Ispe Baseline Pharmaceutical Engineering Guide Volume 5

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Vaccine Development and Manufacturing Emily P. Wen 2014-11-17 Vaccine Manufacturing and Production is an invaluable reference on how to produce a vaccine - from beginning to end - addressing all classes of vaccines from a processing, production, and regulatory viewpoint. It will provide comprehensive information on the various fields involved in the production of vaccines, from fermentation, purification, formulation, to regulatory filing and facility designs. In recent years, there have been tremendous advances in all aspects of vaccine manufacturing. Improved technology and growth media have been developed for the production of cell culture with high cell density or fermentation. Vaccine Manufacturing and Production will serve as a reference on all aspects of vaccine production by providing an in-depth description of the available technologies for making different types of vaccines and the current thinking in facility designs and supply issues. This book will provide insight to the issues scientists face when producing a vaccine, the steps that are involved, and will serve as a reference tool regarding state-of-the-art vaccine manufacturing technologies and facility set-up. Highlights include: Comprehensive coverage of vaccine production : from a process point of view- fermentation to purification to formulation developments; from a production point of view - from facility design to manufacturing; and from a regulatory point of view - requirements from government agencies Authors from different major pharmaceutical and biotechnology companies Describes the challenges and issues involved in vaccine production and manufacturing of the different classes of vaccines, an area not covered by other books currently on the market

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.

Recepteerkunde Yvonne Bouwman-Boer 2010-01-18 Recepteerkunde is compleet vernieuwd en helemaal bij de tijd. Van een vraag van de arts tot quality by design, van mortier tot autoclaaf, van ingangs-tot eindcontrole, van recept tot productdossier, van apotheek tot thuiszorg, het komt allemaal aan de orde. Zowel voor de specialist als voor de generalist is Recepteerkunde onmisbaar.Voor de apotheek was de kleinschalige bereiding vanouds de core business, tot steeds meer apotheken de bereiding gingen uitbesteden. Het klassieke bereiden uit grondstoffen is een specialisme geworden. Maar elke apotheek heeft te maken met productzorg: beschikbaarheid. Bewaren en bewerken van handelspreparaten. Ook voor toediening gereed maken (VTGM) gebeurt in elke apotheek, elke dag, met toewijding en kennis van zaken.Recepteerkunde is een naslagwerk voor iedereen die betrokken is bij de bereiding en aflevering van geneesmiddelen: openbare apothekers, ziekenhuisapothekers, industrieapothekers en apothekersassistenten. Tevens is het een leerboek voor studenten farmacie. Wie zelf bereidt uit grondstoffen op kleine of grote schaal, of handelspreparaten aanpast, kan niet zonder Recepteerkunde, maar ook zij die bereidingen van anderen afleveren op preparaten voor toediening gereed maken, vinden er noodzakelijke informatie.

Good Manufacturing Practices for Pharmaceuticals, Seventh Edition Graham P. Bunn 2019-02-04 This book provides insight into the world of pharmaceutical quality systems and the key elements that must be in place to change the business and organizational dynamics from task-oriented procedure-based cultures to truly integrated quality business systems that are self-detecting and correcting. Chapter flow has been changed to adopt a quality systems organization approach, and supporting chapters have been updated based on current hot topics including the impact of the worldwide supply chain complexity and current regulatory trends.

Applying ISA-88 in Discrete and Continuous Manufacturing World Batch Forum 2010 The ISA standards 88 and 95 are manufacturing standards established in the late 1990s and periodically updated by the governing bodies responsible for them -Instrumentation Society of America and American National Standards Institute. This book finds applications of ISA batch recipes to continuous and semi-continuous manufacturing operations.

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

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

Trends on the Role of PET in Drug Development

Rules of Thumb for Chemical Engineers Stephen Hall 2012 Annotation A handbook for chemical and process engineers who need a solution to their practical on-the-job problems. It solves process design problems quickly, accurately and safely, with hundreds of techniques, shortcuts and calculations.

Pharmaceutical Production Institution of Chemical Engineers (Great Britain) 2003 This title is a general introduction aimed at all those involved in the engineering stages required for the manufacturr of the active ingredient and its dosage forms.

