Pat Applied In Biopharmaceutical Process Development And Manufacturing An Enabling Tool For Quality By Design Biotechnology And Bioprocessing

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Biopharmaceutical Processing - Gunter Jagschies 2018-01-18
Biopharmaceutical Processing: Development, Design, and Implementation of Manufacturing Processes covers bioprocessing from cell line development to bulk drug substances. The methods and strategies described are essential learning for every scientist, engineer or manager in the biopharmaceutical and vaccines industry. The integrity of the bioprocess ultimately determines the quality of the product in the biotherapeutics arena, and this book covers every stage including all technologies related to downstream purification and upstream processing fields. Economic considerations are included throughout, with recommendations for lowering costs and improving efficiencies. Designed for quick reference and easy accessibility of facts, calculations and guidelines, this book is an essential tool for industrial scientists and managers in the biopharmaceutical industry. Offers a comprehensive, go-to reference for daily work decisions Covers both upstream and downstream processes Includes case studies that emphasize financial outcomes Presents summaries, decision grids, graphs and overviews for quick reference

Handbook of Analytical Quality by Design - Sarwar Beg 2021-01-09
Handbook of Analytical Quality by Design addresses the steps involved in analytical method development and validation in an effort to avoid quality crises in later stages. The AQbD approach significantly enhances method performance and robustness which are crucial during inter-laboratory studies and also affect the analytical lifecycle of the developed method. Sections cover sample preparation problems and the usefulness of the QbD concept involving Quality Risk Management (QRM), Design of Experiments (DoE) and Multivariate (MVT) Statistical Approaches to solve by optimizing the developed method, along with validation for different techniques like HPLC, UPLC, UFLC, LC-MS and electrophoresis. This will be an ideal resource for graduate students and professionals working in the pharmaceutical industry, analytical chemistry, regulatory agencies, and those in related academic fields. Concise language for easy understanding of the novel and holistic concept Covers key aspects of analytical development and validation

Provides a robust, flexible, operable range for an analytical method with greater excellence and regulatory compliance

Disposable Bioreactors II - Dieter Eibl 2013-12-17

Dynamic Single-Use Bioreactors Used in Modern Liter- and m3- Scale Biotechnological Processes: Engineering Characteristics and Scaling Up, by Christian Löffelholz, Stephan C. Kaiser, Matthias Kraume, Regine Eibl , Dieter Eibl. Orbitally Shaken Single-Use Bioreactors, by Wolf Klöckner, Sylvia Diederichs, Jochen Büchs. Therapeutic Human Cells: Manufacture for Cell Therapy/Regenerative Medicine by Christian van den Bos, Robert Keefe, Carmen Schirmaier, Michael McCaman. Fast Single-Use VLP Vaccine Productions Based on Insect Cells and the Baculovirus Expression Vector System: Influenza as Case Study by Regine Eibl, Nina Steiger, Sabine Wellnitz, Tiago Vicente, Corinne John, Dieter Eibl. Microbial High Cell Density Fermentations in a Stirred Single-Use Bioreactor by Thomas Dreher, Bart Walcarius, Ute Husemann, Franziska Klingenberg, Christian Zahnow, Thorsten Adams, Davy de Wilde, Peter Casteels, Gerhard Greller. Quorus Bioreactor: A New Perfusion-Based Technology for Microbial Cultivation by Sheena J. Fraser, Christian Endres. Cultivation of Marine Microorganisms in Single-Use Systems by Friederike Hillig, Maciej Pilarek, Stefan Junne, Peter Neubauer. Flexible Biomanufacturing Processes that Address the Needs of the Future by Bernhard Diel, Christian Manzke, Thorsten Peuker. An Approach to Quality and Security of Supply for Single-Use Bioreactors by Magali Barbaroux, Susanne Gerighausen, Heiko Hackel. A Risk Analysis for Production Processes with Disposable Bioreactors by Tobias Merseburger, Ina Pahl, Daniel Müller, Markus Tanner.

