A Mab A Case Study In Bioprocess Development

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This is a detailed case study to stimulate discussion around how the core principles contained in Q8(R2), Q9 and Q10 guidelines could be applied to product realisation programs for a biotechnology-derived monoclonal antibody.

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Product Development and Realisation Case Study A-Mab The CMC Biotech Working Group Page 5 of 278 4.6.2.5 Characterization Studies to Assess Impact to Product Quality

~~CMC Biotech Working Group~~
A-mab a case study in bioprocess development. Arthur Downer-November 14, 2020 0. Popes November Reflections. Pope Francis-October 31, 2020 0. No one saves himself in a pandemic.

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The case study, which discusses a fictional monoclonal antibody product, referred to as " A-MAb, " was developed over the course of a year by participants of the working group representing Abbott, Amgen, Genentech, GlaxoSmithKline, Eli Lilly, MedImmune, and Pfizer.

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A case study is a detailed study of a specific subject, such as a person, group, place, event, organization, or phenomenon. Case studies are commonly used in social, educational, clinical, and business research. A case study research design usually involves qualitative methods, but quantitative methods are sometimes also used.

~~How to Do a Case Study | Examples and Methods~~
Home; Work; Sonic DNA; amp News; Team & Career; Artist Network; 101 Great Minds; Best Audio Brands. Ranking; Insights; Methodology; Press Release 2020; Report 2020 ...

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Case Study 4 — Biosimilar MAb Showed Significant Conformational Differences: Several biosimilar MAb molecules we have tested fall into this category. In one instance, the biosimilar developer noticed changes in MAb stability. Bioassay testing showed that the biosimilar MAb lost potency in an ELISA-based binding assay; however, no analytical testing used could detect structural changes.

~~Higher-Order Structure Comparability: Case Studies of ...~~
In addition to highlighting the case study here on our web site, we have plans to use it extensively around the world in discussions with industry and regulators throughout 2010 and beyond. Look for sessions in the programs of the CMC Forum Europe (April 2010) and CMC Strategy Forum (July 2010) as well other workshops to be announced focusing on the A-Mab Case Study.

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30 October 2009: A – Mab: A Case Study in Bioprocess Development, CMC Biotech Working Group, version 2.1 This is a detailed case study to stimulate discussion around how the core principles contained in Q8(R2), Q9 and Q10 guidelines could be applied to product realisation programs for a biotechnology-derived monoclonal antibody.

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Product Development and Realisation Case Study A-Mab CMC Biotech Working Group Page 25 of 278 2 Design of Molecule and Quality Attributes Assessment A-Mab is a humanized IgG1 monoclonal antibody that was designed to maximize clinical performance and minimize potential impact from undesirable product quality attributes.

~~QbD Model Case Study of MONOCLONAL ANTIBODY : A-Mab.~~
This study aims to elucidate the formation of various kinds of aggregates as outcomes of a variety of mechanical, chemical, and thermal stresses applied to a monoclonal antibody therapeutic. The extent of aggregation, nature of aggregates, and impact of aggregates on biological activity and potency, all depend on the source of aggregate formation.

~~Impact of mAb Aggregation on Its Biological Activity ...~~
Case Study: Robustness Study for Virus Filtration of mAb Processes Peter Kosiol; Anika Manzke Sartorius Stedim Biotech GmbH, August-Spindler-Str. 11, D-37079 Goettingen, Germany 1. Introduction All biopharmaceutical products derived from human or animal origins must have a proven virus safety concept to ensure

~~Case Study: Robustness Study for Virus Filtration~~
The A-Mab case study discusses the development of a monoclonal antibody and incorporates many advanced and aspirational QbD concepts.

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MAB created a custom WordPress theme and was able to streamline tipsntrends ' content creation process by building a unique admin interface. This allowed tipsntrends staff to easily control and modify content on various pages of the site.

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

Still the most comprehensive reference source on the development, production and therapeutic application of antibodies, this second edition is thoroughly updated and now has 30% more content. Volume 1 covers selection and engineering strategies for new antibodies, while the second volume presents novel therapeutic concepts and antibodies in clinical study, as well as their potential. Volumes 3 and 4 feature detailed and specific information about each antibody approved for therapeutic purposes, including clinical data. This unique handbook concludes with a compendium of marketed monoclonal antibodies and an extensive index. Beyond providing current knowledge, the authors discuss emerging technologies, future developments, and intellectual property issues, such that this handbook meets the needs of academic researchers, decision makers in industry and healthcare professionals in the clinic.

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.

