Chemical Engineering In The Pharmaceutical Industry

"Use of packaging is often thought of as an industrial age concept but this is entirely untrue. In more ancient times products of economic or nutritional value were always wrapped in a suitable material to convey the need to protect the contents. The Roman emperors and Byzantine kings frequently wrapped precious good in all manner of materials from woven rattan baskets to carved and gilded in-laid ebony boxes. Expensive luxury goods such as chalices, and ceremonial goods are almost always stored in a suitable presentation case that demonstrated the value of the product contained within. Perfumes, chrism oils and ceremonial jewellery has always been containered in sculpted and carved lidded-boxes and glazed pottery. The use of bespoke packaging is really a modern age phenomenon. However, the footsteps of packaging use began with leaves and birch bark and other natural materials. In antiquity and prehistoric times humans wrapped their foods in crudely fashioned carriers and containers but also pelts and hides. Mass production of containers later involved woven materials e.g. rushes and reeds to create baskets and carriers but also the use of, textiles, pottery and bronze amphora and carved objects e.g. ivory, antler horn and wood. Recent estimates place "crude glass" or vitrified materials and wood packaging use to at least 3000 BC and these artifacts come from the Indus Valley civilisations and Mesopotamia"--

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.

????:Mixing in the process industries

Advances in Chemical Engineering, Volume 19 reflects the major impact of chemical engineering on medical practice, with chapters covering polymer systems for controlled release, receptor binding and signaling,and transport phenomena in tumors. Other key topics include oil refining, pollution prevention in engineering design, and atmospheric dynamics.

Chemical engineering students and chemical engineers are being asked to solve problems that are complex, whether the applications are in refineries, chemical or pharmaceutical plants. The aim of this book is to demonstrate the problems in chemical engineering which have to solve by Finite Difference Methods. This book is a thorough presentation of Finite Difference Methods used in Chemical Engineering. The goal of this book is to help you practice better chemical engineering. It also contains case studies with worked out examples to demonstrate the Finite Difference Method. This book is for the Chemical Engineer lays down a foundation for numerical problem solving and sets up a basis for more in-depth theory and applications. This text addresses the needs of senior undergraduates in chemical engineering, and students in applied chemistry and biochemical process engineering/food process engineering also.

This title is a general introduction aimed at all those involved in the engineering stages required for the manufacturr of the active ingredient and its dosage forms.

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

This book highlights key ideas and factors to coach and guide professionals involved in learning about Sterile Manufacturing and operational requirements. It covers regulations and guidelines instituted by the FDA, ISPE, EMA, MHRA, and ICH, emphasizing good manufacturing practice and inspection requirements in the manufacturing of medicinal products. Additionally, this book provides the fundamentals of aseptic techniques, quality by design, risk assessment, and management in support of sterile operations applications. It creates a link to the implementation of business practices in drug manufacturing and healthcare and forms a correlation between design strategies including a step-by-step process to ensure reliability, safety, and efficacy of healthcare products for human and animal use. The book also provides a connection between drug production and regulated applications by offering a review of the basic elements of sterile

processing, and how to remain viable with solid strategic planning. The book is a concise reference for professionals and learners in the field of sterile operations that governs primarily, pharmaceutical and medical device space, but can also extend to food and cosmetics that require clean (aseptic) manufacturing applications. It also helps compounding pharmacists and GMP inspectors and auditors.

????!???3000????????????? ??????????????????????????? ?????????????????????? ??????????????????? ???????????? ? ??????????????????????Jennifer Lawrence??? ? ??????????????????? ? ??Amazon?????????800???????5?? ? ??????????????(??????????????) ?????????Elizabeth Holmes?????????????SARS??? ???19?????????????????26?????????????????????: ??????????????????????????? ??????????????? ???Time?????????????????????? ?? ??……? ?????????????Elon Musk?SpaceX???????DFJ??????????????Donald L. Lucas????????????????????Larry Ellison??????????????George Shultz?????????Henry Kissinger?????????????????????????William Perry??????????James Mattis???????????????Rupert Murdoch????????????????……??????????????Theranos ???????????????????Theranos?????????????????? ???90?????????????? ???Tyler Shultz??Theranos???????????????????????????????Booklist?? ????????Theranos????????????????????????…… ??|| ???? ||?? ??????????????? ???? Li Ke Tai Tai???NERD Skincare??????????? ?????????????????? ????The News Lens?????????? ??????????????? ????????? ??|| ???? ||?? ????????Theranos???Publishers Weekly????? ???……Theranos???????Enron??Yashar Ali?????????New York Magazine?

