Sterile Product Development Formulation Process Quality And Regulatory Considerations Aaps Advances In The Pharmaceutical Sciences Series

The Textbook of Pharmaceutical Medicine is the standard reference for everyone working and learning in pharmaceutical medicine. It is a comprehensive resource covering the processes and practices by which medicines are developed, tested and approved, and the recognised text for the Diploma in Pharmaceutical Medicine from the Faculty of Pharmaceutical Medicine. This fully revised Seventh Edition, which includes two new Editors, encompasses current developments within pharmaceutical medicine with new chapters on biological therapeutics, pharmacovigilance, vaccines, drugs for cancer, drug development in paediatrics and neonatalogy, the clinical trials directive, life cycle management of medicines, counterfeit medicines and medical marketing. Also included for easy reference, and referred to throughout the text, are the Declaration of Helsinki, Guidelines and Documentation for Implementation of Clinical Trials, relevant European Directives and the Syllabus for Pharmaceutical Medicine. Written by an international team of leading academics, medical directors and lawyers, The Textbook of Pharmaceutical Medicine, Seventh Edition meets the needs of both those working in pharmaceutical medicine and preparing for the Diploma in Pharmaceutical Medicine. The text breaks down into three core sections: Part I: Research and Development Part II: Regulation Part III: Healthcare marketplace View Table of Contents in detail

Aseptic Processing and Packaging of Food explains how aseptic processing and packaging first began and traces its fascinating progression over the last fifty years. It explores current technologies, discusses why they are used today, and explains why certain basic approaches to critical operations, such as pumping, heat exchange, fluid flow, and controls, must be applied. Commercially used heating and holding concepts are also explained, with emphasis on avoiding problems. This unique book states the technique and method of choice for accurate flow control (timing). It includes an explanation of secondary flow and describes its use to solve many of the heat exchange and fluid flow problems associated with particle-containing products. It also discusses the manufacturers of aseptic packaging equipment, exploring the types of products they produce and the advantages and disadvantages of their product design. Aseptic Processing and Packaging of Food fills in many of the information gaps left by other sources - a must-have reference for anyone working in this area.

To successfully bring an Active Pharmaceutical Ingredient (API) to market, many steps must be followed to ensure compliance with governmental regulations. Active Pharmaceutical Ingredients is an unparalleled guide to the development, manufacturing, and regulation of the preparation and use of APIs globally. Topics include:Safety, efficacy, and envi

The suspension dosage form has long been used for poorly soluble active ingre- ents for various therapeutic indications. Development of stable suspensions over the shelf life of the drug product continues to be a challenge on many fronts. A good understanding of the fundamentals of disperse systems is essential in the development of a suitable pharmaceutical suspension. The development of a s- pension dosage form follows a very complicated path. The selection of the proper excipients (surfactants, viscosity imparting agents etc.) is important. The particle size distribution in the finished drug product dosage form is a critical parameter that significantly impacts the bioavailability and pharmacokinetics of the product. Appropriate analytical methodologies and instruments (chromatographs, visco- ters, particle size analyzers, etc.) must be utilized to properly characterize the s- pension formulation. The development process continues with a successful scale-up of the manufacturing process. Regulatory agencies around the world require cli- cal trials to establish the safety and efficacy of the drug product. All of this devel- ment work should culminate into a regulatory filing in accordance with the regulatory guidelines. Pharmaceutical Suspensions, From Formulation Development to Manufacturing, in its organization, follows the development approach used widely in the pharmaceutical industry. The primary focus of this book is on the classical disperse system – poorly soluble active pharmaceutical ingredients s- pended in a suitable vehicle.

No other area of regulatory compliance receives more attention and scrutiny by regulatory authorities than the regulation of sterile products, for obvious reasons. With the increasing number of potent products, particularly the new line of small protein products, joining the long list of proven sterile products, the technology of manufacturing ster

This carefully-researched book covers exciting trends in consulting in such fields as marketing, information technology, management, logistics, supply chain, manufacturing, health care and more. Includes complete details on the prestigious management consulting sector, plus our analysis of the information technology consulting business. This reference tool includes thorough market analysis as well as our highly respected trends analysis. You'll find a complete overview, industry analysis and market research report in one superb, value-priced package. It contains thousands of contacts for business and industry leaders, industry associations, Internet sites and other resources. This book also includes statistical tables, an industry glossary and thorough indexes. The corporate profiles section of the book includes our proprietary, in-depth profiles of the 275 leading companies in all facets of consulting. Here you'll find complete profiles of the hot companies that are making news today, the largest, most successful corporations in the business. Purchasers of either the book or PDF version can receive a free copy of the company profiles database on CD-ROM, enabling key word search and export of key information, addresses, phone numbers and executive names with titles for every company profiled.

