Chemical Engineering In The Pharmaceutical Industry

P. J. Cullen,Rodolfo J. Romañach,Nicolas Abatzoglou,Chris D. Rielly

Chemical Engineering in the Pharmaceutical Industry Mary T. am Ende,David J. am Ende,2019-04-08 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.

Chemical Engineering in the Pharmaceutical Industry David J. am Ende,Mary T. am Ende,2019-04-23 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 Industryf ocuses on the development and chemical engineering as well as operations specific to the design, formulation, and manufacture of drug substance and products.

Chemical Engineering in the Pharmaceutical Industry David J. am Ende,2011-03-10 This book deals with various unique elements in the drug development process within chemical engineering science and pharmaceutical R&D. The book is intended to be used as a professional reference and potentially as a text book reference in pharmaceutical engineering and pharmaceutical sciences. Many of the experimental methods related to pharmaceutical process development are learned on the job. This book is intended to provide many of those important concepts that R&D Engineers and manufacturing Engineers should know and be familiar if they are going to be successful in the Pharmaceutical Industry. These include basic analytics for quantitation of reaction components– often skipped in ChE Reaction Engineering and kinetics books. In addition Chemical Engineering in the Pharmaceutical Industry introduces contemporary methods of data analysis for kinetic modeling and extends these concepts into Quality by Design strategies for regulatory filings. For the current professionals, in-silico process modeling tools that streamline experimental screening approaches is also new and presented here. Continuous flow processing, although mainstream for ChE, is unique in this context given the range of scales and the complex economics associated 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 techniques for engineers, thermodynamic modeling, and finally provides an appendix with common engineering tools and examples of their applications.

Chemical Engineering in the Pharmaceutical Industry David J. am Ende,Mary T. am Ende,2019-03-28 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 Industryf ocuses on the development and chemical engineering as well as operations specific to the design, formulation, and manufacture of drug substance and products.

Pharmaceutical Process Development John Blacker,Michael T Williams,2011-08-17 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.

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Chemical Engineering Design Gavin Towler,Ray Sinnott,2012-01-25 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

Practical Pharmaceutical Engineering Gary Prager,2018-12-18 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.

Process Systems Engineering for Pharmaceutical Manufacturing Ravendra Singh,Zhihong Yuan,2018-03-16 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

The Chemical and Pharmaceutical Industry in China G. Festel,A. Kreimeyer,U. Oels,Maximilian von Zedtwitz,2005-12-05 A detailed examination of China’s increasingly important chemical and pharmaceutical industry. Numerous case studies describe how western companies, such as BASF, Bayer, Bicoll, Ciba, Degussa, DSM and Novartis are managing their market entry in China.

Design & Development of Biological, Chemical, Food and Pharmaceutical Products Johannes A. Wesselingh,Soren Kiil,Martin E. Vigild,2007-09-27 Design and Development of Biological, Chemical, Food and Pharmaceutical Products has been developed from course material from the authors’ course in Chemical and Biochemical Product Design which has been running at the Technical University Denmark for years. The book draws on the authors’ years of experience in academia and industry to provide an accessible introduction to this field, approaching product development as a subject in its own right rather than a sideline of process engineering In this subject area, practical experience is the key to learning and this textbook provides examples and techniques to help the student get the best out of their projects. Design and Development of Biological, Chemical, Food and Pharma Products aims to aid students in developing good working habits for product development. Students are challenged with examples of real problems that they might encounter as engineers. Written in an informal, student-friendly tone, this unique book includes examples of real products and experiences from real companies to bring the subject alive for the student as well as placing emphasis on problem solving and team learning to set a foundation for a future in industry. The book includes an introduction to the subject of Colloid Science, which is important in product development, but neglected in many curricula. Knowledge of engineering calculus and basic physical chemistry as well as basic inorganic and organic chemistry are assumed. An invaluable text for students of product design in chemical engineering, biochemistry, biotechnology, pharmaceutical sciences and product development. Uses many examples and case

studies drawn from a range of industries. Approaches product development as a subject in its own right rather than a sideline of process engineering Emphasizes a problem solving and team learning approach. Assumes some knowledge of calculus, basic physical chemistry and basic transport phenomena as well as some inorganic and organic chemistry.

