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

The importance of biofuels in greening the transport sector in the future is unquestionable, given the limited available fossil energy resources, the environmental issues associated to the utilization of fossil fuels, and the increasing attention to security of supply. This comprehensive reference presents the latest technology in all aspects of biofuels production, processing, properties, raw materials, and related economic and environmental aspects. Presenting the application of methods and technology with minimum math and theory, it compiles a wide range of topics not usually covered in one single book. It discusses development of new catalysts, reactors, controllers, simulators, online analyzers, and waste minimization as well as design and operational aspects of processing units and financial and economic aspects. The book rounds out by describing properties, specifications, and quality of various biofuel products and new advances and trends towards future technology.
In the last few decades, significant advancements in the biology and engineering of stem cells have enabled progress in their clinical application to revascularization therapies. Some strategies involve the mobilization of endogenous stem cell populations, and others employ cell transplantation. However, both techniques have benefited from multidis
The premise of Quality by Design (QbD) is that the quality of the pharmaceutical product should be based upon a thorough understanding of both the product and the manufacturing process. This state-of-the-art book provides a single source of information on emerging statistical approaches to QbD and risk-based pharmaceutical development. A comprehensive resource, it combines in-depth explanations of advanced statistical methods with real-life case studies that illustrate practical applications of these methods in QbD implementation.
Biopharmaceuticals: Challenges and Opportunities This book highlights how the traditional microbial process technology has been upgraded for the production of biologic drugs how manufacturing processes have evolved to meet the global market demand with quality products under the guidelines of internally recognized regulatory bodies. It also carries information on how, armed with a deeper understanding of life-threatening diseases, biopharmaceutical companies and the life sciences industry have developed formal and informal partnerships with researchers in institutes, universities, and other R&D organizations to fulfil timely, quality production with perfect safety and security. One of the most interesting aspects of this book is the conceptual development of personalized medicine (or precision medicine) to provide the right treatment to the right patient, at the right dose at an earlier stage of development, for genetic diseases. Besides this, it also highlights the most challenging aspects of modern biopharmaceutical science, focusing on the hot topics such as design and development of biologic drugs; the use of diversified groups of host cells belonging to animals, plants, microbes, insects, and mammals; stem cell therapy and gene therapy; supply chain management of biopharmaceuticals; and the future scope of biopharmaceutical industry development. This book is the latest resource for a wide circle of scientists, students, and researchers involved in understanding and implementing the knowledge of biopharmaceuticals to develop life-saving biologic drugs and to bring awareness to the development of personalized treatment that can potentially offer patients a faster diagnosis, fewer side effects, and better outcomes. Features: Explains how the traditional cell culture methodology has been changed to a fully continuous or partially continuous process Explains how to design and fabricate living organs of body by 3D bioprinting technology Focuses on how a biopharmaceutical company deals with various problems of regulatory bodies and develops innovative biologic drugs Narrates in detail the updated information on stem cell therapy and gene therapy Explains the

development strategies and clinical significance of biosimilars and biobetters Highlights the supply chain management of biopharmaceuticals 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

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

Advances and Challenges in Pharmaceutical Technology: Materials, Process Development and Drug Delivery Strategies examines recent advancements in pharmaceutical technology. The book discusses common formulation strategies, including the use of tools for statistical formulation optimization, Quality by design (QbD), process analytical technology, and the uses of various pharmaceutical biomaterials, including natural polymers, synthetic polymers, modified natural polymers, bioceramics, and other bioinorganics. In addition, the book covers rapid advancements in the field by providing a thorough understanding of pharmaceutical processes, formulation developments, explorations, and exploitation of various pharmaceutical biomaterials to formulate pharmaceutical dosage forms. Provides extensive information and analysis on recent advancements in the field of pharmaceutical technology Includes contributions from global leaders and experts in academia, industry and regulatory agencies Uses high quality illustrations, flow charts and tables to explain concepts and text to readers, along with practical examples and research case studies