This work ushers in a change in the approach of books on hospital administration. To make the text interesting authors have used the case based learning approach. Apart from this many new topics have been introduced in this book which had not been addressed so far in the available books. For example:- due importance has been given to the role of

engineering department in ensuring provision of good quality of medical care by the hospitals. New concepts in hospital administration like information therapy, use of information and communication technology, health promoting hospital approach, impact of globalization on hospital care etc. have also introduced through this book. USP of the book is giving due importance to the feedback from experienced hospital administrators across public and private hospitals of country. This book will surely be of use to medical superintendents and hospital administrators in government and private hospitals in India and other countries. Students as well as teachers of various courses namely, regular and distant learning courses of MBA in Health Care/Hospital Administration, Diploma of masters in Hospital Administrator, MD in hospital administrator , MD in community medicine, Diploma/masters in laws, master's in public health will also find this book of immense value. This book will also be helpful for civil surgeons and senior medical officers of state health services. The book comprehensively consolidates a lot of practical aspects by incorporating plenty of illustrations, photographs, case studies, real life situations etc. which will help the readers to get a realistic practical experience. Salient Features New concepts in hospital administration like use of information and communication technology, health promoting hospital approach, impact of globalization on hospital care, role of engineering department and information therapy, etc. have been introduced Case Studies presented in the chapters are useful for case based learning approach Comprehensively consolidates a lot of practical aspects by incorporating plenty of Flowcharts, Figures and Tables help the readers to get a realistic practical experience

This three-volume set of Pharmaceutical Dosage Forms: Parenteral Medications is an authoritative, comprehensive reference work on the formulation and manufacture of parenteral dosage forms, effectively balancing theoretical considerations with the practical aspects of their development. As such, it is recommended for scientists and engineers in the pharmaceutical industry and academia, and will also serve as an excellent reference and training tool for regulatory scientists and quality assurance professionals. First published in 1984 (as two volumes) and then last revised in 1993 (when it grew to three volumes), this latest revision will address the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration. The third edition of this book maintains the features that made the last edition so popular but comprises several brand new chapters, revisions to all other chapters, as well as high quality illustrations. Volume two presents: • Chapters on aseptic facility design, environmental monitoring, and cleanroom operations. • A comprehensive chapter on pharmaceutical water systems. • A discussion of quality attributes of sterile dosage forms, including particulate matter, endotoxin, and sterility testing. • A detailed chapter on processing of parenteral drug products (SVPs and LVPs). • Presentations on widely used sterilization technologies – steam, gas / chemical, radiation, filtration and dry heat. • An in-depth chapter on lyophilization.

New Scientist magazine was launched in 1956 "for all those men and women who are interested in scientific discovery, and in its industrial, commercial and social consequences". The brand's mission is no different today - for its consumers, New Scientist reports, explores and interprets the results of human endeavour set in the context of society and culture.

This book provides a detailed account of the most recent developments, challenges and solutions to seamlessly advance and launch a lyophilized biologics or vaccine product, based on diverse modalities, ranging from antibodies (e.g., monoclonal, fused), complex biologics (e.g., antibody drug conjugate, PEGylated proteins), and vaccines (e.g., recombinant-protein based). The authors adeptly guide the reader through all crucial aspects, from biophysical and chemical stability considerations of proteins, analytical methods, advances in controlled ice nucleation and quality-by-design approaches, alternate drying technology, to latest regulatory, packaging and technology transfer considerations to develop a stable, safe and effective therapeutic protein, vaccine and biotechnology products. Lyophilized Biologics and Vaccines: Modality-Based Approaches is composed of four sections with a total of 17 chapters. It serves as a reference to all critical assessments and steps from early pre-formulation stages to product launch: Provides recent understanding of heterogeneity of protein environment and selection of appropriate buffer for stabilization of lyophilized formulations Details the latest developments in instrumental analysis and controlled ice nucleation technology Explains in-depth lyophilized (or dehydrated) formulation strategies considering diverse modalities of biologics and vaccines, including plasmid DNA and lipid-based therapeutics Details an exhaustive update on quality-by-design and process analytical technology approaches, illustrated superbly by case studies and FDA perspective Provides the latest detailed account of alternate drying technologies including spray drying, bulk freeze-drying and crystallization, supported exceptionally by case studies Provides a step-by-step guide through critical considerations during process scale-up, technology transfer, packaging and drug delivery device selection, for a successful lyophilization process validation, regulatory submission and product launch Chapters are written by one or more world-renowned leading authorities from academia, industry or regulatory agencies, whose expertise cover lyophilization of the diverse modalities of biopharmaceuticals. Their contributions are based on the exhaustive review of literature coupled with excellent hands-on experiences in laboratory or GMP setup, making this an exceptional guide to all stages of lyophilized or dehydrated product development.

