Quality By Design For Biopharmaceutical Drug Product Development Aaps Advances In The Pharmaceutical Sciences Series

MILA JANIYA

Preparative Chromatography for Separation of Proteins John Wiley & Sons
In recent years, emerging trends in the design and development of drug products have indicated ever greater need for integrated characterization of excipients and in-depth understanding of their roles in drug delivery applications. This book presents a concise summary of relevant scientific and mechanistic information that can aid the use of excipients in formulation design and drug delivery applications. Each chapter is contributed by chosen experts in their respective fields, which affords truly in-depth perspective into a spectrum of excipient-focused topics. This book captures current subjects of interest – with the most up to date research updates – in the field of pharmaceutical excipients. This includes areas of interest to the biopharmaceutical industry users, students, educators, excipient manufacturers, and regulatory bodies alike.

Biophysical Characterization of Proteins in Developing Biopharmaceuticals Elsevier
(Cont.) The business case demonstrated that internal drivers do exist for the systematic implementation of QbD. Up-front investment early in the product life cycle offers economic and operational benefits later in development and commercial production. In addition, organizational learning and process development evolution lead to cumulative benefits for subsequent pipeline products. Though the magnitude and timing of investment depends on the available resources and long-term strategy of the business, investment should be concentrated in three key areas: Science & Technology, Knowledge Management Systems, and Business Processes.