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

Inbetriebnahme verfahrenstechnischer Anlagen Klaus H. Weber 2019-07-08 Das Buch ist eine praktische Handlungsanleitung für jeden, der an der Planung, Montage und Inbetriebnahme von Anlagen mitwirkt. Zahlreiche Workflows, Checklisten, Templates und Beispiele weisen den Weg zur erfolgreichen Inbetriebnahme und Kosteneinsparung. Die Kosten der Inbetriebnahme von Neuanlagen sind mit 8 bis 15 % der Investitionssumme erheblich; gravierende Einsparpotentiale werden häufig nicht genutzt. Die Inbetriebnahme ist für alle Beteiligten die „Stunde der Wahrheit" und mit vielen Unwägbarkeiten verbunden. Sie beinhaltet u.a. den Leistungsnachweis und die rechtsverbindliche Abnahme der Anlage sowie der AS BUILT-Dokumentation. Die 5. Auflage ist eine vollständige Überarbeitung, Aktualisierung und wesentliche Erweiterung. Dies betrifft insbesondere - die Umsetzung neuer Rechtsvorschriften, - die Spezifikation der Reinheit und die systematische Reinigung der Anlage, - die Beschreibung effizienter spezifischer Organisationsstrukturen, - die GMP-konforme Vorgehensweise in Pharmaanlagen, - die Darstellung neuer Praxisbeispiele, Workflows und Checklisten. Insgesamt wurden der Textumfang und die Anzahl an Abbildungen, Tabellen, Checklisten und Praxisbeispielen deutlich erweitert. Das Buch ist in einer Reihe mit den bewährten Praxishandbüchern des Autors über „Engineering bzw. Dokumentation verfahrenstechnischer Anlagen" zu sehen.

Facility Validation Graham C. Wrigley 2004-03-29 Often considered a necessary evil by the pharmaceutical industry, validation is still understood by many as unrestrained bureaucracy, paperwork, and procedures whose roots and logic are obscure and only serve to slow down progress. Thoroughly defining the philosophy, application, and processes, Facility Validation: Theory, Practice, and Tools explores the validation issues relevant to the start-up of a new or upgraded manufacturing facility. The author describes policies, guidelines, and regulations relating to GMPs in the pharmaceutical industry and explores the relationship between these GMPs and the validation process. He outlines the theory and clarifies the philosophy and key principles of validation such as life-cycle approach and qualification practices. The book includes coverage of common pitfalls and how to avoid them, the difficulties and constraints a validation team has to manage, and the dangers of not adopting and following the recommended best practices. Facility validation has, in fact, become good business. It can be a tool for enhancing reliability, cost, and quality. This book makes the case that design, engineering, commissioning, and validation activities can be integrated and streamlined to accelerate a pharmaceutical manufacturing plant start-up effort, and demonstrates how to use best practices to achieve the results you desire in your organization.

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.

Quality Assurance of Pharmaceuticals World Health Organization 2007 Quality assurance of pharmaceutical products is a continuing concern of WHO. Despite efforts made around the world to ensure a supply of quality and effective medicines, substandard, spurious and counterfeit products still compromise health care delivery in many countries. To respond to the global need for adequate quality assurance of pharmaceuticals, WHO's Expert Committee on Specifications for Pharmaceutical Preparations has over the years made numerous recommendations to establish standards and guidelines and to promote the effective functioning of national regulatory and control systems and the implementation of internationally agreed standards by trained personnel. Many of the relevant documents endorsed by the Committee are reproduced in this volume providing guidance covering all aspects of good manufacturing practices (GMP). Important texts on inspection are also included. Most of the material has been published separately in the Expert Committee's reports. This compendium brings it together to make it more accessible and of greater practical value to those working in faculties of pharmacy, in medicines regulation and control and in the pharmaceutical industry. This is the second updated edition of the compendium and includes texts published in 2005 and 2006 in the WHO Technical Report Series.

Automation Applications in Bio-pharmaceuticals George Buckbee (P.E.) 2008 A guide for engineers and designers new to the field of bio-pharmaceutical process control. For the experienced automation professional, it outlines the unique design and application issues for the bio-pharmaceutical industry. For those already familiar with this industry, it provides specific advice for automating these processes.