This volume explores the application of Quality by Design (QbD) to biopharmaceutical drug product development. Twenty-eight comprehensive chapters cover dosage forms, liquid and lyophilized drug products. The introductory chapters of this book define key elements of QbD and examine how these elements are integrated into drug product development. These chapters also discuss lessons learned from the FDA Office of Biotechnology Products pilot program. Following chapters demonstrate how QbD is used for formulation development ranging from screening of formulations to developability assessment to development of lyophilized and liquid formats. The next few chapters study the use of small-scale and surrogate models as well as QbD application to drug product processes such as drug substance freezing and thawing, mixing, sterile filtration, filling, lyophilization, inspection and shipping and handling. Later chapters describe more specialized applications of QbD in the drug product realm. This includes the use of QbD in primary containers, devices and combination product development. The volume also explores QbD applied to vaccine development, automation,

mathematical modeling and monitoring, and controlling processes and defining control strategies. It concludes with a discussion on the application of QbD to drug product technology transfer as well as overall regulatory considerations and lifecycle management. Quality by Design for Biopharmaceutical Drug Product Development is an authoritative resource for scientists and researchers interested in expanding their knowledge on QbD principles and uses in creating better drugs.

This up-to-the-minute reference delineates-in a systematic fashion-the appropriate, sequential steps for the formulation of safe, effective, stable, and marketable liquid parenteral biopharmaceutical products-covering fundamentals and essential pathways for each phase as well as its purpose, function, and relation to other stages in the product development process. Written by experts currently involved in state-of-the-art advances in the pharmaceutical drug industry, Development of Biopharmaceutical Parenteral Dosage Forms details biopharmaceuticals that are licensed or undergoing clinical development, including genetically engineered cell and engineered vectors in the fermentation process describes purification and characterization techniques for rDNA therapeutics, discussing several types of unit operations for isolation, purification, and characterization considers preformulation and formulation requirements, such as physicochemical properties, drug delivery, stability studies programs, deactivation/denaturation routes, selection of compatible excipients, and regulatory compliance elucidates basics of analytical techniques, methods development, separation methods using chromatographic and electrophoretic techniques, and bioactivity methods covering bioassays and immunoassays for quantifying the stability of biological activity shows how to select the appropriate filter for maximizing compatibility and minimizing adsorption and inactivation, examining topics from basic filtration theories to future trends reviews the selection process for compatible elastomeric closures, analyzing physical, chemical, toxicological properties, protein adsorption on elastomeric surfaces, strategies to reduce/eliminate adsorption, and specialized containers for biotechnological applications and more! Furnished with helpful references, tables, and drawings, this practical guide is indispensable for pharmaceutical, medicinal, and protein chemists; molecular biologists; process engineers; purification scientists; biopharmaceutical and pharmaceutical formulators and product developers; quality control, quality assurance, and regulatory compliance personnel; and upper-level undergraduate and graduate students in these disciplines.

