

Pharmaceutical Manufacturing Handbook Production And Processes

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

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industry

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

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30 new chapters or revised chapters specific to API, covering topics including: manufacturing quality by design, computational approaches, continuous manufacturing, crystallization and final form, process safety • Expanded topics of scale-up, continuous processing, applications of thermodynamics and thermodynamic modeling, filtration and drying • Presents updated and expanded example calculations • Includes contributions from noted experts in the field
Written for pharmaceutical engineers, chemical engineers, undergraduate and graduate students, and professionals in the field of pharmaceutical sciences and manufacturing, the second edition of Chemical Engineering in the Pharmaceutical Industry focuses on the development and chemical engineering as well as operations specific to the design, formulation, and manufacture of drug substance and products.

In 2002, the U.S. Food and Drug Administration (FDA) launched the Pharmaceutical Quality for the 21st Century Initiative to encourage adoption of innovative technologies that would lead to an agile, flexible pharmaceutical manufacturing sector. The goal was to encourage a transition to manufacturing processes and approaches that could produce high-quality drugs reliably without extensive regulatory oversight. Much progress has been made toward that goal as the industry has developed and advanced new technologies, but more

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progress is required as recent natural disasters and the coronavirus pandemic have revealed vulnerabilities in supply chains and highlighted the need to modernize pharmaceutical manufacturing further. At the request of the FDA Center for Drug Evaluation and Research (CDER), Innovations in Pharmaceutical Manufacturing on the Horizon identifies emerging technologies - such as product technologies, manufacturing processes, control and testing strategies, and platform technologies - that have the potential to advance pharmaceutical quality and modernize pharmaceutical manufacturing for products regulated by CDER. This report describes many innovations to modernize the manufacture of drug substances and drug products, to advance new control approaches, and to develop integrated, flexible, and distributed manufacturing networks within 5-10 years.

The Future of Pharmaceutical Product Development and Research examines the latest developments in the pharmaceutical sciences, also highlighting key developments, research and future opportunities. Written by experts in the field, this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of the product development phase of drug discovery and drug development. Each chapter covers fundamental principles, advanced methodologies and technologies employed by

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pharmaceutical scientists, researchers and the pharmaceutical industry. The book focuses on excipients, radiopharmaceuticals, and how manufacturing should be conducted in an environment that follows Good Manufacturing Practice (GMP) guidelines. Researchers and students will find this book to be a comprehensive resource for those working in, and studying, pharmaceuticals, cosmetics, biotechnology, foods and related industries. Provides an overview of practical information for clinical trials Outlines how to ensure an environment that follows Good Manufacturing Practice (GMP) Examines recent developments and suggests future directions for drug production methods and techniques

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.

Pharmaceutical manufacturing can be viewed as a supply chain which spans from the production and purchase of the starting and packaging materials through the manufacture of dosage forms until the safe reception of the finished

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product by the patient. The entire chain comprises of several processes: auditing, materials purchase (procurement), production, storage, distribution, quality control, and quality assurance. The quality standard for pharmaceutical production is ‘current good manufacturing practice (CGMP)’, which is applied within the frame of a pharmaceutical quality system (PQS). This implementation, however, requires a scientific approach and has to take into account several elements such as risk assessment, life cycle, patient protection, among other factors. Hence, pharmaceutical manufacturing is a complex subject in terms of regulation, given the technical and managerial requirements. This comprehensive handbook describes CGMP for new professionals who want to understand and apply the elements which build up pharmaceutical quality assurance. The book gives details about basic quality control requirements (such as risk management, quality hazards and management systems, documentation, clean environments, personnel training) and gives guidelines on regulatory aspects. This is an ideal handbook for undergraduates studying pharmaceutical or industrial manufacturing and supply chains as well for entrepreneurs and quality control professionals seeking to learn about CGMP standards and implementing quality assurance systems in the pharmaceutical sector.

