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MCKEE MARQUES

Pharmaceutical Dosage Forms - Parenteral Medications CRC Press
This handbook is the first to cover all aspects of stability testing in pharmaceutical development. Written by a group of international experts, the book presents a scientific understanding of regulations and balances methodologies and best practices.
Process Validation in Manufacturing of Biopharmaceuticals John Wiley & Sons
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.
Parenteral Medications, Fourth Edition CRC Press
Pharmaceutical Technology – Concepts and Applications articulates on the various pharmaco-technological concepts associated with industrial pharmacy. The book not only focuses on providing comprehensive information on formulation development and affiliated areas but also emphasizes on their industrial applications. With a plethora of examples that illustrate important concepts, the book equips students of pharmacy to rise to the requirements of the industry.
Handbook of Pharmaceutical Analysis by HPLC John Wiley & Sons
This three-volume set of Pharmaceutical Dosage Forms: Parenteral Medications is an authoritative, comprehensive reference work on the formulation and manufacture of parenteral dosage forms, effectively balancing theoretical considerations with the practical aspects of their development. As such, it is recommended for scientists and engineers in the pharmaceutical industry and academia, and will also serve as an excellent reference and training tool for regulatory scientists and quality assurance professionals. First published in 1984 (as two volumes) and then last revised in 1993 (when it grew to three volumes), this latest revision will address the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration. The third edition of this book maintains the features that made the last edition so popular but comprises several brand new chapters, revisions to all other chapters, as well as high quality illustrations. Volume two presents: • Chapters on aseptic facility design, environmental monitoring, and cleanroom operations. • A comprehensive chapter on pharmaceutical water systems. • A discussion of quality attributes of sterile dosage forms, including particulate matter, endotoxin, and sterility testing. • A detailed chapter on processing of parenteral drug products (SVPs and LVPs). • Presentations on widely used sterilization technologies – steam, gas / chemical, radiation, filtration and dry heat. • An in-depth chapter on lyophilization.
The ASQ Certified Medical Device Auditor Handbook CRC Press
While FDA regulations, cGMP, GLP, GCP, and the industry standard ISO 9000 require that documentation be established and followed, they do not provide guidelines on how to produce that documentation. Pharmaceutical Equipment Validation gives details on how to demonstrate compliance, what data to use, and how to produce the appropriate documentation. This book's user-friendly diagrams and other clear graphics illustrate key ideas throughout each protocol, offering a bird's-eye view of what is coming next-and they quickly guide you through the equipment validation. The author provides a thorough understanding of how to prepare, test, and complete equipment qualification protocols.

He also explains how to perform qualification testing and whether to test the equipment for a worst case scenario. No other book deals exclusively with the key issues of equipment qualification and process validation for pharmaceutical process equipment- and provides instructions on how to achieve it. With pragmatic approach, this book includes 38 useful protocol templates, already completed, that provide instant answers to most protocol writing and testing questions. These templates cover specific equipment types, such, and provide accurate, industry acceptable equipment qualification protocols. Step-by-step, they show how to qualify each piece of equipment, and they provide a check for readers own protocols.

Pharmaceutical Microbiology Manual Frontiers Media SA

Equipment Qualification in the Pharmaceutical Industry provides guidance and basic information for the preparation of a quality qualification program. It has been noted that there is a general lack of understanding in the industry, especially for those new to the industry, as to what constitutes a compliant qualification program. Even experienced professionals have felt a lack of security in reaching a compliant state. This book outlines a guideline for the preparation and execution of qualification protocols including the installation (IQ), operational (OQ), and performance (PQ) protocols. It discusses the importance of related qualification programs (e.g., quality systems, commissioning, computer system, and cleaning) and how to incorporate them into a fully compliant qualification program. Furthermore, it provides matrices of what could be included in each type of protocol for major types of process equipment. While primarily for people entering the pharmaceutical industry, those established in the field will benefit from the multiple examples and matrices as well as integration of related systems. Equipment Qualification in the Pharmaceutical Industry provides students and pharmaceutical scientists a guideline for the preparation and execution of qualification (installation, operational, and performance) protocols. Incorporates good manufacturing processes into a compliant qualification program Provides examples of protocol layout Includes matrices for major process equipment, installation quality, operational quality, and performance quality requirements

