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## NRYSPU - REILLY BRENDEN

Basic Science Methods for Clinical Researchers addresses the specific challenges faced by clinicians without a conventional science background. The aim of the book is to introduce the reader to core experimental methods commonly used to answer questions in basic science research and to outline their relative strengths and limitations in generating conclusive data. This book will be a vital companion for clinicians undertaking laboratory-based science. It will support clinicians in the pursuit of their academic interests and in making an original contribution to their chosen field. In doing so, it will facilitate the development of tomorrow's clinician scientists and future leaders in discovery science. Serves as a helpful guide for clinical researchers who lack a conventional science background Organized around research themes pertaining to key biological molecules, from genes, to proteins, cells, and model organisms Features protocols, techniques for troubleshooting common problems, and an explanation of the advantages and limitations of a technique in generating conclusive data Appendices provide resources for practical research methodology, including legal frameworks for using stem cells and animals in the laboratory, ethical considerations, and good laboratory practice (GLP)
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.

This is a comprehensive research guide that describes both the key new techniques and more established methods. Every chapter discusses the merits and limitations of the various approaches and then provides selected tried-and-tested protocols, as well as a plethora of good practical advice, for immediate use at the bench. It presents the most accessible and comprehensive introduction available to the culture and experimental manipulation of animal cells. Detailed protocols for a wide variety of methods provide the core of each chapter, making new methodology easily accessible. This book is an essential laboratory manual for all undergraduates and graduates about to embark on a cell culture project. It is a book which both experienced researchers and those new to the field will find invaluable.

Animal cell culture is an important laboratory technique in the biological and medical sciences. It has become an essential tool for the study of most biochemical and physiological processes and the use of large-scale animal cell culture has become increasingly important to the commercial production of specific compounds for the pharmaceutical industry. This book describes the basic requirements for establishing and maintaining cell cultures both in the laboratory and in large-scale operations. Minimal background knowledge of the subject is assumed and therefore it will be a readable introduction to animal cell culture for undergraduates, graduates and experienced researchers. Reflecting the latest developments and trends in the field, the new topics include the latest theory of the biological clock of cell lines, the development of improved serum-free media formulations, the increased understanding of the importance and control of protein glycosylation, and the humanization of antibodies for therapeutic use.

antibody production. Whether the increase in antibody production is due to autocrine/paracrine factors, local pH concentrations, pulsatile delivery of growth factors or some other mechanism is unknown and requires further study.

Over the past decade, the transient gene expression (TGE) technology platform has been actively pursued to produce a wide range of therapeutic proteins, monoclonal antibodies, and vaccines for mainly preclinical assessment, due to its short development times and low overall cost. This book updates the latest advances in the field, with focusing on systematic description of the technology from cell lines, cell culture conditions, vector construction, expression strategy, current protocols, optimisation of the procedure, and potential for clinical application. As a conclusion, the author foresees that therapeutic biopharmaceutics will be manufactured for clinical development us-

ing TGE technology in the near future because of its fast development time, good protein expression, acceptable quality of product and due to the progress which has been made in analytical methodology and process quality control. The objectives of this book are to summarise current TGE protocols, to describe optimisation of the technology through the latest advances, and to explore clinical applications of the technology. It gives the reader a good insight into the latest development and future application of the technology platform, including: The current protocols from small to large scale for different cells. Optimisation methods in construction designing, transfection procedures, and cell culture conditions. Overall quality of the product from the transient gene expression. Future clinical application of the technology platform.

Mammalian cell lines command an effective monopoly for the production of therapeutic proteins that require post--translational modifications. This unique advantage outweighs the costs associated with mammalian cell culture, which are far grater in terms of development time and manufacturing when compared to microbial culture. The development of cell lines has undergone several advances over the years, essentially to meet the requirement to cut the time and costs associated with using such a complex hosts as production platforms. This book provides a comprehensive guide to the methodology involved in the development of cell lines and the cell engineering approach that can be employed to enhance productivity, improve cell function, glycosylation and secretion and control apoptosis. It presents an overall picture of the current topics central to expression engineering including such topics as epigenetics and the use of technologies to overcome positional dependent inactivation, the use of promoter and enhancer sequences for expression of various transgenes, site directed engineering of defined chromosomal sites, and examination of the role of eukaryotic nucleus as the controller of expression of genes that are introduced for production of a desired product. It includes a review of selection methods for high producers and an application developed by a major biopharmaceutical industry to expedite the cell line development process. The potential of cell engineering approch to enhance cell lines through the manipulation of single genes that play important roles in key metabolic and regulatory pathways is also explored throughout.

