Monoclonal Antibodies Meeting The Challenges In Manufacturing Formulation Delivery And Stability Of Final Drug Product

Providing practical and proven solutions for antibody-drug conjugate (ADC) drug discovery success in oncology, this book helps readers improve the drug safety and therapeutic efficacy of ADCs to kill targeted tumor cells. • Discusses the basics, drug delivery strategies, pharmacology and toxicology, and regulatory approval strategies • Covers the conduct and design of oncology clinical trials and the use of ADCs for tumor imaging • Includes case studies of ADCs in oncology drug development • Features contributions from highly-regarded experts on the frontlines of ADC research and development

This book is designed to be the first major text to discuss advances in medical genetics in the developing world.

Monoclonal AntibodiesMeeting the Challenges in Manufacturing, Formulation, Delivery and Stability of Final Drug ProductWoodhead Publishing

Contemporary issues in animal cell biotechnology; Protein production by genetically engineered mammalian cell lines; Understanding and controlling fluid-mechanical injury of animal cells in bioreactors; Oxygenating animal cell cultures: the remaining problems; The oxygenation of animal cell cultures by bubbles; Advances in animal cell immobilization technology; Immunoaffinity adsorption: applications in the recovery of high-value biochemical

from animal cell culture; Therapeutic monoclonal antibodies-their production and application; Production and use of non-therapeutic monoclonal antibodies; Chimaeric bispecifc antibodies; Anti-idiotype antibodies and their uses; The growth and production of human immunodeficiency virus; Interferonsderived from human cells; The manufacture and use of a colon cancer antigen-carcinoembryonic antigen; Erythropoietin.

This book is oriented towards post-graduates and researchers with interest in proteomics and its applications in clinical biomarker discovery pipeline. Biomarker discovery has long been the research focus of many life scientists globally. However, the pipeline starting from discovery to validation to regulation as a diagnostic or therapeutic molecule follows a complex trajectory. This book aims to provide an in-depth synopsis on each of these developmental phases attendant to biomarker “life cycle” with emphasis on the emerging and significant role of proteomics. The book begins with a perspective on the role of biorepositories and need for biobanking practices in the developing world. The next chapter focuses on disease heterogeneity in context to geographical bias towards susceptibility to the disease and the role of multi-omics techniques to devise disruptive innovations towards biomarker discovery. Chapter 3 focuses on various omics-based platforms that are currently being used for biomarker discovery, their principles and workflow. Mass spectrometry is emerging as a powerful technology for discovery based studies and targeted validation. Chapter 4 aims at providing a glimpse of the basic workflow and considerations in mass spectrometry based studies. Rapid and aptly targeted research funding has often been deemed as one of the decisive factors enabling excellent science and path breaking innovations. With the need for sophistication required in multi-omics research, Chapter 5 focuses on innovative funding

strategies such as crowdfunding and Angel philanthropy. Chapter 6 provides the latest advances in education innovation, the premise and reality of bioeconomy especially in a specific context of the developing world, not to mention the new concept of “social innovation” to link biomarkers with socially responsible and sustainable applications. Chapter 7, in ways similar to biomarkers, discusses the biosimilars as a field that has received much focus and prominence recently due to their immense potential in clinical and pharmaceutical innovation literatures. The broader goal post-biomarker discovery is to translate their use in clinics. However, the road from bench-to-bed side is arduous and complex that is subject to oversight from various national and international regulatory bodies. Chapter 8 underscores these regulatory science considerations and provides a concise overview on intellectual property rights in biomarker discovery. Thus, this book contributed by eminent biomarker scientists, clinicians, translational researchers and social scientists holistically covers the various facets of the biomarker discovery journey from “cell to society” in developing world. The lessons learned and highlighted here are of interest to the life sciences community in a global and interdependent world.

In response to a request from the Office of Science and Technology Policy and the Office of the Assistant Secretary for Preparedness and Response, the National Academies of Sciences, Engineering, and Medicine convened a standing committee of experts to help inform the federal government on critical science and policy issues related to emerging infectious diseases and other 21st century health threats. This set of Rapid Expert Consultations are the first of their kind and represent the best evidence available to the Committee at the time each publication was released. The science on these issues is continually evolving, and the

scientific consensus the Committee reaches on these topics will likely evolve with it. The standing committee includes members with expertise in emerging infectious diseases, public health, public health preparedness and response, biological sciences, clinical care and crisis standards of care, risk communication, and regulatory issues.