Developing Solid Oral Dosage Forms is intended for pharmaceutical

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professionals engaged in research and development of oral dosage forms. It covers essential principles of physical pharmacy, biopharmaceutics and industrial pharmacy as well as various aspects of state-of-the-art techniques and approaches in pharmaceutical sciences and technologies along with examples and/or case studies in product development. The objective of this book is to offer updated (or current) knowledge and skills required for rational oral product design and development. The specific goals are to provide readers with: Basics of modern theories of physical pharmacy, biopharmaceutics and industrial pharmacy and their applications throughout the entire process of research and development of oral dosage forms Tools and approaches of preformulation investigation, formulation/process design, characterization and scale-up in pharmaceutical sciences and technologies New developments, challenges, trends, opportunities, intellectual property issues and regulations in solid product development The first book (ever) that provides comprehensive and in-depth coverage of what's required for developing high quality pharmaceutical products to meet international standards It covers a broad scope of topics that encompass the entire spectrum of solid dosage form development for the global market, including the most updated science and technologies, practice, applications, regulation, intellectual property protection and new development trends with case

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studies in every chapter A strong team of more than 50 well-established authors/co-authors of diverse background, knowledge, skills and experience from industry, academia and regulatory agencies

Drugs and pharmaceutical industry plays a vital role in the economic development of a nation. It is one of the largest and most advanced sectors in the world, acting as a source for various drugs, medicines and their intermediates as well as other pharmaceutical formulations. India has come a long way in this field, from a country importing more than 95% of its requirement of drugs and pharmaceuticals; India now is exporting it even to developed countries. Being the intense knowledge driven industry, it offers innumerable business opportunities for the investors/ corporate the world over. The existence of well defined and strong pharmaceutical industry is important for promoting and sustaining research and developmental efforts and initiatives in an economy as well as making available the quality medicines to all at affordable prices. That is, it is essential to improve the health status of the individuals as well as the society as a whole, so that positive contributions could be made to the economic growth and regional development of a country. On the global platform, India holds fourth position in terms of volume and thirteenth position in terms of value of production in pharmaceuticals. The pharmaceutical industry has been producing bulk drugs

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belonging to all major therapeutic groups requiring complicated manufacturing processes as well as a wide range of pharmaceutical machinery and equipments. The modern Indian Pharmaceutical Industry is recent and its foundation was laid in the beginning of the current century. The pharmaceutical industry can be broadly categorised as bulk drugs, formulations, IV fluids and pharmaceutical aids (such as medical equipment, hospital disposables, capsules, etc.). Special feature of the pharmaceutical industry is a large number of manufacturers in the small scale sector. The government is also encouraging the SSI sector providing some incentives. The recent developments in the technology and R & D work in this field have led to the increased growth rate of industries and have established Indian Pharmaceutical industries in the international market. The content of the book includes information about properties, general methods of analysis, methods of manufacture, of different types of drugs and pharmaceuticals. Some of the fundamentals of the book are polymeric materials used in drug delivery systems , theoretical aspects of friction and lubrication , a convenient method for conversion of quinine to quinidine, formulation and evaluation of bio-available enteric-coated erythromycin and metronidazole tablets, extraction of virginiamycin, antipyretics and analgesics, column chromatographic assay of aspirin tablets, differentiating titration of phenacetin and caffeine, infrared spectra

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of some compounds of pharmaceutical interest etc. This book covers an intensive study on manufacturing, production, formulation and quality control of drugs and pharmaceuticals with technology involved in it. This book is an invaluable resource for technologists, professionals and those who want to venture in this field.