Process Scale Purification of Antibodies - Uwe Gottschalk 2017-04-03

Promoting a continued and much-needed renaissance in biopharmaceutical manufacturing, this book covers the different strategies and assembles top-tier technology experts to address the challenges of antibody purification. • Updates existing topics and adds new ones that include purification of antibodies produced in novel production systems, novel separation technologies, novel antibody formats and alternative scaffolds, and strategies for ton-scale manufacturing • Presents new and updated discussions of different purification technologies, focusing on how they can address the capacity crunch in antibody purification • Emphasizes antibodies and innovative chromatography methods for processing

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.

Single-Use Technology in Biopharmaceutical Manufacture - Regine Eibl 2019-07-24

Authoritative guide to the principles, characteristics, engineering aspects, economics, and applications of disposables in the manufacture of biopharmaceuticals The revised and updated second edition of Single-Use Technology in Biopharmaceutical Manufacture offers a comprehensive examination of the most-commonly used disposables in the manufacture of biopharmaceuticals. The authors—noted experts on the topic—provide the essential information on the principles, characteristics, engineering aspects, economics, and applications. This authoritative guide contains the basic knowledge and information about disposable equipment. The author also discusses biopharmaceuticals' applications through the lens of case studies that clearly illustrate the role of manufacturing, quality assurance, and environmental influences. This updated second edition revises existing information with recent developments that have taken place since the first edition was published. The book also presents the latest advances in the field of single-use technology and explores topics including applying single-use devices for microorganisms, human mesenchymal stem cells, and T-cells. This important book: • Contains an updated and end-to-end view of the

development and manufacturing of single-use biologics • Helps in the identification of appropriate disposables and relevant vendors • Offers illustrative case studies that examine manufacturing, quality assurance, and environmental influences • Includes updated coverage on cross-functional/transversal dependencies, significant improvements made by suppliers, and the successful application of the single-use technologies Written for biopharmaceutical manufacturers, process developers, and biological and chemical engineers, Single-Use Technology in Biopharmaceutical Manufacture, 2nd Edition provides the information needed for professionals to come to an easier decision for or against disposable alternatives and to choose the appropriate system.

Analytical Techniques in the Pharmaceutical Sciences - Anette Müllertz 2016-08-30

The aim of this book is to present a range of analytical methods that can be used in formulation design and development and focus on how these systems can be applied to understand formulation components and the dosage form these build. To effectively design and exploit drug delivery systems, the underlying characteristic of a dosage form must be understood--from the characteristics of the individual formulation components, to how they act and interact within the formulation, and finally, to how this formulation responds in different biological environments. To achieve this, there is a wide range of analytical techniques that can be adopted to understand and elucidate the mechanics of drug delivery and drug formulation. Such methods include e.g. spectroscopic analysis, diffractometric analysis, thermal investigations, surface analytical techniques, particle size analysis, rheological techniques, methods to characterize drug stability and release, and biological analysis in appropriate cell and animal models. Whilst each of these methods can encompass a full research area in their own right, formulation scientists must be able to effectively apply these methods to the delivery system they are considering. The information in this book is designed to support researchers in their ability to fully characterize and analyze a range of delivery systems, using an appropriate selection of analytical techniques. Due to its consideration of regulatory approval, this book will also be suitable for industrial researchers both at early stage up to pre-clinical research.