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 tech-

nology. 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.

Cell Culture and Its Application covers the proceedings of the First International Cell Culture Congress Symposium, which focuses on how cell culture technology could impact on cell biology. The symposium aims to establish facilities for the cultivation of mammalian cells, which in turn would hopefully enhance basic cell biology research. The book is organized into four symposium and workshop sessions, encompassing 45 chapters. The opening chapter recognizes the interlocking relationship of cell culture technology and substantive cell biology. Chapters 2-5 describe the biochemical events that mark the cell cycle, with emphasis on occurrence of histone phosphorylation at each cycle. A discussion on cell differentiation, as a phenomena of interacting, inductive, and inhomogeneous cell populations, is included in these chapters. The second symposium session deals with signs of a revolution in progress in cell culture technology. This includes impact of tissue culture in physiological research course and in understanding of integrated physiology. The last two symposium sessions cover the large-scale production of virus from tissue cultures for cell antigens. An approach to the study of aging using diploid human cells in culture as a model system is also presented. It involves isolation and characterization of HLA antigens from cultured cells and their contribution to the study of disease. A brief discussion on mycoplasma contamination, microplasma-cell-virus interaction, and advantages and limitations of direct and indirect culture for primary isolation and detection of mycoplasma contamination is provided. The book then proceeds by discussing cell differentiation of specific cell or organ, such as testis, sensory cell, hepatocyte, embryonic muscle cell, and brain cortex. The concluding chapters cover nutritional requirements for cell growth, defined culture media for specific cell type, issues and problems related to large-scale cell production, and quality control. Cell biologists and researchers will find this book invaluable.

An interdisciplinary approach, integrating biochemistry, biology, genetics, and engineering for the effective production of protein pharmaceuticals. The volume offers a biological perspective of large-s-

cale animal cell culture and examines diverse processing strategies, process management, regulator

Large-Scale Mammalian Cell Culture is composed of papers presented as part of a symposium sponsored by the American Chemical Society Division of Microbial and Biochemical Technology at the 188th American Chemical Society National Meeting, held at Philadelphia, Pa., on Aug. 27, 1984. A rapid development of large-scale mammalian cell culture technology for the production of biologically important molecules becomes apparent. This book looks into this technology, its potential for commercial application, and the regulatory concerns posed by its use for the production of human therapeutics.

A diverse team of researchers, technologists, and engineers describe, in simple and practical language, the major current and evolving technologies for improving the biocatalytic capabilities of mammalian, microbial, and plant cells. The authors present state-of-the-art techniques, proven methods, and strategies for industrial screening, cultivation, and scale-up of these cells, and describe their biotech and industrial uses. Special emphasis is given to the solving critical issues encountered during the discovery of new drugs, process development, and the manufacture of new and existing compounds. Other topics include recombinant protein expression, bioinformatics, high throughput screening, analytical tools in biotechnology, DNA shuffling, and genomics discovery.

This second edition of the bestselling Manual of Industrial Microbiology and Biotechnology brings together in one place the biological and engineering methodologies required to develop a successful industrial process, from culture isolation and development to useful product. The editors have enlisted a broad range of experts, including microbial ecologists, physiologists, geneticists, biochemists, molecular biologists, and biochemical engineers. This comprehensive perspective provides a valuable "how to" resource, the structure of which resembles the sequence of operations involved in the development of a commercial biological process and product.