How to Develop Robust Solid Oral Dosage Forms from Conception to Post-Approval uses a practical and hands-on approach to cover the development process of solid oral dosage forms in one single source. The book details all of the necessary steps from formulation through the post-approval phase and contains industry case studies, real world advice, and troubleshooting tips. By merging the latest scientific information with practical instructions, this book provides pharmaceutical scientists in formulation research and development with a concrete look at the key aspects in the development of solid oral dosage forms. Focuses on important topics, such as robustness, bioavailability, formulation design, continuous processing, stability tests, modified release dosage forms, international guidelines, process scale-up, and much more Part of the Expertise in Pharmaceutical Process Technology series edited by Michael Levin Discusses common, real-world problems and offers both theoretical and practical solutions to these everyday issues

Sterile Drug Products: Formulation, Packaging, Manufacturing, and Quality teaches the basic principles of the development and manufacture of high quality sterile dosage forms. The author has 38 years of experience in the development and manufacture of sterile dosage forms including solutions, suspensions, ophthalmics and freeze dried products. This book is based

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on the courses he has delivered for over three decades, to over 3000 participants, and is intended to remain relevant for the indefinite future even as new technologies and new applications of old technologies become common. This is an ideal reference book for those working directly and indirectly with sterile dosage forms, be it product development (formulation, package, process, analytical), manufacturing, quality control, quality assurance, regulatory, purchasing, or project management. This book is also intended as an educational resource for the pharmaceutical and biopharmaceutical industry and pharmacy schools, providing basic knowledge and principles in four main areas of parenteral science and technology: Product development, including formulation, packaging, and process development. Manufacturing, including basic teaching on all the primary unit operations involved in preparation of sterile products and the underlying importance of contamination control. Quality and regulatory, including the application of good manufacturing practice regulations, aseptic processing guidelines, and unique quality control testing methods for the sterile dosage form. Clinical aspects, including administration, potential hazards, and biopharmaceutics of sterile products in a clinical setting.

Biopharmaceutical Processing: Development, Design, and Implementation of Manufacturing Processes covers bioprocessing from cell line development to bulk drug substances. The methods and strategies described are essential learning for every scientist, engineer or manager in the biopharmaceutical and vaccines industry. The integrity of the bioprocess ultimately determines the quality of the product in the biotherapeutics arena, and this book covers every stage including all technologies related to downstream purification and upstream processing fields. Economic considerations are included throughout, with recommendations for

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lowering costs and improving efficiencies. Designed for quick reference and easy accessibility of facts, calculations and guidelines, this book is an essential tool for industrial scientists and managers in the biopharmaceutical industry. Offers a comprehensive, go-to reference for daily work decisions Covers both upstream and downstream processes Includes case studies that emphasize financial outcomes Presents summaries, decision grids, graphs and overviews for quick reference

Argues that doctors are deliberately misinformed by profit-seeking pharmaceutical companies that casually withhold information about drug efficacy and side effects, explaining the process of pharmaceutical data manipulation and its global consequences. By the best-selling author of *Bad Science*.

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

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manufacturing and application of modeling for continuous manufacturing and biologics is also included. Explains the commonly used modeling and simulation tools Details the modeling of various unit operations commonly utilized in solid dosage drug product manufacturing Practical examples of the application of modeling tools through case studies Discussion of modeling techniques used for a risk-based approach to regulatory filings Explores the usage of modeling in upcoming areas such as continuous manufacturing and biologics manufacturing

Bullet points

No other area of regulatory compliance receives more attention and scrutiny by regulatory authorities than the regulation of sterile products, for obvious reasons. With the increasing number of potent products, particularly the new line of small protein products, joining the long list of proven sterile products, the technology of manufacturing ster

Emergence of Pharmaceutical Industry Growth with Industrial IoT Approach uses an innovative approach to explore how the Internet of Things (IoT) and big data can improve approaches, create efficiencies and make discoveries. Rapid growth of the IoT has encouraged many companies in the manufacturing sector to make use of this technology to unlock its potential. Pharmaceutical manufacturing companies are no exception to this, as IoT has the potential to revolutionize aspects of the pharmaceutical manufacturing process, from drug discovery to manufacturing. Using clear, concise language and real world case studies, this book discusses systems level from both a human-factors point-of-view and the perspective of networking, databases, privacy and anti-spoofing. The wide variety of topics presented offers readers multiple perspectives on a how to integrate the Internet of Things into pharmaceutical manufacturing. Covers efficiency improvements of pharmaceutical manufacturing through IoT/Big Data approaches Explores cutting-edge technologies through sensor enabled