Therapeutic Fc-Fusion Proteins Elsevier
A one-stop, definitive resource for readers who need to know what quality by design, or QbD, is, its origins and shortcomings, the connection with continuous improvement, and, most importantly, how to apply it in practice in the pharma and biopharma sectors.
Development of Biopharmaceutical Drug-Device Products CRC Press
Biophysical Characterization of Proteins in Developing Biopharmaceuticals, Second Edition, presents the latest on the analysis and characterization of the higher-order structure (HOS) or conformation of protein based drugs. Starting from the very basics of protein structure, this book explains the best way to achieve this goal using key methods commonly employed in the biopharmaceutical industry. This book will help today's industrial scientists plan a career in this industry and successfully implement these biophysical methodologies. This updated edition has been fully revised, with new chapters focusing on the use of chromatography and electrophoresis and the biophysical characterization of very large biopharmaceuticals. In addition, best practices of applying statistical analysis to biophysical characterization data is included, along with practical issues associated with the concept of a biopharmaceutical's developability and the technical decision-making process needed when dealing with biophysical characterization data. Presents basic protein characterization methods and tools applicable to (bio)pharmaceutical research and development Highlights the capabilities and limitations of each technique Discusses the underlining science of each tool Empowers industrial biophysical chemists by providing a roadmap for applying biophysical tools Outlines the needs for new characterization and analytical tools in the biopharmaceutical industry
Bioprocess Systems Engineering Applications in Pharmaceutical Manufacturing Literatureslight Publishing
Describes the methodologies and best practices of the sterile manufacture of drug products Thoroughly trained personnel and carefully designed, operated, and maintained facilities and equipment are vital for the sterile manufacture of medicinal products using aseptic processing. Professionals in pharmaceutical and biopharmaceutical manufacturing facilities must have a clear understanding of current good manufacturing practice (cGMP) and preapproval inspection (PAI) requirements. Sterile Processing of Pharmaceutical Products: Engineering Practice, Validation, and Compliance in Regulated Environments provides up-to-date coverage of aseptic processing techniques and sterilization methods. Written by a recognized expert with more than 20 years of industry experience in aseptic manufacturing, this practical resource illustrates a comprehensive approach to sterile manufacturing engineering that can achieve drug manufacturing objectives and goals. Topics include sanitary piping and equipment, cleaning and manufacturing process validation, computerized automated systems, personal protective equipment (PPE), clean-in-place (CIP) systems, barriers and isolators, and guidelines for statistical procedure. Offering authoritative guidance on the key aspects of sterile manufacturing engineering, this volume: Covers fundamentals of aseptic techniques, quality by design, risk assessment and management, and operational requirements Addresses various regulations and guidelines instituted by the FDA, ISPE, EMA, MHRA, and ICH Provides techniques for systematic process optimization and good manufacturing practice Emphasizes the importance of attention to detail in process development and validation Features real-world examples highlighting different aspects of drug manufacturing Sterile Processing of Pharmaceutical Products: Engineering Practice, Validation, and Compliance in Regulated Environments is an indispensable reference and guide for all chemists, chemical engineers, pharmaceutical professionals and engineers, and other professionals working in pharmaceutical sciences and manufacturing.
Perfusion Cell Culture Processes for Biopharmaceuticals Academic Press
This book describes the theories, applications, and challenges for different oral controlled release formulations. This book differs from most in its focus on oral controlled release formulation design and process development. It also covers the related areas like preformulation, biopharmaceutics, in vitro-in vivo correlations (IVIVC), quality by design (QbD), and regulatory issues.
Animal Cell Biotechnology Springer Nature
This BASS book Series publishes selected high-quality papers reflecting recent advances in the design and biostatistical analysis of biopharmaceutical experiments – particularly biopharmaceutical clinical trials. The papers were selected from invited presentations at the Biopharmaceutical Applied Statistics Symposium (BASS), which was founded by the first Editor in 1994 and has since become the premier international conference in biopharmaceutical statistics. The primary aims of the BASS are: 1) to raise funding to support graduate students in biostatistics programs, and 2) to provide an opportunity for professionals engaged in pharmaceutical drug research and development to share insights into solving the problems they encounter. The BASS book series is initially divided into three volumes addressing: 1) Design of Clinical Trials; 2) Biostatistical Analysis of Clinical Trials; and 3) Pharmaceutical Applications. This book is the third of the 3-volume book series. The topics covered include: Targeted Learning of Optimal Individualized Treatment Rules under Cost Constraints, Uses of Mixture Normal Distribution in Genomics and Otherwise, Personalized Medicine – Design Considerations, Adaptive Biomarker Subpopulation and Tumor Type Selection in Phase III Oncology Trials, High Dimensional Data in Genomics; Synergy or Additivity - The Importance of Defining the Primary Endpoint, Full Bayesian Adaptive Dose Finding Using Toxicity Probability Interval (TPI), Alpha-recycling for the Analyses of Primary and Secondary Endpoints of Clinical Trials, Expanded Interpretations of Results of Carcinogenicity Studies of Pharmaceuticals, Randomized Clinical Trials for Orphan Drug Development, Mediation Modeling in Randomized Trials with Non-normal Outcome Variables, Statistical Considerations in Using Images in Clinical Trials, Interesting Applications over 30 Years of Consulting, Uncovering Fraud, Misconduct and Other Data Quality Issues in Clinical Trials, Development and Evaluation of High Dimensional Prognostic Models, and Design and Analysis of Biosimilar Studies.
Biopharmaceutical Applied Statistics Symposium Academic Press
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.

