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

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

Pharmaceutical science deals with the whole spectrum of drug development from start to finish. There are many different facets to the pharmaceutical industry, from initial research to the finished product, including the equipment used, trials performed, and regulations that must be followed. Presenting an overview of all of these different aspects, the Encyclopedia of Pharmaceutical Science and Technology, Fourth Edition is a must-have reference guide for all laboratories and libraries in the pharmaceutical field. Bringing together leaders from every specialty related to pharmaceutical science and technology, this is the single-source reference at the forefront of pharmaceutical R&D. The strength of this work is not only its breadth but also the caliber of contributing writers, all experts in their field, writing on all aspects of pharmaceutical science and technology. The fourth edition offers 29 new chapters ranging from biomarkers, computational chemistry, and contamination control to high-throughput screening, orally disintegrating tablets, and quality by design. The encyclopedia details best practices of equipment used, methods for manufacturing, options for packaging, and routes for drug delivery. The volumes also provide a thorough understanding of the choices behind each method. In addition, the regulations, safety aspects, patent guidance, and methods of analysis are presented. Key Areas Covered: Analytics Biomarkers Dosage forms Drug delivery Formulation Informatics Manufacturing Packaging Processing Regulatory affairs Systems validation This is an authoritative reference source for those practicing in any area of pharmaceutical science and technology, enabling the pharmaceutical specialist and novice alike to keep abreast of developments in this constantly evolving and highly competitive field. * Online version coming soon. Contact us to inquire about subscription options and print/online combination packages. US: (Tel) 1.888.318.2367 / (E-mail) e-reference@taylorandfrancis.com International: (Tel) +44 (0) 20 7017 6062 / (E-mail) online.sales@tandf.co.uk

Pharmaceutical process research and development is an exacting, multidisciplinary effort but a somewhat neglected discipline in the chemical curriculum. This book presents an overview of the many facets of process development and how recent advances in synthetic organic chemistry, process technology and chemical engineering have impacted on the manufacture of pharmaceuticals. In 15 concise chapters the book covers such diverse subjects as route selection and economics, the interface with medicinal chemistry, the impact of green chemistry, safety, the crucial role of physical organic measurements in gaining a deeper understanding of chemical behaviour, the role of the analyst, new tools and innovations in reactor design, purification and separation, solid state chemistry and its role in formulation. The book ends with an assessment of future trends and challenges. The book provides a valuable overview of: both early and late stage chemical development, how safe and scaleable synthetic routes are designed, selected and developed, the importance of the chemical engineering, analytical and manufacturing interfaces, the key enabling technologies, including catalysis and biocatalysis, the importance of the green chemical perspective and solid form issues. The book, written and edited by experts in the field, is a contemporary, holistic treatise, with a logical sequence for process development and mini-case histories within the chapters to bring alive different aspects of the process. It is completely pharmaceutical themed, encompassing all essential aspects, from route and reagent selection to manufacture of the active compound. The book is aimed at both graduates and postgraduates interested in a career in the pharmaceutical industry. It informs them about the breadth of the work carried out in chemical research and development departments, and gives them a feel for the challenges involved in the job. The book is also of value to academics who often understand the drug discovery arena, but have far less appreciation of the drug development area, and are thus unable to advise their students about the relative merits of careers in chemical development versus discovery.

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.

Essential Chemistry for Formulators of Semisolid and Liquid Dosages

Generic Drug Product Development

Bringing a Preclinical Candidate to the Clinic

Development, Manufacturing, and Regulation

A Practical Approach to Pharmaceutical Policy

Chemical Engineering in the Pharmaceutical Industry, Active Pharmaceutical Ingredients, 2nd Edition

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.

