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Formulation and Analytical Development for Low-Dose Oral Drug Products - Jack Zheng 2009-02-09
There are unique challenges in the formulation, manufacture, analytical chemistry, and regulatory requirements of low-dose drugs. This book provides an overview of this specialized field and combines formulation, analytical, and regulatory aspects of low-dose development into a single reference book. It describes analytical methodologies like dissolution testing, solid state NMR, Raman microscopy, and LC-MS and presents manufacturing techniques such as granulation, compaction, and compression. Complete with case studies and a discussion of regulatory requirements, this is a core reference for pharmaceutical scientists, regulators, and graduate students.

A Prescription for Success in Pharmaceuticals: Transforming a Startup into a Profitable, Cash-Producing Enterprise - Barrie Levitt

Process Validation in Manufacturing of Biopharmaceuticals - Anurag S. Rathore 2012-05-09
Process Validation in Manufacturing of Biopharmaceuticals, Third Edition delves into the key aspects and current practices of process validation. It includes discussion on the final version of the FDA 2011 Guidance for Industry on Process Validation Principles and Practices, commonly referred to as the Process Validation Guidance or PVG, issued in **GAMP 5** - 2008

Pharmaceutical Dosage Forms - Sandeep Nema 2010-08-26
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

Manufacturing of Quality Oral Drug Products - Sam A. Hout 2022-07-07
This book provides an understanding of what is required to engineer and manufacture drug products. It bridges established concepts and provides for a new outlook by concentrating and creating new linkages in the implementation of manufacturing, quality assurance, and business practices related to drug manufacturing and healthcare products. This book fills a gap by providing a connection between drug production and regulated applications. It focuses on drug manufacturing, quality techniques in oral solid dosage, and capsule filling including equipment and critical systems, to control production and the finished products. The book offers a correlation between design strategies and a step-by-step process to ensure the reliability, safety, and efficacy of healthcare products. Fundamentals of techniques, quality by design, risk assessment, and management are covered along with a scientific method approach to continuous improvement in the usage of computerized manufacturing and dependence on information technology and control operations through data and metrics. Manufacturing and Quality Assurance of Oral Pharmaceutical Products: Processing and Safe Handling of Active Pharmaceutical Ingredients (API) is of interest to professionals and engineers in the fields of manufacturing engineering, quality assurance, reliability, business management, process, and continuous improvement, life cycle management, healthcare products manufacturing, pharmaceutical processing, and computerized manufacturing.

Handbook of Analytical Quality by Design - Sarwar Beg 2021-01-09

Handbook of Analytical Quality by Design addresses the steps involved in analytical method development and validation in an effort to avoid quality crises in later stages. The AQbD approach significantly enhances method performance and robustness which are crucial during inter-laboratory studies and also affect the analytical lifecycle of the developed method. Sections cover sample preparation problems and the usefulness of the QbD concept involving Quality Risk Management (QRM), Design of Experiments (DoE) and Multivariate (MVT) Statistical Approaches to solve by optimizing the developed method, along with validation for different techniques like HPLC, UPLC, UFLC, LC-MS and electrophoresis. This will be an ideal resource for graduate students and professionals working in the pharmaceutical industry, analytical chemistry, regulatory agencies, and those in related academic fields. Concise language for easy understanding of the novel and holistic concept Covers key aspects of analytical development and validation Provides a robust, flexible, operable range for an analytical method with greater excellence and regulatory compliance

Freeze-Drying - Peter Haseley 2018-05-07
This completely updated and enlarged third edition of the classic text adopts a practical approach to describe the fundamentals of freeze-drying, backed by many explanatory examples. Following an introduction to the fundamentals, the book goes on to discuss process and plant automation as well as methods to transfer pilot plant qualifications and process data to production. An entire section is devoted to a large range of different pharmaceutical, biological, and medical products. New to this edition are chapters on antibodies, freeze-dry microscopy, TEMPRIS, microwave freeze-drying, spray freeze-drying, and PAT. Their many years of experience in freeze-drying enable the authors to supply valuable criteria for the selection of laboratory, pilot and production plants, discussing the advantages, drawbacks and limitations of different plant designs. Alongside guidelines for the evaluation and qualification of plants and processes, the author also includes a troubleshooting section.