Separation, extraction and concentration are essential processes in the preparation of key food ingredients. They play a vital role in the quality optimization of common foods and beverages and there is also increasing interest in their use for the production of high-value compounds, such as bioactive peptides from milk and whey, and the recovery of co-products from food processing wastes. Part one describes the latest advances in separation, extraction and concentration techniques, including supercritical fluid extraction, process chromatography and membrane technologies. It also reviews emerging techniques of particular interest, such as pervaporation and pressurised liquid extraction. Part two then focuses on advances in separation technologies and their applications in various sectors of the food, beverage and nutraceutical industries. Areas covered include dairy and egg processing, oilseed extraction, and brewing. This section discusses the characteristics of different foods and fluids, how food constituents are affected by separation processes and how separation processes can be designed and operated to optimize end product quality. With its team of experienced international contributors, Separation, extraction and concentration processes in the food, beverage and nutraceutical industries is an important reference source for professionals concerned with the development and optimisation of these processes. Describes the latest advances in separation, extraction and concentration techniques and their applications in various sectors of the food, beverage and nutraceutical industries Reviews emerging

techniques of particular interest, such as pervaporation and pressurised liquid extraction Explores the characteristics of different foods and fluids and how food constituents are affected by separation processes

This book is a printed edition of the Special Issue "Monoclonal Antibodies" that was published in Antibodies

Proteins are exposed to various interfacial stresses during drug product development. They are subjected to air-liquid, liquid-solid, and, sometimes, liquid-liquid interfaces throughout the development cycle-from manufacturing of drug substances to storage and drug delivery. Unlike small molecule drugs, proteins are typically unstable at interfaces where, on adsorption, they often denature and form aggregates, resulting in loss of efficacy and potential immunogenicity. This book covers both the fundamental aspects of proteins at interfaces and the quantification of interfacial behaviors of proteins. Importantly, this book introduces the industrial aspects of protein instabilities at interfaces, including the processes that introduce new interfaces, evaluation of interfacial instabilities, and mitigation strategies. The audience that this book targets encompasses scientists in the pharmaceutical and biotech industry, as well as faculty and students from academia in the surface science, pharmaceutical, and medicinal chemistry areas.

The advent of hybridoma technology leading to the successful produc tion of

monoclonal antibodies against a variety of tumor-associated antigens has, during the last decade, provided a very powerful tool for research and clinical investigations. These highly specific reagents have essentially replaced the polysera of the earlier days. The successful demonstration of the many wide ranging capabilities of the monoclonal antibody technique has already begun to exert an enormous impact on diverse areas of research in basic science and medicine. In particular, the potential of monoclonal antibodies to serve as carriers for selective targeting of radionuclides to tumors for diagnosis or therapy, has stimulated an intense surge of research interest and even revived hopes of realizing Ehrlich's concept of the "magic bullet". Indeed, the technology appears to be on the threshold of a revolution in diagnosing and treating malignant disease. Much work remains to be done, however, and even though the progress has been impressive, results to date have shown only moderate success. There is no question that the limited success we have achieved thus far is merely a prelude to the many more exciting developments yet to come.

Cancer: New Insights for the Healthcare Professional / 2012 Edition is a ScholarlyEditions™ eBook that delivers timely, authoritative, and comprehensive information about Cancer. The editors have built Cancer: New Insights for the Healthcare Professional / 2012 Edition on the vast information databases of

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Nanostructures for Antimicrobial Therapy discusses the pros and cons of the use of nanostructured materials in the prevention and eradication of infections, highlighting the efficient microbicidal effect of nanoparticles against antibiotic-resistant pathogens and biofilms. Conventional antibiotics are becoming ineffective towards microorganisms due to their widespread and often inappropriate use. As a result, the development of antibiotic resistance in microorganisms is increasingly being reported. New approaches are needed to confront the rising issues related to infectious diseases. The merging of biomaterials, such as chitosan, carrageenan, gelatin, poly (lactic-co-glycolic acid)

with nanotechnology provides a promising platform for antimicrobial therapy as it provides a controlled way to target cells and induce the desired response without the adverse effects common to many traditional treatments. Nanoparticles represent one of the most promising therapeutic treatments to the problem caused by infectious micro-organisms resistant to traditional therapies. This volume discusses this promise in detail, and also discusses what challenges the greater use of nanoparticles might pose to medical professionals. The unique physiochemical properties of nanoparticles, combined with their growth inhibitory capacity against microbes has led to the upsurge in the research on nanoparticles as antimicrobials. The importance of bactericidal nanobiomaterials study will likely increase as development of resistant strains of bacteria against most potent antibiotics continues. Shows how nanoantibiotics can be used to more effectively treat disease Discusses the advantages and issues of a variety of different nanoantibiotics, enabling medics to select which best meets their needs Provides a cogent summary of recent developments in this field, allowing readers to quickly familiarize themselves with this topic area