This third volume in a four-volume set offers new theories and applications for the diagnosis and treatment of mental disorders. Having laid the groundwork in the first two volumes, the authors now embark on significant, real-life scenarios that apply their philosophy to mental disorder treatments. The goal of the project is to take the industry toward sustainability, not just in terms of the chemical engineering used to create medicines, but also environmentally, economically, and personally. Their unique approach uses a more holistic and philosophically cohesive method for treating mental disorders, making the industry "greener" and the patient healthier. The four volumes in "The Greening of Pharmaceutical Engineering" are: Volume 1: Practice, Analysis, and Methodology Volume 2: Theories and Solutions Volume 3: Applications for Mental Disorder Treatments Volume 4: Applications for Physical Disorder Treatments This ground-breaking set of books is a unique and state-of-the-art study that only appears here, within these pages. A fascinating study for the engineer, scientist, and pharmacist working in the pharmaceutical industry and interested in sustainability, it is also a valuable textbook for students and faculty studying these subjects.

Chemical physics and thermodynamics cover a role of the outermost importance in the study of many pharmaceutical-based disciplines, especially whenever a thorough understanding of the involved chemical reactions or materials processing becomes highly desirable. In this line, the present book aims at providing any reader or worker in these fields with a consistent experimental data analysis, carried out exhaustively by a number of theoretical models and discussed in any necessary detail. In comparison with the existing texts, ours will include more practical aspects, with examples of calculus taken from or inspired to the modern literature. It will also tackle the most advanced chemical estimation methods employed in pharmaceutical sciences, taking care of communicating as best as possible a modern way of looking at the arguments involved. In this respect, observe that the ongoing bibliography on open questions which were formerly neglected is now continuously growing. The chapters developing the mathematical modeling will be organized so as to explain and quantify the physical and chemical frames of the complex systems met by pure and applied researchers in their daily activity. The theoretical sections, in particular, will take care of any method assuring an efficient coding for the employed procedures (as those relying on macroscopic or statistical thermodynamics) and of describing the experimental tests for the scrutinized molecular systems. As an example, any equation of state must be able to provide, in addition with density, enthalpy, fugacity coefficients and phase equilibrium conditions, with every (partial) thermodynamic derivative with respect to temperature, pressure and any quantity assigning the mixture composition. We will also emphasize the physical chemistry characterization of the active compounds, and concentrate on their crystal, amorphous and polymorphic forms, as well as on the roles played by their states of matter. An appropriate monographic section will thus be devoted to the application of X-ray diffraction to non-structural issues, like atomic and molecular vibrations, order-disorder transitions, theories of the defect solid state, crystal imperfections, and to structural problems such as the so-called "crystallite size" approaches (see, for instance, Scherrer’s and Warren-Averbach’s, sometimes hardly applicable with the necessary accuracy). At that point, we will try to argue whether the current thermal experiments, normally employed to check the assumptions coming from solid state physics and thermochemistry, may (or may not) introduce some novelty or original prospect within the modern arena of pharmaceutical sciences. A chapter on solubility and precipitation kinetics, particularly on how to exploit and modify their variables in a number of relevant cases, will then be presented. In another one, we will approach the most advanced methods which can estimate (the macroscopic) chemical features from theoretical and numerical tools, avoiding in this way the expenses connected with usual laboratory routes. The plenty of techniques illustrated in the literature, unfortunately, are often unable to return satisfactory estimations of properties associated with complex molecular geometries. Our intention in this respect will be supplying several guidelines bringing to better evaluations of some, at least, among the most important drug, polymer and biopolymer characteristics. A final step, now more related to molecular topology, chemical graph theories and several issues of "group contributions" in physical chemistry, will be inquiring on the relationship between the (atomic/molecular) shape of organic compounds and their larger-scale (thermodynamic) features. This is a long-standing problem of physics and chemistry that, on considering the number of open questions in this matter, could find here the room for new insights, statements and formal approaches.