Practical Pharmaceutical Engineering - Gary Prager 2018-11-28
A practical guide to all key the elements of pharmaceuticals and biotech manufacturing and design Engineers working in the pharmaceutical and biotech industries are routinely called upon to handle operational issues outside of their fields of expertise. Traditionally the competencies required to fulfill those tasks were achieved piecemeal, through years of self-teaching and on-the-job experience—until now. Practical Pharmaceutical Engineering provides readers with the technical information and tools needed to deal with most common engineering issues that can arise in the course of day-to-day operations of pharmaceutical/biotech research and manufacturing. Engineers working in pharma/biotech wear many hats. They are involved in the conception, design, construction, and operation of research facilities and manufacturing plants, as well as the scale-up, manufacturing, packaging, and labeling processes. They have to implement FDA regulations, validation assurance, quality control, and Good Manufacturing Practices (GMP) compliance measures, and to maintain a high level of personal and environmental safety. This book provides readers from a range of engineering specialties with a detailed blueprint and the technical knowledge needed to tackle those critical responsibilities with confidence. At minimum, after reading this book, readers will have the knowledge needed to constructively participate in contractor/user briefings. Provides pharmaceutical industry professionals with an overview of how all the parts fit together and a level of expertise that can take years of on-the-job experience to acquire Addresses topics not covered in

university courses but which are crucial to working effectively in the pharma/biotech industry. It fills a gap in the literature, providing important information on pharmaceutical operation issues required for meeting regulatory guidelines, plant support design, and project engineering. It covers the basics of HVAC systems, water systems, electric systems, reliability, maintainability, and quality assurance, relevant to pharmaceutical engineering. Practical Pharmaceutical Engineering is an indispensable "tool of the trade" for chemical engineers, mechanical engineers, and pharmaceutical engineers employed by pharmaceutical and biotech companies, engineering firms, and consulting firms. It also is a must-read for engineering students, pharmacy students, chemistry students, and others considering a career in pharmaceuticals.

Handbook of Validation in Pharmaceutical Processes, Fourth Edition - James Agalloco 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 biopharmaceutical 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.

Development and Validation of Analytical Methods - Christopher M. Riley 1996-05-29

The need to validate an analytical or bioanalytical method is encountered by analysts in the pharmaceutical industry on an almost daily basis, because adequately validated methods are a necessity for approvable regulatory filings. What constitutes a validated method, however, is subject to analyst interpretation because there is no universally accepted industry practice for assay validation. This book is intended to serve as a guide to the analyst in terms of the issues and parameters that must be considered in the development and validation of analytical methods. In addition to the critical issues surrounding method validation, this book also deals with other related factors such as method development, data acquisition, automation, cleaning validation and regulatory considerations. The book is divided into three parts. Part One, comprising two chapters, looks at some of the basic concepts of method validation. Chapter 1 discusses the general concept of validation and its role in the process of transferring methods from laboratory to laboratory. Chapter 2 looks at some of the critical parameters included in a validation program and the various statistical treatments given to these parameters. Part Two (Chapters 3, 4 and 5) of the book focuses on the regulatory perspective of analytical validation. Chapter 3 discusses in some detail how validation is treated by various regulatory agencies around the world, including the United States, Canada, the European Community, Australia and Japan. This chapter also discusses the International Conference on Harmonization (ICH) treatment of assay validation. Chapters 4 and 5 cover the issues and various perspectives of the recent United States vs. Barr Laboratories Inc. case involving the retesting of samples. Part Three (Chapters 6 - 12) covers the development and validation of various analytical components of the pharmaceutical product development process. This part of the book contains specific chapters dedicated to bulk drug substances and finished products, dissolution studies, robotics and automated workstations, biotechnology products, biological samples, analytical methods for cleaning procedures and computer systems and computer-aided validation. Each chapter goes into some detail describing the critical development and related validation considerations for each topic. This book is not intended to be a practical description of the analytical validation process, but more of a guide to the critical parameters and considerations that must be attended to in a pharmaceutical development program. Despite the existence of numerous guidelines including the recent attempts by the ICH to be implemented in 1998, the practical part of assay validation will always remain, to a certain extent, a matter of the personal

preference of the analyst or company. Nevertheless, this book brings together the perspectives of several experts having extensive experience in different capacities in the pharmaceutical industry in an attempt to bring some consistency to analytical method development and validation.

Sterile Manufacturing - SAM A. HOUT 2021-07-05

This book highlights key ideas and factors to coach and guide professionals involved in learning about Sterile Manufacturing and operational requirements. It covers regulations and guidelines instituted by the FDA, ISPE, EMA, MHRA and ICH emphasizing good manufacturing practice and inspection requirements in the manufacturing of medicinal products. Additionally, this book provides the fundamentals of aseptic techniques, quality by design, risk assessment, and management in support of sterile operations applications. It creates a link to the implementation of business practices in drug manufacturing and healthcare and forms a correlation between design strategies including a step-by-step process to ensure reliability, safety, and efficacy of healthcare products for human and animal use. The book also provides a connection between drug production and regulated applications by offering a review of the basic elements of sterile processing, and how to remain viable with solid strategic planning. The book is a concise reference for professionals and learners in the field of sterile operations that governs primarily, pharmaceutical and medical device space, but can also extend to food and cosmetics that require clean (aseptic) manufacturing applications. It also helps compounding pharmacists and GMP inspectors and auditors.

Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing - Hamid Mollah 2013-02-01

Sets forth tested and proven risk management practices in drug manufacturing. Risk management is essential for safe and efficient pharmaceutical and biopharmaceutical manufacturing, control, and distribution. With this book as their guide, readers involved in all facets of drug manufacturing have a single, expertly written, and organized resource to guide them through all facets of risk management and analysis. It sets forth a solid foundation in risk management concepts and then explains how these concepts are applied to drug manufacturing. Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing features contributions from leading international experts in risk management and drug manufacturing. These contributions reflect the latest research, practices, and industry standards as well as the authors' firsthand experience. Readers can turn to the book for: Basic foundation of risk management principles, practices, and applications. Tested and proven tools and methods for managing risk in pharmaceutical and biopharmaceutical product manufacturing processes. Recent FDA guidelines, EU regulations, and international standards governing the application of risk management to drug manufacturing. Case studies and detailed examples demonstrating the use and results of applying risk management principles to drug product manufacturing. Bibliography and extensive references leading to the literature and helpful resources in the field. With its unique focus on the application of risk management to biopharmaceutical and pharmaceutical manufacturing, this book is an essential resource for pharmaceutical and process engineers as well as safety and compliance professionals involved in drug manufacturing.

Sterile Processing of Pharmaceutical Products - Sam A. Hout 2022-01-26

Describes the methodologies and best practices of the sterile manufacture of drug products. Thoroughly trained personnel and carefully designed, operated, and maintained facilities and equipment are vital for the sterile manufacture of medicinal products using aseptic processing. Professionals in pharmaceutical and biopharmaceutical manufacturing facilities must have a clear understanding of current good manufacturing practice (cGMP) and preapproval inspection (PAI) requirements. Sterile Processing of Pharmaceutical Products: Engineering Practice, Validation, and Compliance in Regulated Environments provides up-to-date coverage of aseptic processing techniques and sterilization methods. Written by a recognized expert with more than 20 years of industry experience in aseptic manufacturing, this practical resource illustrates a comprehensive approach to sterile manufacturing engineering that can achieve drug manufacturing objectives and goals. Topics include sanitary piping and equipment, cleaning and manufacturing process validation, computerized automated systems, personal protective equipment (PPE), clean-in-place (CIP) systems, barriers and isolators, and guidelines for statistical procedure. Offering

authoritative guidance on the key aspects of sterile manufacturing engineering, this volume: Covers fundamentals of aseptic techniques, quality by design, risk assessment and management, and operational requirements Addresses various regulations and guidelines instituted by the FDA, ISPE, EMA, MHRA, and ICH Provides techniques for systematic process optimization and good manufacturing practice Emphasizes the importance of attention to detail in process development and validation Features real-world examples highlighting different aspects of drug manufacturing Sterile Processing of Pharmaceutical Products: Engineering Practice, Validation, and Compliance in Regulated Environments is an indispensable reference and guide for all chemists, chemical engineers, pharmaceutical professionals and engineers, and other professionals working in pharmaceutical sciences and manufacturing.

Generic Drug Product Development - Leon Shargel 2013-10-24

In this era of increased pharmaceutical industry competition, success for generic drug companies is dependent on their ability to manufacture therapeutic-equivalent drug products in an economical and timely manner, while also being cognizant of patent infringement and other legal and regulatory concerns. *Generic Drug Product Development: Solid Oral Dosage Forms, Second Edition* presents in-depth discussions from more than 30 noted specialists describing the development of generic drug products—from the raw materials to the development of a therapeutic-equivalent drug product to regulatory approval. Major topics discussed include: Active pharmaceutical ingredients Experimental formulation development, including a new section on Quality by Design (QbD) Scale-up Commercial product formulation Quality control and bioequivalence Drug product performance ANDA regulatory process Post-approval changes Post-marketing surveillance Legislative and patent challenges This second edition also contains a new chapter on the relationship between the FDA and the United States Pharmacopeia and in Chapter 4, using specific examples, the application of Quality by Design (QbD) during formulation development is examined. The book is a thorough guide to the development of solid oral generic dosage formulations. This textbook is ideal for the pharmaceutical industry, graduate programs in pharmaceutical sciences, and health professionals working in the area of generic drug development.