Stay up to date with changes in the biopharmaceutical products market! With the growth rate of biopharmaceutical products ascending rapidly since the 1980s, the number of biotechnology companies has risen to more than 1200 new

businesses in the Unites States alone. This dramatic increase creates a new set of challenges in education, putting demands on teachers and students to keep pace with innovations in terminology and techniques. The Handbook of Pharmaceutical Biotechnology is essential in meeting those challenges. A practical compendium of biotechnology-produced drugs, the Handbook of Pharmaceutical Biotechnology covers general principles of biotechnology and pharmaceuticals, putting usable information in the hands of those who need it most. The book presents descriptions that break down each pharmaceutical product by pharmacology, pharmacokinetics, clinical applications, toxicities, and dosage guidelines. It also reviews prescription products, discussing clinical uses and trials, adverse reactions, and more. Tables, figures, and extensive references add to each comprehensive summary. The Handbook of Pharmaceutical Biotechnology also includes up-to-date information on: monoclonal antibodies (Abciximab, Muromonab-CD3) enzymes and regulators of enzyme activity (Alteplase, clotting factors, Dornase alpha) anticytokines olgonucleotide and gene therapy hematopoietic growth factors (interleukins, interferons, colony stimulating factors, erythropoietin) As the worldwide production and sales of biotechnology-derived pharmaceuticals and diagnostics continues to grow, teachers, students, and clinical pharmacists need to maintain

a clear and current understanding of the field. The Handbook of Pharmaceutical Biotechnology presents a thoughtful and thorough guide to keeping pace in this evolving industry.

The surprising, behind-the-scenes story of how our medicines are discovered, told by a veteran drug hunter. The search to find medicines is as old as disease, which is to say as old as the human race. Through serendipity— by chewing, brewing, and snorting—some Neolithic souls discovered opium, alcohol, snakeroot, juniper, frankincense, and other helpful substances. Ötzi the Iceman, the five-thousand-year-old hunter frozen in the Italian Alps, was found to have whipworms in his intestines and Bronze-age medicine, a worm-killing birch fungus, knotted to his leggings. Nowadays, Big Pharma conglomerates spend billions of dollars on state-of the art laboratories staffed by PhDs to discover blockbuster drugs. Yet, despite our best efforts to engineer cures, luck, trial-and-error, risk, and ingenuity are still fundamental to medical discovery. The Drug Hunters is a colorful, fact-filled narrative history of the search for new medicines from our Neolithic forebears to the professionals of today, and from quinine and aspirin to Viagra, Prozac, and Lipitor. The chapters offer a lively tour of how new drugs are actually found, the discovery strategies, the mistakes, and the rare successes. Dr. Donald R. Kirsch infuses the book with his own expertise and

experiences from thirty-five years of drug hunting, whether searching for life-saving molecules in mudflats by Chesapeake Bay or as a chief science officer and research group leader at major pharmaceutical companies.

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 advocacy (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.
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

Delivery of therapeutic proteomics and genomics represent an important area of drug delivery research. Genomics and proteomics approaches could be used to

direct drug development processes by unearthing pathways involved in disease pathogenesis where intervention may be most successful. This book describes the basics of genomics and proteomics and highlights the various chemical, physical and biological approaches to protein and gene delivery. Covers a diverse array of topics from basic sciences to therapeutic applications of proteomics and genomics delivery Of interest to researchers in both academia and industry Highlights what's currently known and where further research is needed

The last decade has witnessed remarkable developments in antibody research and its therapeutic applications. With the methods of molecular biology it is now possible to manipulate the specificities and activities of antibody molecules to generate an almost limitless array of structures for both basic investigations and the clinical setting. The contributions to this volume cover all three domains of the antibody: the variable regions, the relatively neglected but crucial hinge, and the constant region. These studies provide critical structural and functional information about antibodies, while also pointing the way to the construction of molecules with enhanced or even novel properties. Bringing together major experts on antibody engineering, this book is highly recommended to faculty, postdoctoral fellows and graduate students in molecular biology, microbiology,

immunology, cancer research and genetics.

