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Chitosan-Based Systems for Biopharmaceuticals Bruno Sarmento 2012-02-16 Chitosan is a linear polysaccharide commercially produced by the deacetylation of chitin. It is non-toxic, biodegradable, biocompatible, and acts as a bioadhesive with otherwise unstable biomolecules - making it a valuable component in the formulation of biopharmaceutical drugs. Chitosan-Based Systems for Biopharmaceuticals provides an extensive overview of the application of chitosan and its derivatives in the development and optimisation of biopharmaceuticals. The book is divided in four different parts. Part I discusses general aspects of chitosan and its derivatives, with particular emphasis on issues related to the development of biopharmaceutical chitosan-based systems. Part II deals with the use of chitosan and derivatives in the formulation and delivery of biopharmaceuticals, and focuses on the synergistic effects between chitosan and this particular subset of pharmaceuticals. Part III discusses specific applications of chitosan and its derivatives for biopharmaceutical use. Finally, Part IV presents diverse viewpoints on different issues such as regulatory, manufacturing and toxicological requirements of chitosan and its derivatives related to the development of biopharmaceutical products, as well as their patent status, and clinical application and potential. Topics covered include: chemical and technological advances in chitins and chitosans useful for the formulation of biopharmaceuticals physical properties of chitosan and derivatives in sol and gel states absorption promotion properties of chitosan and derivatives biocompatibility and biodegradation of chitosan and derivatives biological and pharmacological activity of chitosan and derivatives biological, chemical and physical compatibility of chitosan and biopharmaceuticals approaches for functional modification or crosslinking of chitosan use of chitosan and derivatives in conventional biopharmaceutical dosage forms manufacture techniques of chitosan-based microparticles and nanoparticles for biopharmaceuticals chitosan and derivatives for biopharmaceutical use: mucoadhesive properties chitosan-based systems for mucosal delivery of biopharmaceuticals chitosan-based delivery systems for mucosal vaccination chitosan-based nanoparticulates for oral delivery of biopharmaceuticals chitosan-based systems for ocular delivery of biopharmaceuticals chemical modification of chitosan for delivery of DNA and siRNA target-specific chitosan-based nanoparticle systems for nucleic acid delivery functional PEGylated chitosan systems for biopharmaceuticals stimuli-sensitive chitosan-based systems for biopharmaceuticals chitosan copolymers for biopharmaceuticals application of chitosan for anti-cancer biopharmaceutical delivery chitosan-based biopharmaceuticals scaffolds in tissue engineering and regenerative medicine wound healing properties of chitosan and its use in wound dressing biopharmaceuticals toxicological properties of chitosan and derivatives for biopharmaceutical applications regulatory status of chitosan and derivatives patentability and intellectual property issues quality control and good manufacturing practice preclinical and clinical use of chitosan and derivatives for biopharmaceuticals Chitosan-Based Systems for Biopharmaceuticals is an important compendium of fundamental concepts, practical tools and applications of chitosan-based biopharmaceuticals for researchers in academia and industry working in drug formulation and delivery, biopharmaceuticals, medicinal chemistry, pharmacy, bioengineering and new materials development.

Microbial Limit and Bioburden Tests Lucia Clontz 2008-10-14 In recent years, the field of pharmaceutical microbiology has experienced numerous technological advances, accompanied by the publication of new and harmonized compendial methods. It is therefore imperative for those who are responsible for monitoring the microbial quality of pharmaceutical/biopharmaceutical products to keep

abreast of the latest changes. Microbial Limit and Bioburden Tests: Validation Approaches and Global Requirements guides readers through the various microbiological methods listed in the compendia with easy-to-follow diagrams and approaches to validations of such test methodologies. Includes New and Updated Material Now in its second edition, this work is the culmination of research and discussions with technical experts, as well as USP and FDA representatives on various topics of interest to the pharmaceutical microbiologist and those responsible for the microbial quality of products, materials, equipment, and manufacturing facilities. New in this edition is an entire chapter dedicated to the topic of biofilms and their impact on pharmaceutical and biopharmaceutical operations. The subject of rapid methods in microbiology has been expanded and includes a discussion on the validation of alternative microbiological methods and a case study on microbial identification in support of a product contamination investigation. Substantially updated and revised, this book assists readers in understanding the fundamental issues associated with pharmaceutical microbiology and provides them with tools to create effective microbial contamination control and microbial testing programs for the areas under their responsibility.

