Active Pharmaceutical Ingredients Development Manufacturing And Regulation Drugs And The Pharmaceutical Sciences

Separation of molecules present in organic solvents by membrane (nano)filtration has great potential in industries ranging from refining to fine chemical and pharmaceutical synthesis and is currently an area of intensive studies. This will be the first concise reference book offering a critical analysis on this topic. Nanofiltration, is a pressure driven membrane process used to remove solutes with molecular weight in the range of 200-1,000 g mol-1 typically from aqueous streams. A recent innovation is the extension of nanofiltration processes to organic solvents an emerging technology referred to as Organic Solvent Nanofiltration (OSN). Separation of molecules present in organic solvents by nanofiltration has great potential in various processes such as petroleum refining, fine chemical and pharmaceutical synthesis, catalyst recycle, enrichment of aromatics etc. This book summarizes the developments in the field of OSN. It describes materials and methods used for the preparation of organic solvent stable membranes. Various techniques for manufacturing of OSN membranes, their physico-chemical and performance related characterization and membrane transport mechanisms will be discussed and critically evaluated. A summary of the commercially available OSN membranes, their separation properties and manufacturers will also be presented. Finally a detailed overview of the OSN applications in various industrial and laboratory scale processes as well as their future prospective will be presented. Complete coverage of the field of organic Solvent Nanofiltration: theory and industrial applications Provides all you want to know in this fast developing application of membranes in industrial filtration and water purification Applications of membranes - summary of the existing applications and proposed new applications; review and critical analysis of the data on currently available OSN membranes. The benefit of this feature to the users is outlined in the comment of one referee: "I use these types of books as an instant reference, resource and fact checker when I am writing or researching topics in membrane technology. I also read the content carefully to keep myself at the state-of-the-art in the technology. R&D is an expensive and time consuming endeavor so anything learned from the literature is valuable when it helps to guide my efforts". Contains a large number of diagrams /figures (60 approx) which offer graphical explanations of the processes and the mechanisms underlying the processess provides practical and easy to understand examples of practical applications. The user can easily adapt these to his/her specific application Worked examples 15 (approx) Guide the reader through the various parameters, and show the reader the effect of these parameters in the overall design of the process Includes multimedia content, videos and active tables and diagrams Enable the user to add his/her own data and conditions and

get results relevant to his/her situation. Tables (25 approx) Provides review and critical analysis of the data on currently available OSN membranes Glossary Summary of the main terms used in OSN

A needed resource for pharmaceutical scientists and cosmetic chemists, Essential Chemistry for Formulators of Semisolid and Liquid Dosages provides insight into the basic chemistry of mixing different phases and test methods for the stability study of nonsolid formulations. The book covers foundational surface/colloid chemistry, which forms the necessary background for making emulsions, suspensions, solutions, and nano drug delivery systems, and the chemistry of mixing, which is critical for further formulation of drug delivery systems into semisolid (gels, creams, lotions, and ointments) or liquid final dosages. Expanding on these foundational principles, this useful guide explores stability testing methods, such as particle size, rheological/viscosity, microscopy, and chemical, and closes with a valuable discussion of regulatory issues. Essential Chemistry for Formulators of Semisolid and Liquid Dosages offers scientists and students the foundation and practical guidance to make and analyze semisolid and liquid formulations. Unique coverage of the underlying chemistry that makes possible stable dosages Quality content written by experienced experts from the drug development industry Valuable information for academic and industrial scientists developing topical and liquid dosage formulations for pharmaceutical as well as skin care and cosmetic products

In 2002, the U.S. Food and Drug Administration (FDA) launched the Pharmaceutical Quality for the 21st Century Initiative to encourage adoption of innovative technologies that would lead to an agile, flexible pharmaceutical manufacturing sector. The goal was to encourage a transition to manufacturing processes and approaches that could produce high-quality drugs reliably without extensive regulatory oversight. Much progress has been made toward that goal as the industry has developed and advanced new technologies, but more progress is required as recent natural disasters and the coronavirus pandemic have revealed vulnerabilities in supply chains and highlighted the need to modernize pharmaceutical manufacturing further. At the request of the FDA Center for Drug Evaluation and Research (CDER), Innovations in Pharmaceutical Manufacturing on the Horizon identifies emerging technologies - such as product technologies, manufacturing processes, control and testing strategies, and platform technologies - that have the potential to advance pharmaceutical quality and modernize pharmaceutical manufacturing for products regulated by CDER. This report describes many innovations to modernize the manufacture of drug substances and drug products, to advance new control approaches, and to develop integrated, flexible, and distributed manufacturing networks within 5-10 years.