Animal Cell Bioreactors provides an introduction to the underlying principles and strategies in the in vitro cell culture biotechnology. It addresses engineering aspects such as mass transfer, instrumentation, and control ensuring successful design and operation of animal cell bioreactors. The goal is to provide a comprehensive analysis and review in the advancement of the bioreactor systems for large-scale animal cell cultures. The book is organized into four parts. Part I traces the historical development of animal cell biotechnology. It presents examples of work in progress that seeks to make animal cell biotechnology processes as productive on a cost per unit of product basis as that achieved by other microbial systems. Part II includes chapters dealing with the implications of cell biology in animal cell biotechnology; protein-bound oligosaccharides and their structures; the development of serum-free media and its use in the production of biologically active substances; and the metabolism of mammalian cells. Part III focuses on animal cell cultivation, covering topics such as the fixed bed immobilized culture; three-dimen-

sional microcarriers; and hydrodynamic phenomena in microcarrier cultures. Part IV discusses the design, operation, and control of animal cell bioreactors.

The maturity of biotechnology as a significant, commercial enterprise has led to the large scale production of products from a variety of cell types, including bacterial, fungal, mammalian, and microalgae. While both large scale (>10,000 L) mammalian cell culture and microalgae culture are currently used for commercial purposes, there still exist significant engineering challenges. One of these challenges is to quantify, and minimize, the effect of hydrodynamic forces on cells, which is in direct conflict with the ever pressing need to increase gas mass transfer capability and mixing performance of large scale bioreactors to improve productivity.

It is now more than half a century since animal cells first came into regular use in the laboratory. Instances of laboratory acquired infection and con tamination of therapeutic products, derived from the use of animal cell cultures are rare. The use of animal cells, in addition to an established role in the production of vaccines and therapeutic proteins, has many new medical applications including gene therapy, tissue engineering and cell therapy. Furthermore, C;ldvances in molecular and cell biology are enabling rapid development and application of these technologies and the development of new and more sensitive methods, such as nucleic acid amplification, for the characterisation of cells and the detection of adven titious agents. However, it is clear that there is no room for complacency in this field and the recent expansion in the use of animal cells in the manufacture of medical products and the development of new biological assays for diagnostic and pharmaco--toxicological screening, underlines the need for vigilance regarding the correct and safe use of animal cells as substrates. This book is therefore very timely and should prove to be a highly valuable text, finding a wider audience beyond those with respon sibility for laboratory safety. The book guides the reader from fundamental cell biology issues and the establishment of new in vitro methods, through testing and validation of cell lines and on to issues in the use of animal cells in manufacturing processes.

The American Anti-Vivisection Society (AAVS) petitioned the National Institutes of Health (NIH) on April 23, 1997, to prohibit the use of animals in the production of mAb. On September 18, 1997, NIH declined to prohibit the use of mice in mAb production, stating that "the ascites method of mAb production is scientifically appropriate for some research projects and cannot be replaced." On March 26, 1998, AAVS submitted a second petition, stating that "NIH failed to provide valid scientific reasons for not supporting a proposed ban." The office of the NIH director asked the National Research Council to conduct a study of methods of producing mAb. In response to that request, the Research Council appointed the Committee on Methods of Producing Monoclonal Antibodies, to act on behalf of the Institute for Laboratory Animal Research of the Commission on Life Sciences, to conduct the study. The 11 expert members of the committee had extensive experience in biomedical research, laboratory animal medicine, animal welfare, pain research, and patient advo-

cacy (Appendix B). The committee was asked to determine whether there was a scientific necessity for the mouse ascites method; if so, whether the method caused pain or distress; and, if so, what could be done to minimize the pain or distress. The committee was also asked to comment on available in vitro methods; to suggest what acceptable scientific rationale, if any, there was for using the mouse ascites method; and to identify regulatory requirements for the continued use of the mouse ascites method. The committee held an open data--gathering meeting during which its members summarized data bearing on those questions. A 1-day workshop (Appendix A) was attended by 34 participants, 14 of whom made formal presentations. A second meeting was held to finalize the report. The present report was written on the basis of information in the literature and information presented at the meeting and the workshop.

