Fed-Batch Mammalian Cell Culture in Bioproduction

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Originally developed for optimizing microbial fermentation, the fed-batch approach has become a leading technology in biologics production based on animal cell culture. For manufacturing-scale applications, we can simply address the batch, fed-batch, and perfusion operating modes (1). But as the number of basic reactor types and production modes/strategies grows, absolute categorization and terminology become more difficult. That is especially true when considering small scales and more academic (research) approaches, in which concepts such as "fed perfusion" have been described (2). Such references can be confusing to beginners trying to make sense of the basic approaches available.

Regardless of the cell, product, or reactor addressed, fed-batch mode specifically refers to an approach in which a concentrated solution of nutrients is added at particular intervals, with no product harvested until the end of the run. An early implementation of the fed-batch approach involved an additional charge of sucrose added in mid-process to a quiescent *Saccharomyces* fermentation. That feeding allowed for production of a key biological product: Champagne just wouldn't be the same without bubbles from the CO_2 produced by that sucrose feeding!

In fact, many of today's animal cell fed-batch approaches originate from microbial fermentation systems. For example, in early penicillin fermentation it was first thought that a relatively expensive sugar (lactose) was required for optimal production. It was later revealed that high production (over biomass) resulted from feeding with less expensive glucose at an appropriate rate. Current fed-batch systems for animal cell bioreactor production are based on adaptations and extensions of such earlier work.

PRODUCT FOCUS: ALL PRODUCTS OF MAMMALIAN CELL CULTURE

PROCESS FOCUS: PRODUCTION

WHO SHOULD READ: PROCESS DEVELOPMENT, MANUFACTURING, AND PROJECT MANAGEMENT

KEYWORDS: CELL CULTURE, FED-BATCH, OPTIMIZATION, PAT, MONITORING AND CONTROL, MEDIA AND SUPPLEMENTATION

LEVEL: INTERMEDIATE

THE CASE FOR FED-BATCH

Many combinations of reactor types and culture modes are now available for use in bioproduction: e.g., rocking wave-agitated bag batch, stirred-tank or air-lift fed-batch, and hollow-fiber or spin-filter perfusion. Each presents distinct characteristics, as listed in the "Modes" box. No single production format is inherently superior; that determination depends on many manufacturing capabilities, requirements, and goals (Table 1). Those arise from the nature of each specific product, scale of production, and a manufacturer's total production schedule. Furthermore, there is ongoing evolution in

- available options (e.g., a single-use perfused hollow-fiber system for perfusion cultures from BioVest International, www.biovest.com, and HyClone's single-use stirred-tank systems for batch cultures)
- underlying production demands and goals (e.g., heightened requirements for molecular quality and homogeneity of product)
- system component efficiencies (e.g., often 10- to 100-fold increases in cell and product yields).

The fed-batch version of stirred-tank culture has become most popular at large scales. The primary driver of this trend is obvious: Adding nutrients to a batch culture in mid-run can increase the quantity of product harvested. But the prevalence of fed-batch over other modes is due to many practical factors including reliability, ease of scalability, and application latitude (see the "Reasons" box). Efficiency of a particular production process can be measured several ways, and the fed-batch approach wins in many cases. Its greatest improvements derive from increases in the integral of viable cell concentration and volumetric productivity.

Of the culture processes proven valuable, debate over the best approach for large-scale production has evolved to that between fed-batch

Cell Culture In Bioproduction Fed Batch Mammalian

Don W. Green,Marylee Z. Southard

Cell Culture In Bioproduction Fed Batch Mammalian:

Comprehensive Biotechnology ,2011-08-26 The second edition of Comprehensive Biotechnology Six Volume Set continues the tradition of the first inclusive work on this dynamic field with up to date and essential entries on the principles and practice of biotechnology The integration of the latest relevant science and industry practice with fundamental biotechnology concepts is presented with entries from internationally recognized world leaders in their given fields With two volumes covering basic fundamentals and four volumes of applications from environmental biotechnology and safety to medical biotechnology and healthcare this work serves the needs of newcomers as well as established experts combining the latest relevant science and industry practice in a manageable format It is a multi authored work written by experts and vetted by a prestigious advisory board and group of volume editors who are biotechnology innovators and educators with international influence All six volumes are published at the same time not as a series this is not a conventional encyclopedia but a symbiotic integration of brief articles on established topics and longer chapters on new emerging areas Hyperlinks provide sources of extensive additional related information material authored and edited by world renown experts in all aspects of the broad multidisciplinary field of biotechnology Scope and nature of the work are vetted by a prestigious International Advisory Board including three Nobel laureates Each article carries a glossary and a professional summary of the authors indicating their appropriate credentials An extensive index for the entire publication gives a complete list of the many topics treated in the increasingly expanding field *Cultured Meat - Are We Getting it Right?* Johannes le Coutre,Dietrich Knorr,2021-08-17 **Continuous Biomanufacturing** Ganapathy Subramanian,2017-12-26 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 **Continuous Processing in Pharmaceutical Manufacturing** Ganapathy Subramanian,2015-02-09 With contributions from biotechnologists and bioengineers this ready reference describes the state of the art in industrial biopharmaceutical production with a strong focus on continuous processes Recent advances in single use technology as well as application guidelines for all types of biopharmaceutical products from vaccines to antibodies and from bacterial to insect to mammalian cells are covered The efficiency robustness and quality control of continuous production processes for biopharmaceuticals are reviewed and compared to traditional batch processes for a range of different production systems *Ullmann's Biotechnology and Biochemical Engineering, 2 Volume Set* Wiley-VCH,2007-07-23 The one stop resource for all those involved in the biochemical and biotechnological