Process Chemistry in the Pharmaceutical Industry, Volume 2 Kumar Gadamasetti,Tamim Braish,2007-12-10 As pharmaceutical companies strive to develop safer medicines at a lower cost, they must keep pace with the rapid growth of technology and research methodologies. Defying the misconception of process chemistry as mere scale-up work, Process Chemistry in the Pharmaceutical Industry, Vol. 2: Challenges in an Ever Changing Climate explor

Principles of Process Research and Chemical Development in the Pharmaceutical Industry Oljan Repic,1998 Dr. Oljan Repic clearly explains the goals and basic principles of chemical development. He explores the crucial aspects of a new process that must be considered when scaling up a research synthesis to industrial levels. And, with the help of many case studies and vignettes, he delineates each phase of the development process. Key topics include qualities of an ideal process, techniques for minimizing impurities, criteria for cost-effective synthesis of enantiopure compounds by resolutions, asymmetric synthesis and the chiral pool strategy, synthesis for labeling substances with hydrogen or carbon isotopes, and new drug registration requirements. This book is an invaluable reference for professionals as well as an important source of guidance and inspiration for young chemists considering entering the field.

Rules of Thumb for Chemical Engineers Carl Branan,2002 Fractionators, separators and accumulators, cooling towers, gas treating, blending, troubleshooting field cases, gas solubility, and density of irregular solids * Hundreds of common sense techniques, shortcuts, and calculations.

Green Sustainable Process for Chemical and Environmental Engineering and Science Rajender Boddula,Abdullah M. Asiri,2021-11-17 Green Sustainable Process for Chemical and Environmental Engineering and Science: Switchable Solvents explores the preparation, properties, chemical processes and applications of this class of green solvents. The book provides an in-depth overview on the area of switchable solvents in various industrial applications, focusing on the purification and extraction of chemical compounds utilizing green chemistry protocols that include liquid-liquid, solid-liquid, liquid-gas and lipids separation technologies. In addition, it includes recent advances in greener extraction and separation processes. This book will be an invaluable guide to students, professors, scientists and R&D industrial specialists working in the field of sustainable chemistry, organic, analytical, chemical engineering, environmental and pharmaceutical sciences. - Provides a broad overview of switchable solvents in sustainable chemical processes - Compares the use of switchable solvents as greener solvents over conventional solvents - Outlines eco-friendly organic synthesis and chemical processes using switchable solvents - Lists various industrial separations/extraction processes using switchable solvents

Scalable Green Chemistry Stefan Koenig,2013-09-11 Packed with real-world examples, this book illustrates the 12

principles of green chemistry. These diverse case studies demonstrate to scientists and students that beyond the theory, the challenges of green chemistry in pharmaceutical discovery and development remain an ongoing endeavor. By informing and welcoming additional practitioners to this m

Pharmaceutical Production Bill Bennett,Graham Cole,2003 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.

Chemical Engineering in the Pharmaceutical Industry Mary T. am Ende,David J. am Ende,2019-04-09 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 Chemistry in the Pharmaceutical Industry Kumar Gadamasetti,1999-05-06 Providing guidance for chemists and other scientists entering pharmaceutical discovery and development, this up-to-the-minute reference presents contributions from an international group of nearly 50 renowned researchers—offering a solid grounding in synthetic and physical organic chemistry, and clarifying the roles of various specialties in the development of new drugs. Featuring over 1000 references, tables, and illustrations, Process Chemistry in the Pharmaceutical Industry is sure to find its way to the

bookshelves of organic, physical, analytical, process, and medicinal chemists and biochemists; pharmacists; and upper-level undergraduate and graduate students in these disciplines.

Pharmaceutical Blending and Mixing P. J. Cullen,Rodolfo J. Romañach,Nicolas Abatzoglou,Chris D. Rielly,2015-07-20 Written in four parts, this book provides a dedicated and in-depth reference for blending within the pharmaceutical manufacturing industry. It links the science of blending with regulatory requirements associated with pharmaceutical manufacture. The contributors are a combination of leading academic and industrial experts, who provide an informed and industrially relevant perspective of the topic. This is an essential book for the pharmaceutical manufacturing industry, and related academic researchers in pharmaceutical science and chemical and mechanical engineering.

Enjoying the Beat of Phrase: An Psychological Symphony within **Chemical Engineering In The Pharmaceutical Industry**

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