Biopharmaceutics Practical Manual

Modern BiopharmaceuticalsPractical PharmaceuticsFundamentals of Biofilm ResearchA Manual for Primary Human Cell CulturePractical Pharmaceutical EngineeringThe Challenge of CMC Regulatory Compliance for BiopharmaceuticalsRemingtonBiological Drug ProductsLaboratory Manual of Biopharmaceutics and PharmacokineticsA Lifecycle Approach to Knowledge Excellence in the Biopharmaceutical IndustryBasic Pharmacokinetics and PharmacodynamicsThe BUGS BookManufacturing of Pharmaceutical ProteinsCluster Randomised TrialsBiopharmaceutics Modeling and SimulationsA Comprehensive Guide to Toxicology in Nonclinical Drug DevelopmentFormulation and Process Development Strategies for Manufacturing BiopharmaceuticalsCatalog of Copyright Entries. Third SeriesSolvent Systems and Their Selection in Pharmaceutics and BiopharmaceuticsManual of Laboratory PharmacokineticsDeveloping Solid Oral Dosage FormsThe Immunoassay HandbookMathematical and Statistical Skills in the Biopharmaceutical IndustryMucosal Delivery of BiopharmaceuticalsBiopharmaceutics and PharmacokineticsPharmaceutical Preformulation and FormulationHandbook of Stability Testing in Pharmaceutical DevelopmentApplied Biopharmaceutics and PharmacokineticsProteomics in PracticeBiopharmaceutics and Practical PharmacokineticsFreeze-drying of Pharmaceuticals and BiopharmaceuticalsAnalytical Method Validation and Instrument Performance VerificationPHARMACEUTICAL LAB MANUALLaboratory Manual for Pharmaceutical Technology and Biopharmaceutics ExperimentsPractical Manual Of Pharmaceutical EngineeringComprehensive Practical Manual of Pharmaceutical ChemistryA Biotech Manager's HandbookSolvent Systems and Their Selection in Pharmaceutics and BiopharmaceuticsDevelopment of Biopharmaceutical Drug-Device ProductsQuality by Design for Biopharmaceuticals

Modern Biopharmaceuticals

Still the only concise practical guide to laboratory experiments in proteomics, this new edition now also covers DIGE technology and liquid-chromatography, while the troubleshooting section has been considerably extended. Adopting a practical approach, the authors present the relevant techniques and explain the route to successful experimental design and optimal method selection. They cover such electrophoretic techniques as isoelectric focusing, SDS page, 2-D page, and DIGE, as well as liquid-chromatography techniques, such as ion exchange, affinity chromatography and reversed-phase HPLC. Mass-spectrometric techniques include MALDI, ESI, and FT ICR. Generously illustrated, partly in color, the book also features updates of protocols as well as animations illustrating crucial methodological steps on a companion website.

Practical Pharmaceutics

This handbook is the first to cover all aspects of stability testing in pharmaceutical development. Written by a group of international experts, the book presents a scientific understanding of regulations and balances methodologies and best practices.

Fundamentals of Biofilm Research

Structured like a textbook, the second edition of this reference covers all aspects of biopharmaceutical manufacturing, including legal and regulatory issues, production facility design, and quality assurance, with a focus on supply chain management and regulations in emerging markets and cost control. The author has longstanding industrial expertise in biopharmaceutical production and years of experience teaching at universities. As such, this practical book is ideal for use in academia as well as for internal training within companies.

A Manual for Primary Human Cell Culture

This book is an invaluable source designed to meet the needs of pharm.D and other pharmacy courses. This book was made according to the PCI syllabus. This book covers topics like syrups, elixirs, linctus, solutions, liniments, suspensions, emulsions, powders, suppositories, incompatibilities, with an introduction before it. This book helps the student to write the academic pharmaceutics record more easily. It has been noticed that practical of pharmaceutics leave students a little confused, especially during their examination. Finally, this book aims to present the practicals in a student friendly style so that they can easily grasp and do the practicals in the lab more easily by own which interns will help them to achieve the best grades in examinations.