Vaccines E-Book CRC Press

This revision brings the reader completely up to date on the evolving methods associated with increasingly more complex sample types analyzed using high-performance liquid chromatography, or HPLC. The book also incorporates updated discussions of many of the fundamental components of HPLC systems and practical issues associated with the use of this analytical method. This edition includes new or expanded treatments of sample preparation, computer assisted method development, as well as biochemical samples, and chiral separations.

Carbon Bridge to the Arctic Createspace Independent Publishing Platform

This book provides a detailed account of the most recent developments, challenges and solutions to seamlessly advance and launch a lyophilized biologics or vaccine product, based on diverse modalities, ranging from antibodies (e.g., monoclonal, fused), complex biologics (e.g., antibody drug conjugate, PEGylated proteins), and vaccines (e.g., recombinant-protein

based). The authors adeptly guide the reader through all crucial aspects, from biophysical and chemical stability considerations of proteins, analytical methods, advances in controlled ice nucleation and quality-by-design approaches, alternate drying technology, to latest regulatory, packaging and technology transfer considerations to develop a stable, safe and effective therapeutic protein, vaccine and biotechnology products. Lyophilized Biologics and Vaccines: Modality-Based Approaches is composed of four sections with a total of 17 chapters. It serves as a reference to all critical assessments and steps from early pre-formulation stages to product launch: Provides recent understanding of heterogeneity of protein environment and selection of appropriate buffer for stabilization of lyophilized formulations Details the latest developments in instrumental analysis and controlled ice nucleation technology Explains in-depth lyophilized (or dehydrated) formulation strategies considering diverse modalities of biologics and vaccines, including plasmid DNA and lipid-based therapeutics Details an exhaustive update on quality-by-design and process analytical technology approaches, illustrated superbly by case studies and FDA perspective Provides the latest detailed account of alternate drying technologies including spray drying, bulk freeze-drying and crystallization, supported exceptionally by case studies Provides a step-by-step guide through critical considerations during process scale-up, technology transfer, packaging and drug delivery device selection, for a successful lyophilization process validation, regulatory submission and product launch Chapters are written by one or more world-renowned leading authorities from academia, industry or regulatory agencies, whose expertise cover lyophilization of the diverse modalities of biopharmaceuticals. Their contributions are based on the exhaustive review of literature coupled with excellent hands-on experiences in laboratory or GMP setup, making this an exceptional guide to all stages of lyophilized or dehydrated product development.

Handbook of Pharmaceutical Manufacturing Formulations John Wiley & Sons

The ASQ Certified Medical Device Auditor Handbook (formerly The Biomedical Quality Auditor Handbook) was developed by the ASQ Medical Device Division (formerly Biomedical Division) in support of its mission to promote the awareness and use of quality principles, concepts, and technologies in the medical device community. It principally serves as a resource to candidates preparing for the Certified Medical Device Auditor (CMDA) certification exam. The fourth edition of this handbook has been reorganized to align with the 2020 certification exam Body of Knowledge (BoK) and reference list. The combination of this handbook with other reference materials can provide a well-rounded background in medical device auditing. Updates to this edition include: • A discussion of data privacy, data integrity principles, and the Medical Device Single Audit Program (MDSAP) • Current information about federal and international regulations • New content regarding human factors and usability engineering, general safety and performance requirements, labeling, validation, risk management, and cybersecurity considerations • A thorough explanation of quality tools and techniques