GMP-Qualifizierung und Validierung von Wirkstoffanlagen Ralf Gengenbach 2012-02-16 Unter Validierung bzw. Qualifizierung versteht man die Beweisf hrung, dass Verfahren, Prozesse, Ausr stungsgegenst nde, Materialien, Arbeitsg nge oder Systeme tats chlich zu den erwarteten Ergebnissen f hren. Betroffen sind alle Unternehmen, die Rohstoffe, Halbfertig- oder Fertigprodukte f r medizinische Ger te, Pharmazeutika, Diagnostika, Lebensmittel herstellen. Ebenso sind Labore betroffen, die Dienstleistungen anbieten, deren Ergebnisse direkt in den Herstellungsprozess einflie en. Dieses Buch liefert "harte Fakten" hinsichtlich der Durchf hrung (How to do) von praxiserprobten Qualifizierungs- und Validierungsma nahmen - ein "Must have" f r Wirkstoff- und Arzneimittelhersteller sowie deren Zulieferer. Der deutsche Titel zur Validierung und Qualifizierung

Medicines from Animal Cell Culture Glyn N. Stacey 2007-06-29 Medicines from Animal Cell Culture focuses on the use of animal cell culture, which has been used to produce human and veterinary vaccines, interferon, monoclonal antibodies and genetically engineered products such as tPA and erythropoietin. It also addresses the recent dramatic expansion in cell-based therapies, including the use of live cells for tissue regeneration and the culture of stem cells. Medicines from Animal Cell Culture: Provides comprehensive descriptions of methods for cell culture and nutrition as well as the technologies for the preservation and characterisation of both the cells and the derived products Describes the preparation of stem cells and others for use in cell-based therapies – an area of burgeoning research Includes experimental examples to indicate expected results Covers regulatory issues from the UK, the EU and the USA and reviews how these are developing around the world Addresses the key issues of standardisation and

validation with chapters on GLP and GMP for cell culture processes Delivering insight into the exciting world of biological medicines and directions for further investigation into specific topics, Medicines from Animal Cell Culture is an essential resource for researchers and technicians at all levels using cell culture within the pharmaceutical, biotechnology and biomedical industries. It is of value to laboratory managers in these industries and to all those interested in this topic alike.

ISPE Baseline® Guide Ispe 2019-07-15

Hygienische Produktionstechnologie Gerhard Hauser 2012-02-28 Bei der Herstellung hochreiner Produkte spielt Hygienic Design moderner Anlagen, Apparate, Komponenten und Prozessraume eine entscheidende Rolle. Die Lebensmittel-, Futtermittel-, Pharma-, Kosmetik- und Bioindustrie sind aus hygienischen Grunden, die Chemische- und Farbenindustrie aus Grunden der Produktreinheit auf einwandfreie Sauberkeit ihrer Prozesseinrichtungen angewiesen. Durch Optimierung der Reinigbarkeit lassen sich bei Produkten, die fur den menschlichen Konsum bestimmt sind, Kontaminationen und Ruckrufaktionen vermindern bzw. vermeiden und Anforderungen des Verbraucherschutzes leichter erfullen. In allen Industriezweigen konnen durch Hygienic Design erhebliche Kosten fur den Reinigungsaufwand und zur Reduzierung der Umweltbelastung eingespart werden. Das vorliegende Buch gibt u.a. Antworten auf folgende Fragen: Welche Regelungen, Leitlinien und Normen zur Gestaltung unter hygienischen bzw. reinigungstechnischen Gesichtspunkten sind verfugbar und verpflichtend? Was ist Stand der Technik? Welches sind grundlegende Problembereiche? Welche konstruktiven Verbesserungen sind moglich? Neben rechtlichen Anforderungen werden theoretische Grundlagen, Fragen des Einsatzes von Werkstoffen, notwendige Oberflachenqualitaten sowie hygienegerechte Dichtungs- und Maschinenelemente diskutiert. Fur Anlagen, Apparate, Komponenten, Prozessumgebung und raumliche Ausstattungen werden anhand vieler konstruktiver Praxisbeispiele Schwachstellen und Problembereiche sowie Moglichkeiten zu deren Verbesserung dargestellt. Das Buch richtet sich an Ingenieure im konstruktiven Bereich der genannten Industriezweige im Anlagenbau und in der Zulieferindustrie. Betriebsangehorige, die fur Risikoanalysen, Qualitat und Produktsicherheit bei der Produktherstellung verantwortlich sind, erhalten viele praktische Hinweise auf apparatives Design.

eWork and eBusiness in Architecture, Engineering and Construction Z. Turk 2002-01-01 This is a comprehensive review of research related to construction informatics, with a particular focus on the related 5th framework EU projects on product and process technology and the implementation of the new economy technologies and business models in the construction industry.