This book offers the experiences and improvements made in mammalian cell culture technology. It bridges two scientific cultures, Scientists with no background in cultivation of animal cells and for engineers with a little ground in biology. It was designed to provide you with immediate access to the protocol required every day for animal and mammalian cell lines cultures. It explains the advantages and disadvantages of the methods, different application and gives advice whichever procedure to use. The author supplements the ideas by simple worked examples, making the techniques of scaling up cells by adaptation strategy for pharmaceutical protein production easy to learn. Monitoring cell growth kinetics accompanied by cell metabolism (glucose and glutamine consumption, lactate and ammonia production) and cell imaging established well. It discusses removal of serum, media supplement like insulin and amino acids, osmotic stress and cell morphology. It worth mentioned that, this book open a new gate for biotechnological scientists describing manipulation of productive adherence cell factory in serum medium to grow as suspension cells in serum free medium at high cell density.

The completion of the Human Genome Project and the rapid progress in cell bi- ogy and biochemical engineering, are major forces driving the steady increase of approved biotech products, especially biopharmaceuticals, in the market. Today mammalian cell products (“products from cells”), primarily monoclonals, cytokines, recombinant glycoproteins, and, increasingly, vaccines, dominate the biopharmaceutical industry. Moreover, a small number of products consisting of in vitro cultivated cells (“cells as product”) for regenerative medicine have also been introduced in the market. Their efficient production requires comprehensive knowledge of biological as well as biochemical mammalian cell culture fundamentals (e.g., cell characteristics and metabolism, cell line establishment, culture medium optimization) and related engineering principles (e.g., bioreactor design, process scale-up and optimization). In addition, new developments focusing on cell line development, animal-free c- ture media, disposables and the implications of changing processes (multi-purpo- facilities) have to be taken into account. While a number of excellent books treating the basic methods and applications of mammalian cell culture technology have been published, only

little attention has been afforded to their engineering aspects. The aim of this book is to make a contribution to closing this gap; it particularly focuses on the interactions between biological and biochemical and engineering principles in processes derived from cell cultures. It is not intended to give a c- prehensive overview of the literature. This has been done extensively elsewhere.

This book is a monography about perfusion cell cultures for the production of biopharmaceuticals, such as therapeutic proteins (i.e. biomolecules like monoclonal antibodies), and describes the fundamentals, design and operation of these processes. Context is given in the first chapters to understand the state-of-the-art of the technology. We then give an overview of the challenges and objectives in operating mammalian cell perfusion cultures and provide guidelines for the design and setup of lab-scale bioreactor systems, and the required control structure to achieve stable operation. Scale-down devices and PAT tools are described in the context of continuous manufacturing and guidelines for process optimization are given using a variety of case studies to illustrate different approaches. Scale-up is also adressed with a strong focus on bioreactor aeration and mixing, shear stress and cell retention device. Finally, a general introduction for the application of mechanistic and statistic models in bioreactor process development and optimization is given in the last chapter.

The book "New Insights into Cell Culture Technology" focuses on many advanced methods and techniques concerned with cell culture. The contributing authors have discussed various developments in cell culture methods, the application of insect cells for the efficient production of heterologous proteins, the expansion of human mesenchymal stromal cells for different clinical applications, the remote sensing of cell culture experiments and concepts for the development of cell culture bioprocess, continuous production of retroviral pseudotype vectors, and the production of oncolytic measles virus vectors for cancer therapy. This book is an original contribution of experts from different parts of the globe, and the in-depth information will be a significant resource for students, scientists, and physicians who are directly dealing with cells.["Culture" is essential for human life and also the life of a cell. - Sivakumar Gowder]

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.

Stem Cell Manufacturing discusses the required technologies that enable the transfer of the current laboratory-based practice of stem cell tissue culture to the clinic environment as therapeutics, while concurrently achieving control, reproducibility, automation, validation, and safety of the process and the product. The advent of stem cell research unveiled the therapeutic potential of stem cells and

their derivatives and increased the awareness of the public and scientific community for the topic. The successful manufacturing of stem cells and their derivatives is expected to have a positive impact in the society since it will contribute to widen the offer of therapeutic solutions to the patients. Fully defined cellular products can be used to restore the structure and function of damaged tissues and organs and to develop stem cell-based cellular therapies for the treatment of cancer and hematological disorders, autoimmune and other inflammatory diseases and genetic disorders. Presents the first 'Flowchart' of stem cell manufacturing enabling easy understanding of the various processes in a sequential and coherent manner Covers all bioprocess technologies required for the transfer of the bench findings to the clinic including the process components: cell signals, bioreactors, modeling, automation, safety, etc. Presents comprehensive coverage of a true multidisciplinary topic by bringing together specialists in their particular area Provides the basics of the processes and identifies the issues to be resolved for large scale cell culture by the bioengineer Addresses the critical need in bioprocessing for the successful delivery of stem cell technology to the market place by involving professional engineers in sections of the book