“Biobetters: Protein Engineering to Approach the Curative” discusses the optimization of protein therapeutic products for treatment of human diseases. It is based on the fact that though numerous important therapeutic protein products have been developed for life threatening and chronic diseases that possess acceptable safety and efficacy profiles, these products have generally not been reexamined and modified for an improved clinical performance, with enhancements both to safety and efficacy profiles. Advances in protein engineering, coupled with greatly enhanced understanding of critical product quality attributes for efficacy and safety, make it possible to optimize predecessor products for clinical performance, thereby enhancing patient quality of life and with the potential for great savings in health care costs. Yet despite such knowledge, there is little movement towards such modifications. This book examines engineering protein therapeutic products such that they exhibit an optimal, not just an adequate, clinical performance profile. Two product classes, therapeutic enzymes for lysosomal storage diseases (enzyme replacement therapies, ERT) and monoclonal antibodies (mAbs), are used as examples of what modifications to such proteins could be made to enhance clinical performance, “closer to a cure” as it were. For ERT, the key to optimizing clinical performance is to ensure the ERT is endowed with moieties that target the protein to the relevant target tissue. Thus, for Gaucher Disease, our best example of how to optimize an ERT to address a disease that manifests in specific target tissues (macrophages and monocytes), the enzyme has been extensively modified to target macrophages. For diseases such as Pompe Disease, largely a disorder of muscle, optimal performance of ERT will depend on endowing the enzyme with the ability to be taken up via the Mannose 6 Phosphate Receptor, and so one of the chapters in the book will discuss such approaches. Moreover, a major failure of biotechnology based products is to gain access to the CNS, a key target tissue in numerous diseases. Thus, a chapter has been devoted to strategies to access the CNS. Additionally, immune responses to therapeutic proteins can be highly problematic, eliminating the efficacy of life saving or highly effective protein therapeutics. This is especially poignant in the case of Pompe Disease wherein great improvement in muscle strength and functionality is lost following development of an immune response to the ERT with consequent patient deterioration and death. Thus, a chapter regarding protein engineering, as well as other non-clinical approaches to diminishing immunogenicity is a valuable part of the book. Monoclonal antibodies (mAbs) can be engineered to bind targets relevant to a wide variety of diseases; binding affinity, however, is only part of the equation and one of the chapters will present a molecular assessment approach that balances affinity with pharmacokinetics and manufacturability. As with other proteins immunogenicity can be problematic, being responsible for loss of efficacy of anti-TNF mAbs, often after prolonged successful treatment. The authors will also share their perspective on the consequences of physico-chemical modifications occurring to mAbs once they reach the circulation or their target, a research area open to further development from a protein engineering as well as analytical perspective. This book will also discuss novel platforms for protein therapeutics, technologies that exceed mAbs with respect to potency, and hence, potentially efficacy. These platforms consist largely of repeat domain proteins with very high affinity for their target ligands, but while potentially more efficacious, immunogenicity may be a major problem limiting use. The economics surrounding the issue of biobetters is another high-profile issue - this final chapter will explore the incentives and disincentives for developing biobetters and consider incentives that might make their pursuit more rewarding.

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.

This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.

Completely revised and updated to reflect the significant advances in pharmaceutical production and regulatory expectations, this third edition of Validation of Pharmaceutical Processes examines and blueprints every step of the validation process needed to remain compliant and competitive. The many chapters added to the prior compilation examine va

In this volume, the authors discuss the many significant challenges currently faced in biotechnology dosage form development, providing guidance, shared experience and thoughtful reflection on how best to address these potential concerns. As the field of therapeutic recombinant therapeutic proteins enters its fourth decade and the market for biopharmaceuticals becomes increasingly competitive, companies are increasingly dedicating resources to develop innovative biopharmaceuticals to address unmet medical needs. Often, the pharmaceutical development scientist is encountering challenging pharmaceutical properties of a given protein or by the demands placed on the product by stability, manufacturing and preclinical or clinical expectations, as well as the evolving regulatory expectations and landscape. Further, there have been new findings that require close assessment, as for example those related to excipient quality, processing, viscosity and device compatibility and administration, solubility and opalescence and container-closure selection. The literature varies widely in its discussion of these critical elements and consensus does not exist. This topic is receiving a great deal of attention within the biotechnology industry as well as with academic researchers and regulatory agencies globally. Therefore, this book is of interest for business leaders, researchers, formulation and process development scientists, analytical scientists, QA and QC officers, regulatory staff, manufacturing leaders and regulators active in the pharmaceutical and biotech industry, and expert reviewers in regulatory agencies.

