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Good Quality Practice (GQP) in Pharmaceutical Manufacturing: A Handbook Good Design Practices for GMP Pharmaceutical Facilities Quality *Manufacturing of Pharmaceutical Proteins* **International IT Regulations and Compliance ISPE GAMP® Good Practice Guide** GMP Compliance, Productivity, and Quality *Handbook of Validation in Pharmaceutical Processes, Fourth Edition Engineering verfahrenstechnischer Anlagen* Reinraumtechnik **Hygienegerechte Apparate und Anlagen** Hygienische Produktionstechnologie **Validation of Pharmaceutical Processes** Industrielle Wasseraufbereitung Process Architecture in Biomanufacturing Facility Design *GMP-Qualifizierung und Validierung von Wirkstoffanlagen* Parenteral Medications, Fourth Edition **Verfahrenstechnische Methoden in der Wirkstoffherstellung Downstream Industrial Biotechnology Pharmaceutical Production Inbetriebnahme verfahrenstechnischer Anlagen Rotierende Verdrängerpumpen für die Prozesstechnik Reinraumtechnik Pharmaceutical Dosage Forms Pharmaceutical Dosage Forms - Parenteral Medications Vaccine Development and Manufacturing** Pharmaceutical Computer Systems Validation *Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing* **Quality Assurance of Pharmaceuticals Cell Culture Technology for Pharmaceutical and Cell-Based Therapies** *WHO Expert Committee on Specifications for Pharmaceutical Preparations* **Tissue Engineering and Plastic Surgery Encyclopedia of Pharmaceutical Technology Pharmaceutical Microbiological Quality Assurance and Control Pharmaceutical Quality by Design Sterile Manufacturing Filtration and Purification in the Biopharmaceutical Industry, Third Edition Automation Applications in Bio-pharmaceuticals Rules of Thumb for Chemical Engineers Microbial Contamination Control in Parenteral Manufacturing**

WHO Expert Committee on Specifications for Pharmaceutical Preparations Apr 04 2020 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.

International IT Regulations and Compliance Jun 30 2022 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.

Sterile Manufacturing Oct 30 2019 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.

Good Quality Practice (GQP) in Pharmaceutical Manufacturing: A Handbook Nov 04 2022 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.

Downstream Industrial Biotechnology Apr 16 2021 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.

Reinraumtechnik Jan 26 2022 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.

Pharmaceutical Production Mar 16 2021 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.

Process Architecture in Biomanufacturing Facility Design Aug 21 2021 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.

Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing Jul 08 2020 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.

Industrielle Wasseraufbereitung Sep 21 2021 Wasser ist ein wichtiger Rohstoff für viele Industriezweige. Eine stabile und kontrollierte Wasserqualität ist eine entscheidende Voraussetzung für die Herstellung von Pharmazeutika, Medizinprodukten, Nahrungsmitteln und Kosmetika. Dieses Praxishandbuch für Anwender im Betrieb gibt einen Überblick über die relevanten Daten, Fakten und Bestimmungen für den Umgang mit Wasser in der industriellen Produktion, von der Auslegung der Komponenten bis zur Inbetriebnahme, einschließlich der Zertifizierung und Überwachung der Anlagen im laufenden Betrieb. Nach einer allgemeinen Einführung in die Grundlagen der Wasserchemie und Wassertechnologie stellt der Autor die im industriellen Umfeld üblichen Verfahren und Anlagen zur Wasseraufbereitung vor, von der mechanischen über die thermische bis hin zur chemischen Aufbereitung. Eingehend werden die besonderen Qualitätsanforderungen und Verfahren für hochreine Wässer wie Kesselspeisewasser und Pharmawasser beschrieben. Der letzte Teil des Buches widmet sich der Kontrolle und Vermeidung von mikrobiellen Verunreinigungen, die für viele Anwendungen das größte Problem für die Wasserqualität darstellen.

