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Practical Pharmaceutical Engineering **Chemical Engineering in the Pharmaceutical Industry** **Pharmaceutical Production** **The Greening of Pharmaceutical Engineering, Theories and Solutions** **Pharmaceutical Process Engineering** **Pharmaceutical Engineering** Chemical Engineering in the Pharmaceutical Industry *Chemical Engineering in the Pharmaceutical Industry* **Chemical Engineering in the Pharmaceutical Industry** Process Systems Engineering for Pharmaceutical Manufacturing **Sterile Pharmaceutical Products** **Pharmaceutical Process Development** The Greening of Pharmaceutical Engineering, Practice, Analysis, and Methodology **Pharmaceutical Process Development** **Packaging Technology and Engineering** **Pharmaceutical Engineering Change Control** **Pharmaceutical Engineering** The Greening of Pharmaceutical Engineering, Applications for Mental Disorder Treatments **Essentials of Pharmaceutical Engineering** Chemical Engineering in the Pharmaceutical Industry Oral Controlled Release Formulation Design and Drug Delivery **Engineering Drug Delivery Systems** *Pharmaceutical Crystals Therapeutic Antibody Engineering* Quality **Pharmaceutical Manufacturing Handbook** The Greening of Pharmaceutical Engineering *Introduction to Pharmacuetical Engineering* **Sterile Processing of Pharmaceutical Products** **Pharmaceutical Engineering Drawing** Pharmaceutical Engineering Change Control **Comprehensive Quality by Design for Pharmaceutical Product Development and Manufacture** **Principles of Pharmaceutical Engineering** Continuous Manufacturing for the Modernization of Pharmaceutical Production **Engineering of Biomaterials for Drug Delivery Systems** **Pharmaceutical Engineering (English Edition)** **Design of Controlled Release Drug Delivery Systems** **Engineering Polymer Systems for Improved Drug Delivery** **Pharmaceutical Engineering** **Fermentation and Biochemical Engineering Handbook, 2nd Ed.**

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The goal of every drug delivery system is to deliver the precise amount of a drug at a pre-programmed rate to the desired location in order to achieve the drug level necessary for the treatment. An essential guide for biomedical engineers and pharmaceutical designers, this resource combines physicochemical principles with physiological processes to facilitate the design of systems that will deliver medication at the time and place it is most needed. This book mainly aims in guiding the teachers and students, the fundamental principles of Pharmaceutical Engineering. This book helps the students in overcoming the obstacles faced by them in understanding the aspects of Pharmaceutical Engineering. Topics, which usually confuse the students, are explained along with applications to broaden their mental horizon regarding the subject. This book is meant to serve as an introductory text for undergraduate students doing Bachelor of Pharmaceutical Sciences (B. Pharm). It will also prove useful to people working in pharmaceutical and allied industries. In keeping with its initiatory approach to pharmaceutical engineering, only the important aspects of the subject have been discussed in a simple and easily comprehensible manner. 1 Mass transfer 2 Drying 3 Heat transfer 4 Evaporation 5 Crystallization 6 Flow of fluids 7 Distillation 8 Corrosion Introduction - Flow of Fluids - Heat Transfer - Mass Transfer - Size Reduction - Size Separation - Filtration - Mixing - Extraction - Crystallization - Evaporation - Drying - Distillation - Pumps - Transportation of Solids - Corrosion - Fire Hazards - Pollution From Pharmaceutical Industry - Conversion Tables - Index 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. The subject matter of this book covers the entire syllabus of pharmaceutical engineering drawing courses. It discusses lettering, lines and dimensioning, sheet layout, symbols of materials, free hand sketching, construction of scales, geometrical drawing, principles of projection, first angle and third angle methods of projection, isometric views, sectional views, nuts and bolts, valves, pipe joints, rivets and riveted joints, assembly drawings, and flow diagrams. Covers a widespread view of Quality by Design (QbD) encompassing the many stages involved in the development of a new drug product. The book provides a broad view of Quality by Design (QbD) and shows how QbD concepts and analysis facilitate the development and manufacture of high quality products. QbD is seen as a framework for building process understanding, for implementing robust and effective manufacturing processes and provides the underpinnings for a science-based regulation of the pharmaceutical industry. Edited by the three renowned researchers in the field, Comprehensive Quality by Design for Pharmaceutical Product Development and Manufacture guides pharmaceutical engineers and scientists involved in product and process development, as well as teachers, on how to utilize QbD practices and applications effectively while complying with government regulations. The material is divided into three main sections: the first six chapters address the role of key technologies, including process modeling, process analytical technology, automated process control and statistical methodology in supporting QbD and establishing the associated design space. The second section consisting