

A-Mab: a Case Study in Bioprocess Development

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A Mab A Case Study In Bioprocess Development

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Fundamentals of Biologicals Regulation Rebecca Sheets, Christopher Hamlin, Susan Neadle, Ivana Knezevic, Mark Schenerman, Mehmet Tosun, Kathryn C. Zoon, 2026-03-20 *Fundamentals of Biologicals Regulation Vaccines and Biotechnology Medicines Second Edition* serves as an introduction to the international regulatory arena in which biologicals are developed offering an overview of processes and insights into the scientific concepts underpinning global regulations This edition provides in depth coverage of Quality by Design Combination Products Risk Management Plans REMS and switching from reliance on in vivo to in vitro analytical methods It reflects new developments and processes accelerated by the COVID 19 vaccine experience including emergency use authorizations and conditional marketing authorizations New pedagogic elements and case studies have been added to improve learning outcomes This book provides multiple levels of readership with guidance on basic concepts a detailed look at regulatory challenges and practical insights into how regulators consider regulatory science and regulatory process issues across various regions with an emphasis on the European Medicines Agency and the U S Food and Drug Administration Features new chapters on Advanced Therapy Medicinal Products including cell and gene therapies Combination Products and Pharmacovigilance Presents new and updated case studies including lessons learned from the development of COVID Vaccines Provides more in depth coverage on Quality by Design and Pharmacovigilance Focuses on the principles in regulating Biosimilars In Vitro Diagnostics Advanced Therapy Medicinal Products and Combination Products Covers general biologicals development authorization regulatory processes and scientific principles for CMC preclinical and clinical development *The Challenge of CMC Regulatory Compliance for Biopharmaceuticals* John Geigert, 2023-06-15 Each year for the past three years there have been about 50 new molecular medicines approved by the United States Food Addresses current FDA and EMA requirements and expectations for CMC regulatory compliance Now includes CMC regulatory compliance for the new gene based biopharmaceuticals

Therapeutic Fc-Fusion Proteins Steven M. Chamow, Thomas Ryll, Henry B. Lowman, Deborah Farson, 2013-12-18 Edited by three pioneers in the field each with longstanding experience in the biotech industry and a skilled scientific writer this is the first book to cover every step in the development and production of immunoglobulin Fc fusion proteins as therapeutics for human disease from choosing the right molecular design to pre clinical characterization of the purified product through to batch optimization and quality control for large scale cGMP production The whole of the second part is devoted to case studies of Fc fusion proteins that are now commercially successful products In this section the authors several of whom were personally involved in clinical development of the products themselves detail the product s background and give insight into issues that were faced and how these issues were overcome during clinical development This section also includes a chapter on promising new developments for the future An invaluable resource for professionals already working on Fc fusion proteins and an excellent and thorough introduction for physicians researchers and students entering

the field **Biopharmaceutical Processing** Gunter Jagschies, Eva Lindskog, Karol Lacki, Parrish M. Galliher, 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 *Practical Aspects of Vaccine Development* Parag Kolhe, Satoshi Ohtake, 2021-09-08 Formulation Development and Manufacturing of Vaccines The Practical Aspects provides an industry perspective on vaccine product development and manufacture that covers their formulation development manufacture and delivery in use considerations of vaccine production With the increasing complexity of vaccine products in development there is a need for a comprehensive review of the current state of the industry and its challenges While formulation scientists working in biotherapeutic development may be familiar with proteins vaccines present unique challenges including the wide range of vaccine components that may comprise proteins polysaccharides protein polysaccharide conjugates adjuvants etc and the varying stability and behavior of solution and suspension based systems This book is an essential resource for formulation scientists researchers in vaccine development throughout medical and life sciences and advanced students Includes formulation considerations for various vaccine types including proteins polysaccharides conjugates and live vaccines Considers process development for solution suspension and lyophilized products Explores the future potential of vaccines including multi component vaccines and novel delivery mechanisms devices **Animal Cell Biotechnology** Hansjörg Hauser, Roland Wagner, 2014-11-10 This book introduces fundamental principles and practical application of techniques used in the scalable production of biopharmaceuticals with animal cell cultures A broad spectrum of subjects relevant to biologics production and manufacturing are reviewed including the generation of robust cell lines a survey of functional genomics for a better understanding of cell lines and processes as well as advances in regulatory compliant upstream and downstream development The book is an essential reference for all those interested in translational animal cell based pharmaceutical biotechnology *Digital Twins* Christoph Herwig, Ralf Pörtner, Johannes Möller, 2021-04-25 This is the first of two volumes that together provide an overview of the latest advances in the generation and application of digital twins in bioprocess design and optimization Both processes have undergone significant changes over the past few decades moving from data

driven approaches into the 21st century digitalization of the bioprocess industry Moreover the high demand for biotechnological products calls for efficient methods during research and development as well as during tech transfer and routine manufacturing In this regard one promising tool is the use of digital twins which offer a virtual representation of the bioprocess They reflect the mechanistics of the biological system and the interactions between process parameters key performance indicators and product quality attributes in the form of a mathematical process model Furthermore digital twins allow us to use computer aided methods to gain an improved process understanding to test and plan novel bioprocesses and to efficiently monitor them This book explains the mathematical structure of digital twins their development and the model s respective parts as well as concepts for the knowledge driven generation and structural variability of digital twins Covering fundamentals as well as applications the two volumes offer the ideal introduction to the topic for researchers in academy and industry alike