Handbook of Validation in Pharmaceutical Processes,

Fourth Edition Springer Science & Business Media
The legislative requirement for cannabis to undergo laboratory testing has followed legalization of medical and recreational use in every U.S. state to date. Cannabis safety testing is a new investment opportunity within the emerging cannabis market that is separate from cultivation, processing, and distribution, allowing individuals and organizations who may have been reluctant to enter previously a new entry route to the cannabis space. However, many of the costs, timelines, operational requirements, and compliance issues are overlooked by people who have not been exposed to regulated laboratory testing. Cannabis Laboratory Fundamentals provides an in-depth review of the key issues that impact cannabis testing laboratories and provides recommendations and solutions to avoid common – but expensive – mistakes. The text goes beyond methodology to include sections on economics, regulation, and operational challenges, making it useful for both new and experienced cannabis laboratory operators, as well as all those who want to understand the opportunities and risks of this industry.
Thomas Register of American Manufacturers and Thomas Register Catalog File CRC Press
Vols. for 1970-71 includes manufacturers catalogs.
Veterinary and Human Toxicology Elsevier
Validation describes the procedures used to analyze pharmaceutical products so that the data generated will comply with the requirements of regulatory bodies of the US, Canada, Europe and Japan. Calibration of Instruments describes the process of fixing, checking or correcting the graduations of instruments so that they comply with those regulatory bodies. This book provides a thorough explanation of both the fundamental and practical aspects of biopharmaceutical and bioanalytical methods validation. It teaches the proper procedures for using the tools and analysis methods in a regulated lab setting. Readers will learn the appropriate procedures for calibration of laboratory instrumentation and validation of analytical methods of analysis. These procedures must be executed properly in all regulated laboratories, including pharmaceutical and biopharmaceutical laboratories, clinical testing laboratories (hospitals, medical offices) and in food and cosmetic testing laboratories.
Capillary Electrophoresis Methods for Pharmaceutical Analysis Springer
This handbook provides an in-depth review of information across the developmental spectrum of gene and cell therapy products. From introductory information to state-of-the-art technologies and concepts, the book provides insights into upstream processes such as vector design and construction, purification, formulation and fill/finish, as well as delivery options. Planning steps for compliance with current good manufacturing practice (cGMP) to readiness for chemistry, manufacturing and controls (CMC) are also discussed. This book wraps up with examples of successes and pitfalls addressed by experts who have navigated the multiple challenges that are part of any innovative endeavor. Features Provides the most up-to-date information on the development of gene therapy, from the technology involved to gene correction and genome editing Discusses siRNA, mRNA, and plasmid manufacturing Describes the importance of supplier-sponsor synergies on the path to commercialization Written for a

diverse audience with a large number of individuals in the core technologies and supportive practices It is intended as a one-stop resource for the availability of state-of-the-art information related to cell and gene therapy products for researchers, scientists, management and other academic and research institutions.

ASHRAE Handbook Academic Press

This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.

Principles of Parenteral Solution Validation Elsevier

The preparation of sterile products using aseptic processing is considered perhaps the most critical process in the pharmaceutical industry and has witnessed continual improvement over the last half century. New approaches that have transformed classical aseptic production methods are appearing almost daily. This book reviews emerging technologies for aseptic processing that will markedly reduce the level of contamination risk for sterile products and includes coverage on: The use of isolator and barrier concepts for aseptic processing and assembly. The application of robotics as an alternative to gowned personnel. The increasing reliance on automation to minimize or eliminate operator intervention. The design, operational, monitoring and compliance changes necessary for success with advanced aseptic processing. Advanced Aseptic Processing Technology is an essential reference for anyone working with sterile products, and is recommended for individuals in manufacturing,, compliance, regulatory affairs, microbiology, environmental monitoring, sterility testing, sterilization, validation, engineering, development, facility and equipment design, component and equipment suppliers, automation, and robotics.