Hot-Melt Extrusion - Dennis Douroumis 2012-04-24

Hot-melt extrusion (HME) - melting a substance and forcing it through an orifice under controlled conditions to form a new material - is an emerging processing technology in the pharmaceutical industry for the preparation of various dosage forms and drug delivery systems, for example granules and sustained release tablets. Hot-Melt Extrusion: Pharmaceutical Applications covers the main instrumentation, operation principles and theoretical background of HME. It then focuses on HME drug delivery systems, dosage forms and clinical studies (including pharmacokinetics and bioavailability) of HME products. Finally, the book includes some recent and novel HME applications, scale -up considerations and regulatory issues. Topics covered include: principles and die design of single screw extrusion twin screw extrusion techniques and practices in the laboratory and on production scale HME developments for the pharmaceutical industry solubility parameters for prediction of drug/polymer miscibility in HME formulations the influence of plasticizers in HME applications of polymethacrylate polymers in HME HME of ethylcellulose, hypromellose, and polyethylene oxide bioadhesion properties of polymeric films produced by HME taste masking using HME clinical studies, bioavailability and pharmacokinetics of HME products injection moulding and HME processing for pharmaceutical materials laminar dispersive & distributive mixing with dissolution and applications to HME technological considerations related to scale-up of HME processes devices and implant systems by HME an FDA perspective on HME product and process understanding improved process understanding and control of an HME process with near-infrared spectroscopy Hot-Melt Extrusion: Pharmaceutical Applications is an essential multidisciplinary guide to the emerging pharmaceutical uses of this processing technology for researchers in academia and industry working in drug formulation and delivery, pharmaceutical engineering and processing, and polymers and materials science. This is the first book from our brand new series Advances in Pharmaceutical Technology.

Find out more about the series here.

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

In this era of increased pharmaceutical industry competition, success for generic drug companies is dependent on their ability to manufacture therapeutic-equivalent drug products in an economical and timely manner, while also being cognizant of patent infringement and other legal and regulatory concerns.Generic Drug Product Development: Solid Oral

New Directions in Bioprocess Modeling and Control - Michael A. Boudreau 2007

Models offer benefits even before they are put on line. Based on years of experience, the authors reveal in New Directions in Bioprocess Modeling and Control that significant improvements can result from the process knowledge and insight that are gained when building experimental and first-principle models for process monitoring and control. Doing modeling in the process development and early commercialization phases is advantageous because it increases process efficiency and provides ongoing opportunities for improving process control. This technology is important for maximizing benefits from analyzers and control tool investments. If you are a process design, quality control, information systems, or automation engineer in the biopharmaceutical, brewing, or bio-fuel industry, this handy resource will help you define, develop, and apply a virtual plant, model predictive control, first-principle models, neural networks, and multivariate statistical process control. The synergistic knowledge discovery on bench top or pilot plant scale can be ported to industrial scale processes. This learning process is consistent with the intent in the Process Analyzer and Process Control Tools sections of the FDA_s Guidance for Industry PAT _ A Framework for Innovative Pharmaceutical Development, Manufacturing and Quality Assurance. It states in the Process Analyzer section of the FDA_s guidance: _For certain applications, sensor-based measurements can provide a useful process signature that may be related to the underlying process steps or transformations. Based on the level of process understanding these signatures may also be useful for the process monitoring, control, and end point determination when these patterns or signatures relate to product and process quality._

Crystallization Processes - H. Ohtaki 1998

An overview of crystallization processes of organic and inorganic substances from various homogeneous liquids. Crystal structures, phase transitions and crystallization rates are described in the book in connection with the structure of ions, complexes and molecules of the solution phase.

Practical Process Research and Development – A guide for Organic Chemists - Neal G. Anderson 2012-05-23

Designed to provide a comprehensive, step-by-step approach to organic process research and development in the pharmaceutical, fine chemical, and agricultural chemical industries, this book describes the steps taken, following synthesis and evaluation, to bring key compounds to market in a cost-effective manner. It describes hands-on, step-by-step, approaches to solving process development problems, including route, reagent, and solvent selection; optimising catalytic reactions; chiral syntheses; and "green chemistry." Second Edition highlights: • Reflects the current thinking in chemical process R&D for small molecules • Retains similar structure and orientation to the first edition. • Contains approx. 85% new material • Primarily new examples (work-up and prospective considerations for pilot plant and manufacturing scale-up) • Some new/expanded topics (e.g. green chemistry, genotoxins, enzymatic processes) • Replaces the first edition, although the first edition contains useful older examples that readers may refer to Provides insights into generating rugged, practical, cost-effective processes for the chemical preparation of "small molecules" Breaks down process optimization into route, reagent and solvent selection, development of reaction conditions, workup, crystallizations and more Presents guidelines for implementing and troubleshooting processes