Practical Pharmaceutical Engineering

This manual is designed to serve as a practical guide to primary human cell culture, which is integral in both academic and industrial biotechnology research. As in the first edition, the content of the manual is not exhaustive, but rather contains selected protocols for specific cell types from major tissue groupings in the body. This improved second edition also includes a new section on stem cells and additional material on transfection. It should serve as a foundation for individual researchers to experiment, explore, and establish niche protocols for their specific needs. With its compact physical format that makes it portable and flexible for usage in a laboratory setting, the manual will be a useful guide for all beginners in primary human cell culture work.

The Challenge of CMC Regulatory Compliance for Biopharmaceuticals

A biotech manager's handbook lays out - in a simple, straightforward manner - for the manager or would-be entrepreneur the basic principles of running a biotech company. Most managers in biotechnology companies are working in their first company or in their first managerial role. Their expertise and experience in the scientific part of the work can be taken as a given but there is a whole range of other skills to be learned and areas of expertise to come to terms with. Small companies do not have big budgets to hire people or time to become an expert in so many areas. The book starts by outlining the state of the biopharmaceutical industry and goes on to explain the importance of planning (no matter what the size of the company). Succeeding chapters deal with the basics of intellectual

property, perspectives from a university technology transfer office and how to raise some initial funding from an investor and entrepreneur. No other 'how to' manual exists for this sector Written by a range of expert professionals in each area, all in one book Is the only 'bench to bedside' book covering the whole spectrum of development

Remington

Biological Drug Products

Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form reflects the mounting pressure on pharmaceutical companies to accelerate the new drug development and launch process, as well as the shift from developing small molecules to the growth of biopharmaceuticals. The book meets the need for advanced information for drug preformulation and formulation and addresses the current trends in the continually evolving pharmaceutical industry. Topics include: Candidate drug selection Drug discovery and development Preformulation predictions and drug selections Product design to commercial dosage form Biopharmaceutical support in formulation Development The book is ideal for practitioners working in the pharmaceutical arena—including R&D scientists, technicians, and managers—as well as for undergraduate and postgraduate courses in industrial pharmacy and pharmaceutical technology.

Laboratory Manual of Biopharmaceutics and Pharmacokinetics

Provides a wide range of reliable, straightforward experiments for training laboratory workers. Covers all relevant areas from instrumental and chromatographic techniques through chemical properties and theoretical pharmacokinetics to response studies. Uses readily available, important drug examples and discusses a wide variety of techniques, with emphasis on classical applications. Includes model data sheets.

A Lifecycle Approach to Knowledge Excellence in the Biopharmaceutical Industry

Cluster Randomised Trials, Second Edition discusses the design, conduct, and analysis of trials that randomise groups of individuals to different treatments. It explores the advantages of cluster randomisation, with special attention given to evaluating the effects of interventions against infectious diseases. Avoiding unnecessary mathematical detail, the book covers basic concepts underlying the use of cluster randomisation, such as direct, indirect, and total effects. In the time since the publication of the first edition, the use of cluster randomised trials (CRTs) has increased substantially, which is reflected in the updates to this edition. There are greatly expanded sections on randomisation, sample size estimation, and alternative designs, including new material on stepped wedge designs. There is a new section on handling ordinal outcome data, and an appendix with descriptions and/or generating code of the example data sets. Although the book mainly

focuses on medical and public health applications, it shows that the rigorous evidence of intervention effects provided by CRTs has the potential to inform public policy in a wide range of other areas. The book encourages readers to apply the methods to their own trials, reproduce the analyses presented, and explore alternative approaches.

Basic Pharmacokinetics and Pharmacodynamics

This collection of high-profile contributions provides a unique insight into the development of novel, successful biopharmaceuticals. Outstanding authors, including Nobel laureate Robert Huber as well as prominent company researchers and CEOs, present valuable insider knowledge, limiting their scope to those procedures and developments with proven potential for the biotechnology industry. They cover all relevant aspects, from the establishment of biotechnology parks, the development of successful compounds and the implementation of efficient manufacturing processes, right up to the establishment of advanced delivery routes.