International IT Regulations and Compliance Siri H. Segalstad 2008-11-20 Standards, technologies, and requirements for computer validation have changed dramatically in recent years, and so have the interpretation of the standards and the understanding of the processes involved. International IT Regulations and Compliance brings together current thinking on the implementation of standards and regulations in relation to IT for a wide variety of industries. The book provides professionals in pharmaceutical and semiconductor industries with an updated overview of requirements for handling IT systems according to various Quality Standards and how to ?translate? these requirements in the regulations.

Quality Kate McCormick 2022-07-27 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

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 sectionss: Section 1 - Parenteral Drug Administration and Delivery Devices; Section 2 - Formulation Design and Development; Section 3 - Specialized Drug Delivery Systems; Section 4 - Primary Packaging and Container Closure Integrity; Section 5 - Facility Design and Environmental Control; Section 6 - Sterilization and Pharmaceutical Processing; Section 7 - Quality Testing and Regulatory Requirements

Reinraumtechnik Lothar Gail 2018-05-22 Der Band bietet eine fundierte Darstellung der Reinraumtechnik als branchenübergreifende Disziplin. Dabei verknüpfen die Autoren die Grundlagen der Reinraumtechnik mit deren Anwendungen und mit einer Anleitung zum selbständigen Erarbeiten von Problemlösungen. Für die 3. Auflage wurden Ergebnisse der nationalen und internationalen Reinraumkongresse ebenso berücksichtigt wie neue Regulierungen der Pharmazie, aktuelle Richtlinien und Anwendungen. Die Themen Hygienetechnik und Reinstwassertechnologie werden jetzt ausführlicher behandelt.

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.

Validation of Pharmaceutical Processes James P. Agalloco 2007-09-25 Completely revised and updated to reflect the significant advances in pharmaceutical production and regulatory expectations, this third edition of Validation of Pharmaceutical Processes examines and blueprints every step of the validation process needed to remain compliant and competitive. The many chapters added to the prior compilation examine va

Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing Hamid Mollah 2013-02-01 Sets forth tested and proven risk management practices indrug manufacturing Risk management is essential for safe and efficientpharmaceutical and biopharmaceutical manufacturing, control, anddistribution. With this book as their guide, readers involved inall facets of drug manufacturing have a single, expertly written,and organized resource to guide them through all facets of riskmanagement and analysis. It sets forth a solid foundation in riskmanagement concepts and then explains how these concepts areapplied to drug manufacturing. Risk Management Applications in Pharmaceutical andBiopharmaceutical Manufacturing features contributions fromleading international experts in risk management and drugmanufacturing. These contributions reflect the latest research,practices, and industry standards as well as the authors' firsthandexperience. Readers can turn to the book for: Basic foundation of risk management principles, practices, andapplications Tested and proven tools and methods for managing risk inpharmaceutical and biopharmaceutical product manufacturingprocesses Recent FDA guidelines, EU regulations, and internationalstandards governing the application of risk management to drugmanufacturing Case studies and detailed examples demonstrating the use andresults of applying risk management principles to drug productmanufacturing Bibliography and extensive references leading to the literatureand helpful resources in the field With its unique focus on the application of risk management tobiopharmaceutical and pharmaceutical manufacturing, this book is anessential resource for pharmaceutical and process engineers as wellas safety and compliance professionals involved in drugmanufacturing.

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.