Provides clear and comprehensive coverage of recently developed applied biocatalysis for synthetic organic chemists with an emphasis to promote green chemistry in pharmaceutical and process chemistry This book aims to make biocatalysis more accessible to both academic and industrial synthetic organic chemists. It focuses on current topics

within the applied industrial biocatalysis field and includes short but detailed experimental methods on timely novel biocatalytic transformations using new enzymes or new methodologies using known enzymes. The book also features reactions that are “expanding and making the enzyme toolbox available to chemists”—providing readers with comprehensive methodology and detailed key sourcing information of a wide range of enzymes. Chapters in Applied Biocatalysis: The Chemist’s Enzyme Toolkit are organized by reaction type and feature a short introductory section describing the current state of the art for each example. Much of the book focuses on processes for which the enzymes are readily available so that organic chemists can synthesize appropriate quantities of chemicals with available materials in a standard chemical laboratory. Advanced methods are included to present examples of new enzymes that might encourage collaboration with suppliers or academic groups and that will educate chemists of rapidly expanding future possibilities. Focuses on current topics within the applied industrial biocatalysis field Offers experimental methods on novel biocatalytic transformations using new enzymes or new methodology using known enzymes Covers the hot topics of enzyme and chemoenzymatic cascades and biocatalysis in flow Edited by noted experts from both academia and industry with years of experience in the field of biocatalysis—particularly, the industrial applications of enzymes Written for synthetic organic chemists working in all industries but especially the pharmaceutical industry and for those in academia with an eye for biocatalysis, Applied Biocatalysis: The Chemist’s Enzyme Toolkit will also benefit academic groups in chemistry and related sciences that are using enzymes for synthetic purposes, as well as those working in the area of enzymology and molecular biology.

This unique book focuses on the currently 'hot topic' of Pharmaceutical Salts and Co-crystals. Combining both reports of the latest academic research and comprehensive overviews of basic principles, with more applied contributions from selected experts in industry.

30th European Symposium on Computer Aided Chemical Engineering, Volume 47 contains the papers presented at the 30th European Symposium of Computer Aided Process Engineering (ESCAPE) event held in Milan, Italy, May 24-27, 2020. It is a valuable resource for chemical engineers, chemical process engineers, researchers in industry and academia, students, and consultants for chemical industries. Presents findings and discussions from the 30th European Symposium of Computer Aided Process Engineering (ESCAPE) event Offers a valuable resource for chemical engineers, chemical process engineers, researchers in industry and academia, students, and consultants for chemical industries

A guide to the development and manufacturing of pharmaceutical products written for professionals in the industry, revised second edition The revised and updated second edition of Chemical Engineering in the Pharmaceutical Industry

is a practical book that highlights chemistry and chemical engineering. The book's regulatory quality strategies target the development and manufacturing of pharmaceutically active ingredients of pharmaceutical products. The expanded second edition contains revised content with many new case studies and additional example calculations that are of interest to chemical engineers. The 2nd Edition is divided into two separate books: 1) Active Pharmaceutical Ingredients (API's) and 2) Drug Product Design, Development and Modeling. The active pharmaceutical ingredients book puts the focus on the chemistry, chemical engineering, and unit operations specific to development and manufacturing of the active ingredients of the pharmaceutical product. The drug substance operations section includes information on chemical reactions, mixing, distillations, extractions, crystallizations, filtration, drying, and wet and dry milling. In addition, the book includes many applications of process modeling and modern software tools that are geared toward batch-scale and continuous drug substance pharmaceutical operations. This updated second edition: • Contains 30new chapters or revised chapters specific to API , covering topics including: manufacturing quality by design, computational approaches, continuous manufacturing, crystallization and final form, process safety • Expanded topics of scale-up, continuous processing, applications of thermodynamics and thermodynamic modeling, filtration and drying • Presents updated and expanded example calculations • Includes contributions from noted experts in the field Written for pharmaceutical engineers, chemical engineers, undergraduate and graduate students, and professionals in the field of pharmaceutical sciences and manufacturing, the second edition of Chemical Engineering in the Pharmaceutical Industry focuses on the development and chemical engineering as well as operations specific to the design, formulation, and manufacture of drug substance and products.