Statistics for Censored Environmental Data Using Minitab and R - Dennis R. Helsel 2012-02-01

Praise for the First Edition " . . . an excellent addition to an upper-level undergraduate course on environmental statistics, and . . . a 'must-have' desk reference for environmental practitioners dealing with censored datasets." —Vadose Zone Journal *Statistics for Censored Environmental Data Using Minitab® and R, Second Edition* introduces and explains methods for analyzing and interpreting censored data in the environmental sciences. Adapting survival analysis techniques from other fields, the book translates well-established methods from other disciplines into new solutions for environmental studies. This new edition applies methods of survival analysis, including methods for interval-censored data to the interpretation of low-level contaminants in environmental sciences and occupational health. Now incorporating the freely available R software as well as Minitab® into the discussed analyses, the book features newly developed and updated material including: A new chapter on multivariate methods for censored data Use of interval-censored methods for treating true nondetects as lower than and separate from values between the detection and quantitation limits ("remarked data") A section on summing data with nondetects A newly written introduction that discusses invasive data, showing why substitution methods fail Expanded coverage of graphical methods for censored data The author writes in a style that focuses on applications rather than derivations, with chapters organized by key objectives such as computing intervals, comparing groups, and correlation. Examples accompany each procedure, utilizing real-world data that can be analyzed using the Minitab® and R software macros available on the book's related website, and extensive references direct readers to authoritative literature from the environmental sciences. *Statistics for Censored Environmental Data Using Minitab® and R, Second Edition* is an excellent book for courses on environmental statistics at the upper-undergraduate and graduate levels. The book also serves as a valuable reference for environmental professionals, biologists, and ecologists who focus on the water sciences, air quality, and soil science.

Handbook of Stability Testing in Pharmaceutical Development - Kim Huynh-Ba 2008-11-16

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.

Sterile Manufacturing - Sam A. Hout 2021-07-05

This book highlights key ideas and factors to coach and guide professionals involved in learning about Sterile Manufacturing and operational requirements. It covers regulations and guidelines instituted by the FDA, ISPE, EMA, MHRA, and ICH, emphasizing good manufacturing practice and inspection requirements in the manufacturing of medicinal products. Additionally, this book provides the fundamentals of aseptic techniques, quality by design, risk assessment, and management in support of sterile operations applications. It creates a link to the implementation of business practices in drug manufacturing and healthcare and forms a correlation between design strategies including a step-by-step process to ensure reliability, safety, and efficacy of healthcare products for human and animal use. The book also provides a connection between drug production and regulated applications by offering a review of the basic elements of sterile processing, and how to remain viable with solid strategic planning. The book is a concise reference for professionals and learners in the field of sterile operations that governs primarily, pharmaceutical and medical device space, but can also extend to food and cosmetics that require clean (aseptic) manufacturing applications. It also helps compounding pharmacists and GMP inspectors and auditors.

Therapeutic Enzymes: Function and Clinical Implications - Nikolaos Labrou 2019-09-03

Therapeutic enzymes exhibit fascinating features and opportunities, and represent a significant and promising subcategory of modern biopharmaceuticals for the treatment of several severe diseases. Research and drug development efforts and the advancements in biotechnology over the past twenty years have greatly assisted the introduction of efficient and safe enzyme-based therapies for a range of both rare and common disorders. The introduction and regulatory approval of twenty different recombinant enzymes has enabled effective enzyme-replacement therapy. This volume aims to overview these therapeutic enzymes, focusing in particular on more recently approved enzymes produced by recombinant DNA technology. This volume is composed of four sections. Section 1 provides an overview of the production process and biochemical characterization of therapeutic enzymes, while Section 2 focuses upon the engineering strategies and delivery methods of therapeutic enzymes. Section 3 highlights the clinical applications of approved therapeutic enzymes, including aspects on their structure, indications and mechanisms of action. Together with information on these mechanisms, safety and immunogenicity issues and various adverse events of the recombinant enzymes used for therapy are discussed. Section 4, provides discussion on the prospective and future developments of new therapeutic enzymes. This book is aimed at academics, researchers and students undertaking advanced undergraduate/postgraduate programs in the biopharmaceutical/biotechnology area who wish to gain a comprehensive understanding of enzyme-based therapeutic molecules.

Developing Solid Oral Dosage Forms - Yihong Qiu 2016-11-08

Developing Solid Oral Dosage Forms: Pharmaceutical Theory and Practice, Second Edition illustrates how to develop high-quality, safe, and effective pharmaceutical products by discussing the latest techniques, tools, and scientific advances in preformulation investigation, formulation, process design, characterization, scale-up, and production operations. This book covers the essential principles of physical pharmacy, biopharmaceutics, and industrial pharmacy, and their application to the research and development process of oral dosage forms. Chapters have been added, combined, deleted, and completely revised as necessary to produce a comprehensive, well-organized, valuable reference for industry professionals and academics engaged in all aspects of the development process. New and important topics include spray drying, amorphous solid dispersion using hot-melt extrusion, modeling and simulation, bioequivalence of complex modified-released dosage forms, biowaivers, and much more. Written and edited by an international team of leading experts with experience and knowledge across industry, academia, and regulatory settings Includes new chapters covering the pharmaceutical applications of surface phenomenon, predictive biopharmaceutics and pharmacokinetics, the development of formulations for drug discovery support, and much more Presents new case studies throughout, and a section completely devoted to regulatory aspects, including global product regulation and international perspectives