This study presents a business model of continuous improvement in pharmaceutical production processes. The model covers the lifecycle of an improvement, i.e. opportunity identification, project execution and change implementation, with considering various pharma-specific constraints such as GMP (Good Manufacturing Practice). The model is described as so-called an activity model using IDEF0 (Integrated DEFinition type 0) in order to define activities and sub-activities in a clear and consistent manner. A roll-defining model termed RACI (responsible,

accountable, consulted and informed) is uniquely combined with the IDEF0 model, for characterizing roles of various stakeholders in each improvement step. The model was developed and applied in a new sterile drug product manufacturing facility of Roche in Kaiseraugst, Switzerland. In this start-up facility, a case study was performed for reducing losses of valuable biologics drug products with a continuous and organization-wide effort.

The use of modeling and simulation tools is rapidly gaining prominence in the pharmaceutical industry covering a wide range of applications. This book focuses on modeling and simulation tools as they pertain to drug product manufacturing processes, although similar principles and tools may apply to many other areas. Modeling tools can improve fundamental process understanding and provide valuable insights into the manufacturing processes, which can result in significant process improvements and cost savings. With FDA mandating the use of Quality by Design (QbD) principles during manufacturing, reliable modeling techniques can help to alleviate the costs associated with such efforts, and be used to create in silico formulation and process design space. This book is geared toward detailing modeling techniques that are utilized for the various unit operations during drug product manufacturing. By way of examples that include case studies, various modeling principles are explained for the nonexpert end users. A discussion on the role of modeling in quality risk management for manufacturing and application of modeling for continuous manufacturing and biologics is also included. Explains the commonly used modeling and simulation tools Details the modeling of various unit operations commonly utilized in solid dosage drug product manufacturing Practical examples of the application of modeling tools through case studies Discussion of modeling techniques used for a risk-based approach to regulatory filings Explores the usage of modeling in upcoming areas such as continuous manufacturing and biologics manufacturingBullet points

Physicochemical Approaches to the Characterization of Pharmaceutical Systems provides consistent data analysis on the basic physics and chemistry involved in pharmaceutical systems that are carried out using various theoretical models. The book explores states of matter and thermodynamics, how to estimate chemical properties, solubility and distribution phenomena, kinetic processes and drug delivery, and thermodynamics versus the shape of molecules. It supplies several guidelines for achieving better estimations of properties associated with complex molecular geometries, such as important drug, polymer and biopolymer characteristics. Researchers will find it to be a crucial resource for studies in pharmaceutical science and chemical engineering. Covers a wide range of pharmaceutical systems, with an emphasis on chemical physics and thermodynamics Considers contemporary issues in pharmaceutical sciences through interdisciplinary frameworks Suggests novel approaches to complex molecular structures Serves as a comprehensive guide for academic and industrial researchers across pharmaceutical disciplines

??????????????,??????,???,????,????,?????????????.

The pharmaceutical industry is one of the most important industriesin the world, offering new medicines, vaccines, and cures to aglobal population. It is a massive industry, worthy of a deepand thorough examination of its processes and chemistry, with aview toward sustainability. The authors describe what is andisn't truly sustainable, offering a new approach and a newdefinition of the sustainability of pharmaceutical and chemicalengineering and the science behind it. This is a cutting-edgework, aimed at engineers, scientists, researchers, chemists, andstudents.

While emphasizing conservation and sustainable strategies, this book provides steps to improve the manufacturing technologies used in creating products. By simplifying the chemistry, process development, manufacturing practices and processes, the book provides a structured approach to producing quality products with little waste, making the process not only efficient but environmentally friendly. Illustrated with case studies, this is an essential resource for chemical engineers, chemists, plant engineers, and operating personnel in any chemical related businesses.

