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Pharmaceutical Quality by Design Current Pharmaceutical Design Current Pharmaceutical Design Current Pharmaceutical Design Current Pharmaceutical Design Green and Sustainable Medicinal Chemistry Adaptive Design Theory and Implementation Using SAS and R Chemical Engineering in the Pharmaceutical Industry Current Pharmaceutical Design Current Pharmaceutical Design Pharmaceutical Formulation How to Validate a Pharmaceutical Process Pharmaceutical and Medical Device Validation by Experimental Design Current Pharmaceutical Design The Design and Development of Novel Drugs and Vaccines Current Pharmaceutical Design Current Pharmaceutical Design Current Pharmaceutical Design Adhesion in Pharmaceutical, Biomedical, and Dental Fields Medicinal Chemistry for the 21st Century Current Pharmaceutical Design Current Pharmaceutical Design Recent Advances in Novel Drug Carrier Systems Steric Effects in Drug Design Pharmaceutical Inhalation Aerosol Technology, Third Edition Neuroethical Policy Design Pharmaceutical Experimental Design Practical Pharmaceutical Engineering Current Pharmaceutical Design Current Pharmaceutical Design Statistics In the Pharmaceutical Industry Handbook of Pharmaceutical Salts Properties, Selection, and Use Pharmaceutical Chemistry- VI Controlled Drug Delivery Systems The Nanotechnology Revolution Pharmaceutical Dosage Forms Good Design Practices for GMP Pharmaceutical Facilities Analytical Scientists in Pharmaceutical Product Development Pharmaceutical Process Design and Management

Pharmaceutical manufacturing was one of the first industries to recognize the importance of green chemistry, with pioneering work including green chemistry metrics and alternative solvents and reagents. Today, other topical factors also have to be taken into consideration, such as rapidly depleting resources, high energy costs and new legislation. This book addresses current challenges in modern green chemical technologies and sustainability thinking. It encompasses a broad range of topics covered by the CHEM21 project – Europe's largest public-private partnership project which aims to develop a toolbox of sustainable technologies for green chemical intermediate manufacture. Divided into two sections, the book first gives an overview of the key green chemistry tools, guidance and considerations aimed at developing greener processes, before moving on to look at cutting-edge synthetic methodologies. Featuring innovative research, this book is an invaluable reference for chemists across academia and industry wanting to further their knowledge and understanding of this important topic. This book will describe current research on drug delivery systems that encompass four broad categories, namely: routes of delivery, delivery vehicles, payload, and targeting strategies. Where appropriate delivery vehicles and relevant release of specific agents in any of these categories in clinical application

will be discussed. All chapters will highlight the translational aspects of the various technologies discussed and will provide insights into the advantages of such delivery systems over current ones in clinical or research use. Each technology reviewed in this book will have significant potential to improve patients' lives by enhancing the therapeutic efficacy of drugs. This book: Discusses the various factors that mitigate effective oral insulin delivery and the current status of research efforts to overcome these barriers along with recent clinical projections Examines the advantages and disadvantages of each drug delivery system Examines the standard method of accomplishing controlled drug release through the incorporation of the drugs within polymeric biomaterials such as capsules and microcapsules as well as other vehicles such as liposomes Discusses various controlled drug delivery systems, including sustained release delivery systems and pulse or delayed release, e.g. to target different regions of the gastrointestinal tract. In view of these wide-ranging technological areas, and the up-to-date discussions of opportunities and challenges associated with these applications, the book should provide readers from technology, materials science, pharmacology and clinical disciplines with very valuable information. The phenomenon of adhesion is of cardinal importance in the pharmaceutical, biomedical and dental fields. A few eclectic examples will suffice to underscore the importance/relevance of adhesion in these three areas. For example, the adhesion between powdered solids is of crucial importance in tablet manufacture. The interaction between biodevices (e.g., stents, bio-implants) and body environment dictates the performance of such devices, and there is burgeoning research activity in modifying the surfaces of such implements to render them compatible with bodily components. In the field of dentistry, the modern trend is to shift from retaining of restorative materials by mechanical interlocking to adhesive bonding. This unique book addresses all these three areas in an easily accessible single source. The book contains 15 chapters written by leading experts and is divided into four parts: General Topics; Adhesion in Pharmaceutical Field; Adhesion in Biomedical Field; and Adhesion in Dental Field. The topics covered include: - Theories or mechanisms of adhesion. - Wettability of powders. - Role of surface free energy in tablet strength and powder flow behavior. - Mucoadhesive polymers for drug delivery systems. - Transdermal patches. - Skin adhesion in long-wear cosmetics. - Factors affecting microbial adhesion. - Biofouling and ways to mitigate it. - Adhesion of coatings on surgical tools and bio-implants. - Adhesion in fabrication of microarrays in clinical diagnostics. - Antibacterial polymers for dental adhesives and composites. - Evolution of dental adhesives. - Testing of dental adhesives joints. This comprehensive up-to-date guide and information source is an instructive companion for all scientists involved in research and development of drugs and, in particular, of pharmaceutical dosage forms. The editors have taken care to address every conceivable aspect of the preparation of pharmaceutical salts and present the necessary theoretical foundations as well as a wealth of detailed practical experience in the choice of pharmaceutically active salts. Altogether, the contributions reflect the multidisciplinary nature of the science involved in selection of suitable salt forms for new drug products. Pharmaceutical Quality by Design: Principles and Applications discusses the