Research and Development in the Pharmaceutical Industry (A CBO Study) - Congressional Budget Office 2013-06-09

Perceptions that the pace of new-drug development has slowed and that the pharmaceutical industry is highly profitable have sparked concerns

that significant problems loom for future drug development. This Congressional Budget Office (CBO) study-prepared at the request of the Senate Majority Leader-reviews basic facts about the drug industry's recent spending on research and development (R&D) and its output of new drugs. The study also examines issues relating to the costs of R&D, the federal government's role in pharmaceutical research, the performance of the pharmaceutical industry in developing innovative drugs, and the role of expected profits in private firms' decisions about investing in drug R&D. In keeping with CBO's mandate to provide objective, impartial analysis, the study makes no recommendations. David H. Austin prepared this report under the supervision of Joseph Kile and David Moore. Colin Baker provided valuable consultation...

Bioseparations Science and Engineering - Roger G. Harrison 2015-01-27

Designed for undergraduates, graduate students, and industry practitioners, Bioseparations Science and Engineering fills a critical need in the field of bioseparations. Current, comprehensive, and concise, it covers bioseparations unit operations in unprecedented depth. In each of the chapters, the authors use a consistent method of explaining unit operations, starting with a qualitative description noting the significance and general application of the unit operation. They then illustrate the scientific application of the operation, develop the required mathematical theory, and finally, describe the applications of the theory in engineering practice, with an emphasis on design and scaleup. Unique to this text is a chapter dedicated to bioseparations process design and economics, in which a process simular, SuperPro Designer® is used to analyze and evaluate the production of three important biological products. New to this second edition are updated discussions of moment analysis, computer simulation, membrane chromatography, and evaporation, among others, as well as revised problem sets. Unique features include basic information about bioproducts and engineering analysis and a chapter with bioseparations laboratory exercises. Bioseparations Science and Engineering is ideal for students and professionals working in or studying bioseparations, and is the premier text in the field.

Continuous Biomanufacturing - Ganapathy Subramanian 2017-09-12

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

Pharmaceutical Process Development - John Blacker 2011-08-17

Pharmaceutical process research and development is an exacting, multidisciplinary effort but a somewhat neglected discipline in the chemical curriculum. This book presents an overview of the many facets of process development and how recent advances in synthetic organic chemistry, process technology and chemical engineering have impacted on the manufacture of pharmaceuticals. In 15 concise chapters the book covers such diverse subjects as route selection and economics, the interface with medicinal chemistry, the impact of green chemistry, safety, the crucial role of physical organic measurements in gaining a deeper understanding of chemical behaviour, the role of the analyst, new tools and innovations in reactor design, purification and separation, solid state chemistry and its role in formulation. The book ends with an assessment of future trends and challenges. The book provides a valuable overview of: both early and late stage chemical development, how safe and scaleable synthetic routes are designed, selected and developed, the importance of the chemical engineering, analytical and manufacturing interfaces, the key enabling technologies, including catalysis and biocatalysis, the importance of the green chemical perspective and solid form issues. The book, written and edited by experts in the field, is a contemporary, holistic treatise, with a logical sequence for process development and mini-case histories within the chapters to bring alive different aspects of the process. It is completely

pharmaceutical themed, encompassing all essential aspects, from route and reagent selection to manufacture of the active compound. The book is aimed at both graduates and postgraduates interested in a career in the pharmaceutical industry. It informs them about the breadth of the work carried out in chemical research and development departments, and gives them a feel for the challenges involved in the job. The book is also of value to academics who often understand the drug discovery arena, but have far less appreciation of the drug development area, and are thus unable to advise their students about the relative merits of careers in chemical development versus discovery.

