Pharmaceutical Engineering Practical Unit Operations

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LOGAN DWAYNE

The Greening of Pharmaceutical Engineering, Practice, Analysis, and Methodology CRC Press
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.
2017 CFR Annual Print Title 40 Protection of Environment - Part 52 (52.2020 to end of part 52) Springer Nature
The last two decades have seen a phenomenal growth of the field of genetic or biochemical engineering and have witnessed the development and ultimately marketing of a variety of products-typically through the manipulation and growth of different types of microorganisms, followed by the recovery and purification of the associated products. The engineers and biotechnologists who are involved in the full-scale process design of such facilities must be familiar with the variety of unit operations and equipment and the applicable regulatory requirements. This book describes current commercial practice and will be useful to those engineers working in this field in the design, construction and operation of pharmaceutical and biotechnology plants. It will be of help to the chemical or pharmaceutical engineer who is developing a plant design and who faces issues such as: Should the process be batch or continuous or a combination of batch and continuous? How should the optimum process design be developed? Should one employ a new revolutionary separation which could be potentially difficult to validate or use accepted technology which involves less risk? Should the process be run with ingredients formulated from water for injection, deionized water, or even filtered tap water? Should any of the separations be run in cold rooms or in glycol jacketed lines to minimize microbial growth where sterilization is not possible? Should the process equipment and lines be designed to be sterilized in-place, cleaned-in-place, or should every piece be broken down, cleaned and autoclaved after every turn?
Continuous Pharmaceutical Processing IntraWEB, LLC and Claitor's Law Publishing
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.
Predictive Modeling of Pharmaceutical Unit Operations Elsevier
This immensely valuable book provides a comprehensive, easy-to-understand, and up-to-date glossary of technical and scientific terms used in the fields of bioengineering and biotechnology, including terms used in agricultural sciences. The volume also includes terms for plants, animals, and humans, making it a unique, complete, and easily accessible reference. Scientific and Technical Terms in Bioengineering and Biological Engineering opens with an introduction to bioengineering and biotechnology and presents an informative timeline covering the important developments and events in the fields, dating from 7000 AD to the present, and it even makes predictions for developments up the year 2050. From ab initio gene prediction to zymogen and from agrobacterium to zoonosis, this volume provides concise definitions for over 5400 specialized terms peculiar to the fields of bioengineering and biotechnology, including agricultural sciences. The use of consistent terminology is critical in presenting clear and meaningful information, and this helpful reference manual will be essential for graduate and undergraduate students of biomedical engineering, biotechnology, nanotechnology, nursing, and medicine and health sciences as well as for professionals who work with medicine and health sciences.
The Gopher CRC Press
Special edition of the Federal Register, containing a codification of documents of general applicability and future effect ... with ancillaries.
Good Design Practices for GMP Pharmaceutical Facilities Woodhead Publishing
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
Chemical Engineering Design John Wiley & Sons
This book offers a state-of-the-art overview of controlled drug delivery systems, covering the most important innovative applications. The principles of controlled drug release and the mechanisms involved in controlled release are clearly explained. The various existing polymeric drug delivery systems are reviewed, and new frontiers in material design are examined in detail, covering a wide range of polymer modification techniques. The concluding chapter is a case study focusing on use of a drug-eluting stent. The book is designed to provide the reader with a complete understanding of the mechanisms and design of controlled drug delivery systems, and to this end includes numerous step-by-step tutorials. It illustrates how chemical engineers can advance medical care by designing polymeric delivery systems that achieve either temporal or spatial control of drug delivery and thus ensure more effective therapy that eliminates the potential for both under- and overdosing.
Practical Pharmaceutical Engineering John Wiley & Sons
The Second Edition of the Practical Manual is necessitated for inclusion of the following important experiments: - Organised substances by Percolation Method - Continuous Hot Extraction Method - Factors affecting the Rate of Evaporation
Unit Processes in Pharmacy Springer
How to Develop Robust Solid Oral Dosage Forms from Conception to Post-Approval uses a practical and hands-on approach to cover the development process of solid oral dosage forms in one single source. The book details all of the necessary steps from formulation through the post-approval phase and contains industry case studies, real world advice, and troubleshooting tips. By merging the latest scientific information with practical instructions, this book provides pharmaceutical scientists in formulation research and development with a concrete look at the key aspects in the development of solid oral dosage forms. Focuses on important topics, such as robustness, bioavailability, formulation design, continuous processing, stability tests, modified release dosage forms, international guidelines, process scale-up, and much more Part of the Expertise in Pharmaceutical Process Technology series edited by Michael Levin Discusses common, real-world problems and offers both theoretical and practical solutions to these everyday issues
Process Systems Engineering for Pharmaceutical Manufacturing CRC Press
Enables chemical engineering students to bridge theory andpractice Integrating scientific principles with practical engineeringexperience, this text enables readers to master the fundamentals ofchemical processing and apply their knowledge of such topics asmaterial and energy balances, transport phenomena, reactor design,and separations across a broad range of chemical industries. Theauthor skillfully guides readers step by step through the executionof both chemical process analysis and equipment design. Principles of Chemical Engineering Practice is dividedinto two sections: the Macroscopic View and the Microscopic View.The Macroscopic View examines equipment design and behavior fromthe vantage point of inlet and outlet conditions. The MicroscopicView is focused on the equipment interior resulting from conditionsprevailing at the equipment boundaries. As readers progress throughthe text, they'll learn to master such chemical engineeringoperations and equipment as: Separators to divide a mixture into parts with desirableconcentrations Reactors to produce chemicals with needed properties Pressure changers to create favorable equilibrium and rateconditions Temperature changers and heat exchangers to regulate and changethe temperature of process streams Throughout the book, the author sets forth examples that referto a detailed simulation of a process for the manufacture ofacrylic acid that provides a unifying thread for equipment sizingin context. The manufacture of hexyl glucoside provides a threadfor process design and synthesis. Presenting basic thermodynamics, Principles of ChemicalEngineering Practice enables students in chemical engineeringand related disciplines to master and apply the fundamentals and toproceed to more advanced studies in chemical engineering.
Pharmaceutical Process Engineering, Second Edition John Wiley & Sons
How to Design and Implement Powder-to-Tablet Continuous Manufacturing Systems provides a comprehensive overview on the considerations necessary for the design of continuous pharmaceutical manufacturing processes. The book covers both the theory and design of continuous processing of associated unit operations, along with their characterization and control. In addition, it discusses practical insights and strategies that the editor and chapter authors have learned. Chapters cover Process Analytical Technology (PAT) tools and the application of PAT data to enable distributed process control. With numerous case studies throughout, this valuable guide is ideal for