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environment in the pharmaceutical industry Discusses the systems level from both a human-factors point-of-view and the perspective of networking, databases, privacy and anti-spoofing The Era of Artificial Intelligence, Machine Learning and Data Science in the Pharmaceutical Industry examines the drug discovery process, assessing how new technologies have improved effectiveness. Artificial intelligence and machine learning are considered the future for a wide range of disciplines and industries, including the pharmaceutical industry. In an environment where producing a single approved drug costs millions and takes many years of rigorous testing prior to its approval, reducing costs and time is of high interest. This book follows the journey that a drug company takes when producing a therapeutic, from the very beginning to ultimately benefitting a patient's life. This comprehensive resource will be useful to those working in the pharmaceutical industry, but will also be of interest to anyone doing research in chemical biology, computational chemistry, medicinal chemistry and bioinformatics. Demonstrates how the prediction of toxic effects is performed, how to reduce costs in testing compounds, and its use in animal research Written by the industrial teams who are conducting the work, showcasing how the technology has improved and where it should be further improved Targets materials for a better understanding of techniques from different disciplines, thus creating a complete guide

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

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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.

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

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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 Handbook of Pharmaceutical Manufacturing Formulations, Third Edition: Volume Six, Sterile Products is an authoritative and practical guide to the art and science of formulating drugs for commercial manufacturing. With thoroughly revised and expanded content, this sixth volume of a six-volume set, compiles data from FDA and EMA new drug applications, patents and patent applications, and other sources of generic and proprietary formulations including author's own experience, to cover the broad spectrum of cGMP formulations and issues in using these formulations in a commercial setting. A must-have collection for pharmaceutical manufacturers, educational institutions, and regulatory authorities, this is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent. Features: ? Largest source of authoritative and practical formulations, cGMP compliance guidance and self-audit suggestions ? Differs from other publications on formulation science in that it focuses on readily scalable commercial formulations that can be adopted for cGMP manufacturing ? Tackles common difficulties in formulating drugs and presents details on stability testing, bioequivalence testing, and full compliance with drug product safety elements ? Written by a well-recognized authority on drug and dosage form development including biological drugs and alternative medicines

10.7.3 State of Control

A guide to the important chemical engineering concepts for the development of new drugs,

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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

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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. Biopharmaceuticals, medicines made by or from living organisms (including cells from living organisms), are extremely effective in treating a broad range of diseases. Their importance to human health has grown significantly over the years as more biopharmaceutical products have entered the market, and now the biggest selling drugs in the world are biopharmaceuticals. Biopharmaceutical Manufacturing: Principles, Processes and Practices provides concise, comprehensive, and up-to-date coverage of biopharmaceutical manufacturing. Written in a clear and informal style, the content has been influenced by the authors' substantial industry experience and teaching expertise. That expertise enables the authors to address the many questions posed over the years both by university students and professionals with experience in the field. Consequently, the book will appeal both to undergraduate or graduate students using it as a textbook and specialized industry practitioners seeking to understand the big picture of biopharmaceutical manufacturing. This book:

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

This book provides insight into the world of pharmaceutical quality systems and the key elements that must be in place to change the business and organizational dynamics from task-oriented procedure-based cultures to truly integrated quality business systems that are self-detecting and correcting. Chapter flow has been changed to adopt a quality systems organization approach, and supporting chapters have been updated based on current hot topics including the impact of the worldwide supply chain complexity and current regulatory

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trends.

Pharmaceutical Manufacturing Handbook Production and Processes John Wiley & Sons

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.