Biosimilars Hiten J. Gutka,Harry Yang,Shefali Kakar,2018-12-13 This book provides a comprehensive overview of the biosimilar regulatory framework the development process and clinical aspects for development of biosimilars The development path of a biosimilar is just as unique as a development path of a new drug tailored by the mechanism of action the quality of the molecule published information on the reference product the current competitive environment the target market and regulatory guidance and most importantly the emerging totality of evidence for the proposed biosimilar during development For the ease of readers the book comprises of six sections as follows Section I Business Health Economics and Intellectual Property Landscape for Biosimilars Section II Regulatory Aspects of Development and Approval for Biosimilars Section III Biopharmaceutical Development and Manufacturing of Biosimilars Section IV Analytical Similarity Considerations for Biosimilars Section V Clinical aspects of Biosimilar Development Section VI Biosimilars Global Development and Clinical Experience Chapters have been written by one or more experts from academia industry or regulatory agencies who have been involved with one or more aspects of biosimilar product development The authors and editors have an expertise in commercialization and pricing of biosimilars intellectual property considerations for biosimilars chemistry manufacturing controls CMC and analytical development for biosimilars regulatory and clinical aspects of biosimilar development Besides the industry practitioners the book includes several contributions from regulators across the globe

The Encyclopedia of Bioprocess Technology Michael C. Flickinger,Stephen W. Drew,1999

Model Based Process Design for Bioprocess Optimisation Y. Ji,2012 Developing a bioprocess model can not only reduce cost and time in process development but now also assist the routine manufacturing and guarantee the quality of the final products through Quality by Design QbD and Process Analytical Technology PAT However these activities require a model based process design to efficiently direct identify and execute optimal experiments for the best bioprocess understanding and optimisation Thus an integrated model based process design methodology is desirable to significantly accelerate bioprocess development This will help meet current urgent clinical demands and also lower the cost and time required This thesis

examines the feasibility of a model based process design for bioprocess optimisation A new process design approach has been proposed to achieve such optimal design solutions quickly and provide an accurate process model to speed up process understanding The model based process design approach includes bioprocess modelling model based experimental design and high throughput microwell experimentation The bioprocess design is based on experimental data and a computational framework with optimisation algorithm Innovative model based experimental design is a core part in this approach Directed by the design objectives the method uses D optimal design to identify the most information rich experiments It also employs Random design and Simplex to identify extra experiments to increase the accuracy and will iteratively improve the process design solutions The modelling and implementation method by high throughput experimentation was first achieved and applied to an antibody fragment Fab precipitation case study A new precipitation model based on phase equilibrium has been developed using the data from microwell experimentation which was further validated by statistical tests to provide high confidence The precipitation model based on good data accurately describes not only the Fab solubility but also the solubility of impurities treated as a pseudo single protein whilst changing two critical process conditions salt concentration and pH The comparison study has shown the model was superior to other published models The new precipitation model and the Fab microwell data provided the basis to test the efficiency and robustness of the algorithms in model based process design approach The optimal design solution with the maximum objective value was found by only 5 iterations 24 designed experimental points Two parameterised models were obtained in the end of the optimisation which gave a quantitative understanding of the processes involved The benefit of this approach was well demonstrated by comparing it with the traditional design of experiments DoE The whole model based process design methodology was then applied to the second case study a monoclonal antibody mAb precipitation process The precipitation model was modified according to experimental results following modelling procedures The optimal precipitation conditions were successfully found through only 4 iterations which led to an alternative process design to protein A chromatography in the general mAb purification platform The optimal precipitation conditions were then investigated at lab scale by incorporating a depth filtration process The final precipitation based separation process achieved 93.6% w/w mAb yield and 98.2% w/w purity which was comparable to protein A chromatography Polishing steps after precipitation were investigated in microwell chromatographic experimentation to rapidly select the following chromatography steps and facilitate the whole mAb purification process design The data generated were also used to evaluate the process cost through process simulations Both precipitation based and protein A chromatography based processes were analysed by the process model in the commercial software BioSolve under several relevant titre and scale assumptions The results showed the designed precipitation based processes was superior in terms of process time and cost when facing future process challenges

[Encyclopedia of Bioprocess Technology](#) Michael C. Flickinger, 1999 The five volume set of the Encyclopedia of Bioprocess Technology presents the applications and established

theories in biotechnology focusing on industrial applications of fermentation biocatalysis and bioseparation It is an essential resource for anyone working in industrial biotechnology biochemistry genetics and microbiology laboratories pharmaceutical firms regulatory agencies and chemical and environmental engineering companies **Excerpta Medica** ,1990 Worldwide journal articles Classified arrangement Each entry gives bibliographical information and abstract Subject author indexes

Genetic Engineering News ,2003 *Commercial Biotechnology* ,1984 *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

Presentation of Programs and Progress University of Virginia. Center for Bioprocess Development,Center for Innovative Technology,1991 **Single-Use Technology in Biopharmaceutical Manufacture** Regine Eibl,Dieter 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 **Quality by Design for Biopharmaceutical Drug Product Development** Feroz

Jameel, Susan Hershenson, Mansoor A. Khan, Sheryl Martin-Moe, 2015-04-01 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

Commercializing Successful Biomedical Technologies Shreefal S. Mehta, 2008-04-24

Successful product design and development requires the ability to take a concept and translate the technology into useful patentable commercial products This book guides the reader through the practical aspects of the commercialization process of drug diagnostic and device biomedical technology including market analysis product development intellectual property and regulatory constraints Key issues are highlighted at each stage in the process and case studies are used to provide practical examples The book will provide a sound road map for those involved in the biotechnology industry to effectively plan the commercialization of profitable regulated medical products It will also be suitable for a capstone design course in engineering and biotechnology providing the student with the business acumen skills involved in product development

Development Factory Gary P. Pisano, 1997

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