The BUGS Book

A real-world guide to the production and manufacturing of biopharmaceuticals While much has been written about the science of biopharmaceuticals, there is a need for practical, up-to-date information on key issues at all stages of developing and manufacturing commercially viable biopharmaceutical drug products. This book helps fill the gap in the field, examining all areas of biopharmaceuticals manufacturing, from development and formulation to production and packaging. Written by a group of experts from industry and academia, the book focuses on real-world methods for maintaining product integrity throughout the commercialization process, clearly explaining the fundamentals and essential pathways for all development stages. Coverage includes: Research and early development phase–appropriate approaches for ensuring product stability Development of commercially viable formulations for liquid and lyophilized dosage forms Optimal storage, packaging, and shipping methods Case studies relating to therapeutic monoclonal antibodies, recombinant proteins, and plasma fractions Useful analysis of successful and failed products Formulation and Process Development Strategies for Manufacturing Biopharma-ceuticals is an essential resource for scientists and engineers in the pharmaceutical and biotech industries, for government and regulatory agencies, and for anyone with an interest in the latest developments in the field.

Manufacturing of Pharmaceutical Proteins

Tested and proven solutions to the challenges of biologicaldrug product development Biological drug products play a central role in combating humandiseases; however, developing new successful biological drugspresents many challenges, including labor intensive productionprocesses, tighter regulatory controls, and increased marketcompetition. This book reviews the current state of the science,offering readers a single resource that sets forth the fundamentalsas well as tested and proven development strategies for biologicaldrugs. Moreover,

the book prepares readers for the challenges thattypically arise during drug development, offering straightforwardsolutions to improve their ability to pass through all theregulatory hurdles and deliver new drug products to the market. Biological Drug Products begins with generalconsiderations for the development of any biological drug productand then explores the strategies and challenges involved in thedevelopment of specific types of biologics. Divided into fiveparts, the book examines: Part 1: General Aspects Part 2: Proteins and Peptides Part 3: Vaccines Part 4: Novel Biologics Part 5: Product Administration/Delivery Each chapter has been prepared by one or more leading experts inbiological drug development. Contributions are based on acomprehensive review and analysis of the current literature as wellas the authors' first-hand experience developing and testing newdrugs. References at the end of each chapter serve as a gateway tooriginal research papers and reviews in the field. By incorporating lessons learned and future directions forresearch, Biological Drug Products enables pharmaceuticalscientists and students to improve their success rate in developingnew biologics to treat a broad range of human diseases.

Cluster Randomised Trials

Validation describes the procedures used to analyze pharmaceutical products so that the data generated will comply with the requirements of regulatory bodies of the US, Canada, Europe and Japan. Calibration of Instruments describes the process of fixing, checking or correcting the graduations of instruments so that they comply with those regulatory bodies. This book provides a thorough explanation of both the fundamental and practical aspects of biopharmaceutical and bioanalytical methods validation. It teaches the proper procedures for using the tools and analysis methods in a regulated lab setting. Readers will learn the appropriate procedures for calibration of laboratory instrumentation and validation of analytical methods of analysis. These procedures must be executed properly in all regulated laboratories, including pharmaceutical and biopharmaceutical laboratories, clinical testing laboratories (hospitals, medical offices) and in food and cosmetic testing laboratories.

Biopharmaceutics Modeling and Simulations

A Comprehensive Guide to Toxicology in Nonclinical Drug Development

For over 100 years, Remington has been the definitive textbook and reference on the science and practice of pharmacy. This Twenty-First Edition keeps pace with recent changes in the pharmacy curriculum and professional pharmacy practice. More than 95 new contributors and 5 new section editors provide fresh perspectives on the field. New chapters include pharmacogenomics, application of ethical principles to practice dilemmas, technology and automation, professional communication, medication errors, re-engineering pharmacy practice, management of special risk medicines, specialization in pharmacy practice, disease state management, emergency patient care, and wound care. Purchasers of this textbook are entitled to a new, fully indexed Bonus CD-ROM, affording

instant access to the full content of Remington in a convenient and portable format.