Continuous Manufacturing of Pharmaceuticals - Peter Kleinebudde 2017-09-05

A comprehensive look at existing technologies and processes for continuous manufacturing of pharmaceuticals As rising costs outpace new drug development, the pharmaceutical industry has come under intense pressure to improve the efficiency of its manufacturing processes. Continuous process manufacturing provides a proven solution. Among its many benefits are: minimized waste, energy consumption, and raw material use; the accelerated introduction of new drugs; the use of smaller production facilities with lower building and capital costs; the ability to monitor drug quality on a continuous basis; and enhanced process reliability and flexibility. Continuous Manufacturing of Pharmaceuticals prepares professionals to take advantage of that exciting new approach to improving drug manufacturing efficiency. This book covers key aspects of the continuous manufacturing of pharmaceuticals. The first part provides an overview of key chemical engineering principles and the current regulatory environment. The second covers existing technologies for manufacturing both small-molecule-based products and protein/peptide products. The following section is devoted to process analytical tools for continuously operating manufacturing environments. The final two sections treat the integration of several individual parts of processing into fully operating continuous process systems and summarize state-of-art approaches for innovative new manufacturing principles. Brings together the essential know-how for anyone working in drug manufacturing, as well as chemical, food, and pharmaceutical scientists working on continuous processing Covers chemical engineering principles, regulatory aspects, primary and secondary manufacturing, process analytical technology and quality-by-design Contains contributions from researchers in leading pharmaceutical companies, the FDA, and academic institutions Offers an extremely well-informed look at the most promising future approaches to continuous manufacturing of innovative pharmaceutical products Timely, comprehensive, and authoritative, Continuous Manufacturing of Pharmaceuticals is an important professional resource for researchers in industry and academe working in the fields of pharmaceuticals development and manufacturing.

Model-Based Tools for Pharmaceutical Manufacturing Processes - Krist V. Gernaey 2020-03-13

The Special Issue on “Model-Based Tools for Pharmaceutical Manufacturing Processes” will curate novel advances in the development and application of model-based tools to address ever-present challenges of the traditional pharmaceutical manufacturing practice as well as new trends. This book provides a collection of nine papers on original advances in the model-based process unit, system-level, quality-by-design under uncertainty, and decision-making applications of pharmaceutical manufacturing processes.

Perfusion Cell Culture Processes for Biopharmaceuticals - Moritz Wolf 2020-08-06

This book is a monography about perfusion cell cultures for the production of biopharmaceuticals, such as therapeutic proteins (i.e. biomolecules like monoclonal antibodies), and describes the fundamentals, design and operation of these processes. Context is given in the first chapters to understand the state-of-the-art of the technology. We then give an overview of the challenges and objectives in operating mammalian cell perfusion cultures and provide guidelines for the design and setup of lab-scale bioreactor systems, and the required control structure to achieve stable operation. Scale-down devices and PAT tools are described in the context of continuous manufacturing and guidelines

for process optimization are given using a variety of case studies to illustrate different approaches. Scale-up is also adressed with a strong focus on bioreactor aeration and mixing, shear stress and cell retention device. Finally, a general introduction for the application of mechanistic and statistic models in bioreactor process development and optimization is given in the last chapter.

Process Analytical Technology - Katherine A. Bakeev 2008-04-15

The use of real or near real time measurement of chemical production process parameters as the basis for achieving control or optimisation of a manufacturing process has wide application in the petrochemical, food and chemical industries. Process analytical chemistry (PAC), or process analytical technology (PAT) as it has recently been called, is now being deployed in the pharmaceutical industry, where it is seen as a technology that can help companies to improve their conformity with manufacturing compliance regulations. The objective of this book is to provide a starting point for implementing process analytical chemistry tools in process monitoring applications or as part of a total quality management system. Written from the perspective of the spectroscopist required to implant PAT tools in a process environment, attention is focussed on measurements that are made "in process" at-line or off-line, providing data on product during manufacture. With chapters covering the key spectroscopic tools, their applications in the pharmaceutical and chemical industries and basic chemometrics, the novice can quickly develop a sound understanding of the most practical technologies and applications. Implementation strategies are fully covered and address some of the critical issues that need to be tackled when setting up a PAT project – including choosing a project with a sound business justification in the first place.

Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing - Hamid Mollah 2013-03-18

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

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.

Development of soft sensors for monitoring and control of bioprocesses -

Robert Gustavsson 2018-10-31

In the manufacture of bio-therapeutics the importance of a well-known process is key for a high product titer and low batch to batch variations. Soft sensors are based on the concept that online sensor signals can be used as inputs to mathematical models to derive new valuable process information. This information could then be used for better monitoring and control of the bioprocess. The aim of the present thesis has been to develop soft sensor solutions for upstream bioprocessing and demonstrate their usefulness in improving robustness and increase the batch-to-batch reproducibility in bioprocesses. The thesis reviews the potential and possibilities with soft sensors for use in production of bio-therapeutics to realize FDA´s process analytical technology (PAT) initiative. Modelling and hardware sensor alternatives which could be used in a soft sensor setup are described and critically analyzed. Different soft sensor approaches to control glucose feeding in fed-batch cultures of Escherichia coli are described. Measurements of metabolic fluxes and specific carbon dioxide production was used as control parameters to increase product yield and decrease the variability of produced recombinant proteins. Metabolic heat signals were used in uninduced cultures to estimate and control the specific growth rate at a desired level and thereby also estimate the biomass concentration online. The introduction of sequential filtering of the signal enabled this method to be used in a down-scaled system. The risk and high impact of contaminations in cell cultures are also described. An in situ microscope (ISM) was used as an online tool to estimate cell concentration and also to determine cell diameter size which enabled the detection of contaminant cells at an early stage. The work presented in this thesis supports the idea that soft sensors can be a useful tool in the strive towards robust and reliable bioprocesses, to ensure high product quality and increased economic profit.

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 Process Chromatography - Gunter Jagschies 2007-12-08

This book will update the original edition published in 1997. Since the publication of the first edition, the biotechnology and biologics industries have gained extensive knowledge and experience in downstream processing using chromatography and other technologies associated with recovery and purification unit operations. This book will tie that experience together for the next generation of readers. Updates include: - sources and productivity - types of products made today - experiences in clinical and licensed products - economics - current status of validation - illustrations and tables - automated column packing - automated systems New topics include: - the use of disposables - multiproduct versus dedicated production - design principles for chromatography media and filters - ultrafiltration principles and optimization - risk assessments - characterization studies - design space - platform technologies - process analytical technologies (PATs) - biogenerics - comparability assessments Key Features: - new approaches to process optimiaztion - use of patform technologies - applying risk assessment to process design

Process Scale Purification of Antibodies - Uwe Gottschalk 2017-03-07

Promoting a continued and much-needed renaissance in biopharmaceutical manufacturing, this book covers the different strategies and assembles top-tier technology experts to address the challenges of antibody purification. • Updates existing topics and adds new ones that include purification of antibodies produced in novel production systems, novel separation technologies, novel antibody formats and alternative scaffolds, and strategies for ton-scale manufacturing • Presents new and updated discussions of different purification technologies, focusing on how they can address the capacity crunch in antibody purification • Emphasizes antibodies and innovative chromatography methods for processing

Continuous Biopharmaceutical Processes - David Pfister 2018-10-31

This innovative reference provides a coherent and critical view on the potential benefits of a transition from batch to continuous processes in the biopharmaceutical industry, with the main focus on chromatography. It also covers the key topics of protein stability and protein conjugation, addressing the chemical reaction and purification aspects together with their integration. This book offers a fine balance between theoretical modelling and illustrative case studies, between fundamental concepts and applied examples from the academic and industrial literature. Scientists interested in the design of biopharmaceutical processes will find useful practical methodologies, in particular for single-column and multi-column chromatographic processes.