Quality by Design (QbD) concept implemented by regulatory agencies to ensure the development of a consistent and high-quality pharmaceutical product that safely provides the maximum therapeutic benefit to patients. The book walks readers through the QbD framework by covering the fundamental principles of QbD, the current regulatory requirements, and the applications of QbD at various stages of pharmaceutical product development, including drug substance and excipient development, analytical development, formulation development, dissolution testing, manufacturing, stability studies, bioequivalence testing, risk and assessment, and clinical trials. Contributions from global leaders in QbD provide specific insight in its application in a diversity of pharmaceutical products, including nanopharmaceuticals, biopharmaceuticals, and vaccines. The inclusion of illustrations, practical examples, and case studies makes this book a useful reference guide to pharmaceutical scientists and researchers who are engaged in the formulation of various delivery systems and the analysis of pharmaceutical product development and drug manufacturing process. Discusses vital QbD precepts and fundamental aspects of QbD implementation in the pharma, biopharma and biotechnology industries Provides helpful illustrations, practical examples and research case studies to explain QbD concepts to readers Includes contributions from global leaders and experts from academia, industry and regulatory agencies How to Validate a Pharmaceutical Process provides a "how to approach to developing and implementing a sustainable pharmaceutical process validation program. The latest volume in the Expertise in Pharmaceutical Process Technology Series, this book illustrates the methods and reasoning behind processes and protocols. It also addresses practical problems and offers solutions to qualify and validate a pharmaceutical process. Understanding the "why is critical to a successful and defensible process validation, making this book an essential research companion for all practitioners engaged in pharmaceutical process validation. Thoroughly referenced and based on the latest research and literature Illustrates the most common issues related to developing and implementing a sustainable process validation program and provides examples on how to be successful Covers important topics such as the lifecycle approach, quality by design, risk assessment, critical process parameters, US and international regulatory guidelines, and more This fully revised and updated third edition of Pharmaceutical Inhalation Aerosol Technology encompasses the scientific and technical foundation for the rationale, design, componentry, assembly and quality performance metrics of therapeutic inhalers in their delivery of pharmaceutical aerosols to treat symptoms or the underlying causes of disease. It focuses on the importance of pharmaceutical engineering as a foundational element of all inhaler products and their application to pulmonary drug delivery. The expanded scope considers previously unaddressed aspects of pharmaceutical inhalation aerosol technology and the patient interface by including aerosol delivery, lung deposition and clearance that are used as measures of effective dose delivery. Key Features: Provides a thoroughly revised and expanded reference with authoritative discussions on the physiologic,pharmacologic, metabolic, molecular, cellular and physicochemical factors, influencing the efficacy and utilization of pharmaceutical aerosols Emphasizes the importance of pharmaceutical

engineering as a foundational element of all inhaler products and their application to pulmonary drug delivery Addresses the physics, chemistry and engineering principles while establishing disease relevance Expands the 'technology' focus of the original volumes to address the title more directly Offers an impressive breadth of coverage as well as an international flavour from outstanding editors and contributors 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 title demonstrates how designed experiments are the most scientific, efficient, and cost effective method of data collection for validation in a laboratory setting. Intended as a learn-by-example guide, Pharmaceutical and Medical Device Validation by Experimental Design demonstrates why designed experiments are the most logical and rational ap Nanotechnology is changing the world in a very big way, but at the atomic and sub-atomic level. Although the roots of nanotechnology can be traced back to more than a century ago, the last three decades have witnessed an explosion of nano-based technologies and products. This reference work examines the history, current status, and future directions of