of seven chapters present a range of thoroughly developed case studies in which the tools and methodologies discussed in the first section are used to support specific drug substance and drug-product QbD related developments. The last section discussed the needs for integrated tools and reviews the status of information technology tools available for systematic data and knowledge management to support QbD and related activities. Highlights Demonstrates Quality by Design (QbD) concepts through concrete detailed industrial case studies involving of the use of best practices and assessment of regulatory implications Chapters are devoted to applications of QbD methodology in three main processing sectors—drug substance process development, oral drug product manufacture, parenteral product processing, and solid-liquid processing Reviews the spectrum of process model types and their relevance, the range of state-of-the-art real-time monitoring tools and chemometrics, and alternative automatic process control strategies and methods for both batch and continuous processes The role of the design space is demonstrated through specific examples and the importance of understanding the risk management aspects of design space definition is highlighted Comprehensive Quality by Design for Pharmaceutical Product Development and Manufacture is an ideal book for practitioners, researchers, and graduate students involved in the development, research, or studying of a new drug and its associated manufacturing process. This is a well-rounded handbook of fermentation and biochemical engineering presenting techniques for the commercial production of chemicals and pharmaceuticals via fermentation. Emphasis is given to unit operations fermentation, separation, purification, and recovery. Principles, process design, and equipment are detailed. Environment aspects are covered. The practical aspects of development, design, and operation are stressed. Theory is included to provide the necessary insight for a particular operation. Problems addressed are the collection of pilot data, choice of scale-up parameters, selection of the right piece of equipment, pinpointing of likely trouble spots, and methods of troubleshooting. The text, written from a practical and operating viewpoint, will assist development, design, engineering and production personnel in the fermentation industry. Contributors were selected based on their industrial background and orientation. The book is illustrated with numerous figures, photographs and schematic diagrams. With pharmaceutical engineering growing in importance in all areas of drug development, new opportunities for engineers open in the pharmaceutical industry. This book provides engineers with a much-needed introduction to the field, reviewing the entire drug's life cycle, from discovery through clinical trials and on to pharmacovigilance. It explains the forms and delivery systems used in administration, technologies and equipment used in manufacturing, and issues involving regulatory approval, testing, and safety. The basics of human physiology and anatomy, microbiology, and sanitary design are also covered. Engineering Drug Delivery Systems is an essential resource on a variety of biomaterials engineering approaches for creating drug delivery systems that have market and therapeutic potential. The book comprehensively discusses recent advances in the fields of biomaterials and biomedical sciences in relation to drug delivery. Chapters provide a detailed introduction to various engineering approaches in designing drug delivery systems, delve into the engineering of body functions, cover the selection, design and evaluation of biomaterials, and discuss the engineering of colloids as drug carriers. The book's final chapters address the engineering of implantable drug delivery systems and advances in drug delivery technology. This book is an invaluable resource for drug delivery, materials scientists and bioengineers within the pharmaceutical industry. Examines the properties and synthesis of biomaterials for successful drug delivery Discusses the important connection between drug delivery and tissue engineering Includes techniques and approaches applicable to a wide range of users Reviews innovative technologies in drug delivery systems such as 3-D printed devices for drug delivery 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. 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. 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. This is the second volume in a four-volume series aimed at guiding the pharmaceutical industry toward sustainability. After analyzing and exposing some of the backward and ill-conceived notions that guide the present state of the industry, this volume presents key theories and new, groundbreaking solutions for re-thinking the processes involved in the engineering of pharmaceuticals and offers a fundamental paradigm shift. The 4 volumes in this ambitious project 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. 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 This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear. 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 pharmac Written especially for the pharmaceutical industry professional, this book addresses each part of the life-cycle of engineering change control. It covers issues in the EU and US and describes the operational requirements and responsibilities that ensure change controls are effectively applied and recorded. Providing guidance on how to demonstrate that a change control system is working, the book includes chapters on computer validation, customization of the change process to each project's needs, and case histories and anecdotes illustrate key points and provide a basis for change control training. It gives readers