Cell Culture Technology for Pharmaceutical and Cell-Based Therapies May 06 2020 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

Filtration and Purification in the Biopharmaceutical Industry, Third Edition Sep 29 2019 Since sterile filtration and purification steps are becoming more prevalent and critical within medicinal drug manufacturing, the third edition of Filtration and Purification in the

Biopharmaceutical Industry greatly expands its focus with extensive new material on the critical role of purification and advances in filtration science and technology. It provides state-of-the-science information on all aspects of bioprocessing including the current methods, processes, technologies and equipment. It also covers industry standards and regulatory requirements for the pharmaceutical and biopharmaceutical industries. The book is an essential, comprehensive source for all involved in filtration and purification practices, training and compliance. It describes such technologies as viral retentive filters, membrane chromatography, downstream processing, cell harvesting, and sterile filtration. Features: Addresses recent biotechnology-related processes and advanced technologies such as viral retentive filters, membrane chromatography, downstream processing, cell harvesting, and sterile filtration of medium, buffer and end product Presents detailed updates on the latest FDA and EMA regulatory requirements involving filtration and purification practices, as well as discussions on best practises in filter integrity testing Describes current industry quality standards and validation requirements and provides guidance for compliance, not just from an end-user perspective, but also supplier requirement It discusses the advantages of single-use process technologies and the qualification needs Sterilizing grade filtration qualification and process validation is presented in detail to gain the understanding of the regulatory needs The book has been compilated by highly experienced contributors in the field of pharmaceutical and biopharmaceutical processing. Each specific topic has been thoroughly examined by a subject matter expert.

GMP-Qualifizierung und Validierung von Wirkstoffanlagen Jul 20 2021 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

Pharmaceutical Dosage Forms - Parenteral Medications Oct 11 2020 This three-volume set of Pharmaceutical Dosage Forms: Parenteral Medications is an authoritative, comprehensive reference work on the formulation and manufacture of parenteral dosage forms, effectively balancing theoretical considerations with the practical aspects of their development. As such, it is recommended for scientists and engineers in the pharmaceutical industry and academia, and will also serve as an excellent reference and training tool for regulatory scientists and quality assurance professionals. First published in 1984 (as two volumes) and then last revised in 1993 (when it grew to three volumes), this latest revision will address the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration. The third edition of this book maintains the features that made the last edition so popular but comprises several brand new chapters, revisions to all other chapters, as well as high quality illustrations. Volume two presents: • Chapters on aseptic facility design, environmental monitoring, and cleanroom operations. • A comprehensive chapter on pharmaceutical water systems. • A

discussion of quality attributes of sterile dosage forms, including particulate matter, endotoxin, and sterility testing. • A detailed chapter on processing of parenteral drug products (SVPs and LVPs). • Presentations on widely used sterilization technologies – steam, gas / chemical, radiation, filtration and dry heat. • An in-depth chapter on lyophilization.

ISPE GAMP® Good Practice Guide May 30 2022

Inbetriebnahme verfahrenstechnischer Anlagen Feb 12 2021 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.

Quality Sep 02 2022 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

Hygienegerechte Apparate und Anlagen Dec 25 2021 In der Lebensmittel-, der kosmetischen, pharmazeutischen und chemischen Industrie sowie in der Biotechnologie ist zum Schutz vor Kontamination ein hygienischer Produktionsprozess sehr wichtig. Sichere Qualitatsprodukte lassen sich nur mit Anlagen herstellen, die sich zuverlassig reinigen

lassen. Deshalb spielt bei der Herstellung hochreiner Produkte "Hygienic Design" moderner Anlagen, Apparate, Komponenten und Prozessraume eine entscheidende Rolle. In allen Industriezweigen konnen dadurch erhebliche Kosten fur den Reinigungsaufwand und zur Reduzierung der Umweltbelastung eingespart werden. Das vorliegende Werk baut auf dem Buch Hygienische Produktionstechnologie auf und beschreibt die Komponenten und Bauteile, die fur die Konstruktion hygienegerechter Apparate und Anlagen benotigt werden. Es richtet sich besonders an Ingenieure im konstruktiven Bereich in der Lebensmittel-, Pharma- und Kosmetikindustrie, aber auch an Betriebsangehorige, die fur Qualitat, Risikoanalysen und Produktsicherheit bei der Produktherstellung verantwortlich sind.

Pharmaceutical Microbiological Quality Assurance and Control Jan 02 2020 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

Microbial Contamination Control in Parenteral Manufacturing Jun 26 2019 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

Encyclopedia of Pharmaceutical Technology Feb 01 2020 Presenting authoritative and engaging articles on all aspects of drug development, dosage, manufacturing, and regulation, this Third Edition enables the pharmaceutical specialist and novice alike to keep abreast of developments in this rapidly evolving and highly competitive field. A dependable reference tool and constant companion for years to com