Abstract: Apoptosis, programmed cell death, is a hot topic in recent research due to the potential applications to various areas by regulating its pathway. In industrial large scale animal cell culture processes, research on how to regulate or predict the apoptotic pathway and understanding what signals the apoptotic cascade has lead to a new opportunity to enhance process robustness, improve final performance including productivity, and eventually, reduce production costs. Current industrial cell culture processes normally involve a high cell density process in a large-scale bioreactor as a suspension culture that proliferates the cells beyond their optimal growth conditions. Under these conditions, apoptosis will be triggered, and consequently, cell viability will be decreased, and the chance for product degradation by the release of intracellular proteases and glycosidases will increase. Therefore, characterizing which culture conditions will induce apoptosis during a particular cell culture process can be a valuable tool to optimize cell viability and possibly productivity. Since the conventional method for cell count and viability measurement does not differentiate the cells in early to mid-stage apoptosis from the normal cells, it would be difficult to understand the effect of early stage apoptosis. This study elucidates the correlation between the culture conditions and apoptosis during a mammalian cell culture process and its effects on the productivity using real-time apoptotic assays for accurate cellular growth and death profiles. Apoptosis induced by low pH, glucose and glutamine limitation, lactate toxicity and Camptothecin has been shown to significantly increase the yield and specific productivity most likely due to release of product during secondary necrosis at the culmination of the apoptosis pathway.

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.
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
It is a pleasure to contribute the foreword to Introduction to Cell and Tissue Culture: The ory and Techniques by Mather and Roberts. Despite the occasional appearance of thought ful works devoted to elementary or advanced cell culture methodology, a place remains for a comprehensive and definitive volume that can be used to advantage by both the novice and the expert in the field. In this book, Mather and Roberts present the relevant method ology within a conceptual framework of cell biology, genetics, nutrition, endocrinology, and physiology that renders technical cell culture information in a comprehensive, logical for mat. This allows topics to be presented with an emphasis on troubleshooting problems from a basis of understanding the underlying theory. The material is presented in a way that is adaptable to student use in formal courses; it also should be functional when used on a daily basis by professional cell culturists in a- demia and industry. The volume includes references to relevant Internet sites and other use ful sources of information. In addition to the fundamentals, attention is also given to mod ern applications and approaches to cell culture derivation, medium formulation, culture scale-up, and biotechnology, presented by scientists who are pioneers in these areas. With this volume, it should be possible to establish and maintain a cell culture laboratory devot ed to any of the many disciplines to which cell culture methodology is applicable.
Dynamic Single-Use Bioreactors Used in Modern Liter- and m3- Scale Biotechnological Processes: Engineering Characteristics and Scaling Up, by Christian Löffelholz, Stephan C. Kaiser, Matthias Kraume, Regine Eibl , Dieter Eibl. Orbitally Shaken Single-Use Bioreactors, by Wolf Klöckner, Sylvia Diederichs, Jochen Büchs. Therapeutic Human Cells: Manufacture for Cell Therapy/Regenerative Medicine by Christian van den Bos, Robert

Keefe, Carmen Schirmaier, Michael McCaman. Fast Single-Use VLP Vaccine Productions Based on Insect Cells and the Baculovirus Expression Vector System: Influenza as Case Study by Regine Eibl, Nina Steiger, Sabine Wellnitz, Tiago Vicente, Corinne John, Dieter Eibl. Microbial High Cell Density Fermentations in a Stirred Single-Use Bioreactor by Thomas Dreher, Bart Walcarius, Ute Husemann, Franziska Klingenberg, Christian Zahnow, Thorsten Adams, Davy de Wilde, Peter Casteels, Gerhard Greller. Quorus Bioreactor: A New Perfusion-Based Technology for Microbial Cultivation by Sheena J. Fraser, Christian Endres. Cultivation of Marine Microorganisms in Single-Use Systems by Friederike Hillig, Maciej Pilarek, Stefan Junne, Peter Neubauer. Flexible Biomanufacturing Processes that Address the Needs of the Future by Bernhard Diel, Christian Manzke, Thorsten Peuker. An Approach to Quality and Security of Supply for Single-Use Bioreactors by Magali Barbaroux, Susanne Gerighausen, Heiko Hackel. A Risk Analysis for Production Processes with Disposable Bioreactors by Tobias Merseburger, Ina Pahl, Daniel Müller, Markus Tanner.