A guide to the important chemical engineering concepts for the development of new drugs, revised second edition The revised and updated second edition of Chemical Engineering in the Pharmaceutical Industry offers a guide to the experimental and computational methods related to drug product design and development. The second edition has been greatly expanded and covers a range of topics related to formulation design and process development of drug products. The authors review basic analytics for quantitation of drug product quality attributes, such as potency, purity, content uniformity, and dissolution, that are addressed with consideration of the applied statistics, process analytical technology, and process control. The 2nd Edition is divided into two separate books: 1) Active Pharmaceutical Ingredients (API’s) and 2) Drug Product Design, Development and Modeling. The contributors explore technology transfer and scale-up of batch processes that are exemplified experimentally and computationally. Written for engineers working in the field, the book examines in-silico process modeling tools that streamline experimental screening approaches. In addition, the authors discuss the emerging field of continuous drug product manufacturing. This revised second edition: Contains 21

new or revised chapters, including chapters on quality by design, computational approaches for drug product modeling, process design with PAT and process control, engineering challenges and solutions Covers chemistry and engineering activities related to dosage form design, and process development, and scale-up Offers analytical methods and applied statistics that highlight drug product quality attributes as design features Presents updated and new example calculations and associated solutions Includes contributions from leading experts in the field Written for pharmaceutical engineers, chemical engineers, undergraduate and graduation students, and professionals in the field of pharmaceutical sciences and manufacturing, Chemical Engineering in the Pharmaceutical Industry, Second Edition contains information designed to be of use from the engineer's perspective and spans information from solid to semi-solid to lyophilized drug products.

This book deals with various unique elements in the drugdevelopment process within chemical engineering science andpharmaceutical R&D. The book is intended to be used as aprofessional reference and potentially as a text book reference inpharmaceutical engineering and pharmaceutical sciences. Many of theexperimental methods related to pharmaceutical process developmentare learned on the job. This book is intended to provide many ofthose important concepts that R&D Engineers and manufacturingEngineers should know and be familiar if they are going to besuccessful in the Pharmaceutical Industry. These include basicanalytics for quantitation of reaction components– oftenskipped in ChE Reaction Engineering and kinetics books. In additionChemical Engineering in the Pharmaceutical Industryintroduces contemporary methods of data analysis for kineticmodeling and extends these concepts into Quality by Designstrategies for regulatory filings. For the current professionals,in-silico process modeling tools that streamlineexperimental screening approaches is also new and presented here.Continuous flow processing, although mainstream for ChE, is uniquein this context given the range of scales and the complex economicsassociated with transforming existing batch-plant capacity. The book will be split into four distinct yet related parts.These parts will address the fundamentals of analytical techniquesfor engineers, thermodynamic modeling, and finally provides anappendix with common engineering tools and examples of theirapplications.

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

Providing guidance for chemists and other scientists entering pharmaceutical discovery and development, this up-to-the-minute reference presents contributions from an international group of nearly 50 renowned researchers—offering a solid grounding in synthetic and physical organic chemistry, and clarifying the roles of various specialties in the development of new drugs. Featuring over 1000 references, tables, and illustrations, Process Chemistry in the Pharmaceutical Industry is sure to find its way to the bookshelves of organic, physical, analytical, process, and medicinal chemists and biochemists; pharmacists; and upper-level undergraduate and graduate students in these disciplines.

Roger Bate has spend years on the trail of counterfeit medicines in Asia, Africa, and the Middle East, learning the anatomy of a nebulous, far-reaching black market that has resulted in countless deaths and injuries around the world. Phake: The Deadly World of Falsified and Substandard Medicines is the culmination of Bate's research and travels—both a fascinating first hand account of the counterfeit drug trade and an incisive policy analysis with important ramifications for decision makers in the U.S. Food and Drug Administration and the international World Health Organization.