Structured like a textbook, the second edition of this reference covers all aspects of biopharmaceutical manufacturing, including legal and regulatory issues, production facility design, and quality assurance, with a focus on supply chain management and regulations in emerging markets and cost control. The author

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has longstanding industrial expertise in biopharmaceutical production and years of experience teaching at universities. As such, this practical book is ideal for use in academia as well as for internal training within companies.

With contributions from biotechnologists and bioengineers, this ready reference describes the state of the art in industrial biopharmaceutical production, with a strong focus on continuous processes. Recent advances in single-use technology as well as application guidelines for all types of biopharmaceutical products, from vaccines to antibodies, and from bacterial to insect to mammalian cells are covered. The efficiency, robustness, and quality control of continuous production processes for biopharmaceuticals are reviewed and compared to traditional batch processes for a range of different production systems.

This book is open access under a CC-BY license. The importance of the pharmaceutical industry in Sub-Saharan Africa, its claim to policy priority, is rooted in the vast unmet health needs of the sub-continent. Making Medicines in Africa is a collective endeavour, by a group of contributors with a strong African and more broadly Southern presence, to find ways to link technological development, investment and industrial growth in pharmaceuticals to improve access to essential good quality medicines, as part of moving towards universal access to competent health care in Africa. The authors aim to shift the emphasis

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in international debate and initiatives towards sustained Africa-based and African-led initiatives to tackle this huge challenge. Without the technological, industrial, intellectual, organisational and research-related capabilities associated with competent pharmaceutical production, and without policies that pull the industrial sectors towards serving local health needs, the African sub-continent cannot generate the resources to tackle its populations' needs and demands. Research for this book has been selected as one of the 20 best examples of the impact of UK research on development. See <http://www.ukcds.org.uk/the-global-impact-of-uk-research> for further details.

This textbook is written as a unified approach to various topics, ranging from drug discovery to manufacturing, techniques and technology, regulation and marketing. The key theme of the book is pharmaceuticals - what every student of pharmaceutical sciences should know: from the active pharmaceutical ingredients to the preparation of various dosage forms along with the relevant chemistry, this book makes pharmaceuticals relevant to undergraduate students of pharmacy and pharmaceutical sciences. This book explains how a particular drug was discovered and then converted from lab-scale to manufacturing scale, to the market. It explains the motivation for drug discovery, the reaction chemistry involved, experimental difficulties, various dosage forms and the reasoning

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behind them, mechanism of action, quality assurance and role of regulatory agencies. After having a course based on this book, the student will be able to understand: 1) the career prospects in the pharmaceutical industry, 2) the need for interdisciplinary teamwork in science, 3) the techniques and technology involved in making pharmaceuticals starting from bulk drugs, and 4) different dosage forms and critical factors in the development of pharmaceutical formulations in relation to the principles of chemistry. A few blockbuster drugs including atorvastatin, sildanefil, ranitidine, ciprofloxacin, amoxicillin, and the longest serving drugs such as aspirin and paracetamol are discussed in detail. Finally, the book also covers the important current pharmaceutical issues like quality control, safety, counterfeiting and abuse of drugs, and future prospects for pharmaceutical industry. Unified approach explaining drug discovery, bulk drug manufacturing, formulation of dosage forms, with pharmacological and therapeutic actions Manufacturing processes of representative active pharmaceutical ingredients and their chemistry plus formulation of dosage forms presented in this book are based on actual industrial processes Covers many aspects relevant to students of the pharmaceutical sciences or newly employed pharmaceutical researchers/employees. It contains summary information about regulatory agencies of different countries