"The greater our knowledge increases, the more our ignorance unfolds. " U. S. President John F. Kennedy, speech, Rice University, September 12, 1962 My primary purpose for writing this book was much more than to provide another information source on Chemistry, Manufacturing & Controls (CMC) that would rapidly become out of date. My primary purpose was to provide insight and practical suggestions into a common sense business approach to manage the CMC regulatory compliance requirements for biopharmaceuticals. Such a common sense business approach would need (1) to be applicable for all types of biopharmaceutical products both present and future, (2) to address the needs of a biopharmaceutical manufacturer from the beginning to the end of the clinical development stages and including post market approval, and (3) to be adaptable to the constantly changing CMC regulatory compliance requirements and guidance. Trying to accomplish this task was a humbling experience for this author! In Chapter 1, the CMC regulatory process is explained, the breadth of products included under the umbrella ofbiopharmaceuticals are identified, and the track record for the pharmaceutical and biopharmaceutical industry in meeting CMC regulatory compliance is discussed. In Chapter 2, while there are many CMC commonalities between biopharmaceuticals and chemically-

synthesized pharmaceuticals, the significant differences in the way the regulatory agencies handle them are examined and the reasons for why such differences are necessary is discussed. Also, the importance of CMC FDA is stressed.

Histocompatibility Antigens—Advances in Research and Application: 2012 Edition is a ScholarlyPaper™ that delivers timely, authoritative, and intensively focused information about Histocompatibility Antigens in a compact format. The editors have built Histocompatibility Antigens—Advances in Research and Application: 2012 Edition on the vast information databases of ScholarlyNews.™ You can expect the information about Histocompatibility Antigens in this eBook to be deeper than what you can access anywhere else, as well as consistently reliable, authoritative, informed, and relevant. The content of Histocompatibility Antigens—Advances in Research and Application: 2012 Edition has been produced by the world's leading scientists, engineers, analysts, research institutions, and companies. All of the content is from peer-reviewed sources, and all of it is written, assembled, and edited by the editors at ScholarlyEditions™ and available exclusively from us. You now have a source you can cite with authority, confidence, and credibility. More information is available at http://www.ScholarlyEditions.com/.

Biotechnology for Beginners, Second Edition, presents the latest information and

developments from the field of biotechnology—the applied science of using living organisms and their by-products for commercial development—which has grown and evolved to such an extent over the past few years that increasing numbers of professionals work in areas that are directly impacted by the science. For the first time, this book offers an exciting and colorful overview of biotechnology for professionals and students in a wide array of the life sciences, including genetics, immunology, biochemistry, agronomy, and animal science. This book also appeals to the lay reader without a scientific background who is interested in an entertaining and informative introduction to the key aspects of biotechnology. Authors Renneberg and Demain discuss the opportunities and risks of individual technologies and provide historical data in easy-to-reference boxes, highlighting key topics. The book covers all major aspects of the field, from food biotechnology to enzymes, genetic engineering, viruses, antibodies, and vaccines, to environmental biotechnology, transgenic animals, analytical biotechnology, and the human genome. This stimulating book is the most user-friendly source for a comprehensive overview of this complex field. Provides accessible content to the lay reader who does not have an extensive scientific background Includes all facets of biotechnology applications Covers articles from the most respected scientists, including Alan Guttmacher, Carl Djerassi, Frances

S. Ligler, Jared Diamond, Susan Greenfield, and more Contains a summary, annotated references, links to useful web sites, and appealing review questions at the end of each chapter Presents more than 600 color figures and over 100 illustrations Written in an enthusiastic and engaging style unlike other existing theoretical and dry-style biotechnology books

The 21st ESACT conference was held in the beautiful surroundings of the CityWest Hotel resort in Dublin, Ireland. For the first time in ESACT history the number of participants exceeded 900: a sign of the ever increasing importance of this area. The conference commenced on Sunday June 5th with two sets of parallel workshops on the subjects listed below. An additional workshop was held on Monday lunchtime of the conferenceProcess Analytical Technology (PAT), Quality by Design (QbD) and other recent regulatory developments. 2. Innovative media products for the 21st century biopharmaceutical industry. 3. The impact of high titre media feed-streams on monoclonal antibody purification. 4. Advances in genomics and proteomics. 5. Stem Cell Technology: new developments and clinical applications.