industries Based on the latest online edition of Ullmann s Encyclopedia of Industrial Chemistry containing articles never seen before in print this ready reference meets the need for a detailed survey of the biochemical fundamentals and techniques as well as their applications in biochemical engineering and biobased production Perry's Chemical Engineers' Handbook, 9th Edition Don W. Green,Marylee Z. Southard,2018-07-13 Up to Date Coverage of All Chemical Engineering Topics from the Fundamentals to the State of the Art Now in its 85th Anniversary Edition this industry standard resource has equipped generations of engineers and chemists with vital information data and insights Thoroughly revised to reflect the latest technological advances and processes Perry s Chemical Engineers Handbook Ninth Edition provides unsurpassed coverage of every aspect of chemical engineering You will get comprehensive details on chemical processes reactor modeling biological processes biochemical and membrane separation process and chemical plant safety and much more This fully updated edition covers Unit Conversion Factors and Symbols Physical and Chemical Data including Prediction and Correlation of Physical Properties Mathematics including Differential and Integral Calculus Statistics Optimization Thermodynamics Heat and Mass Transfer Fluid and Particle Dynamics Reaction Kinetics Process Control and Instrumentation Process Economics Transport and Storage of Fluids Heat Transfer Operations and Equipment Psychrometry Evaporative Cooling and Solids Drying Distillation Gas Absorption and Gas Liquid System Design Liquid Liquid Extraction Operations and Equipment Adsorption and Ion Exchange Gas Solid Operations and Equipment Liquid Solid Operations and Equipment Solid Solid Operations and Equipment Chemical Reactors Bio based Reactions and Processing Waste Management including Air Wastewater and Solid Waste Management Process Safety including Inherently Safer Design Energy Resources Conversion and Utilization Materials of Construction *Mammalian Cell Cultures for Biologics Manufacturing* Weichang Zhou,Anne Kantardjieff,2014-01-15 Volumes are organized topically and provide a comprehensive discussion of developments in the respective field over the past 3 5 years The series also discusses new discoveries and applications Special volumes are dedicated to selected topics which focus on new biotechnological products and new processes for their synthesis and purification In general special volumes are edited by well known guest editors The series editor and publisher will however always be pleased to receive suggestions and supplementary information Manuscripts are accepted in English

Large-Scale Mammalian Cell Culture Technology Lubiniecki,1990-09-14 An interdisciplinary approach integrating biochemistry biology genetics and engineering for the effective production of protein pharmaceuticals The volume offers a biological perspective of large scale animal cell culture and examines diverse processing strategies process management regulator *Genetic Engineering & Biotechnology News* ,2007 Cell Culture Engineering Gyun Min Lee,Helene Faustrup Kildegaard,2019-10-01 Offers a comprehensive overview of cell culture engineering providing insight into cell engineering systems biology approaches and processing technology In Cell Culture Engineering Recombinant Protein Production editors Gyun Min Lee and Helene Faustrup Kildegaard assemble top class authors to present expert coverage of topics such as cell

line development for therapeutic protein production development of a transient gene expression upstream platform and CHO synthetic biology They provide readers with everything they need to know about enhancing product and bioprocess attributes using genome scale models of CHO metabolism omics data and mammalian systems biotechnology perfusion culture and much more This all new up to date reference covers all of the important aspects of cell culture engineering including cell engineering system biology approaches and processing technology It describes the challenges in cell line development and cell engineering e g via gene editing tools like CRISPR Cas9 and with the aim to engineer glycosylation patterns Furthermore it gives an overview about synthetic biology approaches applied to cell culture engineering and elaborates the use of CHO cells as common cell line for protein production In addition the book discusses the most important aspects of production processes including cell culture media batch fed batch and perfusion processes as well as process analytical technology quality by design and scale down models Covers key elements of cell culture engineering applied to the production of recombinant proteins for therapeutic use Focuses on mammalian and animal cells to help highlight synthetic and systems biology approaches to cell culture engineering exemplified by the widely used CHO cell line Part of the renowned Advanced Biotechnology book series Cell Culture Engineering Recombinant Protein Production will appeal to biotechnologists bioengineers life scientists chemical engineers and PhD students in the life sciences *Genetic Engineering News* ,2006