ISPE Good Practice Guide Ispe 2019-01-24

Downstream Industrial Biotechnology Michael C. Flickinger 2013-07-17 DOWNSTREAM INDUSTRIAL BIOTECHNOLOGY An affordable, easily accessible desk reference on biomanufacturing, focused on downstream recovery and purification Advances in the fundamental knowledge surrounding biotechnology, novel materials, and advanced engineering approaches continue to be translated into bioprocesses that bring new products to market at a significantly faster pace than most other industries. Industrial scale biotechnology and new manufacturing methods are revolutionizing medicine, environmental monitoring and remediation, consumer products, food production, agriculture, and forestry, and continue to be a major area of research. The downstream stage in industrial biotechnology refers to recovery, isolation, and purification of the microbial products from cell debris, processing medium and contaminating biomolecules from the upstream process into a finished product such as biopharmaceuticals and vaccines. Downstream process design has the greatest impact on overall biomanufacturing cost because not only does the biochemistry of different products (e.g., peptides, proteins, hormones, antibiotics, and complex antigens) dictate different methods for the isolation and purification of these products, but contaminating byproducts can also reduce overall process yield, and may have serious consequences on clinical safety and efficacy. Therefore downstream separation scientists and engineers are continually seeking to eliminate, or combine, unit operations to minimize the number of process steps in order to maximize product recovery at a specified concentration and purity. Based on Wiley's Encyclopedia of Industrial Biotechnology: Bioprocess, Bioseparation, and Cell Technology, this volume features fifty articles that provide information on down- stream recovery of cells and protein capture; process development and facility design; equipment; PAT in downstream processes; downstream cGMP operations; and regulatory compliance. It covers: Cell wall disruption and lysis Cell recovery by centrifugation and filtration Large-scale protein chromatography Scale down of biopharmaceutical purification operations Lipopolysaccharide removal Porous media in biotechnology Equipment used in industrial protein purification Affinity chromatography Antibody purification, monoclonal and polyclonal Protein aggregation, precipitation and crystallization Freeze-drying of biopharmaceuticals Biopharmaceutical facility design and validation Pharmaceutical bioburden testing Regulatory requirements Ideal for graduate and advanced undergraduate courses on biomanufacturing, biochemical engineering, biopharmaceutical facility design, biochemistry, industrial microbiology, gene expression technology, and cell culture technology, Downstream Industrial Biotechnology is also a highly recommended resource for industry professionals and libraries.

WHO Drug Information 2021-04-08

Handbook of Formulating Dermal Applications Nava Dayan 2016-12-07 The conceptualization and formulation of skin care products intended for topical use is a multifaceted and evolving area of science. Formulators must account for myriad skin types, emerging opportunities for product development as well as a very temperamental retail market. Originally published as "Apply Topically" in 2013 (now out of print), this reissued detailed and comprehensive handbook offers a practical approach to the formulation chemist's day-to-day endeavors by: Addressing the innumerable challenges facing the chemist both in design and at the bench, such as formulating with/for specific properties; formulation, processing and production techniques; sensory and elegancy; stability and preservation; color cosmetics; sunscreens; Offering valuable guidance to troubleshooting issues regarding ingredient selection and interaction, regulatory concerns that must be addressed early in development, and the extrapolation of preservative systems, fragrances, stability and texture aids; Exploring the advantages and limitations of raw materials; Addressing scale-up and pilot production process and concerns; Testing and Measurements Methods. The 22 chapters written by industry experts such as Roger L. McMullen, Paul Thau, Hemi Nae, Ada Polla, Howard Epstein, Joseph Albanese, Mark Chandler, Steve Herman, Gary Kelm, Patricia Aikens, and Sam Shefer, along with many

others, give the reader and user the ultimate handbook on topical product development.

Rules of Thumb for Chemical Engineers Stephen Hall 2017-11-22 Rules of Thumb for Chemical Engineers, Sixth Edition, is the most complete guide for chemical and process engineers who need reliable and authoritative solutions to on-the-job problems. The text is comprehensively revised and updated with new data and formulas. The book helps solve process design problems quickly, accurately and safely, with hundreds of common sense techniques, shortcuts and calculations. Its concise sections detail the steps needed to answer critical design questions and challenges. The book discusses physical properties for proprietary materials, pharmaceutical and biopharmaceutical sector heuristics, process design, closed-loop heat transfer systems, heat exchangers, packed columns and structured packings. This book will help you: save time you no longer have to spend on theory or derivations; improve accuracy by exploiting well tested and accepted methods culled from industry experts; and save money by reducing reliance on consultants. The book brings together solutions, information and work-arounds from engineers in the process industry. Includes new chapters on biotechnology and filtration Incorporates additional tables with typical values and new calculations Features supporting data for selecting and specifying heat transfer equipment