The rapid advances in recombinant DNA technology and the increasing availability of peptides and proteins with therapeutic potential are a challenge for pharmaceutical scientists who have to formulate these compounds as drug products. Pharmaceutical Formulation Development of Peptides and Proteins, Second Edition discusses the development of therapeutic peptides and proteins, from the production of active compounds via basic pre-formulation and formulation to the registration of the final product. Providing integrated solutions, this book discusses: The synthesis of peptides and the biotechnological production of proteins through recombinant DNA technology The physicochemical characteristics and stability of peptides and proteins The formulation of proteins as suspensions, solutions, and (mostly freeze-dried) solids The opportunities and challenges of non-parenteral delivery of peptides and proteins Risk factors, specifically the development of an unwanted immune response A simulation approach to describe the fate of peptides and proteins upon administration to a biological system The documentation required to register a protein-based drug Scientists in the pharmaceutical industry and academia as well as postgraduate students in pharmaceutical science will find this a valuable resource.

Formulation, Development and Manufacturing of Vaccines: The Practical Aspects provides an industry perspective on vaccine product development and manufacture that covers their formulation development, manufacture and delivery/in-use considerations of vaccine production. With the increasing complexity of vaccine products in development, there is a need for a comprehensive review of the current state of the industry and its challenges. While formulation scientists working in biotherapeutic development may be familiar with proteins, vaccines present unique challenges, including the wide range of vaccine components that may comprise proteins, polysaccharides, protein-polysaccharide conjugates, adjuvants, etc. and the varying stability and behavior of solution- and suspension-based systems. This book is an essential resource for formulation scientists, researchers in vaccine development throughout medical and life sciences, and advanced students. Includes formulation considerations for various vaccine types, including proteins, polysaccharides, conjugates and live vaccines Considers process development for solution, suspension and lyophilized products Explores the future potential of vaccines, including multi-component vaccines and novel delivery mechanisms/devices

Focusing on the application of physical pharmacy, drug design, and drug regulations as they relate to produce effective dosage forms for drug delivery, Integrated Pharmaceutics provides a comprehensive picture of pharmaceutical product design, describing the science and art behind the concepts of dosage form development. Combining physical pharmacy, product design, and regulatory affairs issues in a single book, the authors address topics governing drug regulations of United States, European, and Japanese agencies and detail new regulatory guidelines, including quality by design, design space analysis, and blend sample uniformity.

Sterile Drug Products: Formulation, Packaging, Manufacturing, and Quality teaches the basic principles of the development and manufacture of high quality sterile dosage forms. The author has 38 years of experience in the development and manufacture of sterile dosage forms including solutions, suspensions, ophthalmics and freeze dried products. This book is based on the courses he has delivered for over three decades, to over 3000 participants, and is

intended to remain relevant for the indefinite future even as new technologies and new applications of old technologies become common. This is an ideal reference book for those working directly and indirectly with sterile dosage forms, be it product development (formulation, package, process, analytical), manufacturing, quality control, quality assurance, regulatory, purchasing, or project management. This book is also intended as an educational resource for the pharmaceutical and biopharmaceutical industry and pharmacy schools, providing basic knowledge and principles in four main areas of parenteral science and technology: Product development, including formulation, packaging, and process development. Manufacturing, including basic teaching on all the primary unit operations involved in preparation of sterile products and the underlying importance of contamination control. Quality and regulatory, including the application of good manufacturing practice regulations, aseptic processing guidelines, and unique quality control testing methods for the sterile dosage form Clinical aspects, including administration, potential hazards, and biopharmaceutics of sterile products in a clinical setting.

The development of liposomes as a drug delivery system has fluctuated since its introduction in the late 1960's by A.D. Bangham. While academic research of liposomes as a model membrane system has always flourished, as the exponential growth of papers can testify, the application of these findings to medically useful products has gone through several crises. Following the original optimism in the 70's and early 80's, a period of severe skepticism ensued at the end of the 80's and beginning of the 90's, culminating in a moderate but real optimism in the mid 90's, as a result of a successful launch of the first products in the US and Europe. In this collection of papers, the editors have gathered the most promising ideas, approaches, applications and commercial developments, thereby presenting an up-to-date compilation of the present status of the field. This includes such broad areas as anti-cancer chemotherapy immune stimulation and infectious diseases. Currently, the major areas of progress are in delivery of anti-fungal agents by conventional liposomes or lipid-based carriers and systemic anticancer therapy using long-circulating liposomes. The future applications as characterized by the direction of present day research is in specific targeting and delivery of informational molecules such as DNA plasmids (genes), antisense oligonucleotides or ribozymes. Other future developments may be in topical delivery, vaccination and in diagnostics. Features of this book: • Contributions from almost all the leading labs in the field • Up-to-date, critical reviews bridged by editors' introductions • Organized into a logical framework.