Guidance for Preparing Standard Operating Procedures (SOPs). Quality Press

Spanning every critical element of validation for any pharmaceutical, diagnostic, medical device or equipment, and biotech product, this Second Edition guides readers through each step in the correct execution of validating processes required for non-aseptic and aseptic pharmaceutical production. With 14 exclusive environmental performance evaluati

Equipment Qualification in the Pharmaceutical Industry CRC Press

High pressure liquid chromatography–frequently called high performance liquid chromatography (HPLC or, LC) is the premier analytical technique in pharmaceutical analysis and is predominantly used in the pharmaceutical industry. Written by selected experts in their respective fields, the Handbook of Pharmaceutical Analysis by HPLC Volume 6, provides a complete yet concise reference guide for utilizing the versatility of HPLC in drug development and quality control. Highlighting novel approaches in HPLC and the latest developments in hyphenated techniques, the book captures the essence of major pharmaceutical applications (assays, stability testing, impurity testing, dissolution testing, cleaning validation, high-throughput

screening). A complete reference guide to HPLC Describes best practices in HPLC and offers 'tricks of the trade' in HPLC operation and method development Reviews key HPLC pharmaceutical applications and highlights currents trends in HPLC ancillary techniques, sample preparations, and data handling

Guideline on Sterile Drug Products Produced by Aseptic Processing John Wiley & Sons

Apply the latest vaccination knowledge with a reference that Bill Gates calls "an indispensable guide to the enhancement of the well-being of our world." Inside Vaccines, you'll find comprehensive and current coverage of every aspect of vaccination, from the development of each vaccine to its use in reducing disease. This medical reference book offers the expert information you need to apply the very latest techniques and information in your practice! Consult this title on your favorite e-reader, conduct rapid searches, and adjust font sizes for optimal readability. Gain a complete understanding of each disease, including clinical characteristics, microbiology, pathogenesis, diagnosis, and treatment, as well as epidemiology and public health and regulatory issues. Update your knowledge of both existing vaccines and vaccines currently in the research and development stage. Get complete answers on each vaccine, including its stability, immunogenicity, efficacy, duration of immunity, adverse events, indications, contraindications, precautions, administration with other vaccines, and disease-control strategies. Analyze the cost-benefit and cost-effectiveness of different vaccine options. Clearly visualize concepts and objective data through an abundance of tables and figures. Make optimal use of the latest vaccines for pneumococcal disease, rotavirus, human papillomavirus, herpes zoster, meningococcal disease, and much more. Stay at the forefront of new developments with completely updated chapters on malaria and HIV vaccines, a new chapter on vaccine regulations across the world, and many other revisions throughout.

HPLC and UHPLC for Practicing Scientists Frontiers Media SA

Manual and is a supplement to the United States Pharmacopeia (USP) for pharmaceutical microbiology testing, including antimicrobial effectiveness testing, microbial examination of non-sterile products, sterility testing, bacterial endotoxin testing, particulate matter, device bioburden and environmental monitoring testing. The goal of this manual is to provide an ORA/CDER harmonized framework on the knowledge, methods and tools needed, and to apply the appropriate scientific standards required to assess the safety and efficacy of medical products within FDA testing laboratories. The PMM has expanded to include some rapid screening techniques along with a new section that covers inspectional guidance for microbiologists that conduct team inspections. This manual was developed by members of the Pharmaceutical Microbiology Workgroup and includes individuals with specialized experience and training. The instructions in this document are guidelines for FDA analysts. When available, analysts should use procedures and worksheets that are standardized and harmonized across all ORA field labs, along with the PMM, when performing analyses related to product testing of pharmaceuticals and medical devices. When changes or deviations are necessary, documentation should be completed per the laboratory's Quality Management System. Generally, these changes should originate from situations such as new

products, unusual products, or unique situations. This manual was written to reduce compendia method ambiguity and increase standardization between FDA field laboratories. By providing clearer instructions to FDA ORA labs, greater transparency can be provided to both industry and the public. However, it should be emphasized that this manual is a supplement, and does not replace any information in USP or applicable FDA official guidance references. The PMM does not relieve any person or laboratory from the responsibility of ensuring that the methods being employed from the manual are fit for use, and that all testing is validated and/or verified by the user. The PMM will continually be revised as newer products, platforms and technologies emerge or any significant scientific gaps are identified with product testing. Reference to any commercial materials, equipment, or process in the PMM does not in any way constitute approval, endorsement, or recommendation by the U.S. Food and Drug Administration.

Quality Assurance of Aseptic Preparation Services CRC Press

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