In this era of increased pharmaceutical industry competition, success for generic drug companies is dependent on their ability to manufacture therapeutic-equivalent drug products in an economical and timely manner, while also being cognizant of patent infringement and other legal and regulatory concerns.Generic Drug Product Development: Solid Oral

Showcases the important role of organometallic chemistry in industrial applications and includes practical examples and case studies This comprehensive book takes a practical approach to how organometallic chemistry is being used in industrial applications. It uniquely offers numerous, real-world examples and case studies that aid working R&D researchers as well as Ph.D. and postdoc students preparing to ace interviews in order to enter the workforce. Edited by two world-leading and established industrial chemists, the book covers flow chemistry (catalytic and non-catalytic organometallic chemistry), various cross-coupling reactions (C-C, C-N, and C-B) in classical batch chemistry, conjugate addition reactions, metathesis, and C-H arylation and achiral hydrogenation reactions. Beginning with an overview of the many industrial milestones within the field over the years, Organometallic Chemistry in Industry: A Practical Approach provides chapters covering: the design, development, and execution of a continuous flow enabled API manufacturing route; continuous manufacturing as an enabling technology for low temperature organometallic chemistry; the development of a nickel-catalyzed enantioselective Mizoroki-Heck coupling; and the development of iron-catalyzed Kumada cross-coupling for the large scale production of Aliskiren intermediates. The book also examines aspects of homogeneous hydrogenation from industrial research; the latest industrial uses of olefin metathesis; and more. -Includes rare industrial case studies difficult to find in current literature -Helps readers successfully carry out their own reactions -Covers topics like flow chemistry, cross-coupling reactions, and dehydrative decarbonylation -Features a foreword by Nobel Laureate R. H. Grubbs -A perfect resource for every R&D researcher in industry -Useful for PhD students and postdocs: excellent preparation for a job interview Organometallic Chemistry in Industry: A Practical Approach is an excellent resource for all chemists, including those working in the pharmaceutical industry and organometallics.

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 processes 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 Practical Approach

Model-Based Tools for Pharmaceutical Manufacturing Processes

Encyclopedia of Pharmaceutical Science and Technology, Fourth Edition, Six Volume Set (Print)

Continuous Manufacturing of Pharmaceuticals

Countering the Problem of Falsified and Substandard Drugs

Production, Chemistry, Techniques and Technology

The adulteration and fraudulent manufacture of medicines is an old problem, vastly aggravated by modern manufacturing and trade. In the last decade, impotent antimicrobial drugs have compromised the treatment of many deadly diseases in poor countries. More recently, negligent production at a Massachusetts compounding pharmacy sickened hundreds of Americans. While the national drugs regulatory authority (hereafter, the regulatory authority) is responsible for the safety of a country's drug supply, no single country can entirely guarantee this today. The once common use of the term counterfeit to describe any drug that is not what it claims to be is at the heart of the argument. In a narrow, legal sense a counterfeit drug is one that infringes on a registered trademark. The lay meaning is much broader, including any drug made with intentional deceit. Some generic drug companies and civil society groups object to calling bad medicines counterfeit, seeing it as the deliberate conflation of public health and intellectual property concerns. Countering the Problem of Falsified and Substandard Drugs accepts the narrow meaning of counterfeit, and, because the nuances of trademark infringement must be dealt with by courts, case by case, the report does not discuss the problem of counterfeit medicines.

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

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.

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.

Peptide Therapeutics

Active Pharmaceutical Ingredients in Synthesis

Drug Product Design, Development, and Modeling

Chemoenzymatic Synthesis of Active Pharmaceutical Ingredients

Phake

From Formulation Development to Manufacturing

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.

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.

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.

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.

Early Drug Development

Organometallic Chemistry in Industry

Pharmaceutical Applications of Raman Spectroscopy

Solid Oral Dosage Forms, Second Edition

Pharmaceutical Extrusion Technology

10.7.3 State of Control

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.

This ready reference not only presents the hot and emerging topic of modern flow chemistry, it is also unique in illustrating the important connection to sustainable chemistry. Focusing on more sustainable methods and applications, the text extensively covers every important field from reaction time optimization to waste minimization, and from safety improvements to microwave applications. In addition, green metrics are presented as a key aspect of the book, helping readers to evaluate the efficiency of flow technologies and their impact on the overall efficiency of a chemical process. An invaluable handbook for every chemist working in the laboratory, whether in academia or industry.