Formulation and Process Development Strategies for Manufacturing Biopharmaceuticals

With its clear, straightforward presentation, this text enables you to grasp all the fundamental concepts of pharmacokinetics and pharmacodynamics. This will allow you to understand the time course of drug response and dosing regimen design. Clinical models for concentration and response are described and built from the basic concepts presented in earlier chapters. Your understanding of the material will be enhanced by guided computer exercises conducted on a companion website. Simulations will allow you to visualize drug behavior, experiment with different dosing regimens, and observe the influence of patient characteristics and model parameters. This makes the book ideal for self-study. By including clinical models of agonism, indirect drug effects, tolerance, signal transduction, and disease progression, author Sara Rosenbaum has created a work that stands out among introductory-level textbooks in this area.You'll find several features throughout the text to help you better understand and apply key concepts: Three fictitious drugs are used throughout the text to progressively illustrate the development and application of pharmacokinetic and pharmacodynamic principles Exercises at the end of each chapter reinforce the concepts and provide the opportunity to perform and solve common dosing problems Detailed instructions let you create custom Excel worksheets to perform simple pharmacokinetic analyses Because this is an introductory textbook, the material is presented as simply as possible. As a result, you'll find it easy to gain an accurate, working knowledge of all the core principles, apply them to optimize dosing regimens, and evaluate the clinical pharmacokinetic and pharmacodynamic literature.

Catalog of Copyright Entries. Third Series

Solvent Systems and Their Selection in Pharmaceutics and Biopharmaceutics

The six years that have passed since the publication of the first edition have brought significant advances in both biofilm research and biofilm engineering, which have matured to the extent that biofilm-based technologies are now being designed and implemented. As a result, many chapters have been updated and expanded with the addition of sections

Manual of Laboratory Pharmacokinetics

This book contains essential knowledge on the preparation, control, logistics, dispensing and use of medicines. It features chapters written by experienced pharmacists working in hospitals and academia throughout Europe, complete with practical examples as well as information on current EU-legislation. From prescription to production, from usage instructions to procurement and the impact of medicines on the environment, the book provides step-by-step coverage that

will help a wide range of readers. It offers product knowledge for all pharmacists working directly with patients and it will enable them to make the appropriate medicine available, to store medicines properly, to adapt medicines if necessary and to dispense medicines with the appropriate information to inform patients and caregivers about product care and how to maintain their quality. This basic knowledge will also be of help to industrial pharmacists to remind and focus them on the application of the medicines manufactured. The basic and practical knowledge on the design, preparation and quality management of medicines can directly be applied by the pharmacists whose main duty is production in community and hospital pharmacies and industries. Undergraduate as well as graduate pharmacy students will find knowledge and backgrounds in a fully coherent way and fully supported with examples.

Developing Solid Oral Dosage Forms

The fourth edition of The Immunoassay Handbook provides an excellent, thoroughly updated guide to the science, technology and applications of ELISA and other immunoassays, including a wealth of practical advice. It encompasses a wide range of methods and gives an insight into the latest developments and applications in clinical and veterinary practice and in pharmaceutical and life science research. Highly illustrated and clearly written, this award-winning reference work provides an excellent guide to this fast-growing field. Revised and extensively updated, with over 30% new material and 77 chapters, it reveals the underlying common principles and simplifies an abundance of innovation. The Immunoassay Handbook reviews a wide range of topics, now including lateral flow, microsphere multiplex assays, immunohistochemistry, practical ELISA development, assay interferences, pharmaceutical applications, qualitative immunoassays, antibody detection and lab-on-a-chip. This handbook is a must-read for all who use immunoassay as a tool, including clinicians, clinical and veterinary chemists, biochemists, food technologists, environmental scientists, and students and researchers in medicine, immunology and proteomics. It is an essential reference for the immunoassay industry. Provides an excellent revised guide to this commercially highly successful technology in diagnostics and research, from consumer home pregnancy kits to AIDS testing. www.immunoassayhandbook.com is a great resource that we put a lot of effort into. The content is designed to encourage purchases of single chapters or the entire book. David Wild is a healthcare industry veteran, with experience in biotechnology, pharmaceuticals, medical devices and immunodiagnostics, which remains his passion. He worked for Amersham, Eastman-Kodak, Johnson & Johnson, and Bristol-Myers Squibb, and consulted for diagnostics and biotechnology companies. He led research and development programs, design and construction of chemical and biotechnology plants, and integration of acquired companies. Director-level positions included Research and Development, Design Engineering, Operations and Strategy, for billion dollar businesses. He retired from full-time work in 2012 to focus on his role as Editor of The Immunoassay Handbook, and advises on product development, manufacturing and marketing. Provides a unique mix of theory, practical advice and applications, with numerous examples Offers explanations of technologies under development and practical insider tips that are sometimes omitted from scientific papers Includes a comprehensive troubleshooting guide, useful for solving problems and improving