Globulins—Advances in Research and Application: 2013 Edition is a ScholarlyBrief™ that delivers timely, authoritative, comprehensive, and specialized information about ZZZAdditional Research in a concise format. The editors have

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Upstream processing refers to the production of proteins by cells genetically engineered to contain the human gene which will express the protein of interest. The demand for large quantities of specific proteins is increasing the pressure to boost cell culture productivity, and optimizing bioreactor output has become a primary concern for most pharmaceutical companies. Each chapter in Cell Culture and Upstream Processing is taken from presentations at the highly acclaimed IBC conferences as well as meetings of the European Society for Animal Cell Technology (ESACT) and Protein Expression in Animal Cells

(PEACe) and describes how to improve yield and optimize the cell culture production process for biopharmaceuticals, by focusing on safety, quality, economics and operability and productivity issues. Cell Culture and Upstream Processing will appeal to a wide scientific audience, both professional practitioners of animal cell technology as well as students of biochemical engineering or biotechnology in graduate or high level undergraduate courses at university.

Promoting a continued and much-needed renaissance in biopharmaceutical manufacturing, this book covers the different strategies and assembles top-tier technology experts to address the challenges of antibody purification. • Updates existing topics and adds new ones that include purification of antibodies produced in novel production systems, novel separation technologies, novel antibody formats and alternative scaffolds, and strategies for ton-scale manufacturing • Presents new and updated discussions of different purification technologies, focusing on how they can address the capacity crunch in antibody purification • Emphasizes antibodies and innovative chromatography methods for processing

Protein Actions: Principles and Modeling is aimed at graduates, advanced undergraduates, and any professional who seeks an introduction to the

biological, chemical, and physical properties of proteins. Broadly accessible to biophysicists and biochemists, it will be particularly useful to student and professional structural biologists and molecular biophysicists, bioinformaticians and computational biologists, biological chemists (particularly drug designers) and molecular bioengineers. The book begins by introducing the basic principles of protein structure and function. Some readers will be familiar with aspects of this, but the authors build up a more quantitative approach than their competitors. Emphasizing concepts and theory rather than experimental techniques, the book shows how proteins can be analyzed using the disciplines of elementary statistical mechanics, energetics, and kinetics. These chapters illuminate how proteins attain biologically active states and the properties of those states. The book ends with a synopsis the roles of computational biology and bioinformatics in protein science.

Monoclonal antibodies (MAbs) are currently the major class of protein bio therapeutic being developed by biotechnology and pharmaceutical companies. Monoclonal Antibodies discusses the challenges and issues revolving around development of a monoclonal antibody produced by recombinant DNA technology into a therapeutic agent.This book covers downstream processing which includes design of processes to manufacture the formulation, formulation

design, fill and finish into closure systems and routes of administration. The characterization of the final drug product is covered where the use of biophysical methods combined with genetic engineering is used to understand the solution properties of the formulation. The latter has become very important since many indications such as arthritis and asthma require the development of formulations for subcutaneous delivery (SC). The development of formulations for IV delivery is also important and comes with a different set of challenges. The challenges and strategies that can overcome these limitations are discussed in this book, starting with an introduction to these issues, followed by chapters detailing strategies to deal with them. Subsequent chapters explore the processing and storage of mAbs, development of delivery device technologies and conclude with a chapter on the future of mAbs in therapeutic remedies. Discusses the challenges to develop MAbs for intravenous (IV) and subcutaneous delivery (SC) Presents strategies to meet the challenges in development of MAbs for SC and IV administration Discusses the use of biophysical analytical tools coupled with MAb engineering to understand what governs MAb properties at high concentration

Fermentation is a theme widely useful for food, feed and biofuel production. Indeed each of these areas, food industry, animal nutrition and energy

production, has considerable presence in the global market. Fermentation process also has relevant applications on medical and pharmaceutical areas, such as antibiotics production. The present book, Fermentation Processes, reflects that wide value of fermentation in related areas. It holds a total of 14 chapters over diverse areas of fermentation research.

