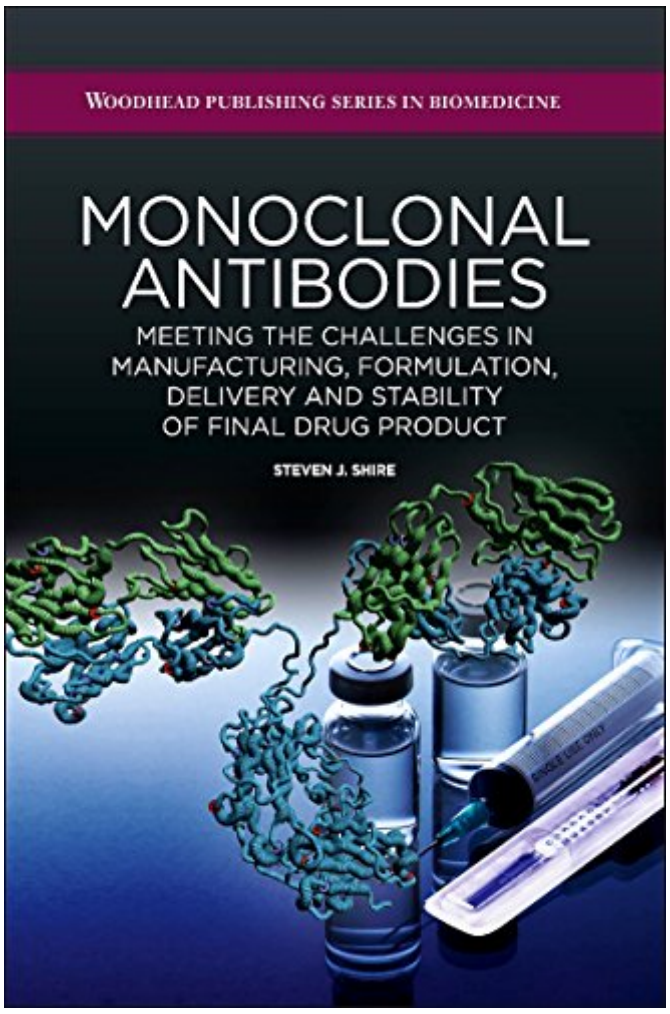

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Monoclonal Antibodies-Steven Shire 2015-04-24 Monoclonal antibodies (MAbs) are currently the major class of protein bio therapeutic being developed by biotechnology and pharmaceutical companies. Monoclonal Antibodies discusses the challenges and issues 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

Meeting the Challenge-Jon Paugh 1997

Abstracts of the Annual Meeting of the American Society for Microbiology-American Society for Microbiology 1991

Proceedings of the ... Annual Meeting of the Northeastern Conference on Avian Diseases- 1991

The Challenge of CMC Regulatory Compliance for Biopharmaceuticals-John Geigert 2012-12-06 "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.

Monoclonal Antibody Production-National Research Council 1999-06-06 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.

Abstracts, 15th Annual Meetings, January 20-February 15, 1986-1986

Annual Meeting of the American Association for Cancer Research-American Association for Cancer Research 1988 Contains abstracts of the scientific proceedings of the 73rd- annual meetings of the American Association for Cancer Research (1982-).

Development of Antibody-Based Therapeutics-Mohammad A. Tabrizi 2018-09-11 With a key focus on recent developments and advances in the field, this book provides in-depth coverage of topics fundamental to the development of targeted therapeutics. The expansion of targeted modalities in rapidly evolving therapeutic areas, such as immune-oncology, and developments with respect to combination therapies, novel technologies, and the therapeutic application of antibody-drug conjugates, are presented. Additionally, the book builds upon topics discussed in the first edition (2012) where recent innovations warrant elaboration. This, the second edition of Development of Antibody-Based Therapeutics: Translational Considerations, represents a comprehensive evaluation of progress in the field, which sits alongside the first edition to inform, in detail, professional and academic researchers, as well as graduate students.