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 bio-pharmaceutical 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

Technical Report Series 1950

Good Quality Practice (GQP) in Pharmaceutical Manufacturing: A Handbook Jordi Botet 2015-09-28 Pharmaceutical manufacturing can be viewed as a supply chain which spans from the production and purchase of the starting and packaging materials through the manufacture of dosage forms until the safe reception of the finished product by the patient. The entire chain comprises of several processes: auditing, materials purchase (procurement), production, storage, distribution, quality control, and quality assurance. The quality standard for pharmaceutical production is ‘current good manufacturing practice (CGMP)’‘, which is applied within the frame of a pharmaceutical quality system (PQS). This implementation, however, requires a scientific approach and has to take into account several elements such as risk assessment, life cycle, patient protection, among other factors. Hence, pharmaceutical manufacturing is a complex subject in terms of regulation, given the technical and managerial requirements. This comprehensive handbook describes CGMP for new professionals who want to understand and apply the elements which build up pharmaceutical quality assurance. The book gives details about basic quality control requirements (such as risk management, quality hazards and management systems, documentation, clean environments, personnel training) and gives guidelines on regulatory aspects. This is an ideal handbook for undergraduates studying pharmaceutical or industrial manufacturing and supply chains as well for entrepreneurs and quality control professionals seeking to learn about CGMP standards and implementing quality assurance systems in the pharmaceutical sector.

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.

WHO Drug Information 2021-04-08

Manufacturing of Pharmaceutical Proteins Stefan Behme 2009-06-01 This comprehensive introduction covers all aspects of biopharmaceutical manufacturing, including legal and regulatory issues as well as costing procedures. Written by a leading expert at one of the largest pharmaceutical companies worldwide, this practical text is aimed at a wide audience, ranging from libraries, via biotech companies to students and technicians planning to enter biopharmaceutical manufacturing. In addition, it is well suited for academic teaching as well as

internal training within larger biotech or pharmaceutical companies.
WHO Expert Committee on Specifications for Pharmaceutical Preparations WHO Expert Committee on Specifications for Pharmaceutical Preparations 2006 This report presents the recommendations of an international group of experts convened by the World Health Organization to consider matters concerning the quality assurance of pharmaceuticals and specifications for drug substances and dosage forms. The report is complemented by a number of annexes. These include: a list of available international chemical reference substances and international infrared spectra; supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms; updated supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines; supplementary guidelines on good manufacturing practices for validation; good distribution practices for pharmaceutical products; a model quality assurance system for procurement agencies (recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products); multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability; a proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms; and additional guidance for organizations performing in vivo bioequivalence studies. ...This is an excellent book with a misleading title... a good reference work for anyone seeking to understand the concept of validation and looking for general guidance on validation for both Active Pharmaceutical Ingredients (API) and finished pharmaceutical products. Annex 5 on Good distribution practices (GDP) for pharmaceutical products is an excellent Annex that splits the task of GDP into 20, small, easy to digest sections that guide the reader through the process of understanding the complexity of controlling distribution of pharmaceutical products. It contains a comprehensive glossary of terms used in GDP... a useful reference book for anyone involved in Quality Assurance, Manufacturing of marketed products, Clinical Manufacturing and Development. - Industrial Pharmacy
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.
Reinraumtechnik L. Gail 2013-04-17 Ausgehend von reinraumtechnischen Problemstellungen werden die Grundlagen und Anwendungen beschrieben und daraus Prinzipien für technische Lösungswege hergeleitet. Für alle wichtigen Aspekte der Kontaminationskontrolle werden Methoden zum Nachweis von Mikroverunreinigungen, technische Lösungskonzepte und deren Leistungsgrenzen dargestellt. Eine Besonderheit des Buches liegt in der systematischen Verknüpfung von Grundlagen, Problemstellungen, technischen Lösungswegen und deren praktischer Anwendung. Das Buch vermittelt dem Leser einen direkten Weg von der Problemstellung über die Auswahl der einzelnen Elemente bzw. Instrumente der Reinraumtechnik hin zur praktischen technischen Lösung. Die Herausgeber gelten als Nestoren der Reinraumtechnik, sie haben sich durch ihre Aktivitäten in der Industrie wie den Gremien um die Entwicklung der Thematik besonders verdient gemacht.
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.
Microbial Contamination Control in Parenteral Manufacturing Kevin Williams 2004-05-20 This reference surveys emerging trends, concepts, and procedures used in the characterization and control of contaminants; the sterile production of traditional drugs and biologics; the design, construction, and validation of new parenteral facilities; and the monitoring of clean environments-vividly illustrating the routes by which products, proce