Design and Manufacture of Pharmaceutical Tablets offers real world solutions and outcomes of formulation and processing challenges of pharmaceutical tablets. This book includes numerous practical examples related to actual formulations that have been validated and marketed and covers important data in the areas of stability, dissolution, bioavailibity and processing. It provides important background and theoretical information on design and manufacturing and includes a full section dedicated to design experimental methodology and statistics. In addition, this book offers a a general discussion of excipients used in proper tablet design along with practical examples related to excipients. Drug development scientists in industry and academia, as well as students in the pharmaceutical sciences will greatly benefit from the practical knowledge and case examples provided throughout this book. Incorporates important mathematical models and computational applications Includes unique content on central composite design and augmented simplex lattice Provides background on important design principles with emphasis on quality-based design (QBD) of pharmaceutical dosage forms

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

10.7.3 State of Control

The Special Issue on “Model-Based Tools for Pharmaceutical Manufacturing Processes” will curate novel advances in the development and application of model-based tools to address ever-present challenges of the traditional pharmaceutical manufacturing practice as well as new trends. This book provides a collection of nine papers on original advances in the model-based process unit, system-level, quality-by-design under uncertainty, and decision-making applications of pharmaceutical manufacturing processes.

Due to a worldwide need for lower cost drug therapy, use of generic and multi-source drug products have been increasing. To meet international patent and trade agreements, the development and sale of these products must conform to national and international laws, and generic products must prove that they are of the same quality and are therapeutically equivalent to the brand name alternative. However, many countries have limited resources to inspect and verify the quality of all drug products for sale in their country. This title discusses the worldwide legislative and regulatory requirements for the registration of generic and multi-source drug products.

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.

Manufacturing’s central role in global innovation Companies compete on the decisions they make. For years—even decades—in response to intensifying global competition, companies decided to outsource their manufacturing operations in order to reduce costs. But we are now seeing the alarming long-term effect of those choices: in many cases, once manufacturing capabilities go away, so does much of the ability to innovate and compete. Manufacturing, it turns out, really matters in an innovation-driven economy. In Producing Prosperity, Harvard Business School professors Gary Pisano and Willy Shih show the disastrous consequences of years of poor sourcing decisions and underinvestment in manufacturing capabilities. They reveal how today’s undervalued manufacturing operations often hold the seeds of tomorrow’s innovative new products, arguing that companies must reinvest in new product and process development in the US industrial sector. Only by reviving this “industrial commons” can the world’s largest economy build the expertise and manufacturing muscle to regain competitive advantage. America needs a manufacturing renaissance—for restoring itself, and for the global economy as a whole. This will require major changes. Pisano and Shih show how company-level choices are key to the sustained success of industries and economies, and they provide business leaders with a framework for understanding the links between manufacturing and innovation that will enable them to make better outsourcing decisions. They also detail how government must change its support of basic and applied scientific research,

and promote collaboration between business and academia. For executives, policymakers, academics, and innovators alike, Producing Prosperity provides the clearest and most compelling account yet of how the American economy lost its competitive edge—and how to get it back.

This book is aimed at both graduates and postgraduates interested in a career in the pharmaceutical industry by informing them about the breadth of the work carried out in chemical research and development departments. It is also of great value to academics wishing to advise students on the merits of careers in chemical development over discovery.

This textbook is written as a unified approach to various topics, ranging from drug discovery to manufacturing, techniques and technology, regulation and marketing. The key theme of the book is pharmaceuticals - what every student of pharmaceutical sciences should know: from the active pharmaceutical ingredients to the preparation of various dosage forms along with the relevant chemistry, this book makes pharmaceuticals relevant to undergraduate students of pharmacy and pharmaceutical sciences. This book explains how a particular drug was discovered and then converted from lab-scale to manufacturing scale, to the market. It explains the motivation for drug discovery, the reaction chemistry involved, experimental difficulties, various dosage forms and the reasoning behind them, mechanism of action, quality assurance and role of regulatory agencies. After having a course based on this book, the student will be able to understand: 1) the career prospects in the pharmaceutical industry, 2) the need for interdisciplinary teamwork in science, 3) the techniques and technology involved in making pharmaceuticals starting from bulk drugs, and 4) different dosage forms and critical factors in the development of pharmaceutical formulations in relation to the principles of chemistry. A few blockbuster drugs including atorvastatin, sildanefil, ranitidine, ciprofloxacin, amoxicillin, and the longest serving drugs such as aspirin and paracetamol are discussed in detail. Finally, the book also covers the important current pharmaceutical issues like quality control, safety, counterfeiting and abuse of drugs, and future prospects for pharmaceutical industry. Unified approach explaining drug discovery, bulk drug manufacturing, formulation of dosage forms, with pharmacological and therapeutic actions Manufacturing processes of representative active pharmaceutical ingredients and their chemistry plus formulation of dosage forms presented in this book are based on actual industrial processes Covers many aspects relevant to students of the pharmaceutical sciences or newly employed pharmaceutical researchers/employees. It contains summary information about regulatory agencies of different countries

