Parenteral Quality Control

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Parenteral Quality Control National Academies 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.
GMP in Practice Springer Science & Business Media
First multi-year cumulation covers six years: 1965-70.
Quality Assurance of Aseptic Preparation Services Springer Science & Business Media
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.

Sterile Product Development John Wiley & Sons

EXTRACTABLES AND LEACHABLES Learn to address the safety aspects of packaged drug products and medical devices Pharmaceutical drug products and medical devices are expected to be effective and safe to use. This includes minimizing patient, user or product exposure to impurities leached from these items when the drug product is administered or when the medical device is used. Clearly, patient or user exposure to leachables must not adversely impact their health and safety. Furthermore, these impurities must not adversely affect key quality attributes of the drug product or medical device, including its manufacturability, stability, efficacy, appearance, shelf-life and conformance to standards. Extractables and leachables are derived from the drug product's packaging, manufacturing systems and/or delivery systems or from the medical device's materials of construction. It is imperative to understand and quantify the release of extractables from these items, the accumulation of leachables in drug products and the release of leachables from medical devices. Once extractables and leachables have been discovered, identified and quantified, their effect on the key product or device quality attributes, including safety, must be systematically and scientifically established according to recognized, rigorous and relevant regulatory and compendial standards and industry-driven best practices. In Extractables and Leachables, the chemical compatibility (including safe use) of drugs (and their containers, delivery devices and manufacturing systems) and medical devices is examined at length, focusing particularly on how trace-level extractables and leachables affect the quality and safety of a medical product and how to assess the magnitude of the effect. This is accomplished by addressing the two critical activities required to develop, register and commercialize safe, effective and affordable clinical therapies; measuring extractables and leachables (chemical characterization) and assessing their impact (for example, toxicological safety risk assessment). Each of these activities is addressed in-depth, based on the existing and developing international regulations and guidelines, current published literature and the author's extensive personal experience. Written by a key contributor to standards, guidelines, recommended practices and the scientific literature, the book provides "insider" insights beyond those gained by merely reading the relevant texts. Given that the rapidly evolving extractables and leachables landscape, this book provides the most current and crucial information on new and forthcoming regulations and best practices. Extractables and Leachables readers will also find: A thorough summary of regulatory and compendial guidelines and the steps required to meet them A detailed and in-depth review of essential scientific principles and recommended best practices for the design, implementation, interpretation and reporting of chemical characterization studies A practical resource for optimizing the development, registration, and commercialization of safe and effective medical products A helpful tool to maximize product development and successful regulatory outcomes Extractables and Leachables is the essential reference for pharmaceutical scientists, analytical chemists, regulatory affairs professionals, engineers, and toxicologists in areas such as product research and development, product registration and approval, regulatory affairs, analytical science, quality control, and manufacturing.

Practical Pharmaceutics Pharmaceutical 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.

Laboratory Manual of Pharmaceutics Cambridge University 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

Medication Safety ASHP

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 Elsevier

This reference surveys emerging trends, concepts, and procedures used in the characterization and control of contaminants; the sterile production of traditional drugs and biologics; the design, construction, and validation of new parenteral facilities; and the monitoring of clean environments-vividly illustrating the routes by which products, proce

Competence Assessment Tools for Health-System Pharmacies Academic Press

Relying on practical examples from the authors' experience, this book provides a thorough and modern approach to controlling and monitoring microbial contaminations during the manufacturing of non-sterile pharmaceuticals. Offers a comprehensive guidance for non-sterile pharmaceuticals microbiological QA/QC Presents the latest developments in both regulatory expectations and technical advancements Provides guidance on statistical tools for risk assessment and trending of microbiological data Describes strategy and practical examples from the authors' experience in globalized pharmaceutical companies and expert networks Offers a comprehensive guidance for non-sterile pharmaceuticals microbiological QA/QC Presents the latest developments in both regulatory expectations and technical advancements Provides guidance on statistical tools for risk assessment and trending of microbiological data Describes strategy and practical examples from the authors' experience in globalized pharmaceutical companies and expert networks

Extractables and Leachables CRC Press

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

Concepts in Sterile Preparation and Aseptic Technique (book) David Horwood International Pub Limited