Issues in Chemical Engineering and other Chemistry Specialties: 2011 Edition is a ScholarlyEditions™ eBook that delivers timely, authoritative, and comprehensive information about Chemical Engineering and other Chemistry Specialties. The editors have built Issues in Chemical Engineering and other Chemistry Specialties: 2011 Edition on the vast information databases of ScholarlyNews.™ You can expect the information about Chemical Engineering and other Chemistry Specialties in this eBook to be deeper than what you can access anywhere else, as well as consistently reliable, authoritative, informed, and relevant. The content of Issues in Chemical Engineering and other Chemistry Specialties: 2011 Edition has been produced by the world’s leading scientists, engineers, analysts, research institutions, and companies. All of the content is from peer-reviewed sources, and all of it is written, assembled, and edited by the editors at ScholarlyEditions™ and available exclusively from us. You now have a source you can cite with authority, confidence, and credibility. More information is available at http://www.ScholarlyEditions.com/.

Chemical Engineering in the Pharmaceutical Industry, Active Pharmaceutical IngredientsWiley

Heat Transfer in the Chemical, Food and Pharmaceutical Industries, a new volume in the Industrial Equipment for Chemical Engineering set, includes thirteen independent volumes on how to perform the selection and calculation of equipment involved in the thirteen basic operations of process engineering, offering readers reliable and simple, easy to follow methods. Throughout these concise and easy-to-use books, the author uses his vast practical experience and precise knowledge of global research to present an in-depth study of a variety of aspects within the field of chemical engineering. In this volume, the author focuses the heat exchanges between gases, liquids, divided solids and compact solids without changes of phase. This book includes discussion on changes of phase, heat exchange processes, combustion and the necessary equipment to measure these. The chapters are complemented with appendices which provide additional information as well as any associated references.

The most complete guide of its kind, this is the favored handbook for chemical and process engineers who need a reliable and authoritative solution to their practical on the job problems. Includes all new material on new processing sectors, include biopharmaceuticals. The text is comprehensively revised and updated with new data and formulas. Rules

of Thumb for Chemical Engineers solves process design problems quickly, accurately and safely, with hundreds of common sense techniques, shortcuts and calculations. Key features; Rules of Thumb for Chemical Engineers brings together solutions, information and work-arounds that engineers in the process industry need to get their job done. New material in the Fifth Edition includes physical properties for proprietary materials, six new chapters, including pharmaceutical, biopharmaceutical sector heuristics, process design with simulation software, and guidelines for hazardous materials and processes. Now includes SI units throughout alongside imperial, and now accompanied by online calculation tools New to this edition; New chapter on biopharmaceutical systems New chapter on closed-loop heat transfer systems Extensively rewritten chapters on fluid flow, fractionation, heat exchangers, pumps, compressors, safety, and controls. Latest information on packed columns and structured packings Excel workbooks, with Visual Basic for Applications function subroutines, that solve many of the problems in the book. Fully updated references Rules of Thumb for Chemical Engineers brings together solutions, information and work-arounds that engineers in the process industry need to get their job done. New material in the Fifth Edition includes physical properties for proprietary materials, six new chapters, including pharmaceutical, biopharmaceutical sector heuristics, process design with simulation software, and guidelines for hazardous materials and processes Now includes SI units throughout alongside imperial, and now accompanied by online calculation tools and a searchable Rules of Thumb library

Process Analytical Technology explores the concepts of PAT and its application in the chemical and pharmaceutical industry from the point of view of the analytical chemist. In this new edition all of the original chapters have been updated and revised, and new chapters covering the important topics of sampling, NMR, fluorescence, and acoustic chemometrics have been added. Coverage includes: Implementation of Process Analytical Technologies UV-Visible Spectroscopy for On-line Analysis Infrared Spectroscopy for Process Analytical Applications Process Raman Spectroscopy Process NMR Spectrscopy: Technology and On-line Applications Fluorescent Sensing and Process Analytical Applications Chemometrics in Process Analytical Technology (PAT) On-Line PAT Applications of Spectroscopy in the Pharmaceutical Industry Future Trends for PAT for Increased Process Understanding and Growing Applications in Biomanufacturing NIR Chemical Imaging This volume is an important starting point for anyone wanting to implement PAT and is intended not only to assist a newcomer to the field but also to provide up-to-date information for those who practice process analytical chemistry and PAT. It is relevant for chemists, chemical and process engineers, and analytical chemists working on process development, scale-up and production in the pharmaceutical, fine and specialty chemicals industries, as well as for academic chemistry, chemical engineering, chemometrics and pharmaceutical science research groups focussing on PAT. Review from the First Edition “The book provides an excellent first port of call for anyone seeking material and discussions to understand the area better. It deserves to be found in every library that serves those who are active in the field of Process Analytical Technology.”—Current Engineering Practice