?Animal cells are the preferred “cell factories” for the production of complex molecules and antibodies for use as prophylactics, therapeutics or diagnostics. Animal cells are required for the correct post-translational processing (including glycosylation) of biopharmaceutical protein

products. They are used for the production of viral vectors for gene therapy. Major targets for this therapy include cancer, HIV, arthritis, cardiovascular and CNS diseases and cystic fibrosis. Animal cells are used as in vitro substrates in pharmacological and toxicological studies. This book is designed to serve as a comprehensive review of animal cell culture, covering the current status of both research and applications. For the student or R&D scientist or new researcher the protocols are central to the performance of cell culture work, yet a broad understanding is essential for translation of laboratory findings into the industrial production. Within the broad scope of the book, each topic is reviewed authoritatively by experts in the field to produce state-of-the-art collection of current research. A major reference volume on cell culture research and how it impacts on production of biopharmaceutical proteins worldwide, the book is essential reading for everyone working in cell culture and is a recommended volume for all biotechnology libraries.

Current Developments in Biotechnology and Bioengineering: Bioprocesses, Bioreactors and Controls provides extensive coverage of new developments, state-of-the-art technologies, and potential future trends, reviewing industrial biotechnology and bioengineering practices that facilitate and enhance the transition of processes from lab to plant scale, which is becoming increasingly important as such transitions continue to grow in frequency. Focusing on industrial bioprocesses, bioreactors for bioprocesses, and controls for bioprocesses, this title reviews industrial practice to identify bottlenecks and propose solutions, highlighting that the optimal control of a bioprocess involves not only maximization of product yield, but also taking into account parameters such as quality assurance and environmental aspects. Describes industrial bioprocesses based on the reaction media Lists the type of bioreactors used for a specific bioprocess/application Outlines the principles of control systems in various bioprocesses

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.

Process Analytical Technology explores the concepts of PAT and its application in the chemical and pharmaceutical industry from the point of view of the analytical chemist. In this new edition all of the original chapters have been updated and revised, and new chapters covering the important topics of sampling, NMR, fluorescence, and acoustic chemometrics have been added. Coverage includes: Implementation of Process Analytical Technologies UV-Visible Spectroscopy for On-line Analysis Infrared Spectroscopy for Process Analytical Applications Process Raman Spectroscopy Process NMR Spectrscopy: Technology and On-line Applications Fluorescent Sensing and Process Analytical Applications Chemometrics in Process Analytical Technology (PAT) On-Line PAT Applications of Spectroscopy in the Pharmaceutical Industry Future Trends for PAT for Increased Process Understanding and Growing Applications in Biomanufacturing NIR Chemical Imaging This volume is an important starting point for anyone wanting to implement PAT and is intended not only to assist a newcomer to the field but also to provide up-to-date information for those who practice process analytical chemistry and PAT. It is relevant for chemists, chemical and process engineers, and analytical chemists working on process development, scale-up and production in the pharmaceutical, fine and specialty chemicals industries, as well as for academic chemistry, chemical engineering, chemometrics and pharmaceutical science research groups focussing on PAT. Review from the First Edition “The book provides an excellent first port of call for anyone seeking material and discussions to understand the area better. It deserves to be found in every library that serves those who are active in the field of Process Analytical Technology.”—Current Engineering Practice

Advances in Biotechnology Research and Application: 2011 Edition is a ScholarlyEditions™ eBook that delivers timely, authoritative, and comprehensive information about Biotechnology. The editors have built Advances in Biotechnology Research and Application: 2011 Edition on the vast information databases of ScholarlyNews.™ You can expect the information about Biotechnology in this eBook to be deeper than what you can access anywhere else, as well as consistently reliable, authoritative, informed, and relevant. The content of Advances in Biotechnology Research and Application: 2011 Edition has been produced by the world’s leading scientists, engineers, analysts, research institutions, and companies. All of the content is from peer-reviewed sources, and all of it is written, assembled, and edited by the editors at ScholarlyEditions™ and available exclusively from us. You now have a source you can cite with authority, confidence, and credibility. More information is available at http://www.ScholarlyEditions.com/.

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.