Quality by Design for Biopharmaceutical Drug Product Development - Feroz Jameel 2015-04-01

This volume explores the application of Quality by Design (QbD) to biopharmaceutical drug product development. Twenty-eight comprehensive chapters cover dosage forms, liquid and lyophilized drug products. The introductory chapters of this book define key elements of QbD and examine how these elements are integrated into drug product development. These chapters also discuss lessons learned from the FDA Office of Biotechnology Products pilot program. Following chapters demonstrate how QbD is used for formulation development ranging from screening of formulations to developability assessment to development of lyophilized and liquid formats. The next few chapters study the use of small-scale and surrogate models as well as QbD application to drug product processes such as drug substance freezing and thawing, mixing, sterile filtration, filling, lyophilization, inspection and shipping and handling. Later chapters describe more specialized applications of QbD in the drug product realm. This includes the use of QbD in primary containers, devices and combination product development. The volume also explores QbD applied to vaccine development, automation, mathematical modeling and monitoring, and controlling processes and defining control strategies. It concludes with a discussion on the application of QbD to drug product technology transfer as well as overall regulatory considerations and lifecycle management. Quality by Design for Biopharmaceutical Drug Product Development is an authoritative resource for scientists and researchers interested in expanding their knowledge on QbD principles and uses in creating better drugs.

PAT Applied in Biopharmaceutical Process Development And Manufacturing - Cenk Undey 2011-12-07

As with all of pharmaceutical production, the regulatory environment for the production of therapeutics has been changing as a direct result of the US FDA-initiated Quality by Design (QbD) guidelines and corresponding activities of the International Committee for Harmonization (ICH). Given the rapid growth in the biopharmaceutical area and the complexity of the molecules, the optimum use of which are still being developed, there is a great need for flexible and proactive teams in order to satisfy the regulatory requirements during process development. Process Analytical Technologies (PAT) applied in biopharmaceutical process development and manufacturing have received significant attention in recent years as an enabler to the QbD paradigm. PAT Applied in Biopharmaceutical Process Development and Manufacturing covers technological advances in measurement sciences, data acquisition, monitoring, and control. Technical leaders present real-life case studies in areas including measuring and monitoring raw materials, cell culture, purification, and cleaning and lyophilization processes via advanced PAT. They also explore how data are collected and analyzed using advanced analytical techniques such as multivariate data analysis, monitoring, and control in real-time. Invaluable for experienced practitioners in PAT in biopharmaceuticals, this book is an excellent reference guide for regulatory officials and a vital training aid for students who need to learn the state of the art in this interdisciplinary and exciting area.

Resource Efficiency of Processing Plants - Stefan Krämer 2018-05-07

This monograph provides foundations, methods, guidelines and examples for monitoring and improving resource efficiency during the operation of processing plants and for improving their design. The measures taken to improve their energy and resource efficiency are strongly influenced by regulations and standards which are covered in Part I of this book. Without changing the actual processing equipment, the way how the processes are operated can have a strong influence on the resource efficiency of the plants and this potential can be exploited with much smaller investments than needed for the introduction of new process technologies. This aspect is the focus of Part II. In Part III we discuss physical changes of the process technology such as heat integration, synthesis and realization of optimal processes, and industrial symbiosis. The last part deals with the people that are needed to make these changes possible and discusses the path towards a resource efficiency culture. Written with industrial solutions in mind, this text will benefit practitioners as well as the academic community.

Good Design Practices for GMP Pharmaceutical Facilities - Terry Jacobs 2016-08-19

This revised publication serves as a handy and current reference for professionals engaged in planning, designing, building, validating and maintaining modern cGMP pharmaceutical manufacturing facilities in the U.S. and internationally. The new edition expands on facility planning, with a focus on the ever-growing need to modify existing legacy facilities, and on current trends in pharmaceutical manufacturing which include strategies for sustainability and LEED building ratings. All chapters have been re-examined with a fresh outlook on current good design practices.