In recent years chemical engineers have become increasingly involved in the design and synthesis of new materials and products as well as the development of biological processes and biomaterials. Such applications often demand that product properties be controlled with precision. Molecular modeling, simulating chemical and molecular structures or processes by computer, aids scientists in this endeavor. Volume 28 of Advances in Chemical Engineering presents discussions of theoretical and computational methods as well as their applications to specific technologies.

10.7.3 State of Control

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.

The report assesses the current state of chemistry and chemical engineering within the context of drug discovery, disease diagnosis, and disease prevention. Also addressed are chemical and chemical engineering challenges in pharmaceutical synthesis, delivery, and manufacture.

Downstream processing is an essential practice in the production and purification of biosynthethic materials, which is especially important in the production of pharmaceutical products. This book covers the fundamentals and the design concepts of various downstream recovery and purification steps (unit operations) involved in biochemical and chemical processes. The book describes cell breakage and recovery of intracellular material, isolation of solids, product recovery, product enrichment, and product polishing and finishing. It also covers basic chemical engineering purification techniques such as distillation, absorption, adsorption, etc. Described in the book are several case studies that discuss the various unit operation in each of the processes. An important point to consider is the economics of the downstream operation, and this book provides practical information on capital costs and operating expenses in addition to other operating cost factors with respect to downstream processing. Green chemistry and safety issues are also addressed. Practicing chemical engineers in biotechnology and pharmaceutical chemistry and other areas will find this book valuable as a reference on downstream techniques used in biological processes. Students in chemical engineering would benefit from this book as well.

Unlike extensive major reference works or handbooks, Chemical Engineering: Trends and Developments provides readers with a ready-reference to latest techniques in selected areas of chemical engineering where research is and will be focused in the future. These areas are: bioseparations; particle science and design; nanotechnology; and reaction engineering. The aim of the book is to provide academic and R&D researchers with an overview of the main areas of technical development and how these techniques can be applied. Each chapter focuses on a technique, plus a selection of applications or examples of where the technique could be applied.

Process Systems Engineering for Pharmaceutical Manufacturing: From Product Design to Enterprise-Wide Decisions, Volume 41 covers the following process systems engineering methods and tools for the modernization of the pharmaceutical industry: computer-aided pharmaceutical product design and pharmaceutical production processes design/synthesis; modeling and simulation of the pharmaceutical processing unit operation, integrated flowsheets and applications for design, analysis, risk assessment, sensitivity analysis, optimization, design space identification and control system design; optimal operation, control and monitoring of pharmaceutical production processes; enterprise-wide optimization and supply chain management for pharmaceutical manufacturing processes. Currently, pharmaceutical companies are going through a paradigm shift, from traditional manufacturing mode to modernized mode, built on cutting edge technology and computer-aided methods and tools. Such shifts can benefit tremendously from the application of methods and tools of process systems engineering. Introduces Process System Engineering (PSE) methods and tools for discovering, developing and deploying greener, safer, cost-effective and efficient pharmaceutical production processes Includes a wide spectrum of case studies where different PSE tools and methods are used to improve various pharmaceutical production processes with distinct final products Examines the future benefits and challenges for applying PSE methods and tools to pharmaceutical manufacturing

Rules of Thumb for Chemical Engineers, Sixth Edition, is the most complete guide for chemical and process engineers who need reliable and authoritative solutions to on-the-job problems. The text is comprehensively revised and updated with new data and formulas. The book helps solve process design problems quickly, accurately and safely, with hundreds of common sense techniques, shortcuts and calculations. Its concise sections detail the steps needed to answer critical design questions and challenges. The book discusses physical properties for proprietary materials, pharmaceutical and biopharmaceutical sector heuristics, process design, closed-loop heat transfer systems, heat exchangers, packed columns and structured packings. This book will help you: save time you no longer have to spend on theory or derivations; improve accuracy by exploiting well tested and accepted methods culled from industry experts; and save money by reducing reliance on consultants. The book brings together solutions, information and work-arounds from engineers in the process industry. Includes new chapters on biotechnology and filtration Incorporates additional tables with typical values and new calculations Features supporting data for selecting and specifying heat transfer equipment

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.

