

NEW DIRECTIONS IN BIOPROCESS MODELING AND CONTROL

Maximizing Process Analytical Technology Benefits

Michael A. Boudreau and Gregory K. McMillan



Serving the Global Need for Automation

New Directions In Bioprocess Modeling And Control Maximizing Process Analytical Technology Benefits

Ian Pickup



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New Directions in Bioprocess Modeling and Control Michael A. Boudreau, Gregory K. McMillan, 2007 Models offer benefits even before they are put on line Based on years of experience the authors reveal in *New Directions in Bioprocess Modeling and Control* that significant improvements can result from the process knowledge and insight that are gained when building experimental and first principle models for process monitoring and control Doing modeling in the process development and early commercialization phases is advantageous because it increases process efficiency and provides ongoing opportunities for improving process control This technology is important for maximizing benefits from analyzers and control tool investments If you are a process design quality control information systems or automation engineer in the biopharmaceutical brewing or bio fuel industry this handy resource will help you define develop and apply a virtual plant model predictive control first principle models neural networks and multivariate statistical process control The synergistic knowledge discovery on bench top or pilot plant scale can be ported to industrial scale processes This learning process is consistent with the intent in the Process Analyzer and Process Control Tools sections of the FDA's Guidance for Industry PAT _ A Framework for Innovative Pharmaceutical Development Manufacturing and Quality Assurance It states in the Process Analyzer section of the FDA's guidance _For certain applications sensor based measurements can provide a useful process signature that may be related to the underlying process steps or transformations Based on the level of process understanding these signatures may also be useful for the process monitoring control and end point determination when these patterns or signatures relate to product and process quality _ *New Directions in Bioprocess Modeling and Control* Gregory McMillan, Christopher Stuart, Rehman Fazeem, Zachary Sample, Timothy Schieffer, 2020-12-15 *Bioprocessing Technology for Production of Biopharmaceuticals and Bioproducts* Claire Komives, Weichang Zhou, 2018-12-27 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 Discusses a wide selection of host strain types and disruptive bioprocess technologies **15th European Workshop on Advanced Control and Diagnosis (ACD 2019)** Elena Zatonni, Silvio Simani, Giuseppe Conte, 2022-06-13 This book published in two volumes embodies the proceedings of the 15th European Workshop on Advanced Control and Diagnosis ACD 2019 held in Bologna Italy in November 2019 It features contributed and invited papers from academics and professionals specializing in an important aspect of control and automation The book discusses current theoretical research developments and open problems and illustrates practical applications and industrial priorities With a focus on both theory and applications it spans a wide variety of up to date topics in the field of systems and control including robust control adaptive control fault tolerant control control reconfiguration and

model based diagnosis of linear nonlinear and hybrid systems As the subject coverage has expanded to include cyber physical production systems industrial internet of things and sustainability issues some contributions are of an interdisciplinary nature involving ICT disciplines and environmental sciences This book is a valuable reference for both academics and professionals in the area of systems and control with a focus on advanced control automation fault diagnosis and condition monitoring

Control Loop Foundation Terrence L. Blevins, Mark Nixon, 2011 In this in depth book the authors address the concepts and terminology that are needed to work in the field of process control The material is presented in a straightforward manner that is independent of the control system manufacturer It is assumed that the reader may not have worked in a process plant environment and may be unfamiliar with the field devices and control systems Much of the material on the practical aspects of control design and process applications is based on the authors personal experience gained in working with process control systems Thus the book is written to act as a guide for engineers managers technicians and others that are new to process control or experienced control engineers who are unfamiliar with multi loop control techniques After the traditional single loop and multi loop techniques that are most often used in industry are covered a brief introduction to advanced control techniques is provided Whether the reader of this book is working as a process control engineer working in a control group or working in an instrument department the information will set the solid foundation needed to understand and work with existing control systems or to design new control applications At various points in the chapters on process characterization and control design the reader has an opportunity to apply what was learned using web based workshops The only items required to access these workshops are a high speed Internet connection and a web browser Dynamic process simulations are built into the workshops to give the reader a realistic hands on experience Also one chapter of the book is dedicated to techniques that may be used to create process simulations using tools that are commonly available within most distributed control systems At various points in the chapters on process characterization and control design the reader has an opportunity to apply what was learned using web based workshops The only items required to access these workshops are a high speed Internet connection and a web browser Dynamic process simulations are built into the workshops to give the reader a realistic hands on experience Also one chapter of the book is dedicated to techniques that may be used to create process simulations using tools that are commonly available within most distributed control systems As control techniques are introduced simple process examples are used to illustrate how these techniques are applied in industry The last chapter of the book on process applications contains several more complex examples from industry that illustrate how basic control techniques may be combined to meet a variety of application requirements As control techniques are introduced simple process examples are used to illustrate how these techniques are applied in industry The last chapter of the book on process applications contains several more complex examples from industry that illustrate how basic control techniques may be combined to meet a variety of application requirements