Millions of Americans are taking prescription drugs made in China and don't know it--and pharmaceutical companies are not eager to tell them. This is a disturbing, well-researched wake-up call for improving the current system of drug supply and manufacturing. Several decades ago, penicillin, vitamin C, and many other prescription and over-the-counter products were manufactured in the United States. But with the rise of globalization, antibiotics, antidepressants, birth

control pills, blood pressure medicines, cancer drugs, among many others are made in China and sold in the United States. China's biggest impact on the US drug supply is making essential ingredients for thousands of medicines found in American homes and used in hospital intensive care units and operating rooms. The authors convincingly argue that there are at least two major problems with this scenario. First, it is inherently risky for the United States to become dependent on any one country as a source for vital medicines, especially given the uncertainties of geopolitics. For example, if an altercation in the South China Sea causes military personnel to be wounded, doctors may rely upon medicines with essential ingredients made by the adversary. Second, lapses in safety standards and quality control in Chinese manufacturing are a risk. Citing the concerns of FDA officials and insiders within the pharmaceutical industry, the authors document incidents of illness and death caused by contaminated medications that prompted reform. This probing book examines the implications of our reliance on China on the quality and availability of vital medicines.

This volume provides an insight into the future strategies for commercial biocatalysis with a focus on sustainable technologies, together with chemoenzymatic and biotechnological approaches to synthesize various types of approved and new active pharmaceutical ingredients (APIs) via proven and latest synthetic routes using single-step biocatalytic or enzyme cascade reactions. Many of these drugs act as enzyme inhibitors, as discussed in a chapter with a variety of examples. The targeted enzymes are involved in diseases such as different cancers, metastatic and infectious diseases, osteoporosis, and cardiovascular disorders. The biocatalysts employed for API synthesis include hydrolytic enzymes, alcohol dehydrogenases, laccases, imine reductases, reductive aminases, peroxygenases, cytochrome P450 enzymes, polyketide synthases, transaminases, and halogenases. Many of them have been improved with respect to their properties by engineering methods. The book discusses the syntheses of drugs, including alkaloids and antibiotics, non-ribosomal peptides, antimalarial and antidiabetic drugs, prenylated xanthones, antioxidants, and many important (chiral) intermediates required for the synthesis of pharmaceuticals.

Active Pharmaceutical IngredientsDevelopment, Manufacturing, and Regulation, Second EditionCRC Press

This one-stop reference systematically covers key aspects in early drug development that are directly relevant to the discovery phase and are required for first-in-human studies. Its broad scope brings together critical knowledge from many disciplines, ranging from process technology to pharmacology to intellectual property issues. After introducing the overall early development workflow, the critical steps of early drug development are described in a sequential and enabling order: the availability of the drug substance and that of the drug product, the prediction of pharmacokinetics and -dynamics, as well as that of drug safety. The final section focuses on intellectual property aspects during early clinical development. The emphasis throughout is on recent case studies to exemplify salient points, resulting in an abundance

of practice-oriented information that is usually not available from other sources. Aimed at medicinal chemists in industry as well as academia, this invaluable reference enables readers to understand and navigate the challenges in developing clinical candidate molecules that can be successfully used in phase one clinical trials.

A guide to the development and manufacturing of pharmaceutical products written for professionals in the industry, revised second edition The revised and updated second edition of Chemical Engineering in the Pharmaceutical Industry is a practical book that highlights chemistry and chemical engineering. The book's regulatory quality strategies target the development and manufacturing of pharmaceutically active ingredients of pharmaceutical products. The expanded second edition contains revised content with many new case studies and additional example calculations that are of interest to chemical engineers. The 2nd Edition is divided into two separate books: 1) Active Pharmaceutical Ingredients (API's) and 2) Drug Product Design, Development and Modeling. The active pharmaceutical ingredients book puts the focus on the chemistry, chemical engineering, and unit operations specific to development and manufacturing of the active ingredients of the pharmaceutical product. The drug substance operations section includes information on chemical reactions, mixing, distillations, extractions, crystallizations, filtration, drying, and wet and dry milling. In addition, the book includes many applications of process modeling and modern software tools that are geared toward batch-scale and continuous drug substance pharmaceutical operations. This updated second edition: • Contains 30new chapters or revised chapters specific to API, covering topics including: manufacturing quality by design, computational approaches, continuous manufacturing, crystallization and final form, process safety • Expanded topics of scale-up, continuous processing, applications of thermodynamics and thermodynamic modeling, filtration and drying • Presents updated and expanded example calculations • Includes contributions from noted experts in the field Written for pharmaceutical engineers, chemical engineers, undergraduate and graduate students, and professionals in the field of pharmaceutical sciences and manufacturing, the second edition of Chemical Engineering in the Pharmaceutical Industry focuses on the development and chemical engineering as well as operations specific to the design, formulation, and manufacture of drug substance and products.