Micro- and Nanotechnologies-Based Product Development - Neelesh Kumar Mehra 2021-09-06

This book provides comprehensive information of the nanotechnology-based pharmaceutical product development including a diverse range of arenas such as liposomes, nanoparticles, fullerenes, hydrogels, thermally responsive externally activated theranostics (TREAT), hydrogels, microspheres, micro- and nanoemulsions and carbon nanomaterials. It covers the micro- and nanotechnological aspects for pharmaceutical product development with the product development point of view and also covers the industrial aspects, novel technologies, stability studies, validation, safety and toxicity profiles, regulatory perspectives, scale-up technologies and fundamental concept in the development of products. Salient Features: Covers micro- and nanotechnology approaches with current trends with safety and efficacy in product development. Presents an overview of the recent progress of stability testing, reverse engineering, validation and regulatory perspectives as per regulatory requirements. Provides a comprehensive overview of the latest research related to micro- and nanotechnologies including designing, optimisation, validation and scale-up of micro- and nanotechnologies. Is edited by two well-known researchers by contribution of vivid chapters from renowned scientists across the globe in the field of pharmaceutical sciences. Dr. Neelesh Kumar Mehra is working as an Assistant Professor of Pharmaceutics & Biopharmaceutics at the Department of Pharmaceutics, National Institute of Pharmaceutical Education & Research (NIPER), Hyderabad, India. He received 'TEAM AWARD' for successful commercialisation of an ophthalmic suspension product. He has authored more than 60 peer-reviewed publications in highly reputed international journals and more than 10 book chapter contributions. He has filed patents on manufacturing process and composition to improved therapeutic efficacy for topical delivery. He guided PhD and MS students for their dissertations/research projects. He has received numerous outstanding awards including Young Scientist Award and Team Award for his research output. He recently published one edited book, 'Dendrimers in Nanomedicine: Concept, Theory and Regulatory Perspectives', in CRC Press. Currently, he is editing books on nano drug delivery-based products with Elsevier Pvt Ltd. He has rich research and teaching experience in the formulation and development of complex, innovative ophthalmic and injectable biopharmaceutical products including micro- and nanotechnologies for regulated market. Dr. Arvind Gulbake is working as an Assistant Professor at the Faculty of Pharmacy, School of Pharmaceutical & Population Health Informatics, at DIT University, Dehradun, India. He has authored more than 40 peer-reviewed publications in highly reputed international journals, four book chapters and a patent contribution. He has received outstanding awards including Young Scientist Award and BRG Travel Award for his research. He is an assistant editor for IJAP. He guided PhD and MS students for their dissertations/research projects. He has successfully completed extramural project funded by SERB, New Delhi, Government of India. He has more than 12 years of research and teaching experience in the formulation and development of nanopharmaceuticals.

Handbook for Critical Cleaning: Applications, processes, and controls - Barbara Kanegsberg 2011

"Updated, re-organized, and rewritten, this second edition of a bestseller covers cleaning processes, applications, management, safety, and environmental concerns. A two-volume set, it discusses cleaning process applications, management, and safety and environmental concerns. International contributors give the text a global viewpoint. Color illustrations, video clips, and animations that make the information accessible are available from the website. The handbook is available for purchase individually or as the two-volume set"--

Specification of Drug Substances and Products - Christopher M. Riley 2020-07-23

Specification of Drug Substances and Products: Development and Validation of Analytical Methods, Second Edition, presents a comprehensive and critical analysis of the requirements and approaches to setting specifications for new pharmaceutical products, with an emphasis on phase-appropriate development, validation of analytical methods, and their application in practice. This thoroughly revised second edition covers topics not covered or not substantially covered in the first edition, including method development and validation in the clinical phase, method transfer, process analytical technology, analytical life cycle management, special challenges with generic drugs, genotoxic impurities, topical products, nasal sprays and inhalation products, and biotechnology products. The book's authors have been carefully selected as former members of the ICH Expert Working Groups charged with developing the ICH guidelines, and/or

subject-matter experts in the industry, academia and in government laboratories. Presents a critical assessment of the application of ICH guidelines on method validation and specification setting Written by subject-matter experts involved in the development and application of the guidelines Provides a comprehensive treatment of the analytical methodologies used in the analysis, control and specification of new drug substances and products Covers the latest statistical approaches (including analytical quality by design) in the development of specifications, method validation and shelf-life prediction

Parenteral Medications, Fourth Edition - Sandeep Nema 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

Quality by Design for Biopharmaceuticals - Anurag S. Rathore 2011-09-20

The concepts, applications, and practical issues of Quality by Design Quality by Design (QbD) is a new framework currently being implemented by the FDA, as well as EU and Japanese regulatory agencies, to ensure better understanding of the process so as to yield a consistent and high-quality pharmaceutical product. QbD breaks from past approaches in assuming that drug quality cannot be tested into products; rather, it must be built into every step of the product creation process. Quality by Design: Perspectives and Case Studies presents the first systematic approach to QbD in the biotech industry. A comprehensive resource, it combines an in-depth explanation of basic concepts with real-life case studies that illustrate the practical aspects of QbD implementation. In this single source, leading authorities from the biotechnology industry and the FDA discuss such topics as: The understanding and development of the product's critical quality attributes (CQA) Development of the design space for a manufacturing process How to employ QbD to design a formulation process Raw material analysis and control strategy for QbD Process Analytical Technology (PAT) and how it relates to QbD Relevant PAT tools and applications for the pharmaceutical industry The uses of risk assessment and management in QbD Filing QbD information in regulatory documents The application of multivariate data analysis (MVDA) to QbD Filled with vivid case studies that illustrate QbD at work in companies today, Quality by Design is a core reference for scientists in the biopharmaceutical industry, regulatory agencies, and students.