assay performancee Provides valuable chapter updates, now available on www.immunoassayhandbook.com

The Immunoassay Handbook

Solvent systems are integral to drug development and pharmaceutical technology. This single topic encompasses numerous allied subjects running the gamut from recrystallization solvents to biorelevant media. The goal of this contribution to the AAPS Biotechnology: Pharmaceutical Aspects series is to generate both a practical handbook as well as a reference allowing the reader to make effective decisions concerning the use of solvents and solvent systems. To this end, the monograph was created by inviting recognized experts from a number of fields to author relevant sections. Specifically, 15 chapters have been designed covering the theoretical background of solubility, the effect of ionic equilibria and pH on solubilization, the use of solvents to effect drug substance crystallization and polymorph selection, the use of solvent systems in high throughput screening and early discovery, solvent use in preformulation, the use of solvents in bio-relevant dissolution and permeation experiments, solvents and their use as toxicology vehicles, solubilizing media and excipients in oral and parenteral formulation development, specialized vehicles for protein formulation and solvent systems for topical and pulmonary drug administration. The chapters are organized such that useful decision trees are included together with the scientific underpinning for their application. In addition, trends in the use of solvent systems and a balance of current views make this monograph useful to both the novice and experienced researcher and to scientists at all developmental stages from early discovery to late pharmaceutical operations.

Mathematical and Statistical Skills in the Biopharmaceutical Industry

A Comprehensive Guide to Toxicology in Nonclinical Drug Development, Second Edition, is a valuable reference designed to provide a complete understanding of all aspects of nonclinical toxicology in the development of small molecules and biologics. This updated edition has been reorganized and expanded to include important topics such as stem cells in nonclinical toxicology, inhalation and dermal toxicology, pitfalls in drug development, biomarkers in toxicology, and more. Thoroughly updated to reflect the latest scientific advances and with increased coverage of international regulatory guidelines, this second edition is an essential and practical resource for all toxicologists involved in nonclinical testing in industry, academic, and regulatory settings. Provides unique content that is not always covered together in one comprehensive resource, including chapters on stem cells, abuse liability, biomarkers, inhalation toxicology, biostatistics, and more Updated with the latest international guidelines for nonclinical toxicology in both small and large molecules Incorporates practical examples in order to illustrate day-to-day activities and the expectations associated with working in nonclinical toxicology

Mucosal Delivery of Biopharmaceuticals

Mathematical and Statistical Skills in the Biopharmaceutical Industry: A Pragmatic Approach describes a philosophy of efficient problem solving showcased using examples pertinent to the biostatistics function in clinical drug development. It was written to share a quintessence of the authors' experiences acquired during many years of relevant work in the biopharmaceutical industry. The book will be useful will be useful for biopharmaceutical industry statisticians at different seniority levels and for graduate students who consider a biostatistics-related career in this industry. Features: Describes a system of principles for pragmatic problem solving in clinical drug development. Discusses differences in the work of a biostatistician in small pharma and big pharma. Explains the importance/relevance of statistical programming and data management for biostatistics and necessity for integration on various levels. Describes some useful statistical background that can be capitalized upon in the drug development enterprise. Explains some hot topics and current trends in biostatistics in simple, non-technical terms. Discusses incompleteness of any system of standard operating procedures, rules and regulations. Provides a classification of scoring systems and proposes a novel approach for evaluation of the safety outcome for a completed randomized clinical trial. Presents applications of the problem solving philosophy in a highly problematic transfusion field where many investigational compounds have failed. Discusses realistic planning of open-ended projects.