nanotechnology through an exhaustive search of the technical and scientific literature. The more than 4000 bibliographic citations it includes are carefully organized into core subject areas, and a geographic and subject index allows readers to quickly locate documents of interest. Although a sense of the global reach and interest in nanotechnology can be gleaned from the reference sections of countless journal articles, conference papers, and books, this is the only reference work providing an in-depth global perspective that is ready-made for nanotechnology professionals and those interested in learning more about all things nanotechnology. Despite the abundance of online resources, there is still an urgent need for well-researched, well-presented, concise, and thematically organized reference works. Instead of relying on wiki pages, citation aggregators, and related websites, the author searched the databases and databanks of scholarly literature search providers such as EBSCO, ProQuest, PUBMED, STN International, and Thomson Reuters. In addition, he used select serials-related databases to account for pertinent documents from countries in which English is not the primary national language (i.e., China Online Journals, e-periodica, J-STAGE, and SciELO Brazil among others). 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. This useful reference describes the statistical planning and design of pharmaceutical experiments, covering all stages in the development process-including preformulation, formulation, process study and optimization, scale-up, and robust process and formulation development.Shows how to overcome pharmaceutical, technological, and economic constraint This volume focuses on the emergent field of neuroethics comparing and contrasting how two democracies, Canada and the United States, have begun adapting public policy design to better fit human minds. The book focuses on issues relevant to all members of the general population and discusses a series of policy issues arranged roughly in the order in which they become relevant in a typical person's lifetime. After the introductory chapter each chapter considers an area of public policy particularly relevant to a different stage of life—from early childhood education policy, to policies for higher education and the workplace, to end of life decisions in living wills and advance directives. The author puts forth that making the shift towards more neurologically appropriate policy will likely be a gradual process hampered primarily by two issues. The first is the inability of neuroscientists to come to agreement on increasingly sophisticated research findings. The second issue points out that bringing policy and neurology into a more synchronous relationship requires a commitment to prolonged effort involves the largely unrecognized reality of entrenched neurological interests. The first chapter introduces the concept of disconnect between policy design with traditional understandings of the brain and goes on to highlight developments in the science

of human neurology in recent years. To help contextualize the book, examples of neurological misperceptions are explored in this introductory chapter. Chapters Two through Eleven each explores a specific type of policy, incorporating understandings of the human brain which, modern neuroscience suggests, are debatable. With contributions by numerous experts The growth of the pharmaceutical industry over the past decade is astounding, but the impact of this growth on statistics is somewhat confusing. While software has made analysis easier and more efficient, regulatory bodies now demand deeper and more complex analyses, and pharmacogenetic/genomic studies serve up an entirely new set of challenges. For more than two decades, Statistics in the Pharmaceutical Industry has been the definitive guide to sorting through the challenges in the industry, and this Third Edition continues that tradition. Updated and expanded to reflect the most recent trends and developments in the field, Statistics in the Pharmaceutical Industry, Third Edition presents chapters written by experts from both regulatory agencies and pharmaceutical companies who discuss everything from experimental design to post-marketing studies. This approach sheds light on what regulators consider acceptable methodologies and what methods have proven successful for industrial statisticians. Both new and revised chapters reflect the increasingly global nature of the industry as represented by authors from Japan and Europe, the increasing trend toward non-inferiority/equivalence testing, adaptive design in clinical trials, global harmonization of regulatory standards, and multiple comparison studies. The book also examines the latest considerations in anti-cancer studies. Statistics in the Pharmaceutical Industry, Third Edition demystifies the approval process by combining regulatory and industrial points of view, making it a must-read for anyone performing statistical analysis at any point in the drug approval process. Pharmaceutical Dosage Forms: Capsules covers the development, composition, and manufacture of capsules. Despite the important role that capsules play in drug delivery and product development, few comprehensive texts on the science and technology of capsules have been available for the research and academic environments. This text addresses this gap, discussing how capsules provide unique capabilities and options for dosage form design and formulation. 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. A quality product or service is the successful and profitable outcome of organising resources, as judged by the final customer. Every business unit needs processes in order to do this effectively; and all processes must be documented so that achievements can be measured and future improvements planned and implemented. Pharmaceutical Process Design and Management takes a step-wise approach to process management. It presents the various elements comprising a process (man, machine, materials, method and environment); it looks at quality control and quality assurance, tools for quality improvements and ways of structuring a process into discrete, fully accountable elements; it proposes that for processes to run successfully, all operators must be the initial problem-solvers; finally, it illustrates how, with the right tools, every problem can be broken down into solvable elements. Learn how to deploy a science and risk-based approach to pharmaceutical manufacturing, by taking a fundamental approach to process design and management and, as a consequence, keep your customers satisfied and your profits healthy. This book explains task management concepts and outlines practical knowledge to help pharmaceutical analytical scientists become productive and enhance their career. •Presents broad topics such as product development process, regulatory requirement, task and project management, innovation mindset, molecular recognition, separation science, degradation chemistry, and statistics. •Provokes thinking through figures, tables, and case studies to help understand how the various functions integrate and how analytical development can work efficiently and effectively by applying science and creativity in their work. •Discusses how to efficiently develop a fit-for-purpose HPLC method without screening dozens of columns, gradients, or mobile phase combinations each time, since the extra effort may not provide enough of a benefit to justify the cost and time in a fast-paced product development environment. This book explains task management concepts and outlines practical knowledge to help pharmaceutical analytical scientists become productive and enhance their career. •Presents broad topics such as product development process, regulatory requirement, task and project management, innovation mindset, molecular recognition, separation science, degradation chemistry, and statistics. •Provokes thinking through figures, tables, and case