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

Offers a comprehensive overview of cell culture engineering, providing insight into cell engineering, systems biology approaches and processing technology In Cell Culture Engineering: Recombinant Protein Production, editors Gyun Min Lee and Helene Faustrup Kildegaard assemble top class authors to present expert coverage of topics such as: cell line development for therapeutic protein production; development of a transient gene expression upstream platform; and CHO synthetic biology. They provide readers with everything they need to know about enhancing product and bioprocess attributes using genome-scale models of CHO metabolism; omics data and mammalian systems biotechnology; perfusion culture; and much more. This all-new, up-to-date reference covers all of the important aspects of cell culture engineering, including cell engineering, system biology approaches, and processing technology. It describes the challenges in cell line development and cell engineering, e.g. via gene editing tools like CRISPR/Cas9 and with the aim to engineer glycosylation patterns. Furthermore, it gives an overview about synthetic biology approaches applied to cell culture engineering and elaborates the use of CHO cells as common cell line for protein production. In addition, the book

discusses the most important aspects of production processes, including cell culture media, batch, fed-batch, and perfusion processes as well as process analytical technology, quality by design, and scale down models. -Covers key elements of cell culture engineering applied to the production of recombinant proteins for therapeutic use -Focuses on mammalian and animal cells to help highlight synthetic and systems biology approaches to cell culture engineering, exemplified by the widely used CHO cell line -Part of the renowned "Advanced Biotechnology" book series Cell Culture Engineering: Recombinant Protein Production will appeal to biotechnologists, bioengineers, life scientists, chemical engineers, and PhD students in the life sciences.

Methodologies for Biosimilar Product Development covers the practical and challenging issues that are commonly encountered during the development, review, and approval of a proposed biosimilar product. These practical and challenging issues include, but are not limited to the mix-up use of interval hypotheses testing (i.e., the use of TOST) and confidence interval approach, a risk/benefit assessment for non-inferiority/similarity margin, PK/PD bridging studies with multiple references, the detection of possible reference product change over time, design and analysis of biosimilar switching studies, the assessment of sensitivity index for assessment of extrapolation across indications without collecting data from those indications not under study, and the feasibility and validation of non-medical switch post-approval. Key Features: Reviews withdrawn draft guidance on analytical similarity assessment. Evaluates various methods for analytical similarity evaluation based on FDA’s current guidelines. Provides a general approach for the use of n-of-1 trial design for assessment of interchangeability. Discusses the feasibility and validity of the non-medical switch studies. Provides innovative thinking for detection of possible reference product change over time. This book embraces innovative thinking of design and analysis for biosimilar studies, which are required for review and approval of biosimilar regulatory submissions.

Bacteria, yeast, fungi and microalgae can act as producers (or catalysts for the production) of food ingredients, enzymes and nutraceuticals. With the current trend towards the use of natural ingredients in foods, there is renewed interest in microbial flavours and colours, food bioprocessing using enzymes and food biopreservation using bacteriocins. Microbial production of substances such as organic acids and hydrocolloids also remains an important and fast-changing area of research. Microbial production of food ingredients, enzymes and nutraceuticals provides a comprehensive overview of microbial production of food ingredients, enzymes and nutraceuticals. Part one reviews developments in the metabolic engineering of industrial microorganisms and advances in fermentation technology in the production of fungi, yeasts, enzymes and nutraceuticals. Part two discusses the production and application in food processing of substances such as carotenoids, flavonoids and terponoids, enzymes, probiotics and prebiotics, bacteriocins, microbial polysaccharides,

polyols and polyunsaturated fatty acids. Microbial production of food ingredients, enzymes and nutraceuticals is an invaluable guide for professionals in the fermentation industry as well as researchers and practitioners in the areas of biotechnology, microbiology, chemical engineering and food processing. Provides a comprehensive overview of microbial flavours and colours, food bioprocessing using enzymes and food biopreservation using bacteriocins Begins with a review of key areas of systems biology and metabolic engineering, including methods and developments for filamentous fungi Analyses the use of microorganisms for the production of natural molecules for use in foods, including microbial production of food flavours and carotenoids

This book is a printed edition of the Special Issue "Design and Engineering of Microreactor and Smart-Scaled Flow Processes" that was published in Processes

This second volume offers numerous approaches to using Chinese medicine for the prevention and treatment of various diseases in medical practice. It brings the concepts and theories learned in the first volume and applies them in clinical settings with real patient examples. It goes over the four natures and five flavors of herbal drugs, and covers the different techniques of acupuncture. The book considers how the advancements in modern technology have shaped Traditional Chinese Medicine (TCM), and discusses the revolutionary innovations that are occurring in the Chinese medicine industry today and how they will shape the future.