a toolbox for ensuring that adequate controls are implemented. This book is aimed at both graduates and postgraduates interested in a career in the pharmaceutical industry by informing them about the breadth of the work carried out in chemical research and development departments. It is also of great value to academics wishing to advise students on the merits of careers in chemical development over discovery. This book describes the theories, applications, and challenges for different oral controlled release formulations. This book differs from most in its focus on oral controlled release formulation design and process development. It also covers the related areas like preformulation, biopharmaceutics, in vitro-in vivo correlations (IVIVC), quality by design (QbD), and regulatory issues. Polymers have played a critical role in the rational design and application of drug delivery systems that increase the efficacy and reduce the toxicity of new and conventional therapeutics. Beginning with an introduction to the fundamentals of drug delivery, Engineering Polymer Systems for Improved Drug Delivery explores traditional drug delivery techniques as well as emerging advanced drug delivery techniques. By reviewing many types of polymeric drug delivery systems, and including key points, worked examples and homework problems, this book will serve as a guide to for specialists and non-specialists as well as a graduate level text for drug delivery courses. Covers chemistry, physics, engineering, and therapeutic aspects of packaging—universal to pharmaceutical, medical, and food applications This book covers the chemistry, physics, materials science, engineering, and therapeutic aspects of many different types of packaging materials, emphasizing throughout the applicability of various aspects of packaging science and technology. It also provides a simultaneous discussion of interrelated fields, and addresses the universal issues within these fields' application areas. Intended as a technical reference and as a study aid, it is relevant to anyone who studies or uses packaging or packaging materials. Packaging Technology and Engineering: Pharmaceutical, Medical and Food Applications begins with an overview of the history of the topic. It then offers chapters on the methods of obtaining raw materials, the chemistry of polymeric and non-polymeric packaging materials, physico-chemical quality parameters, and the manufacturing of packaging. Other topics look at: additives, use, suppliers, safety and environmental concerns, regulation, anti-fraud activities, new trends, and the future of packaging technology. The book also features numerous problems and worked solutions to aid student comprehension. Covers packaging and packaging materials, their properties and technologies Addresses the chemical engineering, physics, and chemistry of packaging materials, and the individual requirements for food, pharmaceutical, and medical device packaging Includes current issues such as environmental concerns and sustainability, recycling and after-use, anti-counterfeiting technology, and packaging regulations and guidelines Packaging Technology and Engineering: Pharmaceutical, Medical and Food Applications will appeal to all packaging technologists, scientists, and engineers in industry, and in regulatory agencies. It is also an excellent book for advanced students studying packaging courses, within pharmacy, pharmaceutical sciences, chemical sciences, biomedical sciences, medical sciences, engineering, product design and technology, and food science/technology. Sterile Pharmaceutical Products: Process Engineering Applications addresses the key concepts and applications of the sterile pharmaceutical manufacturing industry. It covers elements of the design, installation, validation, and usage of critical processes associated with sterile product manufacture. From water systems to clean-in-place systems, to sterile powder handling and robotic applications in sterile production environments, this book addresses the issues of system implementation, integration, and operations. Written by recognized experts and peer reviewed for accuracy, all chapters include references to supplemental resources and numerous illustrations. It Is Well Known That The Applications Of Unit Operations Like Heat Transfer, Evaporation, Extraction, Mixing, Filtration And A Host Of Others Are Quite Common In The Pharmaceutical Industry, Be It In The Production Of Synthetic Drugs, Biological And Microbiological Products Or In The Manufacture Of Pharmaceutical Formulations. As Such Anyone Who Is To Look After These Manufacturing Operations Must Be Quite Knowledgeable With The Theoretical And Equipment Aspects Involved In The Relevant Unit Operations.Since A Major Involvement Of The Pharmacy Graduates Lies In The Numerous Manufacturing Operations Mentioned Above, It Is Very Much Necessary That The Subject Is Taught With A Pharmacy Orientation. There Is No Book So Far Which Has Achieved