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.

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.

Focusing on the three most critical components that successfully bring an API to market-process development, manufacturing, and governmental regulation and approval-this reference serves as a step-by-step guide to the planning and clear understanding of the bulk manufacturing of APIs. This guide offers current and timely discussions of the process development cycle, design engineering, the approval process, quality control and assurance, and validation, as well as plant manufacturing activities including materials management, maintenance, and safety.

A guide to the latest industry principles for optimizing the production of solid state active pharmaceutical ingredients Solid State Development and Processing of Pharmaceutical Molecules is an authoritative guide that covers the entire pharmaceutical value chain. The authors—noted experts on the topic—examine the importance of the solid state form of chemical and biological drugs and review the development, production, quality control, formulation, and stability of medicines. The book explores the most recent trends in the digitization and automation of the pharmaceutical production processes that reflect the need for consistent high quality. It also includes information on relevant regulatory and intellectual property considerations. This resource is aimed at professionals in the pharmaceutical industry and offers an in-depth examination of the commercially relevant issues facing developers, producers and distributors of drug substances. This important book: Provides a guide for the effective development of solid drug forms Compares different characterization methods for solid state APIs Offers a resource for understanding efficient production methods for solid state forms of chemical and biological drugs Includes information on automation, process control, and machine learning as an integral part of the development and production workflows Covers in detail the regulatory and quality control aspects of drug development Written for medicinal chemists, pharmaceutical industry professionals, pharma engineers,

solid state chemists, chemical engineers, Solid State Development and Processing of Pharmaceutical Molecules reviews information on the solid state of active pharmaceutical ingredients for their efficient development and production. Peptide therapy has become a key strategy in innovative drug development, however, one of the potential barriers for the development of novel peptide drugs in the clinic is their deficiencies in clearly defined chemistry, manufacturing and controls (CMC) strategy from clinical development to commercialization. CMC can often become a rate-limiting step due to lack of knowledge and lack of a formal policy or guidelines on CMC for peptide-based drugs. Regulators use a risk-based approach, reviewing applications on a case-by-case basis. Peptide Therapeutics: Strategy and Tactics for Chemistry, Manufacturing, and Controls covers efficient manufacturing of peptide drug substances, a review of the process for submitting applications to the regulatory authority for drug approval, a holistic approach for quality attributes and quality control from a regulatory perspective, emerging analytical tools for the characterisation of impurities, and the assessment of stability. This book is an essential reference work for students and researchers, in both academia and industry, with an interest in learning about CMC, and facilitating development and manufacture of peptide-based drugs. Presents the most effective catalytic reactions in use today, with a special focus on process intensification, sustainability, waste reduction, and innovative methods This book demonstrates the importance of efficient catalytic transformations for producing pharmaceutically active molecules. It presents the key catalytic reactions and the most efficient catalytic processes, including their significant advantages over compared previous methods. It also places a strong emphasis on asymmetric catalytic reactions, process intensification (PI), sustainability and waste mitigation, continuous manufacturing processes as enshrined by continuous flow catalysis, and supported catalysis. Active Pharmaceutical Ingredients in Synthesis: Catalytic Processes in Research and Development offers chapters covering: Catalysis and Prerequisites for the Modern Pharmaceutial Industry Landscape; Catalytic Process Design - The Industrial Perspective; Hydrogenation, Hydroformylation and Other Reductions; Oxidation; ; Catalytic Addition Reactions; Catalytic Cross-Coupling Reactions; Catalytic Metathesis Reactions; Catalytic Cycloaddition Reactions: Coming Full-Circle; Catalytic Cyclopropanation Reactions; Catalytic C-H insertion Reactions; Phase Transfer Catalysis; and Biocatalysis. -Provides the reader with an updated clear view of the current state of the challenging field of catalysis for API production -Focuses on the application of catalytic methods for the synthesis of known APIs -Presents every key reaction, including Diels-Alder, CH Insertions, Metal-catalytic coupling-reactions, and many more -Includes recent patent literature for completeness Covering a topic of great interest for synthetic chemists and R&D researchers in the pharmaceutical industry, Active Pharmaceutical Ingredients in Synthesis: Catalytic Processes in Research and Development is a must-read for every synthetic chemist working with APIs.