Monoclonal antibodies (mAbs) are naturally occurring complex biomolecules. New engineering methods have turned mAbs into a leading therapeutic modality for addressing immunotherapeutic challenges and led to the rise of mAbs as the dominant class of protein therapeutics. mAbs have already demonstrated a great potential in developing safe and reliable treatments for complex diseases and creating more affordable healthcare alternatives. Developing mAbs into well-characterized antibody therapeutics that meet regulatory expectations, however, is extremely challenging. Obstacles to overcome include the determination and development of physiochemical characteristics such as aggregation, fragmentation, charge variants, identity, carbohydrate structure, and higher-order structure (HOS). This book dives deep into mAbs structure and the array of physiochemical testing and characterization methods that need to be developed and validated to establish a mAb as a therapeutic molecule. The main focus of this book is on physiochemical aspects, including the importance of establishing quality attributes such as glycosylation, primary sequence, purity, and HOS and elucidating the structure of new antibody formats by mass spectrometry. Each of the aforementioned quality attributes has been discussed in detail; this will help scientists in researching and developing biopharmaceuticals and biosimilars to find practical solutions to physicochemical testing and characterization. Describes the spectrum of analytical tests and characterization methods necessary for developing and releasing mAb batches Details antibody heterogeneity in terms of size, charge, and carbohydrate content Gives special focus to the structural analysis of mAbs, including mass spectrometry analysis Presents the basic structure of mAbs with clarity and rigor Addresses regulatory guidelines - including ICH Q6B - in relation to quality attributes Lays out characterization and development case studies including biosimilars and new antibody formats

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Translational Medicine: Optimizing Preclinical Safety Evaluation of Biopharmaceuticals provides scientists responsible for the translation of novel biopharmaceuticals into clinical trials with a better understanding of how to navigate the obstacles that keep innovative medical research discoveries from becoming new therapies or even making it to clinical trials. The book includes sections on protein-based therapeutics, modified proteins, oligonucleotide-based therapies, monoclonal antibodies, antibody – drug conjugates, gene and cell-based therapies, gene-modified cell-based therapies, combination products, and therapeutic vaccines. Best practices are defined for efficient discovery research to facilitate a science-based, efficient, and predictive preclinical development program to ensure clinical efficacy and safety. Key Features: Defines best practices for leveraging of discovery research to facilitate a development program Includes general principles, animal models, biomarkers, preclinical toxicology testing paradigms, and practical applications Discusses rare diseases Discusses "What-Why-When-How" highlighting different considerations based upon product attributes. Includes special considerations for rare diseases About the Editors Joy A. Cavagnaro is an internationally recognized expert in preclinical development and regulatory strategy with an emphasis on genetic medicines.. Her 40-year career spans academia, government (FDA), and the CRO and biotech industries. She was awarded the 2019 Arnold J Lehman Award from the Society of Toxicology for introducing the concept of science-based, case-by-case approach to preclinical safety evaluation, which became the foundation of ICH S6. She currently serves on scientific advisory boards for advocacy groups and companies and consults and lectures in the area of preclinical development of novel therapies. Mary Ellen Cosenza is a regulatory toxicology consultant with over 30 years of senior leadership experience in the biopharmaceutical industry in the U.S., Europe, and emerging markets. She has held leadership position in both the American College of Toxicology (ACT) and the International Union of Toxicology (IUTOX) and is also an adjunct assistant professor at the University of Southern California where she teaches graduate-level courses in toxicology and regulation of biologics.

This introductory text explains both the basic science and the applications of biotechnology-derived pharmaceuticals, with special emphasis on their clinical use. It serves as a complete one-stop source for undergraduate/graduate pharmacists, pharmaceutical science students, and for those in the pharmaceutical industry. The Fifth Edition completely updates the previous edition, and also includes additional coverage on the newer approaches such as oligonucleotides, siRNA, gene therapy and nanotech and enzyme replacement therapy.

Medicinal chemistry is both science and art. The science of medicinal chemistry offers mankind one of its best hopes for improving the quality of life. The art of medicinal chemistry continues to challenge its practitioners with the need for both intuition and experience to discover new drugs. Hence sharing the experience of drug research is uniquely beneficial to the field of medicinal chemistry. Drug research requires interdisciplinary team-work at the interface between chemistry, biology and medicine. Therefore, the topic-related series Topics in Medicinal Chemistry covers all relevant aspects of drug research, e.g. pathobiochemistry of diseases, identification and validation of (emerging) drug targets, structural biology, drugability of targets, drug design approaches, chemogenomics, synthetic chemistry including combinatorial methods, bioorganic chemistry, natural compounds, high-throughput screening, pharmacological in vitro and in vivo investigations, drug-receptor interactions on the molecular level, structure-activity relationships, drug absorption, distribution, metabolism, elimination, toxicology and pharmacogenomics. In general, special volumes are edited by well known guest editors

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 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 final form on January 24, 2011. The book also provides guidelines and current practices, as well as industrial case studies illustrating the different approaches that can be taken for successful validation of biopharmaceutical processes. Case studies include Process validation for membrane chromatography Leveraging multivariate analysis tools to qualify scale-down models A matrix approach for process validation of a multivalent bacterial vaccine Purification validation for a therapeutic monoclonal antibody expressed and secreted by Chinese Hamster Ovary (CHO) cells Viral clearance validation studies for a product produced in a human cell line A much-needed resource, this book presents process characterization techniques for scaling down unit operations in biopharmaceutical manufacturing, including chromatography, chemical modification reactions, ultrafiltration, and microfiltration. It also provides practical methods to test raw materials and in-process samples. Stressing the importance of taking a risk-based approach towards computerized system compliance, this book will help you and your team ascertain process validation is carried out and exceeds expectations.