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 bioproducts • Discuses a wide selection of host strain types and disruptive bioprocess technologies

The Book This book provides the most detailed and comprehensive survey available of the different methods for production of biotechnology products from large scale mammalian and plant cell culture. Methods ranging from fermentation and encapsulation to hollow fibers and fluidized beds are described by the leaders in the field with a section on regulatory considerations. Each production method is described in detail in terms of principles, equipment and results so that informed comparisons and evaluations can be made. Contents Antibody Production with Airlift Fermentors * Monoclonal Antibody Production in Stirred Reactors * Microcarrier Cell Culture * Cellular Microencapsulation for Large-Scale Production of Monoclonal Antibodies * Entrapment of Cultured Cells in Agarose Beads * An Automated Hollow Fiber System for the Large Scale Manufacture of Mammalian Cell Secreted Product * Continuous Cell Culture with Fluidized Sponge Beads * Perfusion Cell Culture System Based on Ceramic Matrices * Large Scale Plant Cell Culture * Safety Considerations for Cell Culture-Derived Biologicals

Animal cell technology is a discipline of growing importance, which aims not merely at understanding structure, function and behaviour of differentiated animal cells, but especially at the development of their abilities useful for clinical application. Topics of interest in this regard include: viral vaccines, pharmaceutical proteins and novel applications such as gene therapy and organ culture. Undoubtedly, these Proceedings of the joint Meeting of the European Society for Animal Cell Technology and the Japanese Association for Ani-

mal Cell Technology (Veldhoven, The Netherlands, September 1994) review the most recent status of the field, and will be most valuable to anyone actively involved in the culture of animal cells and its applications. The contributions to this volume were strictly selected on the basis of quality and novelty of contents. Kluwer is honoured to be able to add this work to its strongly developing publication programme in cell and tissue culture, which now has its connections to all major Societies in this field worldwide. Audience: Cell biologists, biochemists, molecular biologists, immunologists, virologists and all other disciplines related to animal cell technology, working in an academic environment, as well as in (biotechnology or pharmaceutical) industry.

Published in 1997: Antibody Therapeutics is a comprehensive evaluation of progress toward using humanized antibodies as a new generation of therapeutics. The humanized antibodies that have led the way in product approval are discussed as case studies, offering an insight into the preclinical and clinical data acquired during the regulatory approval process. Leading experts offer their findings as examples of what works and what does not, saving you time and making your research more cost effective. This book is essential reading for researchers, clinicians, development and regulatory staff in pharmaceutical and biotechnology companies, and hospital staff, including policy and decision makers. It also provides postgraduate and medical students with an authoritative overview of the field.

Dissolved carbon dioxide has been identified as an important process parameter affecting cell growth, productivity and product quality (e.g. glycosylation) of recombinant proteins when exceeding critical levels, occurring especially in industrial large-scale cell culture processes due to the increased hydrostatic pressure. As CO2 can easily pass the cellular membrane and thereby influence intracellular pH, important cellular processes (e.g. cell cycle regulation, enzymes of TCA cycle) are directly influenced by pCO2 and dependent bicarbonate concentration. Consequently, process control strategies attend to keep pCO2 within physiological range. In a metabolic engineering approach an antibody producing CHO cell line stably expressing human carbonic anhydrase (hCAII), the enzyme that catalyzes the equilibrium of CO2 in aqueous solutions, was generated and used to characterize CO2 effects in simulated CO2 acid load and high CO2 levels as they occur in large scale mammalian cell culture. The cell line expressing active hCAII showed more rapid initial re-alkalinization of cytoplasm after induced CO2 acid load.