Bioprocess Engineering Colloquium American Society of Mechanical Engineers. Winter Annual Meeting,1987

Production of Biologicals from Animal Cells in Culture R. E. Spier,J. B. Griffiths,B. Meignier,2013-09-24 Production of Biologicals from Animal Cells in Culture reviews the state of the art in animal cell biotechnology with emphasis on the sequence of events that occur when generating a biological from animal cells in culture Methods that enable adjustment of nutrient feed streams into perfusion bioreactors so as to increase productivity are described A number of issues are also addressed such as the usefulness of the fingerprint method for cell characterization Comprised of 135 chapters this book begins with an overview of the problems and benefits of animal cell culture followed by a discussion on the isolation of immortal murine macrophage cell lines The reader is systematically introduced to the use of DNA fingerprinting to characterize cell banks immortalization of cells with oncogenes lipid metabolism of animal cells in culture and energetics of glutaminolysis Subsequent chapters explore serum free and protein free media the physiology of animal cells gene expression in animal cell systems and animal cell bioreactors The monitoring and assay of animal cell parameters are also considered along with downstream processing and regulatory issues This monograph will be of interest to students practitioners and investigators in the fields of microbiology and biotechnology Cell Culture Technology for Pharmaceutical and Cell-Based Therapies Sadettin Ozturk,Wei-Shou Hu,2005-08-30 Edited by two of the most distinguished pioneers in genetic manipulation and bioprocess technology this bestselling reference presents a comprehensive overview of current cell culture technology used in the pharmaceutical industry Contributions from several leading researchers showcase

the importance of gene discovery and genomic technology devel **Animal Cell Culture** Mohamed Al-Rubeai,2014-11-28 Animal cells are the preferred cell factories for the production of complex molecules and antibodies for use as prophylactics therapeutics or diagnostics Animal cells are required for the correct post translational processing including glycosylation of biopharmaceutical protein products They are used for the production of viral vectors for gene therapy Major targets for this therapy include cancer HIV arthritis cardiovascular and CNS diseases and cystic fibrosis Animal cells are used as in vitro substrates in pharmacological and toxicological studies This book is designed to serve as a comprehensive review of animal cell culture covering the current status of both research and applications For the student or R D scientist or new researcher the protocols are central to the performance of cell culture work yet a broad understanding is essential for translation of laboratory findings into the industrial production Within the broad scope of the book each topic is reviewed authoritatively by experts in the field to produce state of the art collection of current research A major reference volume on cell culture research and how it impacts on production of biopharmaceutical proteins worldwide the book is essential reading for everyone working in cell culture and is a recommended volume for all biotechnology libraries **Development of Mathematical Descriptions of Mammalian Cell Culture Kinetics for the Optimization of Fed-batch Bioreactors** ,1987 Perfusion Cell Culture Processes for Biopharmaceuticals Moritz Wolf,Jean-Marc Bielser,Massimo Morbidelli,2020-08-06 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 **Analysis and Control of Mammalian Cell Metabolism at Multiple Steady States in Continuous Cultures** Anshu Gambhir,1999 Mammalian Cell Biotechnology in Protein Production Hansjörg Hauser,Roland Wagner,1997 Hauser and Wagner have presented the new possibilities of Mammalian Cell Biology in a very informative and stimulating manner Prof Dr Hans Fritz Ludwig Maximilians University Munich Cell Culture Engineering Wei-Shu Hu,2006-08-16 Since the introduction of recombinant human growth hormone and insulin a quarter century ago protein therapeutics has greatly broadened the ho zon of health care Many patients suffering with life threatening diseases or chronic dysfunctions which were medically untreatable not long ago can attest to the wonder these drugs have achieved Although the rst generation of p tein therapeutics was produced in recombinant Escherichia coli most recent products use mammalian cells as production hosts Not long after the rst p duction

of recombinant proteins in E coli it was realized that the complex tasks of most post translational modi cations on proteins could only be ef ciently carried out in mammalian cells In the 1990s we witnessed a rapid expansion of mammalian cell derived protein therapeutics chie y antibodies In fact it has been nearly a decade since the market value of mammalian cell derived protein therapeutics surpassed that of those produced from E coli A common characteristic of recent antibody products is the relatively large dose required for effective therapy demanding larger quantities for the treatment of a given disease This coupled with the broadening repertoire of protein drugs has rapidly expanded the quantity needed for clinical applications The increasing demand for protein therapeutics has not been met exclusively by construction of new manufacturing plants and increasing total volume capacity More portantly the productivity of cell culture processes has been driven upward by an order of magnitude in the past decade

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