This comprehensive book encompasses various facets of sterile product development. Key concepts relevant to the successful development of sterile products are illustrated through case studies and are covered under three sections in this book: • Formulation approaches that discuss a variety of dosage forms including protein therapeutics, lipid-based controlled delivery systems, PEGylated biotherapeutics, nasal dosage form, and vaccines • Process, container closure and delivery considerations including freeze-thaw process challenges, best practices for technology transfer to enable commercial product development, innovations and advancement in aseptic fill-finish operations, approaches to manufacturing lyophilized parenteral products, pen / auto-injector delivery devices, and associated container closure integrity testing hurdles for sterile product closures • Regulatory and quality aspects in the areas of particulate matter and appearance evaluation, sterile filtration, admixture compatibility considerations, sterilization process considerations, microbial contamination investigations and validation of rapid microbiological methods, and dry and moist heat sterilizers This book is a useful resource to scientists and researchers in both industry and academia, and it gives process and product development engineers insight into current industry practices and evolving regulatory expectations for sterile product development.

This comprehensive volume discusses approaches for a systematic selection of delivery systems for various classes of therapeutic agents including small molecule, protein, and nucleic acid drugs. Specific topics covered in this book include: Solution, suspension, gel, nanoparticle, microparticle, and implant dosage forms Refillable and microneedle devices Intravitreal, suprachoroidal, intrascleral, transscleral, systemic, and topical routes of delivery Physical methods including iontophoresis for drug delivery Rational selection of routes of administration and delivery systems Noninvasive and continuous drug monitoring Regulatory path to drug product development Clinical endpoints for drug product development Emerging and existing drugs and drug targets Drug Product Development for the Back of the Eye is authored by renowned ocular drug delivery experts, representing academic, clinical, and industrial organizations and serves as indispensable resource for ophthalmic researchers, drug formulation scientists, drug delivery and drug disposition scientists, as well as clinicians involved in designing and developing novel therapeutics for the back of the eye diseases. This book is also relevant for students in various disciplines including ophthalmology, pharmaceutical sciences, drug delivery, and biomedical engineering. Refillable and microneedle devices Intravitreal, suprachoroidal, intrascleral, transscleral, systemic, and topical routes of delivery Physical methods including iontophoresis for drug delivery Rational selection of routes of administration and delivery systems Noninvasive and continuous drug monitoring Regulatory path to drug product development Clinical endpoints for drug product development Emerging and existing drugs and drug targets Drug Product Development for the Back of the Eye is authored by renowned ocular drug delivery experts, representing academic, clinical, and industrial organizations and serves as indispensable resource for ophthalmic researchers, drug formulation scientists, drug delivery and drug disposition scientists, as well as clinicians involved in designing and developing novel therapeutics for the back of the eye diseases. This book is also relevant for students in various disciplines including ophthalmology, pharmaceutical sciences, drug delivery, and biomedical engineering. Refillable and microneedle devices Intravitreal, suprachoroidal, intrascleral, transscleral, systemic, and topical routes of delivery Physical methods including iontophoresis for drug delivery Rational selection of routes of administration and delivery systems Noninvasive and continuous drug monitoring Regulatory path to drug product development Clinical endpoints for drug product development Emerging and existing drugs and drug targets Drug Product Development for the

Back of the Eye is authored by renowned ocular drug delivery experts, representing academic, clinical, and industrial organizations and serves as indispensable resource for ophthalmic researchers, drug formulation scientists, drug delivery and drug disposition scientists, as well as clinicians involved in designing and developing novel therapeutics for the back of the eye diseases. This book is also relevant for students in various disciplines including ophthalmology, pharmaceutical sciences, drug delivery, and biomedical engineering.

The objective of this volume is to consolidate within a single text the most current knowledge, practical methods, and regulatory considerations pertaining to formulations development with poorly water-soluble molecules. A pharmaceutical scientist’s approach toward solubility enhancement of a poorly water-soluble molecule typically includes detailed characterization of the compound’s physiochemical properties, solid-state modifications, advanced formulation design, non-conventional process technologies, advanced analytical characterization, and specialized product performance analysis techniques. The scientist must also be aware of the unique regulatory considerations pertaining to the non-conventional approaches often utilized for poorly water-soluble drugs. One faced with the challenge of developing a drug product from a poorly soluble compound must possess at minimum a working knowledge of each of the abovementioned facets and detailed knowledge of most. In light of the magnitude of the growing solubility problem to drug development, this is a significant burden especially when considering that knowledge in most of these areas is relatively new and continues to develop

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.