This book offers the latest scientific research on applied microbiology presented at the IV International Conference on Environmental, Industrial and Applied Microbiology (BioMicroWorld2011) held in Spain in 2011. A wide-ranging set of topics including agriculture, environmental, food, industrial and medical microbiology makes this book interesting not only for microbiologists, but also for anyone who likes to keep up with cutting-edge research in microbiology and microbial biotechnology. Readers will find a major collection of knowledge, approaches, methods and discussions on the latest advances and challenges in applied microbiology in a compilation of 136 chapters written by active researchers in the field from around the world. The topics covered in this single volume include biodegradation of pollutants, water, soil and plant microorganisms, biosurfactants, antimicrobial natural products, antimicrobial susceptibility, antimicrobial resistance, human pathogens, food microorganisms, fermentation, biotechnologically relevant enzymes and proteins, microbial

physiology, metabolism and gene expression mainly, although many other subjects are also discussed. Sample Chapter(s) A microcosm study on the die-off response of the indicator bacteria, Enterococcus faecium and Enterococcus faecalis (267 KB) Contents:Agriculture, Soil, Environmental and Marine–Aquatic MicrobiologyFood MicrobiologyIndustrial Microbiology. Methods. Quantitative Models and BioinformaticsMedical and Pharmaceutical Microbiology. Antimicrobial Agents and ChemotherapyMicrobial Physiology, Metabolism and Gene ExpressionBiotechnologically Relevant Enzymes and Proteins Readership: Professionals, microbiologists, clinicians, (bio)chemists, physicists, and engineers. Keywords:Microorganisms;Applied Microbiology;Environmental Microbiology;Industrial Microbiology;Microbial Biotechnology;BioMicroWorld2011 Conference Proceedings Book;Mendez-VilasKey Features:The topics covered in this single volume include biodegradation of pollutants, water, soil and plant microorganisms, biosurfactants, antimicrobial natural products, antimicrobial susceptibility, antimicrobial resistance, human pathogens, food microorganisms, fermentation, biotechnologically relevant enzymes and proteins, microbial physiology, metabolism and gene expression mainly, although many other subjects are also discussed

Over the last six decades, there has been tremendous improvement in the

survival rate for the majority of children affected by cancer in the United States and in Western Europe. Despite dramatic advances in the “developed” world, 85% of children diagnosed with cancer globally will not survive this disease. Cancer in Children and Adolescents is an accessible textbook that covers the complexities and interdisciplinary nature of cancer occurrences and provides the fundamentals of diagnosis and management of cancers that affect children and adolescents. Distinguished for its global focus, many chapters in Cancer in Children and Adolescents are co-authored by recognized specialists from around the world. Cancer in Children and Adolescents is divided into four major sections: Section 1: The Laboratory Biology and Diagnostic Evaluation of Childhood Cancer Section 2: Principles of Cancer Therapy in Children Section 3: Tumors of Children Section 4: Supportive Care

Biopharmaceuticals (i.e., biological medicines sourced from genetically-engineered living systems) for treatment of human diseases have become a significant percentage of the pharmaceutical industry. And not just the recombinant DNA-derived proteins and monoclonal antibodies (both from the innovators and biosimilars); but now, an increasing awareness of the importance of gene therapy and genetically engineered cellular medicinal products. These biopharmaceuticals are being developed by many companies whose Chemistry,

Manufacturing & Control (CMC) teams have varying degrees of familiarity or experience with the CMC strategy and regulatory compliance requirements for these challenging products. Companies clearly plan out the strategy for their clinical study plans, but frequently, the development of a strategy for CMC is an afterthought. Coupled with the complexity of the biopharmaceutical manufacturing processes and products, and this can be a recipe for disaster. The third edition of this book provides insights and practical guidance for the CMC teams to develop an acceptable cost-effective, risk-based CMC regulatory compliance strategy for all biopharmaceuticals (recombinant proteins, monoclonal antibodies, genetically engineered viruses and genetically engineered human cells) from early clinical stage development through market approval. The third edition of this book provides added coverage for the biosimilars, antibody drug conjugates (ADCs), bispecific antibodies, genetically engineered viruses, and genetically engineered cells. This third edition of the book also addresses the heightened pressure on CMC regulatory compliance timelines due to the introduction of expedited clinical pathways moving the clinical development closer to a seamless phase process (e.g., FDA Breakthrough Therapy designation, CBER Regenerative Medicine Advanced Therapy (RMAT) designation, EMA Priority Medicines (PRIME) designation). The

Challenge of CMC Regulatory Compliance for Biopharmaceuticals is essential, practical information for all pharmaceutical development scientists, Manufacturing and Quality Unit staff, Regulatory Affairs personnel, and senior management involved in the manufacture of biopharmaceuticals.