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

American Book Publishing Record ,2006

Process Control, Intensification, and Digitalisation in Continuous Biomanufacturing Ganapathy Subramanian,2021-12-20 Process Control Intensification and Digitalisation in Continuous Biomanufacturing Explore new trends in continuous biomanufacturing with contributions from leading practitioners in the field With the increasingly widespread acceptance and investment in the technology the last decade has demonstrated the utility of continuous processing in the pharmaceutical industry In Process Control Intensification and Digitalisation in Continuous Biomanufacturing distinguished biotechnologist Dr Ganapathy Subramanian delivers a comprehensive exploration of the potential of the continuous processing of biological products and discussions of future directions in advancing continuous processing to meet new challenges and demands in the manufacture of therapeutic products A stand alone follow up to the editor s Continuous Biomanufacturing Innovative Technologies and Methods published in 2017 this new edited volume focuses on critical aspects of process intensification process control and the digital transformation of biopharmaceutical processes In addition to topics like the use of multivariant data analysis regulatory concerns and automation processes the book also includes Thorough introductions to capacitance sensors to control feeding strategies and the continuous production of viral vaccines Comprehensive explorations of strategies for the continuous upstream processing of induced microbial systems Practical discussions of preparative hydrophobic interaction chromatography and the design of modern protein A resins for continuous biomanufacturing In depth examinations of bioprocess intensification approaches and the benefits of single use for process intensification Perfect for biotechnologists bioengineers pharmaceutical engineers and process engineers Process Control Intensification and Digitalisation in Continuous Biomanufacturing is also an indispensable resource for chemical engineers seeking a one stop reference on continuous biomanufacturing

Measurement, Monitoring, Modelling and Control of Bioprocesses Carl-Fredrik Mandenius,Nigel J Titchener-Hooker,2014-07-08 Automated Measurement and Monitoring of Bioprocesses Key Elements of the M3C Strategy by Bernhard Sonnleitner Automatic Control of Bioprocesses by Marc Stanke Bernd Hitzmann An Advanced Monitoring Platform for Rational Design of Recombinant Processes by G Striedner K Bayer Modelling Approaches for Bio Manufacturing Operations by Sunil Chhatre Extreme Scale Down Approaches for Rapid Chromatography Column Design and Scale Up During Bioprocess Development by Sunil Chhatre Applying Mechanistic Models in Bioprocess Development by Rita Lencastre Fernandes Vijaya Krishna Bodla Magnus Carlquist Anna Lena Heins Anna Eliasson Lantz G rkan Sin and Krist V