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This book contains both the theory and practice of risk management (RM) and provides the background, tools, and application of risk in pharmaceutical and biologics manufacturing and operations. It includes case studies and specific examples of use of RM for biological and pharmaceutical product manufacture. The book also includes useful references and a bibliography for the reader who wishes to gain additional knowledge in the subject. It aids in assisting both industry and regulatory agencies to implement compliant and effective risk management approaches, and includes case studies to help with understanding. Equipment Qualification in the Pharmaceutical Industry provides guidance and basic information for the preparation of a quality qualification program. It has been noted that there is a general lack of understanding in the industry, especially for those new to the industry, as to what constitutes a compliant qualification program. Even experienced professionals have felt a lack of security in reaching a compliant state. This book outlines a guideline for the preparation and execution of qualification protocols including the installation (IQ), operational (OQ), and performance (PQ) protocols. It discusses the importance of related qualification programs (e.g., quality systems, commissioning, computer system, and cleaning) and how to incorporate them into a fully compliant qualification program. Furthermore, it provides matrices of what could be included in each

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type of protocol for major types of process equipment. While primarily for people entering the pharmaceutical industry, those established in the field will benefit from the multiple examples and matrices as well as integration of related systems. Equipment Qualification in the Pharmaceutical Industry provides students and pharmaceutical scientists a guideline for the preparation and execution of qualification (installation, operational, and performance) protocols. Incorporates good manufacturing processes into a compliant qualification program Provides examples of protocol layout Includes matrices for major process equipment, installation quality, operational quality, and performance quality requirements

Multivariate Analysis in the Pharmaceutical Industry provides industry practitioners with guidance on multivariate data methods and their applications over the lifecycle of a pharmaceutical product, from process development, to routine manufacturing, focusing on the challenges specific to each step. It includes an overview of regulatory guidance specific to the use of these methods, along with perspectives on the applications of these methods that allow for testing, monitoring and controlling products and processes. The book seeks to put multivariate analysis into a pharmaceutical context for the benefit of pharmaceutical practitioners, potential practitioners, managers and regulators. Users will find a resources that addresses an unmet need on how

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pharmaceutical industry professionals can extract value from data that is routinely collected on products and processes, especially as these techniques become more widely used, and ultimately, expected by regulators. Targets pharmaceutical industry practitioners and regulatory staff by addressing industry specific challenges Includes case studies from different pharmaceutical companies and across product lifecycle of to introduce readers to the breadth of applications Contains information on the current regulatory framework which will shape how multivariate analysis (MVA) is used in years to come

Revised to reflect significant advances in pharmaceutical production and regulatory expectations, Handbook of Validation in Pharmaceutical Processes, Fourth Edition examines and blueprints every step of the validation process needed to remain compliant and competitive. This book blends the use of theoretical knowledge with recent technological advancements to achieve applied practical solutions. As the industry's leading source for validation of sterile pharmaceutical processes for more than 10 years, this greatly expanded work is a comprehensive analysis of all the fundamental elements of pharmaceutical and bio-pharmaceutical production processes. Handbook of Validation in Pharmaceutical Processes, Fourth Edition is essential for all global health care manufacturers and pharmaceutical industry professionals. Key Features: Provides an in-depth discussion of recent advances in sterilization Identifies obstacles that may be encountered at any stage of the validation program, and

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suggests the newest and most advanced solutions Explores distinctive and specific process steps, and identifies critical process control points to reach acceptable results New chapters include disposable systems, combination products, nano-technology, rapid microbial methods, contamination control in non-sterile products, liquid chemical sterilization, and medical device manufacture

Design and Manufacture of Pharmaceutical Tablets offers real world solutions and outcomes of formulation and processing challenges of pharmaceutical tablets. This book includes numerous practical examples related to actual formulations that have been validated and marketed and covers important data in the areas of stability, dissolution, bioavailability and processing. It provides important background and theoretical information on design and manufacturing and includes a full section dedicated to design experimental methodology and statistics. In addition, this book offers a a general discussion of excipients used in proper tablet design along with practical examples related to excipients. Drug development scientists in industry and academia, as well as students in the pharmaceutical sciences will greatly benefit from the practical knowledge and case examples provided throughout this book.