Abstracts of the ... General Meeting of the American Society for Microbiology-American Society for Microbiology. General Meeting 2008

Index of Conference Proceedings Received-British Library. Document

Supply Centre 1986

Abstracts of Papers Presented at the 1988 Meeting on Modern Approaches to New Vaccines Including Prevention of AIDS- 1988

From Clone to Clinic-Daan J.A. Crommelin 2012-12-06 This book contains a selection of the papers presented at the meeting "Between Clone and Clinic" which was organised in March 1990 in Amsterdam by the dutch Organisation for Applied Research, TNO, and the University of Utrecht. The scope of this meeting was the development of biotechnological pharmaceuticals mainly made by recombinant DNA technology or monoclonal antibody techniques. All aspects concerning the development of the products after host cells producing them are obtained where discussed. The meeting was attended by twohundred specialists from all over the globe, including phar macologists, toxicologists, registration experts, Quality Assurence managers, production en gineers and physicians. Biotechnological pharmaceuticals are in general large and complex protein molecules. Bringing these products to the market poses other problems than encountered with the classical chemical drugs. The source of biotechnological pharmaceuticals are living cells. The function of cells are depend ent on many factors and the stability of production may be a problem. Good Laboratory and Manufactory Practices with Quality Control (GLP and GMP) are of paramount importance and are discussed in a number of papers. The products of the new biotechnology are often highly specific and only active in the human species. Also the side effects can only be studied in the clinical setting. Even when the product is active in animals there is the problem of antigenicity. During treatment the animals will produce antibodies which neutralise the activity. So safety testing may prove difficult.

Proceedings of the 7th General Meeting on Advances in Animal Cell Technology-European Society of Animal Cell Technology. General Meeting 1987

Abstracts of Papers Presented at the 1990 Meeting on Modern Approaches to New Vaccines Including Prevention of AIDS- 1990

Proceedings ... National Meeting on Poultry Health and Condemnations- 1988

Abstracts of the Annual Meeting of the American Society for Microbiology-American Society for Microbiology. Meeting 1988

Abstracts of Papers Presented at the ... Annual Meeting of the Conference of Research Workers in Animal Disease-

Transactions of the ... Meeting of the American Surgical Association- 1993

Program of the ... Annual Meeting of the American Society for Microbiology ...-American Society for Microbiology 1984

Government Reports Annual Index- 1993

Meetings on Atomic Energy- 1984

Nanostructures for Antimicrobial Therapy-Anton Ficai 2017-05-29 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

Proceedings of ... Annual Meeting-American Association of Veterinary Laboratory Diagnosticians. Meeting

Abstracts of Papers Presented at the 1987 Meeting on Modern Approaches to New Vaccines Including Prevention of AIDS- 1987

Handbook of Pharmaceutical Biotechnology-Jay P Rho 2003-03-31 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.

ICRDB Cancergram- 1986

Annual Meeting-Association for Academic Surgery. Meeting 1996

Handbook of Neuroemergency Clinical Trials-Brett E. Skolnick 2017-11-13 Handbook of Neuroemergency Clinical Trials, Second Edition, focuses on the practice of clinical trials in acute neuroscience populations, or what have been called neuroemergencies. Neuroemergencies are complex, life-threatening diseases and disorders, often with devastating consequences, including death or disability. The overall costs are staggering in terms of annual incidence and costs associated with treatment and survival, yet despite their significance as public health issues, there are few drugs and devices available for definitive treatment. The book focuses on novel therapies and the unique challenges their intended targets pose for the design and analysis of clinical trials. This volume provides neurologists, neuroscientists, and drug developers with a more complete understanding of the scientific and medical issues of relevance in designing and initiating clinical development plans for novel drugs intended for acute neuroscience populations. The editors provide the best understanding of the pitfalls associated with acute CNS drug development and the best information on how to approach and solve issues that have plagued drug development. Presents a comprehensive overview on clinical trials and drug development challenges in acute neuroscience populations Provides neurologists, neuroscientists and drug developers with a complete understanding of scientific and medical issues related to designing clinical trials Edited by leaders in the field who have designed and managed over 50 neuroemergency clinical trials