those engaged in, or learning about, continuous processing in pharmaceutical manufacturing. Discusses the development of strategy blueprints in the design of continuous processes Shows how to create process flowsheet models from individual unit operation models Includes a chapter on characterization methods for materials, the use of statistical methods to analyze material property data, and the use of material databases Covers the evolving regulatory expectations for continuous manufacturing Provides readers with ways to more effectively navigate these expectations

Pharmaceutical Engineering Elsevier

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

Practical Manual Of Pharmaceutical Engineering John Wiley & Sons

Suitable for practicing engineers and engineers in training, this book covers the most important operations involving particulate solids. Through clear explanations of theoretical principles and practical laboratory exercises, the text provides an understanding of the behavior of powders and pulverized systems. It also helps readers develop skills for operating, optimizing, and innovating particle processing technologies and machinery in order to carry out industrial operations. The author explores common bulk solids processing operations, including milling, agglomeration, fluidization, mixing, and solid-fluid separation.

Chemical Engineering in the Pharmaceutical Industry, Active Pharmaceutical Ingredients Pharmamed Press

Summarizing fundamental engineering principles and operations critical to converting bulk pharmaceutical products into patient-ready and appropriate drug delivery dosage forms, Pharmaceutical Process Engineering facilitates comprehensive understanding of the practical aspects of drug production in an accessible, step-by-step format. It provides a pharmaceutical perspective on unit operations that improves communication among diverse professionals in the field-from pharmaceutical researchers to chemical and industrial engineers-and fully covers the relationship of pharmaceutical development to the application of key concepts and major unit operations in pharmaceutical engineering.

Pharmaceutical Process Engineering John Wiley & Sons

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.

Handbook of Downstream Processing Butterworth-Heinemann

FASTtrack Pharmaceutics – Dosage Form and Design focuses on what you really need to know in order to pass your pharmacy exams. It provides concise, bulleted information, key points, tips and an all-important self-assessment section, including MCQs.

Code of Federal Regulations New Age International

This revised publication serves as a handy and current reference for professionals engaged in planning, designing, building, validating and maintaining modern cGMP pharmaceutical manufacturing facilities in the U.S. and internationally. The new edition expands on facility planning, with a focus on the ever-growing need to modify existing legacy facilities, and on current trends in pharmaceutical manufacturing which include strategies for sustainability and LEED building ratings. All chapters have been re-examined with a fresh outlook on current good design practices.