This. The Existing Books On Unit Operations Give Extensive Theory And Also Deal With A Lot Of Equipment Not Employed In The Pharmaceutical Industry. Due To A Lack Of A Pharmacy-Oriented Book In This Area, The Students And The Teachers Are Facing Difficulties In Many Ways.The Present Book Is The First One Of Its Kind On Pharmaceutical Engineering. The Special Features Of This Book Are As Follows: It Includes Theoretical And Equipment Aspects Relevant To Thepharmaceutical Industry And That Too To The Extent Needed For Pharmacy Graduates And Examples From Pharmaceutical Industry Are Quoted Extensively; Solutions To A Number Of Simpler Numerical Problems Are Given. At The End Of Each Chapter, A Large Number Of Questions, Both Theoretical And Numerical, Are Given. There Is Therefore No Doubt That The Book Will Be Of Great Use Not Only To The Students But Also To The Teachers In The Subject In India And Abroad As Well. Describes the methodologies and best practices of the sterile manufacture of drug products Thoroughly trained personnel and carefully designed, operated, and maintained facilities and equipment are vital for the sterile manufacture of medicinal products using aseptic processing. Professionals in pharmaceutical and biopharmaceutical manufacturing facilities must have a clear understanding of current good manufacturing practice (cGMP) and preapproval inspection (PAI) requirements. Sterile Processing of Pharmaceutical Products: Engineering Practice, Validation, and Compliance in Regulated Environments provides up-to-date coverage of aseptic processing techniques and sterilization methods. Written by a recognized expert with more than 20 years of industry experience in aseptic manufacturing, this practical resource illustrates a comprehensive approach to sterile manufacturing engineering that can achieve drug manufacturing objectives and goals. Topics include sanitary piping and equipment, cleaning and manufacturing process validation, computerized automated systems, personal protective equipment (PPE), clean-in-place (CIP) systems, barriers and isolators, and guidelines for statistical procedure. Offering authoritative guidance on the key aspects of sterile manufacturing engineering, this volume: Covers fundamentals of aseptic techniques, quality by design, risk assessment and management, and operational requirements Addresses various regulations and guidelines instituted by the FDA, ISPE, EMA, MHRA, and ICH Provides techniques for systematic process optimization and good manufacturing practice Emphasizes the importance of attention to detail in process development and validation Features real-world examples highlighting different aspects of drug manufacturing Sterile Processing of Pharmaceutical Products: Engineering Practice, Validation, and Compliance in Regulated Environments is an indispensable reference and guide for all chemists, chemical engineers, pharmaceutical professionals and engineers, and other professionals working in pharmaceutical sciences and manufacturing. On July 30-31, 2018, the National Academies of Sciences, Engineering, and Medicine held a workshop titled Continuous Manufacturing for the Modernization of Pharmaceutical Production. This workshop discussed the business and regulatory concerns associated with adopting continuous

manufacturing techniques to produce biologics such as enzymes, monoclonal antibodies, and vaccines. The participants also discussed specific challenges for integration across the manufacturing system, including upstream and downstream processes, analytical techniques, and drug product development. The workshop addressed these challenges broadly across the biologics domain but focused particularly on drug categories of greatest FDA and industrial interest such as monoclonal antibodies and vaccines. This publication summarizes the presentations and discussions from the workshop. 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 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. Buy E-Book of Pharmaceutical Engineering (English Edition) Book For B. Pharm 3rd Semester of U.P. State Universities An important resource that puts the focus on understanding and handling of organic crystals in drug development Since a majority of pharmaceutical solid-state materials are organic crystals, their handling and processing are critical aspects of drug development. Pharmaceutical Crystals: Science and Engineering offers an introduction to and thorough coverage of organic crystals, and explores the essential role they play in drug development and manufacturing. Written contributions from leading researchers and practitioners in the field, this vital resource provides the fundamental knowledge and explains the connection between pharmaceutically relevant properties and the structure of a crystal. Comprehensive in scope, the text covers a range of topics including: crystallization, molecular interactions, polymorphism, analytical methods, processing, and chemical stability. The authors clearly show how to find solutions for pharmaceutical form selection and crystallization processes. Designed to be an accessible guide, this book represents a valuable resource for improving the drug development process of small drug molecules. This important text: Includes the most important aspects of solid-state organic chemistry and its role in drug development Offers solutions for pharmaceutical form