Engineering verfahrenstechnischer Anlagen Feb 24 2022 Die 2. Auflage dieses Buches ist eine vollständige Überarbeitung, Aktualisierung und wesentliche Erweiterung der vorherigen Auflage. Dies betrifft insbesondere die Darlegung und Beachtung neuer Rechtsvorschriften der EU und BRD sowie von aktuellen EU-Normen. Die Ausführungen zum Explosionsschutz, zur Risikobeurteilung und zur schutzrechtlichen Sicherung der Ergebnisse wurden wesentlich vertieft. Die Engineeringkosten machen bei Anlageninvestitionen ca. 15 bis 30 Prozent der Investitionssumme aus. Dabei liefert das Engineering die Basis, um die Investi-tionsentscheidung begründet herbeizuführen sowie die Anlage wirtschaftlich und zielgerecht zu errichten, in Betrieb zu nehmen und zu betreiben. Das Buch ist eine praktische Handlungsanleitung für jeden, der an der Abwicklung von Anlagenprojekten mitwirkt. Zahlreiche Checklisten, Templates und Beispiele weisen den Weg zum erfolgreichen Engineering (Anlagenplanung) und zur

Kosteneinsparung. Insgesamt wurde der Seitenumfang deutlich erweitert und die Anzahl an Abbildungen, Tabellen, Beispielen und Checklisten um ca. 30 Prozent erhöht. Das Buch ist in einer Reihe mit den bewährten Praxishandbüchern des Autors zur Inbetriebnahme bzw. Dokumentation verfahrenstechnischer Anlagen zu sehen.

Handbook of Validation in Pharmaceutical Processes, Fourth Edition Mar 28 2022 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

Tissue Engineering and Plastic Surgery Mar 04 2020

Verfahrenstechnische Methoden in der Wirkstoffherstellung May 18 2021 Bei der Herstellung von pharmakologischen Wirkstoffen kommen eine Vielzahl verfahrenstechnischer Grundoperationen zur Anwendung. Dies sind beispielsweise Zentrifugation, Filtration und Ultrafiltration, Chromatographie und Gefriertrocknung. Insbesondere zur Herstellung von Produkten aus Blutplasma gelten besondere Anforderungen wie Steril- und Reinraumtechnik und schonende Weiterverarbeitung. Das vorliegende Buch gibt einen praktischen Uberblick uber verfahrenstechnische Methoden und bewahrte Losungen in der pharmazeutischen Wirkstoffherstellung und beschreibt erstmals die Besonderheiten und verfahrenstechnischen Modifikationen in der Blutplasma-Industrie. Neben Hilfestellungen, Tipps und Tricks fur Ingenieure, Praktiker und Berufseinsteiger beinhaltet das Buch bislang unveroffentlichte Stoffwerte von Blutplasma und Blutproteinen. Die beiliegende CD-ROM enthalt 30 praxisorientierte Berechnungsprogramme, mit deren Hilfe der Leser sehr schnell zu Losungen eigener Fragestellungen kommen kann.

Pharmaceutical Dosage Forms Nov 11 2020 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

Parenteral Medications, Fourth Edition Jun 18 2021 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

Hygienische Produktionstechnologie Nov 23 2021 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.

Automation Applications in Bio-pharmaceuticals Aug 28 2019 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.

Rotierende Verdrängerpumpen für die Prozesstechnik Jan 14 2021

Vaccine Development and Manufacturing Sep 09 2020 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

GMP Compliance, Productivity, and Quality Apr 28 2022 Written by twenty-eight experts, filled with recommendations that can immediately be put into action, this book provides the strategies and tactics required to link and harmonize manufacturing processes with GMP to achieve optimum operability and cost-effective regulatory compliance. Drawn from name brand and generic companies and regulatory and contract organizations across the globe, the contributing authors bring readers a combined 450+ years of hands-on experience. They offer thought-provoking questions to help readers diagnose their company's challenges, needs, and available options, all with the single purpose of achieving their ultimate goals: quality, high productivity, and profitability.

Rules of Thumb for Chemical Engineers Jul 28 2019 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.

Quality Assurance of Pharmaceuticals Jun 06 2020 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.

Pharmaceutical Computer Systems Validation Aug 09 2020 Thoroughly revised to include the latest industry developments, the Second Edition presents a comprehensive overview of computer validation and verification principles and how to put them into practice. To provide the current best practice and guidance on identifying and implementing improvements for computer systems, the text extensively reviews r

Reinraumtechnik Dec 13 2020 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.

Pharmaceutical Quality by Design Dec 01 2019 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.

Manufacturing of Pharmaceutical Proteins Aug 01 2022 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.

Good Design Practices for GMP Pharmaceutical Facilities Oct 03 2022 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 Oct 23 2021 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