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.

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

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

Perfusion Cell Culture Processes for Biopharmaceuticals - Moritz Wolf 2020-08-31

Master the design and operation of perfusion cell cultures with this authoritative reference. Discover the current state-of-the-art in the design and operation of continuous bioreactors, with emphasis on mammalian cell cultures for producing therapeutic proteins. Topics include the current market for recombinant therapeutic proteins, current industry challenges and the potential contribution of continuous manufacturing. Provides coverage of every step of process development and reactor operation, including small scale screening to lab-scale and scale-up to manufacturing scale. Illustrated through real-life case studies, this is a perfect resource for groups active in the cell culture field, as well as graduate students in areas such as chemical engineering, biotechnology, chemistry and biology, and to those in the pharmaceutical industry, particularly biopharma, biotechnology and food or agro industry.

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

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

from different pharmaceutical companies and across product lifecycle of to introduce readers to the breadth of applications Contains information on the current regulatory framework which will shape how multivariate analysis (MVA) is used in years to come

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

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

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

As with all of pharmaceutical production, the regulatory environment for the production of therapeutics has been changing as a direct result of the US FDA-initiated Quality by Design (QbD) guidelines and corresponding activities of the International Committee for Harmonization (ICH). Given the rapid growth in the biopharmaceutical area and the comp

Process Systems Engineering for Pharmaceutical Manufacturing - Ravendra Singh 2018-03-16

Process Systems Engineering for Pharmaceutical Manufacturing: From Product Design to Enterprise-Wide Decisions, Volume 41, covers the following process systems engineering methods and tools for the modernization of the pharmaceutical industry: computer-aided pharmaceutical product design and pharmaceutical production processes design/synthesis; modeling and simulation of the pharmaceutical processing unit operation, integrated flowsheets and applications for design, analysis, risk assessment, sensitivity analysis, optimization,

design space identification and control system design; optimal operation, control and monitoring of pharmaceutical production processes; enterprise-wide optimization and supply chain management for pharmaceutical manufacturing processes. Currently, pharmaceutical companies are going through a paradigm shift, from traditional manufacturing mode to modernized mode, built on cutting edge technology and computer-aided methods and tools. Such shifts can benefit tremendously from the application of methods and tools of process systems engineering. Introduces Process System Engineering (PSE) methods and tools for discovering, developing and deploying greener, safer, cost-effective and efficient pharmaceutical production processes Includes a wide spectrum of case studies where different PSE tools and methods are used to improve various pharmaceutical production processes with distinct final products Examines the future benefits and challenges for applying PSE methods and tools to pharmaceutical manufacturing

Pharmaceutical Quality by Design - Sarwar Beg 2019-03-27

Pharmaceutical Quality by Design: Principles and Applications discusses the Quality by Design (QbD) concept implemented by regulatory agencies to ensure the development of a consistent and high-quality pharmaceutical product that safely provides the maximum therapeutic benefit to patients. The book walks readers through the QbD framework by covering the fundamental principles of QbD, the current regulatory requirements, and the applications of QbD at various stages of pharmaceutical product development, including drug substance and excipient development, analytical development, formulation development, dissolution testing, manufacturing, stability studies, bioequivalence testing, risk and assessment, and clinical trials. Contributions from global leaders in QbD provide specific insight in its application in a diversity of pharmaceutical products, including nanopharmaceuticals, biopharmaceuticals, and vaccines. The inclusion of illustrations, practical examples, and case studies makes this book a useful reference guide to pharmaceutical scientists and researchers who are engaged in the formulation of various delivery systems and the analysis of pharmaceutical product development and drug manufacturing process. Discusses vital QbD precepts and fundamental aspects of QbD implementation in the pharma, biopharma and biotechnology industries Provides helpful illustrations, practical examples and research case studies to explain QbD concepts to readers Includes contributions from global leaders and experts from academia, industry and regulatory agencies