Steam Trap Performance Assessment: Advanced Technologies for Evaluating the Performance of Steam Traps

Cell Culture Technology for Pharmaceutical and Cell-Based Therapies Sadettin Ozturk 2005-08-30 Edited by two of the most distinguished pioneers in genetic manipulation and bioprocess technology, this bestselling reference presents a comprehensive overview of current cell culture technology used in the pharmaceutical industry. Contributions from several leading researchers showcase the importance of gene discovery and genomic technology devel

GAMP Good Practice Guide ISPE 2002

Quality Kathleen E. McCormick 2022-07-14 Quality, second edition, provides comprehensive application of regulatory guidelines and quality concepts and methodologies related to pharmaceutical manufacturing. It is an excellent resource for practitioners, those pursuing pharmaceutical related certifications, and for students trying to learn more about pharmaceutical manufacturing. This book provides the background theory, applied descriptions of the guidelines and concepts, plus questions and problems at the end of the chapters that will help provide practice for the reader to apply the concepts. In this book the authors share their combined 60+ years of extensive practical experience in the industry and in process improvement combined with detailed understanding of the needs of the industry and education system. This book provides real-life examples from industry and guidelines for practical application of tools that can be referenced by operators, engineers, and management.This book is fully revised, updated, and expanded with new content in areas such as QbD, Lean, Six Sigma, basic data analysis, and CAPA tools. Fully revised, updated, and expanded new edition Features new topics such as QbD, Lean, Six Sigma, basic data analysis, and CAPA tools Includes end-of-chapter summaries and end-of-chapter question and/or problems Provides detailed steps and examples for applying the guidelines and quality tools Written in an accessible style making the content easy to understand and apply

Medical Devices and In Vitro Diagnostics Christian Baumgartner

Good Research Practice in Non-Clinical Pharmacology and Biomedicine Anton Bespalov 2020-01-01 This open access book, published under a CC BY 4.0 license in the Pubmed indexed book series Handbook of Experimental Pharmacology, provides up-to-date information on best practice to improve experimental design and quality of research in non-clinical pharmacology and biomedicine.

Method Validation in Pharmaceutical Analysis Joachim Ermer 2006-03-06 Adopting a practical approach, the authors provide a detailed interpretation of the existing regulations (GMP, ICH), while also discussing the appropriate calculations, parameters and tests. The book thus allows readers to validate the analysis of pharmaceutical compounds while complying with both the regulations as well as the industry demands for robustness and cost effectiveness. Following an introduction to the basic parameters and tests in pharmaceutical validation, including specificity, linearity, range, precision, accuracy, detection and quantitation limits, the text focuses on a life-cycle approach to validation and the integration of validation into the whole analytical quality assurance system. The whole is rounded off with a look at future trends. With its first-hand knowledge of the industry as well as regulating bodies, this is an invaluable reference for analytical chemists, the pharmaceutical industry, pharmaceutists, QA officers, and public authorities.

ISPE Guide International Society for Pharmaceutical Engineering 2011

GAMP 5 Sion Wyn 2008 GAMP 5 provides pragmatic and practical industry guidance to achieve compliant computerized systems fit for intended use in an efficient and effective manner. This technical document describes a flexible risk-based approach to compliant GxP regulated computerized systems, based on scalable specification and verification. It points to the future of computer systems compliance by centering on principles behind major industry developments such as PQLI; ICH Q8, Q9, Q10; and ASTM E2500. This revolutionary Guide addresses the entire lifecycle of an automated system and its applicability to a wide

range of information systems, lab equipment, integrated manufacturing systems, and IT infrastructures. It contains new information on outsourcing, electronic batch recording, end user applications (such as spreadsheets and small database applications), and patch management.

Pharmaceutical Quality by Design Walkiria S. Schlindwein 2018-01-05 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.

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 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.

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21 CFR Part 11 Orlando L[illegible] pez 2004-01-15 Covering regulatory requirements stipulated by the FDA, this book delineates the organization, planning,

verification, and documentation activities and procedural controls required for compliance with worldwide computer systems validation regulations. The author introduces supporting technologies such as encryption and digital signatures and places

Analytical Method Validation and Instrument Performance Verification Chung Chow Chan 2004-04-23 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.

Rules of Thumb for Chemical Engineers Carl Branan 2002 Fractionators, separators and accumulators, cooling towers, gas treating, blending, troubleshooting field cases, gas solubility, and density of irregular solids * Hundreds of common sense techniques, shortcuts, and calculations.

Pharmaceutical Quality by Design Walkiria S. Schlindwein 2018-03-19 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.