Although the United States (U.S.) and the more developed nations of the remainder of the world are blessed with a variety of pharmaceuticals, feed additives, and biological products to treat, prevent, and control animal diseases, there is a healthy desire among persons involved in animal health issues to increase our animal medicine chest. The interest stems from the desire to efficiently produce food that is safe and plentiful and from the desire to have more and better government-approved products available for the prevention and treatment of diseases of dogs, cats, and horses and for an increasing variety of minor animal species. For the animal health industry, increased drug availability means broader markets, increased revenues, and an opportunity to better serve their customers. For the veterinarian, more animal health products means that he or she is better able to treat the usual and the unusual conditions, and to prevent animal disease and suffering. No doubt, we are all winners when new technology and industrial and regulatory initiatives hasten the availability of safe and effective animal health products.

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.

Long acting injections and implants improve therapy, enhance patient compliance, improve dosing convenience, and are the most appropriate formulation choice for drugs that undergo extensive first pass metabolism or that exhibit poor oral bioavailability. An intriguing variety of technologies have been developed to provide long acting injections and implants.

Many considerations need to go into the design of these systems in order to translate a concept from the lab bench to actual therapy for a patient. This book surveys and summarizes the field. Topics covered in Long Acting Injections and Implants include the historical development of the field, drugs, diseases and clinical applications for long acting injections and implants, anatomy and physiology for these systems, specific injectable technologies (including lipophilic solutions, aqueous suspensions, microspheres, liposomes, in situ forming depots and self-assembling lipid formulations), specific implantable technologies (including osmotic implants, drug eluting stents and microfabricated systems), peptide, protein and vaccine delivery, sterilization, drug release testing and regulatory aspects of long acting injections and implants. This volume provides essential information for experienced development professionals but was also written to be useful for scientists just beginning work in the field and for others who need an understanding of long acting injections and implants. This book will also be ideal as a graduate textbook. Dr. Jeremy Wright is a Principal Engineer at the DURECT Corporation in Cupertino, California. He has over 30 years of experience in the development of drug delivery systems. He has been a key contributor to the development of implantable osmotic systems for veterinary and human use (DUROS®) and is currently involved in research and development of injectable depot systems. Dr. Wright is the inventor on over 50 patents. Dr. Diane J. Burgess is Distinguished Professor of Pharmaceutics, at the University of Connecticut. Her research efforts focus on gene and drug delivery and she has over 140 refereed publications. Dr. Burgess was the 2010 President of the Controlled Release Society (CRS), the 2002 President of the American Association of Pharmaceutical Scientists (AAPS) and is a CRS, AAPS and an American Institute for Medical and Biological Engineering (AIMBE) fellow. She is editor of the International Journal of Pharmaceutics.

The preparation of sterile products using aseptic processing is considered perhaps the most critical process in the pharmaceutical industry and has witnessed continual improvement over the last half century. New approaches that have transformed classical aseptic production methods are appearing almost daily. This book reviews emerging technologies for aseptic processing that will markedly reduce the level of contamination risk for sterile products and includes coverage on: The use of isolator and barrier concepts for aseptic processing and assembly. The application of robotics as an alternative to gowned personnel. The increasing reliance on automation to minimize or eliminate operator intervention. The design, operational, monitoring and compliance changes necessary for success with advanced aseptic processing. Advanced Aseptic Processing Technology is an essential reference for anyone working with sterile products, and is recommended for individuals in manufacturing,, compliance, regulatory affairs, microbiology, environmental monitoring, sterility testing, sterilization, validation, engineering, development, facility and equipment design, component and equipment suppliers, automation, and robotics.