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

Parenteral Quality Control Trinity Publishing House, Satara

Principles of Parenteral Solution Validation: A Practical Lifecycle Approach covers all aspects involved in the development and process validation of a parenteral product. By using a lifecycle approach, this book discusses the latest technology, compliance developments, and regulatory considerations and trends, from process design, to divesting. As part of the Expertise in Pharmaceutical Process Technology series edited by Michael Levin, this book incorporates numerous case studies and real-world examples that address timely problems and offer solutions to the daily challenges facing practitioners in this area. - Discusses international and domestic regulatory considerations in every section - Features callout boxes that contain points-of-interest for each segment of the audience so readers can quickly find their interests and needs - Contains important topics, including risk management, the preparation and execution of properly designed studies, scale-up and technology transfer activities, problem-solving, and more

Quality Assurance of Aseptic Preparation Services ASHP

This book describes how to address the analysis of aggregates and particles in protein pharmaceuticals, provides a comprehensive overview of current methods and integrated approaches used to quantify and characterize aggregates and particles, and discusses regulatory requirements. Analytical methods covered in the book include separation, light scattering, microscopy, and spectroscopy.

Current Catalog CRC Press

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.

Pharmaceutical Dosage Forms CRC Press

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

Guideline on General Principles of Process Validation 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
Principles of Parenteral Solution Validation Pergamon
A practical guide to Quality by Design for pharmaceutical product development Pharmaceutical Quality by Design: A Practical Approach outlines a new and proven approach to pharmaceutical product development which is now being rolled out across the pharmaceutical industry internationally. Written by experts in the field, the text explores the QbD approach to product development. This innovative approach is based on the application of product and process understanding underpinned by a systematic methodology which can enable pharmaceutical companies to ensure that quality is built into the product. Familiarity with Quality by Design is essential for scientists working in the pharmaceutical industry. The authors take a practical approach and put the focus on the industrial aspects of the new QbD approach to pharmaceutical product development and manufacturing. The text covers quality risk management tools and analysis, applications of QbD to analytical methods, regulatory aspects, quality systems and knowledge management. In addition, the book explores the development and manufacture of drug substance and product, design of experiments, the role of excipients, multivariate analysis, and include several examples of applications of QbD in actual practice. This important resource: Covers the essential information about Quality by Design (QbD) that is at the heart of modern pharmaceutical development Puts the focus on the industrial aspects of the new QbD approach Includes several illustrative examples of applications of QbD in practice Offers advanced specialist topics that can be systematically applied to industry Pharmaceutical Quality by Design offers a guide to the principles and application of Quality by Design (QbD), the holistic approach to manufacturing that offers a complete understanding of the manufacturing processes involved, in order to yield consistent and high quality products.

Pharmaceutical Dosage Forms - Parenteral Medications CRC Press
This book contains essential knowledge on the preparation, control, logistics, dispensing and use of medicines. It features chapters written by experienced pharmacists working in hospitals and academia throughout Europe, complete with practical examples as well as information on current EU-legislation. From prescription to production, from usage instructions to procurement and the impact of medicines on the environment, the book provides step-by-step coverage that will help a wide range of readers. It offers product knowledge for all pharmacists working directly with patients and it will enable them to make the appropriate medicine available, to store medicines properly, to adapt medicines if necessary and to dispense medicines with the appropriate information to inform patients and caregivers about product care and how to maintain their quality. This basic knowledge will also be of help to industrial pharmacists to remind and focus them on the application of the medicines manufactured. The basic and practical knowledge on the design, preparation and quality management of medicines can directly be applied by the pharmacists whose main duty is production in community and hospital pharmacies and industries. Undergraduate as well as graduate pharmacy students will find knowledge and backgrounds in a fully coherent way and fully supported with examples.
Sterile Drug Products Springer
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
Quality Control CRC Press
Providing a well-written and easy-to-read review of the subject, this reference describes the most recent breakthroughs in the validation and execution of testing schemes for parenteral quality control. Emphasize testing methodologies for the evaluation of package integrity, finished product contamination, and sterility, the book is a guide to test