Biopharmaceutical Applied Statistics Symposium Springer
This third edition retains the basic scientific principles associated with the previous editions but brings to light the latest challenges associated with preparing, characterizing, formulating and delivering the ever-increasing types of biopharmaceutical molecules into therapeutics. New chapters include biopharmaceutical structure and drug delivery, protein design and engineering, quality by design for biopharmaceuticals, manufacturing and purification of biopharmaceuticals, immune response triggers by route of administration, proteins in the solid state, the challenge of biosimilars, and transdermal delivery of protein therapeutics.
Handbook of Pharmaceutical Wet Granulation Walter de Gruyter GmbH & Co KG
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 Biomanufacturing John Wiley & Sons
Cost-effective manufacturing of biopharmaceutical products is rapidly gaining in importance, while healthcare systems across the globe are looking to contain costs and improve efficiency. To adapt to these changes, industries need to review and streamline their manufacturing processes. This two volume handbook systematically addresses the key steps and challenges in the production process and provides valuable information for medium to large scale producers of biopharmaceuticals. It is divided into seven major parts: - Upstream Technologies - Protein Recovery - Advances in Process Development - Analytical Technologies - Quality Control - Process Design and Management - Changing Face of Processing With contributions by around 40 experts from academia as well as small and large biopharmaceutical companies, this unique handbook is full of first-hand knowledge on how to produce biopharmaceuticals in a cost-effective and quality-controlled manner.
Process Architecture in Biomanufacturing Facility Design Walter de Gruyter GmbH & Co KG
Focusing on the application of physical pharmacy, drug design, and drug regulations as they relate to produce effective dosage forms for drug delivery, Integrated Pharmaceutics provides a comprehensive picture of pharmaceutical product design, describing the science and art behind the concepts of dosage form development. Combining physical pharmacy, product design, and regulatory affairs issues in a single book, the authors address topics governing drug regulations of United States, European, and Japanese agencies and detail new regulatory guidelines, including quality by design, design space analysis, and blend sample uniformity.
Emerging Non-Clinical Biostatistics in Biopharmaceutical Development and Manufacturing Springer Science & Business Media
This book highlights the challenges facing quality assurance/quality control (QA/QC) in today's biopharmaceutical environment and presents the strategic importance and value generated by QA/QC for their involvement in control of manufacturing. It will put into perspective the need for a graded approach to QA/QC from early clinical trials through market approval. Since the first edition published in 2004, there have been more than 50 new regulatory guidances released by the Food and Drug Administration (FDA), European Medicines Agency (EMA) and ICH that affect the CMC regulatory compliance of biopharmaceuticals; also the application of biosimilars has been developed in Europe and is under development in the USA. The revised update will be broadened to include not only biopharmaceuticals (biotech drugs) but also other biologics (vaccines, cell therapy, plasma-derived proteins, etc.)
Quality by Design for Biopharmaceutical Drug Product Development Cambridge University Press
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.
Biopharmaceutical Production Technology John Wiley & Sons
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
PAT Applied in Biopharmaceutical Process Development And Manufacturing Academic Press
This BASS book Series publishes selected high-quality papers reflecting recent advances in the design and biostatistical analysis of biopharmaceutical experiments – particularly biopharmaceutical clinical trials. The papers were selected from invited presentations at the Biopharmaceutical Applied Statistics Symposium (BASS), which was founded by the first Editor in 1994 and has since become the premier international conference in biopharmaceutical statistics. The primary aims of the BASS are:

1) to raise funding to support graduate students in biostatistics programs, and 2) to provide an opportunity for professionals engaged in pharmaceutical drug research and development to share insights into solving the problems they encounter.The BASS book series is initially divided into three volumes addressing: 1) Design of Clinical Trials; 2) Biostatistical Analysis of Clinical Trials; and 3) Pharmaceutical Applications. This book is the first of the 3-volume book series. The topics covered include: A Statistical Approach to Clinical Trial Simulations, Comparison of Statistical Analysis Methods Using Modeling and Simulation for Optimal Protocol Design, Adaptive Trial Design in Clinical Research, Best Practices and Recommendations for Trial Simulations in the Context of Designing Adaptive Clinical Trials, Designing and Analyzing Recurrent Event Data Trials, Bayesian Methodologies for Response-Adaptive Allocation, Addressing High Placebo Response in Neuroscience Clinical Trials, Phase I Cancer Clinical Trial Design: Single and Combination Agents, Sample Size and Power for the Mixed Linear Model, Crossover Designs in Clinical Trials, Data Monitoring: Structure for Clinical Trials and Sequential Monitoring Procedures, Design and Data Analysis for Multiregional Clinical Trials – Theory and Practice, Adaptive Group-Sequential Multi-regional Outcome Studies in Vaccines, Development and Validation of Patient-reported Outcomes, Interim Analysis of Survival Trials: Group Sequential Analyses, and Conditional Power – A Non-proportional Hazards Perspective.