Gernaey Multivariate Data Analysis for Advancing the Interpretation of Bioprocess Measurement and Monitoring Data by Jarka Glassey Design of Pathway Level Bioprocess Monitoring and Control Strategies Supported by Metabolic Networks by Inés A Isidro Ana R Ferreira João J Clemente António E Cunha João M L Dias Rui Oliveira Knowledge Management and Process Monitoring of Pharmaceutical Processes in the Quality by Design Paradigm by Anurag S Rathore Anshuman Bansal Jaspinder Hans The Choice of Suitable Online Analytical Techniques and Data Processing for Monitoring of Bioprocesses by Ian Marison Siobhán Hennessy Róisín Foley Moira Schuler Senthilkumar Sivaprakasam Brian Freeland Mathematical Modeling and Control of Bioprocesses Philippe Bogaerts, Alain Vande Wouwer, 2023-04-25 Mathematical modeling is at the heart of most current developments in biological system analysis and bioprocess optimization and control At the industrial scale this evolution is reflected in process analytical technologies PAT digital twins and Industry 4.0 This book focuses on various aspects of mathematical modeling at the microscopic and macroscopic scales respectively and demonstrates the potential of these methodologies to gain insight into the cell metabolism to support the design of software sensors to reconstruct unmeasurable variables or to establish model based optimization of the operating conditions and or feedback control of the bioprocesses The range of applications is vast including biopharmaceuticals bioenergy and the environment

Computational Intelligence Techniques for Bioprocess Modelling, Supervision and Control Maria Carmo Nicoletti, 2009-06-29 Computational Intelligence CI and Bioprocess are well established research areas which have much to offer each other Under the perspective of the CI area Bioprocess can be considered a vast application area with a growing number of complex and challenging tasks to be dealt with whose solutions can contribute to boosting the development of new intelligent techniques as well as to help the refinement and specialization of many of the already existing techniques Under the perspective of the Bioprocess area CI can be considered a useful repertoire of theories methods and techniques that can contribute and offer interesting alternative approaches for solving many of its problems particularly those hard to solve using conventional techniques Although throughout the past years CI and Bioprocess areas have accumulated substantial specific knowledge and progress has been quick and with a high degree of success we believe there is still a long way to go in order to use the potentialities of the available CI techniques and knowledge at their full extent as tools for supporting problem solving in bioprocesses One of the reasons is the fact that both areas have progressed steadily and have been continuously accumulating and refining specific knowledge another reason is the high level of technical expertise demanded by each of them The acquisition of technical skills experience and good insights in either of the two areas is very demanding and a hard task to be accomplished by any professional **Bioprocess Modeling and Control** Mihai Caramihai, 2013 Bioprocess Modeling and Control *Process Monitoring and Quality by Design for Biotechnology Products* Neslihan Delacruz, 2010-09-01 Traditional pharmaceutical development is an unwieldy process requiring extensive experimentation and long lead times before process scientists can fully understand the effect that process parameters such as pH temperature

cell viability or process yield may have on the product acceptability Implementation of quality by design is a science based approach that allows the operating ranges and the acceptance criteria to be established based on the impact on product quality attributes During manufacturing process monitoring becomes part of a continuous verification effort and statistical control limits can be used to signal potential trends or drifts in the process Single manufacturing batches that are aberrant are readily identified The melding of scientific understanding information systems architecture instrumentation software and personnel training provides a large return on investment by ensuring that the manufacturing process produces a consistent pharmaceutical product that meets acceptable release standards for human use Table of Contents Abbreviations Introduction From the Traditional Development Path to Quality by Design Continuous Process Verification and Process Monitoring Process Monitoring and Statistical Control Limits Multivariate Analysis A Mature State of Statistical Process Monitoring Conclusion Bibliography