selection and crystallization processes Contains a balance between the scientific fundamental and pharmaceutical applications Presents coverage of crystallography, molecular interactions, polymorphism, analytical methods, processing, and chemical stability Written for both practicing pharmaceutical scientists, engineers, and senior undergraduate and graduate students studying pharmaceutical solid-state materials, Pharmaceutical Crystals: Science and Engineering is a reference and textbook for understanding, producing, analyzing, and designing organic crystals which is an imperative skill to master for anyone working in the field. Written especially for the pharmaceutical industry professional, this book addresses each part of the life-cycle of engineering change control. It covers issues in the EU and US and describes the operational requirements and responsibilities that ensure change controls are effectively applied and recorded. Providing guidance on how to demonstrate that a change control system is working, the book includes chapters on computer validation, customization of the change process to each project's needs, and case histories and anecdotes illustrate key points and provide a basis for change control training. It gives readers a toolbox for ensuring that adequate controls are implemented. 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

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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. Engineering of Biomaterials for Drug Delivery Systems: Beyond Polyethylene Glycol examines the combined issues of PEGylation and viable biomaterials as alternatives. With a strong focus on polymeric biomaterials, the book first reviews the major issues associated with PEGylation and its use in vivo. Chapters then focus on alternative polymer systems for drug delivery systems. Finally, nanoparticles and future perspectives are examined. This book is a valuable resource for scientists and researchers in biomaterials, pharmaceuticals and nanotechnology, and all those who wish to broaden their knowledge in this field. Provides a self-contained work for the field of biomaterials for drug delivery Summarizes the current knowledge on PEGylation and strategies for bypassing it Presents research on an important, though under-represented issue in biomaterials Written by a world-class team of research scientists, engineers and clinicians 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. Quality, second edition, provides comprehensive application of regulatory guidelines and quality concepts and methodologies related to pharmaceutical manufacturing. It is an excellent resource for practitioners, those pursuing pharmaceutical related certifications, and for students trying to learn more about pharmaceutical manufacturing. This book provides the background theory, applied descriptions of the guidelines and concepts, plus questions and problems at the end of the chapters that will help provide practice for the reader to apply the concepts. In this book the authors share their combined 60+ years of extensive practical experience in the industry and in process improvement combined with detailed understanding of the needs of the industry and education system. This book provides real-life examples from industry and guidelines for practical application of tools that can be referenced by operators, engineers, and management.This book is fully revised, updated, and expanded with new content in areas such as QbD, Lean, Six Sigma, basic data analysis, and CAPA tools. Fully revised, updated, and expanded new edition Features new topics such as QbD, Lean, Six Sigma, basic data analysis, and CAPA tools Includes end-of-chapter summaries and end-of-chapter question and/or problems Provides detailed steps and examples for applying the guidelines and quality tools Written in an accessible style making the content easy to understand and apply The field of antibody engineering has become a vital and integral part of making new, improved next generation therapeutic monoclonal antibodies, of which there are currently more than 300 in clinical trials across several therapeutic areas. Therapeutic antibody engineering examines all aspects of engineering monoclonal antibodies and analyses the effect that various genetic engineering approaches will have on future candidates. Chapters in the first part of the book provide an introduction to monoclonal antibodies, their discovery and development and the fundamental technologies used in their production. Following chapters cover a number of specific issues relating to different aspects of antibody engineering, including variable chain engineering, targets and mechanisms of action, classes of antibody and the use of antibody fragments, among many other topics. The last part of the book examines development issues, the interaction of human IgGs with non-human systems, and cell line development, before a conclusion looking at future issues affecting the field of therapeutic antibody engineering. Goes beyond the standard engineering issues covered by most books and delves into structure-function relationships Integration of knowledge across all areas of antibody engineering, development, and marketing Discusses how current and future genetic engineering of cell lines will pave the way for much higher productivity 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.