Biopharmaceutics and Pharmacokinetics

Pharmaceutical Preformulation and Formulation

Handbook of Stability Testing in Pharmaceutical Development

This book addresses the rapidly emerging field of Knowledge Management in the pharmaceutical, medical devices and medical diagnostics industries. In particular, it explores the role that Knowledge Management can play in ensuring the delivery of safe and effective products to patients. The book also provides good practice examples of how the effective use of an organisation's knowledge assets can provide a path towards business excellence.

Applied Biopharmaceutics and Pharmacokinetics

Developing Solid Oral Dosage Forms is intended for pharmaceutical professionals engaged in research and development of oral dosage forms. It covers essential principles of physical pharmacy, biopharmaceutics and industrial pharmacy as well as various aspects of state-of-the-art techniques and approaches in pharmaceutical sciences and technologies along with examples and/or case studies in product development. The objective of this book is to offer updated (or current) knowledge and skills required for rational oral product design and development. The specific goals are to provide readers with: Basics of modern theories of physical pharmacy, biopharmaceutics and industrial pharmacy and their applications throughout the entire process of research and development of oral dosage forms Tools and approaches of preformulation investigation, formulation/process design,

characterization and scale-up in pharmaceutical sciences and technologies New developments, challenges, trends, opportunities, intellectual property issues and regulations in solid product development The first book (ever) that provides comprehensive and in-depth coverage of what's required for developing high quality pharmaceutical products to meet international standards It covers a broad scope of topics that encompass the entire spectrum of solid dosage form development for the global market, including the most updated science and technologies, practice, applications, regulation, intellectual property protection and new development trends with case studies in every chapter A strong team of more than 50 well-established authors/co-authors of diverse background, knowledge, skills and experience from industry, academia and regulatory agencies

Proteomics in Practice

The edition of Comprehensive Practical Manual of Pharmaceutical Chemistry is authored in simple and comprehensive style according to PCI (Pharmacy Council of India) syllabus to meet the specific needs of the pharmacy students. It provides comprehensive yet concise chemistry for D.Pharmacy, B.Pharmacy, M.Pharmacy and Pharm D students. The main objective of this manual is to attract students to learn the basic theories of pharmaceutical chemistry thus the manual is aimed to enrich the inadequancy in teaching and learning of pharmaceutical chemistry by providing enormous information. The style of presentation of this manual is such that it not only gives deeper understanding of the subject but also will help the beginners to overcome the fright of the subject. The manual gives concise and pointwise information required during practicals in single book and eliminates the need of too many reference books during practicals. The manual authored in simple,lucid and easy language.

Biopharmaceutics and Practical Pharmacokinetics

Biopharmaceutical medicines, the newest class of therapeutics, are quite heterogeneous and include a range of molecules such as proteins, peptides, vaccines and nucleic acids, with use in virtually all therapeutic fields (e.g. cancer and infectious diseases, vaccination, metabolic dysfunctions) and diagnostics. This edited book gives a concise and up-to-date overview of the biological features justifying the use of different human mucosa as delivery routes for biopharmaceuticals, the technological strategies that have been followed so far regarding the optimization of mucosal potentialities as well as the challenges that arise with the advent of new biopharmaceutical drugs and alternative means of administration. Following a brief introduction, the first section addresses general aspects of the biology of mucosal tissues and their unique aspects toward beneficial or deleterious interaction with biopharmaceuticals and their delivery systems. The second part reviews the different delivery strategies that have recently been investigated for different mucosal sites. The third section describes the development and clinical applications of drug delivery systems and products enclosing biopharmaceuticals for mucosal delivery, with a focus on the most successful case studies of recent years. The last section briefly centers on relevant aspects of the regulatory, toxicological and market issues of mucosal delivery of biopharmaceuticals. Scientists and researchers in the fields of drug delivery, material science, biomedical science and bioengineering as well as professionals,

regulators and policy makers in the pharmaceutical, biotechnology and healthcare industries will find in this book an important compendium of fundamental concepts and practical tools for their daily research and activities.