“... a must-read for all modern bio-scientists and engineers working in the field of biotechnology.” – Biotechnology Journal, 2012, 7 A cutting-edge guide on the fundamentals, theory, and applications of biomechatronic design principles Biomechatronic Design in Biotechnology presents a complete methodology of biomechatronics, an emerging variant of the mechatronics field that marries biology, electronics, and mechanics to create products where biological and biochemical, technical, human, management-and-goal, and information systems are combined and integrated in order to solve a mission that fulfills a human need. A biomechatronic product includes a biological, mechanical, and electronic part. Beginning with an overview of the fundamentals and theory behind biomechatronic technology, this book describes how general engineering design science theory can be applied when designing a technical system where biological species or components are integrated. Some research methods explored include schemes and matrices for analyzing the functionality of the designed products, ranking methods for screening and scoring the best design solutions, and structuring graphical tools for a thorough investigation of the subsystems and sub-functions of products. This insightful guide also: Discusses tools for creating shorter development times, thereby reducing the need for prototype testing and verification Presents case study-like examples of the technology used such as a surface plasmon resonance sensor and a robotic cell culturing system for human embryonic stem cells Provides an interdisciplinary and unifying approach of the

many fields of engineering and biotechnology used in biomechatronic design By combining designs between traditional electronic and mechanical subsystems and biological systems, this book demonstrates how biotechnology and bioengineering design can utilize and benefit from commonly used design tools— and benefit humanity itself.

The submersed cultivation of organisms in sterile containments or fermenters has become the standard manufacturing procedure, and will remain the gold standard for some time to come. This book thus addresses submersed cell culture and fermentation and its importance for the manufacturing industry. It goes beyond expression systems and integrally investigates all those factors relevant for manufacturing using suspension cultures. In so doing, the contributions cover all industrial cultivation methods in a comprehensive and comparative manner, with most of the authors coming from the industry itself. Depending on the maturity of the technology, the chapters address in turn the expression system, basic process design, key factors affecting process economics, plant and bioreactor design, and regulatory aspects.

Rapid, inexpensive, and easy-to-deploy, near-infrared (NIR) spectroscopy can be used to analyze samples of virtually any composition, origin, and condition. The Handbook of Near Infrared Analysis, Fourth Edition, explores the factors necessary to perform accurate and time- and cost-effective analyses across a growing spectrum of disciplines. This updated and expanded edition incorporates the latest advances in instrumentation, computerization, chemometrics applied to NIR spectroscopy, and method development in NIR spectroscopy, and underscores current trends in sample preparation, calibration transfer, process control, data analysis, instrument performance testing, and commercial NIR instrumentation. This work offers readers an unparalleled combination of theoretical foundations, cutting-edge applications, and practical experience. Additional features include the following: Explains how to perform accurate as well as time- and cost-effective analyses. Reviews software-enabled chemometric methods and other trends in data analysis. Highlights novel applications in pharmaceuticals, polymers, plastics, petrochemicals, textiles, foods and beverages, baked products, agricultural products, biomedicine, nutraceuticals, and counterfeit detection. Underscores current trends in sample preparation, calibration transfer, process control, data analysis, and multiple aspects of commercial NIR instrumentation. Offering the most complete single-source guide of its kind, the Handbook of Near Infrared Analysis, Fourth Edition, continues to offer practicing chemists and spectroscopists an unparalleled combination of theoretical foundations, cutting-edge applications, and detailed practical experience provided firsthand by more than 50 experts in the field.

