preparation in the UK, as well as practical information to aid implementation of the standards. The handbook delivers essential standards in a practical way and in a format that will be useful for pharmacy management, staff working in aseptic preparation units and those whose role it is to audit the services. The accompanying support resources help with understanding the complexities of relevant topics including microbiology, radiopharmaceuticals, advanced therapy medicinal products, technical (quality) agreements and capacity planning. All the standards have been revised and updated for this 5th edition. The text is produced on behalf of the Royal Pharmaceutical Society (RPS) and the NHS Pharmaceutical Quality Assurance Committee. New in this edition: Replaces the 4th edition standards and forms the basis for an ongoing audit program in the NHS Many new and revised standards Greater emphasis on Pharmaceutical Quality Systems; the responsibilities of pharmacy management, Chief Pharmacists (or equivalent), has been expanded in line with developments in Good Manufacturing Practice Reformatted into 2 parts: standards and support resources. This is a new collaboration between the RPS and NHS. Since the previous edition the RPS has become the professional body for pharmacists and pharmaceutical scientists. RPS launched these standards as part of a library of professional standards and a programme of work to create standards for all areas of pharmacy. The Handbook is essential for pharmacists, hospital pharmacy management and technical services teams, and auditors of unlicensed NHS hospital pharmacy aseptic preparation services in the UK, pharmacists and regulators. The text is used to inform standards used in several other countries.

Concepts in Sterile Preparation and Aseptic Technique (book) CRC Press

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.