Freeze-drying of Pharmaceuticals and Biopharmaceuticals

"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.

Analytical Method Validation and Instrument Performance Verification

PHARMACEUTICAL LAB MANUAL

Aimed at product and process developers in the biopharmaceutical industry and academia, this is the first book to describe freeze-drying, as related to the pharmaceutical industry.

Laboratory Manual for Pharmaceutical Technology and Biopharmaceutics Experiments

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.

Practical Manual Of Pharmaceutical Engineering

Solvent systems are integral to drug development and pharmaceutical technology. This single topic encompasses numerous allied subjects running the gamut from recrystallization solvents to biorelevant media. The goal of this contribution to the AAPS Biotechnology: Pharmaceutical Aspects series is to generate both a practical handbook as well as a reference allowing the reader to make effective decisions concerning the use of solvents and solvent systems. To this end, the monograph was created by inviting recognized experts from a number of fields to author relevant sections. Specifically, 15 chapters have been designed covering the theoretical background of solubility, the effect of ionic equilibria and pH on solubilization, the use of solvents to effect drug substance crystallization and polymorph selection, the use of solvent systems in high throughput screening and early discovery, solvent use in preformulation, the use of solvents in bio-relevant dissolution and permeation experiments, solvents and their use as toxicology vehicles, solubilizing media and excipients in oral and parenteral formulation development, specialized vehicles for protein formulation and solvent systems for topical and pulmonary drug administration. The chapters are organized such that useful decision trees are included together with the scientific underpinning for their application. In addition, trends in the use of solvent systems and a balance of

current views make this monograph useful to both the novice and experienced researcher and to scientists at all developmental stages from early discovery to late pharmaceutical operations.

Comprehensive Practical Manual of Pharmaceutical Chemistry

A practical guide to all key the elements of pharmaceuticals and biotech manufacturing and design Engineers working in the pharmaceutical and biotech industries are routinely called upon to handle operational issues outside of their fields of expertise. Traditionally the competencies required to fulfill those tasks were achieved piecemeal, through years of self-teaching and on-the-job experience—until now. Practical Pharmaceutical Engineering provides readers with the technical information and tools needed to deal with most common engineering issues that can arise in the course of day-to-day operations of pharmaceutical/biotech research and manufacturing. Engineers working in pharma/biotech wear many hats. They are involved in the conception, design, construction, and operation of research facilities and manufacturing plants, as well as the scale-up, manufacturing, packaging, and labeling processes. They have to implement FDA regulations, validation assurance, quality control, and Good Manufacturing Practices (GMP) compliance measures, and to maintain a high level of personal and environmental safety. This book provides readers from a range of engineering specialties with a detailed blueprint and the technical knowledge needed to tackle those critical responsibilities with confidence. At minimum, after reading this book, readers will have the knowledge needed to constructively participate in contractor/user briefings. Provides pharmaceutical industry professionals with an overview of how all the parts fit together and a level of expertise that can take years of on-the-job experience to acquire Addresses topics not covered in university courses but which are crucial to working effectively in the pharma/biotech industry Fills a gap in the literature, providing important information on pharmaceutical operation issues required for meeting regulatory guidelines, plant support design, and project engineering Covers the basics of HVAC systems, water systems, electric systems, reliability, maintainability, and quality assurance, relevant to pharmaceutical engineering Practical Pharmaceutical Engineering is an indispensable “tool of the trade” for chemical engineers, mechanical engineers, and pharmaceutical engineers employed by pharmaceutical and biotech companies, engineering firms, and consulting firms. It also is a must-read for engineering students, pharmacy students, chemistry students, and others considering a career in pharmaceuticals.