Abstracts, 16th Annual Meetings, February 2-February 27, 1987-1987

Annual Report-Association of American Medical Colleges 1984

Fiftieth Annual Meeting, the American College of Veterinary Pathologists-American College of Veterinary Pathologists. Meeting 1999

Process Scale Purification of Antibodies-Uwe Gottschalk 2017-04-03 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

Abstracts of Papers Presented at the 1986 Meeting on Modern Approaches to New Vaccines Including Prevention of AIDS- 1986

Abstracts, 21st Annual Meetings , January 25-February 8, 1992- 1992

Development of Biopharmaceutical Drug-Device Products-Feroz Jameel 2020-03-13 The biotechnology/biopharmaceutical sector has tremendously grown which led to the invention of engineered antibodies such as Antibody Drug Conjugates (ADCs), Bispecific T-cell engager (BITES), Dual Variable Domain (DVD) antibodies, and fusion proteins that are currently being used as therapeutic agents for immunology, oncology and other disease conditions. Regulatory agencies have raised the bar for the development and manufacture of antibody-based products, expecting to see the use of Quality by Design (QbD) elements demonstrating an in-depth understanding of product and process based on sound science. Drug delivery systems have become an increasingly important part of the therapy and most biopharmaceuticals for self-administration are being marketed as combination products. A survey of the market indicates that there is a strong need for a new book that will provide “one stop shopping” for the latest information and knowledge of the scientific and engineering advances made over the last few years in the area of biopharmaceutical product development. The new book entitled Development of Biopharmaceutical Drug Device Products is a reference text for scientists and engineers in the biopharmaceutical industry, academia or regulatory agencies. With insightful chapters from experts in the field, this new book reviews first principles, covers recent technological advancements and provides case studies and regulatory strategies relating to the development and manufacture of antibody-based products. It covers topics such as the importance of early preformulation studies during drug discovery to influence molecular selection for development, formulation strategies for new modalities, and the analytical techniques used to characterize them. It also addresses important considerations for later stage development such as the development of robust formulations and processes, including process engineering and modeling of manufacturing unit operations, the design of analytical comparability studies, and characterization of primary containers (pre-filled syringes and vials).Finally, the latter half of the book reviews key considerations to ensure the development and approval of a patient-centered delivery system design. This involves the evolving regulatory framework with perspectives from both the US and EU industry experts, the role of international standards, design control/risk management, human factors and its importance in the product development and regulatory approval process, as well as review of the risk-based approach to bridging between devices used in clinical trials and the to-be-marketed device. Finally, case studies are provided throughout.The typical readership would have biology and/or engineering degrees and would include researchers, scientific leaders, industry specialists and technology developers working in the biopharmaceutical field.

The Global Challenge of Marine Biotechnology-Raymond A. Zilinskas 1995 In 1966 Congress passed the National Sea Grant College Program Act to promote marine research, education, and extension services in institutions along the nation's ocean and Great Lakes coasts. In Maryland a Sea Grant Program -- a partnership among federal and state governments, universities, and industries -- began in 1977, and in 1982 the University of Maryland was named the nation's seventeenth Sea Grant College.The Maryland Sea Grant College focuses its efforts on the Chesapeake Bay, with emphasis on the marine concerns of fisheries, seafood technology, and environmental quality.This report addresses the emerging science and developing technologies encompassed by marine biotechnology. It contains a broad overview of marine biotechnology, sets forth industrial realities, and assesses the future potential of this new field of biotechnology.The report has eight chapters. The first contains a wide range of major scientific achievements in marine biotechnology. The subjects encompassed within marine biotechnology are grouped within six areas: aquaculture, marine animal health, marine natural health, marine natural products, biofilm and bioadhesion in the marine environment, bioremediation, and marine ecology and biological oceanography. The remaining chapters detail an extensive survey and status report on marine biotechnology in the United States, Japan, Australia, and Norway.

Abstracts, 22nd Annual Meetings , March 13-31, 1993- 1993

Energy Research Abstracts- 1987 Includes all works deriving from DOE, other related government-sponsored information and foreign nonnuclear information.

Cambridge Scientific Biochemistry Abstracts- 1985