Pharmaceutics Elsevier

Computer-Aided Applications in Pharmaceutical Technology: Delivery Systems, Dosage Forms, and Pharmaceutical Unit Operations, Second Edition covers the fundamentals of experimental design application and interpretation in pharmaceutical technology, chemometric methods with an emphasis on their applications in process control, neural computing, data science, computer-aided biopharmaceutical characterization, as well as the application of computational fluid dynamics in pharmaceutical technology. Completely updated, the book introduces the theory and practice of computational tools through new case studies. Chapters cover Quality by Design in pharmaceutical development, overview data mining methodologies, present computer-aided formulation development, cover experimental design applications, and much more. Presents a comprehensive review of the current state of the art on various computer-aided applications in pharmaceutical technology Includes case studies to facilitate understanding of various concepts in computer-aided applications Covers applications such as the development of dosage forms and/or delivery systems, pharmaceutical unit operations, and relevant physiologically based pharmacokinetic simulations

Oral Controlled Release Formulation Design and Drug Delivery John Wiley & Sons

The biotechnology/biopharmaceutical sector has tremendously grown which led to the invention of engineered antibodies such as Antibody Drug Conjugates (ADCs), Bispecific T cell engager (BITES), Dual Variable Domain (DVD), Chimeric Antigen Receptor - Modified Tcells (CART) that are currently being used as therapeutic agents for immunology and oncology disease conditions. In addition to other pharmaceuticals and biopharmaceuticals, all these novel formats are fragile with respect to their stability/structure under processing conditions meaning marginal stability in the liquid state and often require lyophilization to enhance their stability and shelf-life. This book contains chapters/topics that will describe every aspect of the lyophilization process and product development and manufacturing starting from the overview of lyophilization process, equipment required, characterization of the material, design and development of the formulation and lyophilization process, various techniques for characterization of the product, scale-up/tech-transfer and validation. It also describes the application of CFD coupled with mathematical modeling in the lyophilization process and product development, scale-up, and manufacturing. Additionally, Principles and Practice of Lyophilization Process and Product Development contains an entire dedicated section on “Preservation of Biologicals” comprised of nine chapters written by experts and including case studies.

Sterile Processing of Pharmaceutical Products CRC Press

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

Computer-Aided Applications in Pharmaceutical Technology CRC Press

The biotechnology/biopharmaceutical sector has tremendously grown which led to the invention of engineered antibodies such as Antibody Drug Conjugates (ADCs), Bispecific T-cell engager (BITES), Dual Variable Domain (DVD) antibodies, and fusion proteins that are currently being used as therapeutic agents for immunology, oncology and other disease conditions. Regulatory agencies have raised the bar for the development and manufacture of antibody-based products, expecting to see the use of Quality by Design (QbD) elements demonstrating an in-depth understanding of product and process based on sound science. Drug delivery systems have become an increasingly important part of the therapy and most biopharmaceuticals for self-administration are being marketed as combination products. A survey of the market indicates that there is a strong need for a new book that will provide “one stop shopping” for the latest

information and knowledge of the scientific and engineering advances made over the last few years in the area of biopharmaceutical product development. The new book entitled Development of Biopharmaceutical Drug Device Products is a reference text for scientists and engineers in the biopharmaceutical industry, academia or regulatory agencies. With insightful chapters from experts in the field, this new book reviews first principles, covers recent technological advancements and provides case studies and regulatory strategies relating to the development and manufacture of antibody-based products. It covers topics such as the importance of early preformulation studies during drug discovery to influence molecular selection for development, formulation strategies for new modalities, and the analytical techniques used to characterize them. It also addresses important considerations for later stage development such as the development of robust formulations and processes, including process engineering and modeling of manufacturing unit operations, the design of analytical comparability studies, and characterization of primary containers (pre-filled syringes and vials).Finally, the latter half of the book reviews key considerations to ensure the development and approval of a patient-centered delivery system design. This involves the evolving regulatory framework with perspectives from both the US and EU industry experts, the role of international standards, design control/risk management, human factors and its importance in the product development and regulatory approval process, as well as review of the risk-based approach to bridging between devices used in clinical trials and the to-be-marketed device. Finally, case studies are provided throughout.The typical readership would have biology and/or engineering degrees and would include researchers, scientific leaders, industry specialists and technology developers working in the biopharmaceutical field.