A Biotech Manager's Handbook

A comprehensive introduction to using modeling and simulation programs in drug discovery and development Biopharmaceutical modeling has become integral to the design and development of new drugs. Influencing key aspects of the development process, including drug substance design, formulation design, and toxicological exposure assessment, biopharmaceutical modeling is now seen as the linchpin to a drug's future success. And while there are a number of commercially available software programs for drug modeling, there has not been a single resource guiding pharmaceutical professionals to the actual tools and practices needed to design and test safe drugs. A guide to the basics of modeling and

simulation programs, Biopharmaceutics Modeling and Simulations offers pharmaceutical scientists the keys to understanding how they work and are applied in creating drugs with desired medicinal properties. Beginning with a focus on the oral absorption of drugs, the book discusses: The central dogma of oral drug absorption (the interplay of dissolution, solubility, and permeability of a drug), which forms the basis of the biopharmaceutical classification system (BCS) The concept of drug concentration How to simulate key drug absorption processes The physiological and drug property data used for biopharmaceutical modeling Reliable practices for reporting results With over 200 figures and illustrations and a peerless examination of all the key aspects of drug research—including running and interpreting models, validation, and compound and formulation selection—this reference seamlessly brings together the proven practical approaches essential to developing the safe and effective medicines of tomorrow.

Solvent Systems and Their Selection in Pharmaceutics and Biopharmaceutics

The third edition of this introductory text covers the factors which influence the release of the drug from the drug product and how the body handles the drug. A stronger focus has been placed on the basics with clear explanations and illustrated examples. There is also more information on statistics and population pharmacokinetics and new chapters on drug distribution, computer applications, enzyme kinetics and pharmacokinetics models.

Development of Biopharmaceutical Drug-Device Products

Bayesian statistical methods have become widely used for data analysis and modelling in recent years, and the BUGS software has become the most popular software for Bayesian analysis worldwide. Authored by the team that originally developed this software, The BUGS Book provides a practical introduction to this program and its use. The text presents complete coverage of all the functionalities of BUGS, including prediction, missing data, model criticism, and prior sensitivity. It also features a large number of worked examples and a wide range of applications from various disciplines. The book introduces regression models, techniques for criticism and comparison, and a wide range of modelling issues before going into the vital area of hierarchical models, one of the most common applications of Bayesian methods. It deals with essentials of modelling without getting bogged down in complexity. The book emphasises model criticism, model comparison, sensitivity analysis to alternative priors, and thoughtful choice of prior distributions—all those aspects of the "art" of modelling that are easily overlooked in more theoretical expositions. More pragmatic than ideological, the authors systematically work through the large range of "tricks" that reveal the real power of the BUGS software, for example, dealing with missing data, censoring, grouped data, prediction, ranking, parameter constraints, and so on. Many of the examples are biostatistical, but they do not require domain knowledge and are generalisable to a wide range of other application areas. Full code and data for examples, exercises, and some solutions can be found on the book’s website.

Quality by Design for Biopharmaceuticals

The concepts, applications, and practical issues of Quality byDesign Quality by Design (QbD) is a new framework currently beingimplemented by the FDA, as well as EU and Japanese regulatoryagencies, to ensure better understanding of the process so as toyield a consistent and high-quality pharmaceutical product. QbDbreaks from past approaches in assuming that drug quality cannot betested into products; rather, it must be built into every step ofthe product creation process. Quality by Design: Perspectives and Case Studies presentsthe first systematic approach to QbD in the biotech industry. Acomprehensive resource, it combines an in-depth explanation ofbasic concepts with real-life case studies that illustrate thepractical aspects of QbD implementation. In this single source, leading authorities from thebiotechnology industry and the FDA discuss such topics as: The understanding and development of the product's criticalquality attributes (CQA) Development of the design space for a manufacturingprocess How to employ QbD to design a formulation process Raw material analysis and control strategy for QbD Process Analytical Technology (PAT) and how it relates toQbD Relevant PAT tools and applications for the pharmaceuticalindustry The uses of risk assessment and management in QbD Filing QbD information in regulatory documents The application of multivariate data analysis (MVDA) toQbD Filled with vivid case studies that illustrate QbD at work incompanies today, Quality by Design is a core reference forscientists in the biopharmaceutical industry, regulatory agencies,and students.