Alarm Management for Process Control, Second Edition Doug Rothenberg 2018-02 This book elevates alarm management from a fragmented collection of procedures, metrics, experiences, and trial-and-error, to the level of a technology discipline. It provides a complete treatment of best practices in alarm management. The technology and approaches found here provide the opportunity to completely understand the what, the why, and the how of successful alarm systems. No modern industrial enterprise, particularly in such areas as chemical processing, can operate without a secure and reliable infrastructure of alarms and controls-they are an integral part of all production management and control systems. Improving alarm management is an effective way to provide operators with high-value support and guidance to successfully manage industrial plant operations. Readers will find: Recommendations and guidelines are developed from fundamental concepts to provide powerful technical tools and workable approaches; Alarms are treated as indicators of abnormal situations, not simply sensor readings that might be out of position; Alarm improvement is intimately linked to infrastructure management, including the vital role of plant maintenance to alarm management, the need to manage operators' charter to continue to operate during abnormal situations vs. cease operation, and the importance of situation awareness without undue reliance upon alarms. The ability to appreciate technical issues is important, but this book requires no previous specific technical, educational, or experiential background. The style and content are very accessible to a broad industrial audience from board operator to plant manager. All critical tasks are explained with workflow processes, examples, and insight into what it all means. Alternatives are offered everywhere to enable users to tailor-make solutions to their particular sites.

ISPE Baseline® Guide Ispe 2019-07-15

ISPE Baseline® Guide Ispe 2018-04-25

ISPE Baseline Pharmaceutical Engineering Guide for New and Renovated Facilities 2013

Transdisciplinary Engineering: A Paradigm Shift C.-H. Chen 2017-07-20 Concurrent Engineering is based on the concept that different phases of a product life cycle should be conducted concurrently and initiated as early as possible within the Product Creation Process (PCP). Its main goal is to increase the efficiency and effectiveness of the PCP and reduce errors in the later stages, and to incorporate considerations for the full lifecycle, through-life operations, and environmental issues of the product. It has become the substantive basic methodology in many industries, and the initial basic concepts have matured and become the foundation of many new ideas, methodologies, initiatives, approaches and tools. This book presents the proceedings of the 24th ISPE Inc. International Conference on Transdisciplinary (formerly: Concurrent) Engineering (TE 2017), held in Singapore, in July 2017. The 120 peer-reviewed papers in the book are divided into 16 sections: air transport and traffic operations and management; risk-aware supply chain intelligence; product innovation and marketing management; human factors in design; human engineering; design methods and tools; decision supporting tools and methods; concurrent engineering; knowledge-based engineering; collaborative engineering; engineering for sustainability; service design; digital manufacturing; design automation; artificial intelligence and data analytics; smart systems and the Internet of Things. The book provides a comprehensive overview of recent advances in transdisciplinary concurrent engineering research and applications, and will be of interest to researchers, design practitioners and educators working in the field.

Validation Standard Operating Procedures Syed Imtiaz Haider 2006-05-30 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

Registries for Evaluating Patient Outcomes Agency for Healthcare Research and Quality/AHRQ 2014-04-01 This User's Guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. For the purposes of this guide, a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry. Although registries can serve many purposes, this guide focuses on registries created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost-effectiveness of health care products and services, to measure or monitor safety and harm, and/or to measure quality of care. Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure. The User's Guide was created by researchers affiliated with AHRQ's Effective Health Care Program, particularly those who participated in AHRQ's DEcIDE (Developing Evidence to Inform Decisions About Effectiveness) program. Chapters were subject to multiple internal and external independent reviews.

Clean-In-Place for Biopharmaceutical Processes Dale A. Seiberling 2007-10-15 An invaluable source instruction on the principles, instrumentation, design, implementation, operation, and maintenance of an effective clean-in-place system (CIP), this guide illustrates best practices and successful applications of CIP in both pharmaceutical and biotechnology facilities. Offering reader-friendly descriptions of the various types of equipment and materials found in typical CIP processes, Clean-In-Place For Biopharmaceutical Processes will take the guess-work out of CIP development, and illustrate all one needs to know for the establishment and optimal functioning of a CIP system.

Pharmaceutical Microbiological Quality Assurance and Control David Roesti 2020-01-02 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

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

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WHO Expert Committee on Specifications for Pharmaceutical Preparations 2021-04-26 The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for the quality assurance of medicines and provision of global regulatory tools. Standards are developed by the Expert Committee through worldwide consultation and an international consensus-building process. The following new guidance texts were adopted and recommended for use: Guidelines and guidance texts adopted by the Expert Committee on Specifications for Pharmaceutical Preparations; Points to consider when including Health Based Exposure Limits (HBELs) in cleaning validation; Good manufacturing practices: water for pharmaceutical use; Guideline on data integrity; WHO/United Nations Population Fund recommendations for condom storage and shipping temperatures; WHO/United Nations Population Fund guidance on testing of male latex condoms; WHO/United Nations Population Fund guidance on conducting post-market surveillance of condoms; WHO "Biowaiver List": proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms; WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce; Good reliance practices in the regulation of medical products: high-level principles and considerations; and Good regulatory practices in the regulations of medical products. All of the above are included in this report and recommended for implementation.