An informative look at the intricacies of today's drug development process Once a discovery organization has identified a potential new drug candidate, it is the daunting task of synthetic organic chemists to identify the chemical process suitable for preparation of this compound in a highly regulated environment. Only through a multi-layered chemical process that takes into account such factors as safety, environmental considerations, freedom to operate and cost-effectiveness can researchers begin to refine the drug in terms of quality and yield. This book covers both recent advances in the design and synthesis of new drugs, as well as the myriad other issues facing a new drug candidate as it moves through the development process. Utilizing recent case studies, the authors provide valuable insights into the complexities of the process, from designing new synthetic methodologies and applying new automated techniques for finding optimal reaction conditions to selecting the final drug form and formulation. Both novice and active researchers will appreciate the inclusion of chapters on such diverse topics as: * Cross-coupling methods * Asymmetric synthesis * Automation * Chemical Engineering * Application of radioisotopes * Final form selection * Formulations * Intellectual property A wealth of real-world examples and contributions from leading process scientists, engineers, and related professionals make this book a valuable addition to the scientific literature.

A comprehensive source of information about modern drying technologies that uniquely focus on the processing of pharmaceuticals and biologicals Drying technologies are an indispensable production step in the pharmaceutical industry and the knowledge of drying technologies and applications is absolutely essential for current drug product development. This book focuses on the application of various drying technologies to the processing of pharmaceuticals and biologicals. It offers a complete overview of innovative as well as standard drying technologies, and addresses the issues of why drying is required and what the critical considerations are for implementing this process operation during drug product development. Drying Technologies for Biotechnology and Pharmaceutical Applications discusses the state-of-the-art of established drying technologies like freeze- and spray- drying and highlights limitations that need to be overcome to achieve the future state of pharmaceutical manufacturing. The book also

describes promising next generation drying technologies, which are currently used in fields outside of pharmaceuticals, and how they can be implemented and adapted for future use in the pharmaceutical industry. In addition, it deals with the generation of synergistic effects (e.g. by applying process analytical technology) and provides an outlook toward future developments. -Presents a full technical overview of well established standard drying methods alongside various other drying technologies, possible improvements, limitations, synergies, and future directions -Outlines different drying technologies from an application-oriented point of view and with consideration of real world challenges in the field of drug product development -Edited by renowned experts from the pharmaceutical industry and assembled by leading experts from industry and academia Drying Technologies for Biotechnology and Pharmaceutical Applications is an important book for pharma engineers, process engineers, chemical engineers, and others who work in related 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.

Development of new drug molecules is costly and requires longitudinal, wide-ranging studies; therefore, designing advanced pharmaceutical formulations for existing and well-known drugs seems to be an attractive device for the pharmaceutical industry. Properly formulated drug delivery systems can improve pharmacological activity, efficacy and safety of the active substances. Advanced materials applied as pharmaceutical excipients in designing drug delivery systems can help solve problems concerning the required drug release—with the defined dissolution rate and at the determined site. Novel drug carriers enable more effective drug delivery, with improved safety and with fewer side effects. Investigations concerning advanced materials represent a rapidly growing research field in material/polymer science, chemical engineering and pharmaceutical technology. Exploring novel materials or modifying and combining existing ones is now a crucial trend in pharmaceutical technology. Eleven articles included in the the Special Issue "Advanced Materials in Drug Release and Drug Delivery Systems" present the most recent insights into the utilization of different materials with promising potential in drug delivery and into different formulation approaches that can be used in the design of pharmaceutical formulations.