FASTtrack Pharmaceutics Dosage Form and Design, 2nd edition John Wiley & Sons

Chemical Engineering Design, Second Edition, deals with the application of chemical engineering principles to the design of chemical processes and equipment. Revised throughout, this edition has been specifically developed for the U.S. market. It provides the latest US codes and standards, including API, ASME and ISA design codes and ANSI standards. It contains new discussions of conceptual plant design, flowsheet development, and revamp design; extended coverage of capital cost estimation, process costing, and economics; and new chapters on equipment selection, reactor design, and solids handling processes. A rigorous pedagogy assists learning, with detailed worked examples, end of chapter exercises, plus supporting data, and Excel spreadsheet calculations, plus over 150 Patent References for downloading from the companion website. Extensive instructor resources, including 1170 lecture slides and a fully worked solutions manual are available to adopting instructors. This text is designed for chemical and biochemical engineering students (senior undergraduate year, plus appropriate for capstone design courses where taken, plus graduates) and lecturers/tutors, and professionals in industry (chemical process, biochemical, pharmaceutical, petrochemical sectors). New to this edition: Revised organization into Part I: Process Design, and Part II: Plant Design. The broad themes of Part I are flowsheet development, economic analysis, safety and environmental impact and optimization. Part II contains chapters on equipment design and selection that can be used as supplements to a lecture course or as essential references for students or practicing engineers working on design projects. New discussion of conceptual plant design, flowsheet development and revamp design Significantly increased coverage of capital cost estimation, process costing and economics New chapters on equipment selection, reactor design and solids handling processes New sections on fermentation, adsorption, membrane separations, ion exchange and chromatography Increased coverage of batch processing, food, pharmaceutical and biological processes All equipment chapters in Part II revised and updated with current information Updated throughout for latest US codes and standards, including API, ASME and ISA design codes and ANSI standards Additional worked examples and homework problems The most complete and up to date coverage of equipment selection 108 realistic commercial design projects from diverse industries A rigorous pedagogy assists learning, with detailed worked examples, end of chapter exercises, plus supporting data and Excel spreadsheet calculations plus over 150 Patent References, for downloading from the companion website Extensive instructor resources: 1170 lecture slides plus fully worked solutions manual available to adopting instructors

Chemical Engineering in the Pharmaceutical Industry Pharmaceutical Press

Continuous pharmaceutical manufacturing is currently receiving much interest from industry and regulatory authorities, with the joint aim of allowing rapid access of novel therapeutics and existing medications to the public, without compromising high quality. Research groups from different academic institutions have significantly contributed to this field with an immense amount of published research addressing a variety of topics related to continuous processing. The book is structured to have individual chapters on the different continuous unit operations involved in drug substance and drug product manufacturing. A wide spectrum of topics are covered, including basic principles of continuous manufacturing, applications of continuous flow chemistry in drug synthesis, continuous crystallization, continuous drying, feeders and blenders, roll compaction and continuous wet granulation.The underlying theme for each of these chapters is to present to the reader the recent advances in modeling, experimental investigations and equipment design as they pertain to each individual unit operation. The book also includes chapters on quality by design (QbD) and process analytical technology (PAT) for continuous processing, process control strategies including new concepts of quality-by-control (QbC), real-time process management and plant optimization, business and supply chain considerations related to continuous manufacturing as well as safety guidelines related to continuous chemistry. A separate chapter is dedicated to discussing regulatory aspects of continuous manufacturing, with description of current regulatory environment quality/GMP aspects, as well as regulatory gaps and challenges. Our aim from publishing this book is to make it a valuable reference for readers interested in this topic, with a desire to gain a fundamental understanding of engineering principles and mechanistic studies utilized in understanding and developing continuous processes. In addition, our advanced readers and practitioners in this field will find that the technical content of Continuous Pharmaceutical Processing is at the forefront of recent technological advances, with coverage of future prospects and challenges for this technology.

Scientific and Technical Terms in Bioengineering and Biological Engineering CRC Press

With step-by-step methods of drug production and knowledge of major unit operations and key concepts of pharmaceutical engineering, this guide will help to improve communication among the varied professionals working in the pharmaceutical industry. Key features: REVISION OF A BESTSELLER - Updates include recent advances in the field to keep pharmaceutical scientists and technologists up-to-date IDEAL INTRODUCTORY TEXT - Covers basic engineering principles, drug production, and development processes, so scientists can easily convert bulk pharmaceutical products into patient-ready dosage forms NEW INFORMATION - on quality principles that include quality by design; mathematical and statistical approaches to experimental design; computer aided design; and PAT (process analytical technology) keeps professionals at the forefront of their field COMPREHENSIVE COVERAGE - Step-by-step methods of drug production, knowledge of major unit operations, and key concepts of pharmaceutical engineering will help to improve communication among the varied professionals working in the pharmaceutical industry