Nutraceutical and Functional Food Regulations in the United States and Around the World Debasis Bagchi 2014-02-25 This fully revised and updated edition begins with insights into the scope, importance and continuing growth opportunities in the nutraceutical and functional food industries and explores the latest regulatory changes and their impacts. The book demonstrates the global scenario of the acceptance and demand for these products and explores the regulatory hurdles and claim substantiation of these foods and dietary supplements, as well as addressing the intricate aspects of manufacturing procedures. As the public gains confidence in the quality of these products based on sophisticated quality control, a broad spectrum of safety studies and GRAS, peer-reviewed publications and cutting-edge human clinical studies have emerged. An increasing number of additional populations around-the-world now recognize the efficacy and functions of nutraceuticals and functional foods as established by those scientific research studies. As a result, a number of structurally and functionally active novel nutraceuticals and several new functional beverages have been introduced into the marketplace around the world. Features fully revised and updated information with current regulations from around the world, including GRAS status and DSHEA regulators Offers 45% new content including three new chapters –NSF: Ensuring the Public Health and Safety Aspects of Nutraceuticals and Functional Foods; Role of the United States Pharmacopeia in the Establishment of Nutraceuticals and Functional Food Safety; An Overview on the New Dietary Ingredient (NDI) and Generally Recognized as Safe (GRAS) Status, and the addition of cGMP regulations for dietary supplements Includes insight into working with regulatory agencies, processes and procedures Provides a link to the contact information for most regulatory bodies for readers wishing to gain further knowledge

Containment in the Pharmaceutical Industry James P. Wood 2020-03-26 Delivering an encompassing overview of the factors, varieties, and applications determining product containment, this concise reference provides authoritative information on containment processes. It reviews the historical context, definition, evolution, and application of containment technology, analyzes a variety of containment techniques in new

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.

Rules and Guidance for Pharmaceutical Manufacturers and Distributors (Orange Guide) 2017 Great Britain. Medicines and Healthcare products Regulatory Agency 2017-01-06 Familiarly known as the Orange Guide, this title is an essential reference work for all those involved in the manufacture and distribution of medicines in Europe. It is compiled by the UK drug regulatory body, MHRA, and brings together the European and UK guidance documents and information on legislation relating to the manufacture and distribution of medicines for human use. It contains EU guidance on good manufacturing and good distribution practice along with relevant information on EU and UK legislation. Changes in this new edition: Revised Annex 15. The revision of Annex 15 takes into account changes to other sections of the EudraLex, Volume 4, Part I, relationship to Part II, Annex 11, ICH Q8, Q9, Q10 and Q11, QWP guidance on process validation, and changes in manufacturing technology. Revised Annex 16. The GMP Guide Annex 16 has been revised to reflect the globalisation of the pharmaceutical supply chains and the introduction of new quality control strategies. The revision has been carried out in the light of Directive 2011/62/EU amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of falsified medicinal products. This version also implements ICH Q8, Q9 and Q10 documents, and interpretation documents, such as the manufacturing and importation authorisation (MIA) interpretation document, as applicable. Also, some areas, where the interpretation by Member States has not been consistent, have been clarified. This revised Annex came into operation 15 April 2016. The introduction of guidelines on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities. The introduction of guidelines on the formalised risk assessment for ascertaining the appropriate GMP for excipients. The addition of the Guidelines on principles of Good Distribution Practice of active substances for medicinal products for human use (2015/C 95/01). These guidelines provide stand-alone guidance on Good Distribution Practice (GDP) for manufacturers, importers and distributors of active substances for medicinal products for human use. These guidelines should be followed as of 21 September 2015. The addition of the principles and guidelines of Good Manufacturing Practice (GMP) for active substances for medicinal products for human use, including active substances intended for export. Revisions to the UK Human Medicines Regulations 2012. MHRA GMP Data Integrity Definitions and Guidance for Industry is now included which sets out MHRA expectations for data integrity in good manufacturing practice (GMP). The Guidance complements existing EU GMP guidance and should be read in conjunction with national medicines legislation and the GMP standards published in Eudralex volume.