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

Microfluidic Platforms for Screening of Crystallization Conditions of Active Pharmaceutical Ingredients

An Introduction to Pharmaceutical Sciences

Current Chemical and Engineering Challenges

Active Pharmaceutical Ingredients

Pharmaceutical Process Chemistry

Development, Manufacturing, and Regulation, Second Edition

This comprehensive up-to-date guide and information source is an instructive companion for all scientists involved in research and development of drugs and, in particular, of pharmaceutical dosage forms. The editors have taken care to address every conceivable aspect of the preparation of pharmaceutical salts and present the necessary theoretical foundations as well as a wealth of detailed practical experience in the choice of pharmaceutically active salts. Altogether, the contributions reflect the multidisciplinary nature of the science involved in selection of suitable salt forms for new drug products.

Solid State Development and Processing of Pharmaceutical Molecules A guide to the lastest 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.

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 includeSafety, efficacy, and envi

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.

Design and Manufacture of Pharmaceutical Tablets

Solid State Development and Processing of Pharmaceutical Molecules

New Paradigm in Membrane Separation Processes

Applied Biocatalysis

Chemical Engineering in the Pharmaceutical Industry

Chemical Engineering in the Pharmaceutical Industry, Active Pharmaceutical Ingredients

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

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 Pharmaceutical 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.

Regulatory Affairs in the Pharmaceutical Industry is a comprehensive reference that compiles all the information available pertaining to regulatory procedures currently followed by the pharmaceutical industry. Designed to impart advanced knowledge and skills required to learn the various concepts of regulatory affairs, the content covers new drugs, generic drugs and their development, regulatory filings in different countries, different phases of clinical trials, and the submission of regulatory documents like IND (Investigational New Drug), NDA (New Drug Application) and ANDA (Abbreviated New Drug Application). Chapters cover documentation in the pharmaceutical industry, generic drug development, code of Federal Regulation (CFR), the ANDA regulatory approval process, the process and documentation for US registration of foreign drugs, the regulation of combination products and medical devices, the CTD and ECTD formats, and much more. Updated reference on drug approval processes in key global markets Provides comprehensive coverage of concepts and regulatory affairs Presents a concise compilation of the regulatory requirements of different countries Introduces the fundamentals of manufacturing controls and their regulatory importance

Covering the whole area of process chemistry in the pharmaceutical industry, this monograph provides the essential knowledge on the basic chemistry needed for future development and key industrial techniques, as well as morphology, engineering and regulatory compliances. Application-oriented and well structured, the authors include recent examples of excellent industrial production of active pharmaceutical ingredients.

Handbook of Pharmaceutical Salts Properties, Selection, and Use

The Deadly World of Falsified and Substandard Medicines

Regulatory Affairs in the Pharmaceutical Industry

Pharmaceutical Process Development

For Scale-Up and Manufacture of Active Ingredients

Process Understanding

Peptide therapy has become a key strategy in innovative drug development, however, one of the potential barriers for 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.

Advances and Challenges in Pharmaceutical Technology: Materials, Process Development and Drug Delivery Strategies examines recent advancements in pharmaceutical technology. The book discusses common formulation strategies, including the use of tools for statistical formulation optimization, Quality by design (QbD), process analytical technology, and the uses of various pharmaceutical biomaterials, including natural polymers, synthetic polymers, modified natural polymers, bioceramics, and other bioinorganics. In addition, the book covers rapid advancements in the field by providing a thorough understanding of pharmaceutical processes, formulation developments, explorations, and exploitation of various pharmaceutical biomaterials to formulate pharmaceutical dosage forms. Provides extensive information and analysis on recent advancements in the field of pharmaceutical technology Includes contributions from global leaders and experts in academia, industry and regulatory agencies Uses high quality illustrations, flow charts and tables to explain concepts and text to readers, along with practical examples and research case studies