studies to help understand how the various functions integrate and how analytical development can work efficiently and effectively by applying science and creativity in their work. •Discusses how to efficiently develop a fit-for-purpose HPLC method without screening dozens of columns, gradients, or mobile phase combinations each time, since the extra effort may not provide enough of a benefit to justify the cost and time in a fast-paced product development environment. Formulation is a key step in the drug design process, where the active drug is combined with other substances that maximise the therapeutic potential, safety and stability of the final medicinal product. Modern formulation science deals with biologics as well as small molecules. Regulatory and quality demands, in addition to advances in processing technologies, result in growing challenges as well as possibilities for the field. Pharmaceutical Formulation provides an up to date source of information for all who wish to understand the principles and practice of formulation in the drug industry. The book provides an understanding of the links between formulation theory and the practicalities of processing in a commercial environment, giving researchers the knowledge to produce effective pharmaceutical products that can be approved and manufactured. The first chapters introduce readers to different dosage forms, including oral liquid products, topical products and solid dosage forms such as tablets and capsules. Subsequent chapters cover pharmaceutical coatings, controlled release drug delivery and dosage forms designed specifically for paediatric and geriatric patients. The final chapter provides an introduction to the vital role intellectual property plays in drug development. Covering modern processing methods and recent changes in the regulatory and quality demands of the industry, Pharmaceutical Formulation is an essential, up to date resource for students and researchers working in academia and in the pharmaceutical industry. The Design and Development of Novel Drugs and Vaccines: Principles and Protocols presents both in silico methods and experimental protocols for vaccine and drug design and development, critically reviewing the most current research and emphasizing approaches and technologies that accelerate and lower the cost of product development. Sections review the technologies and approaches used to identify, characterize and establish a protein as a new drug and vaccine target, cover several molecular methods for in vitro studies of the desired target, and present various physiological parameters for in vivo studies. The book includes preclinical trials and research, along with information on FDA approval. Covers both in silico methods and experimental protocols for vaccine and drug development in a single, accessible volume Offers a holistic accounting of how developments in bioinformatics and large experimental datasets can be used in the development of vaccines and drugs Shows researchers the entire gamut of current therapies, ranging from computational inputs to animal studies Reviews the most current, cutting-edge research available on vaccine and drug design and development This contribution book collects reviews and original articles from eminent experts working in the interdisciplinary arena of novel drug delivery systems and their uses. From their direct and recent experience, the readers can achieve a wide vision on the new and ongoing potentialities of different drug delivery systems. Since the advent of analytical techniques and capabilities to measure particle

sizes in nanometer ranges, there has been tremendous interest in the use of nanoparticles for more efficient methods of drug delivery. On the other hand, this reference discusses advances in the design, optimization, and adaptation of gene delivery systems for the treatment of cancer, cardiovascular, pulmonary, genetic, and infectious diseases, and considers assessment and review procedures involved in the development of gene-based pharmaceuticals. Adaptive design has become an important tool in modern pharmaceutical research and development. Compared to a classic trial design with static features, an adaptive design allows for the modification of the characteristics of ongoing trials based on cumulative information. Adaptive designs increase the probability of success, reduce costs and the time to market, and promote accurate drug delivery to patients. Reflecting the state of the art in adaptive design approaches, Adaptive Design Theory and Implementation Using SAS and R provides a concise, unified presentation of adaptive design theories, uses SAS and R for the design and simulation of adaptive trials, and illustrates how to master different adaptive designs through real-world examples. The book focuses on simple two-stage adaptive designs with sample size re-estimation before moving on to explore more challenging designs and issues that include drop-loser, adaptive dose-funding, biomarker-adaptive, multiple-endpoint adaptive, response-adaptive randomization, and Bayesian adaptive designs. In many of the chapters, the author compares methods and provides practical examples of the designs, including those used in oncology, cardiovascular, and inflammation trials. Equipped with the knowledge of adaptive design presented in this book, you will be able to improve the efficiency of your trial design, thereby reducing the time and cost of drug development.