This book offers policy makers a hands-on approach, tested in the World Bank's field work in many countries, for developing policies that improve access to safe, effective medicines in health systems of low- and middle-income economies.

The first edition of Pharmaceutical Extrusion Technology, published in 2003, was deemed the seminal book on pharmaceutical extrusion. Now it is expanded and improved, just like the usage of extrusion has expanded, improved and evolved into an accepted manufacturing technology to continuously mix active pharmaceutical ingredients with excipients for a myriad of traditional and novel dosage forms. Pharmaceutical Extrusion Technology, Second Edition reflects how this has spawned numerous research activities, in addition to hardware and process advancements. It offers new authors, expanded chapters and contains all the extrusion related technical information necessary for the development, manufacturing, and marketing of pharmaceutical dosage forms. Key Features: Reviews how extrusion has become an accepted technology to continuously mix active pharmaceutical ingredients with excipients Focuses on equipment and process technology Explains various extrusion system configurations as a manufacturing methodology for a variety of dosage forms Presents new opportunities available only via extrusion and future trends Includes contributions of experts from the process and equipment fields

Process Understanding is the underpinning knowledge that allows the manufacture of chemical entities to be carried out routinely, robustly and to the required standard of quality. This area has gained in importance over the last few years, particularly due to the recent impetus from the USA`s Food and Drug Administration. This book covers the multidisciplinary aspects required for successful process design, safety, modeling, scale-up, PAT, pilot plant implementation, plant design as well the rapidly expanding area of outsourcing. In discussing what process understanding means to different disciplines and sectors throughout a product`s life cycle, this handbook and ready reference reveals the factors important to the development and manufacture of chemicals. The book focuses on the fundamental scientific understanding necessary. for a smoother technical transfer between the disciplines, leading to more effective and effi cient process development and manufacturing. A range of case studies are used to exemplify and illustrate the main issues raised. As a result, readers will appreciate that process understanding can deliver a real competitive advantage within the pharmaceuticals and fine chemicals industry. This book serves as an aid to meeting the stringent regulations required by the relevant authorities through demonstrable understanding of the underlying science.

Crystallization is a natural occurring process but also a process abundantly used in the industry. Crystallization can occur from a solution, from the melt or via deposition of material from the gas phase (desublimation). Crystals distinguish themself from liquids, gases and amorphous substances by the long-range order of its building blocks that entail the

crystals to be formed of well-defined faces, and give rise to a large number of properties of the solid. Crystallization is used at some stage in nearly all process industries as a method of production, purification or recovery of solid materials. Crystallization is practiced on all scales: from the isolation of the first milligrams of a newly synthesized substance in the research laboratory to isolating products on the mulit-million tonne scale in industry. The book describes the breadth of crystallization operations, from isolation from a reaction broth to purification and finally to tailoring product properties. In the first section of the book, the basic mechanisms - nucleation, growth, attrition and agglomeration are introduced. It ensures an understanding of supersaturation, the driving force of crystallization. Furthermore, the solubility of the substance and its dependences on process conditions and the various techniques of crystallization and their possibilities and limitations are discussed. Last but not least, the first part includes an intensive treatment of polymorphism . The second part builds on the basics, exploring how crystallization processes can be developed, either batch-wise or continuous, from solution or from the melt. A discussion of the purification during crystallization serves as a link between the two sections, where practical aspects and an insight using theoretical concepts are combined. Mixing and its influence on the crystallization as well as the mutual interference of down-stream processes with the crystallization are also treated. Finally, techniques to characterize the crop are discussed. The third part of the book is dedicated to accounts of actual developments and of carried-out crystallizations. Typical pitfalls and strategies to avoid these as well as the design of robust processes are presented.