In this era of increased pharmaceutical industry competition, success for generic drug companies is dependent on their ability to manufacture therapeutic-equivalent drug products in an economical and timely manner, while also being cognizant of patent infringement and other legal and regulatory concerns. Generic Drug Product Development: Solid Oral Dosage Forms, Second Edition presents in-depth discussions from more than 30 noted specialists describing the development of generic drug products—from the raw materials to the development of a therapeutic-equivalent drug product to regulatory approval. Major topics discussed include: Active pharmaceutical ingredients Experimental formulation development, including a new section on Quality by Design (QbD) Scale-up Commercial product formulation Quality control and bioequivalence Drug product performance ANDA regulatory process Post-approval changes Post-marketing surveillance Legislative and patent challenges This second edition also contains a new chapter on the relationship between the FDA and the United States Pharmacopeia and in Chapter 4, using specific examples, the application of Quality by Design (QbD) during formulation development is examined.The book is a thorough guide to the development of solid oral generic dosage formulations. This textbook is ideal for the pharmaceutical industry, graduate programs in pharmaceutical sciences, and health professionals working in the area of generic drug development.

Raman spectroscopy has advanced in recent years with increasing use both in industry and academia. This is due largely to steady improvements in instrumentation, decreasing cost, and the availability of chemometrics to assist in the analysis of data. Pharmaceutical applications of Raman spectroscopy have developed similarly and this book will focus on those applications. Carefully organized with an emphasis on industry issues, Pharmaceutical Applications of Raman Spectroscopy, provides the basic theory of Raman effect and instrumentation, and then addresses a wide range of pharmaceutical applications. Current applications that are routinely used as well as those with promising potential are covered. Applications cover a broad range from discovery to manufacturing in the pharmaceutical industry and include identifying polymorphs, monitoring real-time processes, imaging solid dosage formulations, imaging active pharmaceutical ingredients in cells, and diagnostics.

Organic Solvent Nanofiltration

Materials, Process Development and Drug Delivery Strategies

Pharmaceutical Suspensions

Catalytic Processes in Research and Development

Advances and Challenges in Pharmaceutical Technology

Methods and Applications

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 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

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 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.

Salts, Cocrystals, and Polymorphism

Pharmaceutical Biocatalysis

The Chemist's Enzyme Toolbox

R&D to Manufacturing

Strategy and Tactics for Chemistry, Manufacturing, and Controls

Sustainable Flow Chemistry

The loss of candidate drugs (CD) due to poor physiological properties or incompatibilities with a patients (more commonly referred to as attrition) in the pharmaceutical research and development (R&D) process limits throughput, hinders productivity and results in large overhead costs. Much of the attrition in the pharmaceutical industry is due to poor physiological properties. As a result, these properties need to be identified as early as possible in the R&D process. The initial step in screening for these properties is identifying (1) all the stable forms of a CD and (2) the conditions resulting in nucleation of these solid forms. Highly complex robotic systems have been developed to increase screening efficiency. These robotic systems enable researchers to work on a scale infeasible by hand; however, the number of conditions screened is still limited by the volumes required (~100 ?el per well), thus the amount of material required, and the limited number of wells per device. Using a microfluidic approach allows for earlier screening due to the reduced volumes required. The development of a microfluidic platform to screen for crystallization conditions of CDs is presented. The chip using as little as 50 nl per well on a 96 well chip. The reduced volume and improved control over fluid handling in our microfluidic platforms allow for more extensive screening before production has been scaled up. The microfluidic platform studied in this thesis utilizes Free Interface Diffusion, Temperature control and Evaporation to control the supersaturation of CDs and therefore induce nucleation. Operation and potential has been demonstrated with Acetaminophen screens on-chip. Successful chip operation is demonstrated in all three modes using a common Active Pharmaceutical Ingredient (API), acetaminophen. Additionally, the chips have been modified to accommodate analysis by Raman spectroscopy for crystal and polymorph identification. Incompatibility of PDMS with a wide range of organic solvents has limited the analysis on-chip. To overcome this challenge, more resistant microfluidic platforms are needed for example using glass instead of PDMS as the main material for chip fabrication. We are in the process of developing a glass-based microfluidic platform to reduce the amount of absorbent material.

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.