This book addresses the rapidly emerging field of Knowledge Management in the pharmaceutical, medical devices and medical diagnostics industries. In particular, it explores the role that Knowledge Management can play in ensuring the delivery of safe and effective products to patients. The book also provides good practice examples of how the effective

use of an organisation's knowledge assets can provide a path towards business excellence.

Biocontamination Control for Pharmaceuticals and Healthcare outlines a biocontamination strategy that tracks bio-burden control and reduction at each transition in classified areas of a facility. This key part of controlling risk escalation can lead to the contamination of medicinal products, hence necessary tracking precautions are essential. Regulatory authorities have challenged pharmaceutical companies, healthcare providers, and those in manufacturing practice to adopt a holistic approach to contamination control. New technologies are needed to introduce barriers between personnel and the environment, and to provide a rapid and more accurate assessment of risk. This book offers guidance on building a complete biocontamination strategy. Provides the information necessary for a facility to build a complete biocontamination strategy Helps facilities understand the main biocontamination risks to medicinal products Assists the reader in navigating regulatory requirements Provides insight into developing an environmental monitoring program Covers the types of rapid microbiological monitoring methods now available, as well as current legislation

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This book review series presents current trends in modern biotechnology. The aim is to cover all aspects of this interdisciplinary technology where knowledge, methods and expertise are required from chemistry, biochemistry, microbiology, genetics, chemical engineering and computer science. Volumes are organized topically and provide a comprehensive discussion of developments in the respective field over the past 3-5 years. The series also discusses new discoveries and applications. Special volumes are dedicated to selected topics which focus on new biotechnological products and new processes for their synthesis and purification. In general, special volumes are edited by well-known guest editors. The series editor and publisher will however always be pleased to receive suggestions and supplementary information. Manuscripts are accepted in English.

A guide to the important chemical engineering concepts for the development of new drugs, revised second edition The revised and updated second edition of Chemical Engineering in the Pharmaceutical Industry offers a guide to the experimental and computational methods related to drug product design and development. The second edition has been greatly expanded and covers a range of topics related to formulation design and process development of drug products. The authors review basic analytics for quantitation of drug product quality attributes, such as potency, purity, content uniformity, and dissolution, that are addressed with consideration of the applied statistics, process analytical technology, and process control. The 2nd Edition is divided into two separate books: 1) Active Pharmaceutical Ingredients (API's) and 2)

Drug Product Design, Development and Modeling. The contributors explore technology transfer and scale-up of batch processes that are exemplified experimentally and computationally. Written for engineers working in the field, the book examines in-silico process modeling tools that streamline experimental screening approaches. In addition, the authors discuss the emerging field of continuous drug product manufacturing. This revised second edition: Contains 21 new or revised chapters, including chapters on quality by design, computational approaches for drug product modeling, process design with PAT and process control, engineering challenges and solutions Covers chemistry and engineering activities related to dosage form design, and process development, and scale-up Offers analytical methods and applied statistics that highlight drug product quality attributes as design features Presents updated and new example calculations and associated solutions Includes contributions from leading experts in the field Written for pharmaceutical engineers, chemical engineers, undergraduate and graduation students, and professionals in the field of pharmaceutical sciences and manufacturing, Chemical Engineering in the Pharmaceutical Industry, Second Edition contains information designed to be of use from the engineer's perspective and spans information from solid to semi-solid to lyophilized drug products.

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.

Comprehensive Chemometrics, Second Edition features expanded and updated coverage, along with new content that covers advances in the field since the previous edition published in 2009. Subject of note include updates in the fields of multidimensional and megavariate data analysis, omics data analysis, big chemical and biochemical data analysis, data fusion and sparse methods. The book follows a similar structure to the previous edition, using the same section titles to frame articles. Many chapters from the previous edition are updated, but there are also many new chapters on the latest developments. Presents integrated reviews of each chemical and biological method, examining their merits and limitations through practical examples and extensive visuals Bridges a gap in knowledge, covering developments in the field since the first edition published in 2009 Meticulously organized, with articles split into 4 sections and 12 sub-sections on key topics to allow students, researchers and professionals to find relevant information quickly and easily Written by academics and practitioners from various fields and regions to ensure that the knowledge within is easily understood and applicable to a large audience Presents integrated reviews of each chemical and biological method, examining their merits and limitations through practical examples and extensive visuals Bridges a gap in knowledge, covering developments in the field since the first edition published in 2009 Meticulously organized, with articles split into 4 sections and 12 sub-sections on key topics to allow students, researchers and professionals to find relevant information quickly and easily Written by academics and practitioners from various fields and regions to ensure that the knowledge within is easily understood and applicable to a large audience