Control in Bioprocessing Pablo A. López Pérez, Ricardo Aguilar López, Ricardo Femat, 2020-03-10 Closes the gap between bioscience and mathematics based process engineering This book presents the most commonly employed approaches in the control of bioprocesses It discusses the role that control theory plays in understanding the mechanisms of cellular and metabolic processes and presents key results in various fields such as dynamic modeling dynamic properties of bioprocess models software sensors designed for the online estimation of parameters and state variables and control and supervision of bioprocesses Control in Bioengineering and Bioprocessing Modeling Estimation and the Use of Sensors is divided into three sections Part I Mathematical preliminaries and overview of the control and monitoring of bioprocess provides a general overview of the control and monitoring of bioprocesses and introduces the mathematical framework necessary for the analysis and characterization of bioprocess dynamics Part II Observability and control concepts presents the observability concepts which form the basis of design online estimation algorithms software sensor for bioprocesses and reviews controllability of these concepts including automatic feedback control systems Part III Software sensors and observer based control schemes for bioprocesses features six application cases including dynamic behavior of 3 dimensional continuous bioreactors observability analysis applied to 2D and 3D bioreactors with inhibitory and non inhibitory models and regulation of a continuously stirred bioreactor via modeling error compensation Applicable across all areas of bioprocess engineering including food and beverages biofuels and renewable energy pharmaceuticals and nutraceuticals fermentation systems product separation technologies wastewater and solid waste treatment technology and bioremediation Provides a clear explanation of the mass balance based mathematical modelling of bioprocesses and the main tools for its dynamic analysis Offers industry based applications on myco diesel for implementing quality of observability developing a virtual sensor based on the Just In Time Model to monitor biological control systems and virtual sensor design for state estimation in a photocatalytic bioreactor for hydrogen production Control in Bioengineering and Bioprocessing is intended as a foundational text for graduate level students in bioengineering as well as a reference text for researchers

engineers and other practitioners interested in the field of estimation and control of bioprocesses **PAT Applied in Biopharmaceutical Process Development And Manufacturing** Cenk Undey,Duncan Low,Jose C. Menezes,Mel Koch,2011-12-07 As with all of pharmaceutical production the regulatory environment for the production of therapeutics has been changing as a direct result of the US FDA initiated Quality by Design QbD guidelines and corresponding activities of the International Committee for Harmonization ICH Given the rapid growth in the biopharmaceutical area and the complexity of the molecules the optimum use of which are still being developed there is a great need for flexible and proactive teams in order to satisfy the regulatory requirements during process development Process Analytical Technologies PAT applied in biopharmaceutical process development and manufacturing have received significant attention in recent years as an enabler to the QbD paradigm PAT Applied in Biopharmaceutical Process Development and Manufacturing covers technological advances in measurement sciences data acquisition monitoring and control Technical leaders present real life case studies in areas including measuring and monitoring raw materials cell culture purification and cleaning and lyophilization processes via advanced PAT They also explore how data are collected and analyzed using advanced analytical techniques such as multivariate data analysis monitoring and control in real time Invaluable for experienced practitioners in PAT in biopharmaceuticals this book is an excellent reference guide for regulatory officials and a vital training aid for students who need to learn the state of the art in this interdisciplinary and exciting area *Development of Sustainable Bioprocesses* Elmar Heinzle,Arno P. Biwer,Charles L. Cooney,2007-01-02 Bioprocess technology involves the combination of living matter whole organism or enzymes with nutrients under laboratory conditions to make a desired product within the pharmaceutical food cosmetics biotechnology fine chemicals and bulk chemicals sectors Industry is under increasing pressure to develop new processes that are both environmentally friendly and cost effective and this can be achieved by taking a fresh look at process development namely by combining modern process modeling techniques with sustainability assessment methods *Development of Sustainable Bioprocesses Modeling and Assessment* describes methodologies and supporting case studies for the evolution and implementation of sustainable bioprocesses Practical and industry focused the book begins with an introduction to the bioprocess industries and development procedures Bioprocesses and bioproducts are then introduced together with a description of the unit operations involved Modeling procedures a key feature of the book are covered in chapter 3 prior to an overview of the key sustainability assessment methods in use environmental economic and societal The second part of the book is devoted to case studies which cover the development of bioprocesses in the pharmaceutical food fine chemicals cosmetics and bulk chemicals industries Some selected case studies include citric acid biopolymers antibiotics biopharmaceuticals Supplementary material provides hands on materials so that the techniques can be put into practice These materials include a demo version of SuperPro Designer software used in process engineering and models of all featured case studies excel sheets of assessment methods Monte Carlo simulations and exercises Previously available on CD

ROM the supplementary material can now be accessed via <http://booksupport.wiley.com> by entering the author name book title or isbn and clicking on the desired entry This will then give a listing of all the content available for download Please read any text files before downloading material *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 were superior in terms of process time and cost when facing future process challenges.

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Introduction

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