Parenteral Medications is an authoritative, comprehensive reference work on the formulation and manufacturing of parenteral dosage forms, effectively balancing theoretical considerations with practical aspects of their development. Previously published as a three-volume set, all volumes have been combined into one comprehensive publication that addresses the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration. Key Features: Provides a comprehensive reference work on the formulation and manufacturing of parenteral dosage forms Addresses changes in the science and advances in the technology associated with parenteral medications and routes of administration Includes 13 new chapters and updated chapters throughout Contains the contributors of leading researchers in the field of parenteral medications Uses full color detailed illustrations, enhancing the learning process The fourth edition not only reflects enhanced content in all the chapters but also highlights the rapidly advancing formulation, processing, manufacturing parenteral technology including advanced delivery and cell therapies. The book is divided into seven sectionss: Section 1 - Parenteral Drug Administration and Delivery Devices; Section 2 - Formulation Design and Development; Section 3 - Specialized Drug Delivery Systems; Section 4 - Primary Packaging and Container Closure Integrity; Section 5 - Facility Design and Environmental Control; Section 6 - Sterilization and Pharmaceutical Processing; Section 7 - Quality Testing and Regulatory Requirements

Sterile Product DevelopmentFormulation, Process, Quality and Regulatory ConsiderationsSpringer Science & Business Media

Upon publication of the first edition of Therapeutic Peptides and Proteins ten years ago there were only 19 biotechology medicines on the market. Currently there are more than 100, with at least 400 more in various stages of development. That alone would be grounds for a new edition. Add to that the fact that it is still difficult to find up

Generic Drug Product Development: Specialty Dosage Forms explores the issues related to providing evidence of pharmaceutical equivalence and bioequivalence for specialty drug products. It describes various scientific approaches and regulatory requirements for manufacturers who need to demonstrate the therapeutic equivalence of generic specialty drug products to brand name alternatives. The contributors discuss measurement of drug product quality and performance, as well as the regulatory and scientific requirements of topical, nasal and inhalation, and transdermal drug delivery products, along with generic biologics and modified release parenteral drug products. The book is essential reading for specialists and researchers in pharmaceutical drug development, regulation, manufacturing, and others in the pharmaceutical sciences.

The fourth volume in the series covers the techniques and technologies involved in the preparation of semisolid products such as ointments, creams, gels, suppositories, and special topical dosage forms. Drug manufacturers need a thorough understanding of the specific requirements that regulatory agencies impose on the formulation and efficacy deter

Plunkett's Biotech & Genetics Industry Almanac 2007 is a complete reference guide to the business side of biotechnology, genetics, proteomics and related services. This new book contains complete profiles of the leading biotech companies, in-depth chapters on trends in genetics, technologies, statistics and finances, a handy glossary and thorough indexes. Plunkett's Biotech & Genetics Industry Almanac, our easy-to-understand reference to the biotech and genetics industry, is an absolutely vital addition to your office. For the first time, in one carefully-researched volume, you'll get all of the data you need. Topics include: A Short History of Biotechnology; The State of the Biotechnology Industry Today; Biotechnology funding and investments; Patents; Biotech activities in Singapore and China; FDA; Gene Therapies; Personalized Medicine; Systems Biology; Drug Development; Clinical Trials; Controversy over Drug Prices; Stem Cells Research; Therapeutic Cloning; Regenerative Medicine Nanotechnology; Agricultural Biotechnology; Drug Delivery Systems; BioShield; Ethical Issues.

The book also includes complete profiles on over 400 Biotech & Genetics companies, our own unique list of companies that are the leaders in biotechnology. These are the largest, most successful corporations in all facets of this exploding business. All of the corporate profile information is indexed and cross-indexed, including contact names, addresses, Internet addresses, fax numbers, toll-free numbers, plus growth and hiring plans, finances, research, marketing, technology, acquisitions and much more for each firm. Purchasers of either the book or PDF version can request a free copy of the company profiles database on CD-ROM, enabling export of contact names, addresses and more.

This book offers a complete discussion of product development in the pharmaceutical and biotechnology industries from discovery, to product launch, through life cycle management. The book is organized for optimal usefulness in the education and training of health care professionals (MD, PharmD, PhD), at universities. The format is a set of figures, tables and lists, along with detailed narrative descriptions, including real-life examples, illustrations, controversies in industry, and references. The editors and authors of the book are industry and research experts in a variety of disciplines.

Since publication of the first edition of this book, Aseptic Processing and Packaging of Food, significant changes have taken place in several aseptic processing and packaging areas. These include changes in aseptic filling of nutritional beverages in plastic bottles; the popularity of value-added commodity products such as juice, concentrate, and