Continuous Biomanufacturing - Ganapathy Subramanian 2017-09-12

This is the most comprehensive treatise of this topic available, providing invaluable information on the technological and economic benefits to be gained from implementing continuous processes in the biopharmaceutical industry. Top experts from industry and academia cover the latest technical developments in the field, describing the use of single-use technologies alongside perfusion production platforms and downstream operations. Special emphasis is given to process control and monitoring, including such topics as 'quality by design' and automation. The book is supplemented by case studies that highlight the enormous potential of continuous manufacturing for biopharmaceutical production facilities.

[Pharmaceutical Manufacturing Handbook](#) - Shayne Cox Gad 2008-03-21

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.

Combination Products - Smita Gopaldaswamy 2008-04-22

The field of combination product development (products born of the integration of medical devices, biologics, and drugs) is so new that, while literature abounds on each part individually, there are very few publications, including FDA documents, available concerning the unique challenges posed by this nascent but fast-growing area. Providing the first in-depth look at this breakthrough field, Combination Products includes practical guidelines and a detailed step-by-step process for the development of these novel technologies. It addresses the technical, scientific, regulatory, and quality issues that arise when combining drugs, biologics, and medical devices into a single product. It takes a practical, readily applicable approach to discussing the challenges, victories, and pitfalls associated with merging technologies and systems and how to implement these products into the market successfully and in a timely manner. Specifically, this text explores the process from start to finish, establishing a workable design and development plan complete with relevant definitions. It reviews FDA and other regulatory expectations and covers resource requirements, manufacturing pitfalls, post-launch compliance requirements, and agency audits and challenges. Drawing on the experience and expertise of two leaders in their respective fields, Combination Products boasts the credentials of Dr. Smita Gopaldaswamy, a 20 year veteran of technical consulting responsibilities in medical device, biologics, and pharmaceutical industries as well as combination products, along with the support of Dr. Venky Gopaldaswamy, an expert in business improvement methodologies such as six sigma, lean, and change management, to provide a comprehensive assessment of the field and an efficient and effective approach to the creation and implementation of combination products.

Practical Approaches to Method Validation and Essential Instrument Qualification - Chung Chow Chan 2011-03-01

Practical approaches to ensure that analytical methods and instruments meet GMP standards and requirements Complementing the authors' first book, Analytical Method Validation and Instrument Performance Verification, this new volume provides coverage of more advanced topics, focusing on additional and supplemental methods, instruments, and electronic systems that are used in pharmaceutical, biopharmaceutical, and clinical testing. Readers will gain new and valuable insights that enable them to avoid common pitfalls in order to seamlessly conduct analytical method validation as well as instrument operation qualification and performance verification. Part 1, Method Validation, begins with an overview of the book's risk-based approach to phase appropriate validation and instrument qualification; it then focuses on the strategies and requirements for early phase drug development, including validation of specific techniques and functions such as process analytical technology, cleaning validation, and validation of laboratory information management systems Part 2, Instrument Performance Verification, explores the underlying principles and techniques for verifying instrument performance—coverage includes analytical instruments that are increasingly important to the pharmaceutical industry, such as NIR spectrometers and particle size analyzers—and offers readers a variety of alternative approaches for the successful verification of instrument performance based on the needs of their labs At the end of each chapter, the authors examine important practical problems and share their solutions. All the methods covered in this book follow Good Analytical Practices (GAP) to ensure that reliable data are generated in compliance with current Good Manufacturing Practices (cGMP). Analysts, scientists, engineers, technologists, and technical managers should turn to this book to ensure that analytical methods and instruments are accurate and meet GMP standards and requirements.

Remington - Linda A. Felton 2013

Provides a concise yet detailed resource covering all aspects of pharmaceuticals, from the scientific fundamentals to the dosage forms and drug delivery systems to drug product analyses. Assists with integrating the science of pharmacy into practice. Chapters from the original parent text Remington: The Science and Practice of Pharmacy 22nd edition were specifically selected to create this new edition. The text pulls heavily from the Pharmaceuticals and Pharmaceutical Dosage Forms sections. Various delivery

systems and dosage forms are covered as well as parenterals, sterilization processes, and sterile compounding. One chapter addresses pharmaceutical excipients and another discusses pharmaceutical packaging. Pharmaceutical analysis, product characterization, quality control, stability, bioavailability, and dissolution are also covered. Fundamental scientific concepts including thermodynamics, ionic solutions and electrolyte equilibria, tonicity, chemical kinetics, rheology, complex formation and interfacial phenomenon are presented. The text also provides an introduction to pharmacokinetics and pharmacodynamics and the principles of absorption, distribution, metabolism and excretion. In addition, some introductory concepts on drug discovery and drug product approval as well as information resources in pharmacy and the pharmaceutical sciences are presented.