Guideline on General Principles of Process Validation - 1987

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

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

Continuous Manufacturing for the Modernization of Pharmaceutical Production - National Academies of Sciences, Engineering, and Medicine 2019-04-05

On July 30-31, 2018, the National Academies of Sciences, Engineering, and Medicine held a workshop titled Continuous Manufacturing for the Modernization of Pharmaceutical Production. This workshop discussed the business and regulatory concerns associated with adopting continuous manufacturing techniques to produce biologics such as enzymes, monoclonal antibodies, and vaccines. The participants also discussed specific challenges for integration across the manufacturing system, including upstream and downstream processes, analytical techniques, and drug product development. The workshop addressed these challenges broadly across the biologics domain but focused particularly on drug categories of greatest FDA and industrial interest such as monoclonal antibodies and vaccines. This publication summarizes the presentations and discussions from the workshop.

Predictive Modeling of Pharmaceutical Unit Operations - Preetanshu Pandey 2016-09-26

The use of modeling and simulation tools is rapidly gaining prominence in the pharmaceutical industry covering a wide range of applications. This book focuses on modeling and simulation tools as they pertain to drug product manufacturing processes, although similar principles and tools may apply to many other areas. Modeling tools can improve fundamental process understanding and provide valuable insights into the manufacturing processes, which can result in significant process improvements and cost savings. With FDA mandating the use of Quality by Design (QbD) principles during manufacturing, reliable modeling techniques can help to alleviate the costs associated with such efforts, and be used to create in silico formulation and process design space. This book is geared toward detailing modeling techniques that are utilized for the various unit operations during drug product manufacturing. By way of examples that include case studies, various modeling principles are explained for the nonexpert end users. A discussion on the role of modeling in quality risk management for manufacturing and application of modeling for continuous manufacturing and biologics is also included. Explains the commonly used modeling and simulation tools Details the modeling of various unit operations commonly utilized in solid dosage drug product manufacturing Practical examples of the application of modeling tools through case studies Discussion of modeling techniques used for a risk-based approach to regulatory filings Explores the usage of modeling in upcoming areas such as continuous manufacturing and biologics manufacturingBullet points

Making Medicines Affordable - National Academies of Sciences, Engineering, and Medicine 2018-03-01

Thanks to remarkable advances in modern health care attributable to science, engineering, and medicine, it is now possible to cure or manage illnesses that were long deemed untreatable. At the same time, however, the United States is facing the vexing challenge of a seemingly uncontrolled rise in the cost of health care. Total medical expenditures are rapidly approaching 20 percent of the gross domestic product and are crowding out other priorities of national importance. The use of increasingly expensive prescription drugs is a significant part of this problem, making the cost of biopharmaceuticals a serious national concern with broad political implications. Especially with the highly visible and very large price increases for prescription drugs that have occurred in recent years, finding a way to make prescription medicinesâ€"and health care at largeâ€"more affordable for everyone has become a socioeconomic imperative. Affordability is a complex function of factors, including not just the prices of the drugs themselves, but also the details of an individual's insurance coverage and the number of medical conditions that an individual or family confronts. Therefore, any solution to the affordability issue will require considering all of these factors together. The current high and increasing costs of prescription drugsâ€"coupled with the broader trends in overall health care costsâ€"is unsustainable to society as a whole. Making Medicines Affordable examines patient access to affordable and effective therapies, with emphasis on drug pricing, inflation in the cost of drugs, and insurance design. This report explores structural and policy factors

influencing drug pricing, drug access programs, the emerging role of comparative effectiveness assessments in payment policies, changing finances of medical practice with regard to drug costs and reimbursement, and measures to prevent drug shortages and foster continued innovation in drug development. It makes recommendations for policy actions that could address drug price trends, improve patient access to affordable and effective treatments, and encourage innovations that address significant needs in health care.