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access anywhere else, as well as consistently reliable, authoritative, informed, and relevant. The content of Advances in Cell Line Research and Application: 2013 Edition has been produced by the world's leading scientists, engineers, analysts, research institutions, and companies. All of the content is from peer-reviewed sources, and all of it is written, assembled, and edited by the editors at ScholarlyEditions™ and available exclusively from us. You now have a source you can cite with authority, confidence, and credibility. More information is available at http://www.ScholarlyEditions.com/.

Written for industrial and academic researchers and development scientists in the life sciences industry, Bioprocessing Technology for Production of Biopharmaceuticals and Bioproducts is a guide to the tools, approaches, and useful developments in bioprocessing. This important guide: • Summarizes state-of-the-art bioprocessing methods and reviews applications in life science industries • Includes illustrative case studies that review six milestone bio-products • Discuses a wide selection of host strain types and disruptive bioprocess technologies

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.

A comprehensive overview of the topic, highlighting ongoing research trends and future directions. Experts from Europe, Asia and the US cover five core areas of imminent importance to the food, feed, pharmaceutical and water treatment industries in terms of sustainable and innovative processing and production. In the field of enzyme engineering, they summarize historic developments and provide an overview of molecular enzyme engineering, while also discussing key principles of microbial process engineering, including chapters on process development and control. Further sections deal with animal and plant cell culture engineering. The final section of the book deals with environmental topics and highlights the application of bioengineering principles in waste treatment and the recovery of valuable resources. With its cutting-edge visions, extensive discussions and unique perspectives, this is a ready reference for biotechnologists, bioengineers, biotechnological institutes, and environmental chemists. Advanced Biotechnology Biotechnology is a broad, interdisciplinary field of science, combining biological sciences and relevant engineering disciplines, that is becoming increasingly important as it benefits the environment and society as a whole. Recent years have seen substantial advances in all areas of biotechnology, resulting in the emergence of brand new fields. To reflect this progress, Sang Yup Lee (KAIST, South Korea), Jens Nielsen (Chalmers University, Sweden), and Gregory Stephanopoulos (MIT, USA) have joined forces as the editors of a new Wiley-VCH book series. Advanced Biotechnology will cover all pertinent aspects of the field and each volume will be prepared by eminent scientists who are experts on the topic in question.

This first chapter introduces the concept of quality-by-design (QbD) and its role in pharmaceutical product development. QbD

assures the quality of a pharmaceutical product through scientific development and risk management tools, and will eventually enable real-time release, regardless of the formulation type. Several guidelines on pharmaceutical development, quality risk management, and pharmaceutical quality systems are presented that are applicable throughout the product lifecycle. Design space appointment and control strategies for risk management are introduced. The meaning of the QbD concept is presented from both regulatory and manufacturers' points of view. Several illustrative examples are provided to facilitate the understanding of the QbD concept and ease of its application.

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

This title introduces the underlying theory and demonstrates practical applications in different process industries using hybrid modeling. The fundamental part covers questions on "How to develop a hybrid model?", "How to represent and identify unknown parts?", "How to enhance the model quality by design of experiments?" and "How to compare different hybrid models?" together with tips and good practices for the efficient development of high quality hybrid models. The application part covers the utilization of hybrid modeling for typical process operation and design applications in industries such as chemical, petrochemical, biochemical, food and pharmaceutical process engineering.

Process Validation in Manufacturing of Biopharmaceuticals, Third Edition delves into the key aspects and current practices of process validation. It includes discussion on the final version of the FDA 2011 Guidance for Industry on Process Validation Principles and Practices, commonly referred to as the Process Validation Guidance or PVG, issued in