Process Architecture in Biomanufacturing Facility Design - Jeffery Odum 2018-01-26

Essential information for architects, designers, engineers, equipment suppliers, and other professionals who are working in or entering the biopharmaceutical manufacturing field. Biomanufacturing facilities that are designed and built today are radically different than in the past. The vital information and knowledge needed to design and construct these increasingly sophisticated biopharmaceutical manufacturing facilities is difficult to find in published literature—and it's rarely taught in architecture or design schools. This is the first book for architects and designers that fills this void. *Process Architecture in Biomanufacturing Facility Design* provides information on design principles of biopharmaceutical manufacturing facilities that support emerging innovative processes and technologies, use state-of-the-art equipment, are energy efficient and sustainable, and meet regulatory requirements. Relying on their many years of hands-on design and operations experience, the authors emphasize concepts and practical approaches toward design, construction, and operation of biomanufacturing facilities, including product-process-facility relationships, closed systems and single use equipment, aseptic manufacturing considerations, design of biocontainment facility and process based laboratory, and sustainability considerations, as well as an outlook on the facility of the future. Provides guidelines for meeting licensing and regulatory requirements for biomanufacturing facilities in the U.S.A and WHO—especially in emerging global markets in India, China, Latin America, and the Asia/Pacific regions. Focuses on innovative design and equipment, to speed construction and time to market, increase energy efficiency, and reduce footprint, construction and operational costs, as well as the financial risks associated with construction of a new facility prior to the approval of the manufactured products by regulatory agencies. Includes many diagrams that clarify the design approach. *Process Architecture in Biomanufacturing Facility Design* is an ideal text for professionals involved in the design of facilities for manufacturing of biopharmaceuticals and vaccines, biotechnology, and life-science industry, including architects and designers of industrial facilities, construction, equipment vendors, and mechanical engineers. It is also recommended for university instructors, advanced undergraduates, and graduate students in architecture, industrial engineering, mechanical engineering, industrial design, and industrial interior design.

Pharmaceutical Blending and Mixing - P. J. Cullen 2015-07-20

Written in four parts, this book provides a dedicated and in-depth reference for blending within the pharmaceutical manufacturing industry. It links the science of blending with regulatory requirements associated with pharmaceutical manufacture. The contributors are a combination of leading academic and industrial experts, who provide an informed and industrially relevant perspective of the topic. This is an

essential book for the pharmaceutical manufacturing industry, and related academic researchers in pharmaceutical science and chemical and mechanical engineering.

Pharmaceutical Dosage Forms - Parenteral Medications - Sandeep Nema 2016-04-19

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 three presents: • An in-depth discussion of regulatory requirements, quality assurance, risk assessment and mitigation, and extractables/leachables. • Specific chapters on parenteral administration devices, injection site pain assessment, and parenteral product specifications and stability testing. • Forward-thinking discussions on the future of parenteral product manufacturing, and siRNA delivery systems. • New chapters covering recent developments in the areas of visual inspection, quality by design (QbD), process analytical technology (PAT) and rapid microbiological methods (RMM), and validation of drug product manufacturing process.

Guideline on General Principles of Process Validation - 1987

Multivariate Analysis in the Pharmaceutical Industry - Ana Patricia Ferreira 2018-04-24

Multivariate Analysis in the Pharmaceutical Industry provides industry practitioners with guidance on multivariate data methods and their applications over the lifecycle of a pharmaceutical product, from process development, to routine manufacturing, focusing on the challenges specific to each step. It includes an overview of regulatory guidance specific to the use of these methods, along with perspectives on the applications of these methods that allow for testing, monitoring and controlling products and processes. The book seeks to put multivariate analysis into a pharmaceutical context for the benefit of pharmaceutical practitioners, potential practitioners, managers and regulators. Users will find a resource that addresses an unmet need on how pharmaceutical industry professionals can extract value from data that is routinely collected on products and processes, especially as these techniques become more widely used, and ultimately, expected by regulators. Targets pharmaceutical industry practitioners and regulatory staff by addressing industry specific challenges. Includes case studies from different pharmaceutical companies and across product lifecycle of to introduce readers to the breadth of applications. Contains information on the current regulatory framework which will shape how multivariate analysis (MVA) is used in years to come.

Pharmaceutical Compounding and Dispensing - Christopher A. Langley 2008

Based on the successful textbook, *Pharmaceutical Compounding and Dispensing*, this book has been designed to assist the student compounder in understanding the key dosage forms encountered within extemporaneous dispensing.