Incorporates important mathematical models and computational applications Includes unique content on central composite design and augmented simplex lattice Provides background on important design principles with emphasis on quality-based design (QBD) of pharmaceutical dosage forms

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This industry standard encyclopedia on pharmaceutical manufacturing processes has been completely updated to include FDA drugs approved up to the summer of 2004. The encyclopedia gives details for the manufacture of 2226 pharmaceuticals that are being marketed as a trade-named product somewhere in the world. Each entry includes: ò Therapeutic function ò Chemical and common name ò Structural Formula ò Chemical Abstracts Registry no. ò Trade name, manufacturer, country, and year introduced ò Raw Materials ò Manufacturing Process In addition, references are also cited under each drug's entry to major pharmaceutical works where additional information can be obtained on synthesis and the pharmacology of the individual products.

A NEW YORK TIMES BESTSELLER New York Times 100 Notable Books of 2019 New York Public Library Best Books of 2019 Kirkus Reviews Best Health and Science Books of 2019 Science Friday Best Books of 2019 New postscript by the author From an award-winning journalist, an explosive narrative investigation of the generic drug boom that reveals fraud and life-threatening dangers on a global scale—The Jungle for pharmaceuticals Many have hailed the widespread use of generic drugs as one of the most important public-health developments of the twenty-first century. Today, almost 90 percent of our pharmaceutical market is comprised of generics, the majority of which are manufactured overseas. We have been reassured by our doctors, our pharmacists and our regulators that generic drugs are identical to their brand-name counterparts,

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just less expensive. But is this really true? Katherine Eban's *Bottle of Lies* exposes the deceit behind generic-drug manufacturing—and the attendant risks for global health. Drawing on exclusive accounts from whistleblowers and regulators, as well as thousands of pages of confidential FDA documents, Eban reveals an industry where fraud is rampant, companies routinely falsify data, and executives circumvent almost every principle of safe manufacturing to minimize cost and maximize profit, confident in their ability to fool inspectors. Meanwhile, patients unwittingly consume medicine with unpredictable and dangerous effects. The story of generic drugs is truly global. It connects middle America to China, India, sub-Saharan Africa and Brazil, and represents the ultimate litmus test of globalization: what are the risks of moving drug manufacturing offshore, and are they worth the savings? A decade-long investigation with international sweep, high-stakes brinkmanship and big money at its core, *Bottle of Lies* reveals how the world's greatest public-health innovation has become one of its most astonishing swindles.

A practical guide to Quality by Design for pharmaceutical product development
Pharmaceutical Quality by Design: A Practical Approach outlines a new and proven approach to pharmaceutical product development which is now being rolled out across the pharmaceutical industry internationally. Written by experts in the field, the text explores the QbD approach to product development. This innovative approach is based on the application of product and process understanding underpinned by a systematic

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methodology which can enable pharmaceutical companies to ensure that quality is built into the product. Familiarity with Quality by Design is essential for scientists working in the pharmaceutical industry. The authors take a practical approach and put the focus on the industrial aspects of the new QbD approach to pharmaceutical product development and manufacturing. The text covers quality risk management tools and analysis, applications of QbD to analytical methods, regulatory aspects, quality systems and knowledge management. In addition, the book explores the development and manufacture of drug substance and product, design of experiments, the role of excipients, multivariate analysis, and include several examples of applications of QbD in actual practice. This important resource: Covers the essential information about Quality by Design (QbD) that is at the heart of modern pharmaceutical development Puts the focus on the industrial aspects of the new QbD approach Includes several illustrative examples of applications of QbD in practice Offers advanced specialist topics that can be systematically applied to industry Pharmaceutical Quality by Design offers a guide to the principles and application of Quality by Design (QbD), the holistic approach to manufacturing that offers a complete understanding of the manufacturing processes involved, in order to yield consistent and high quality products.

With its coverage of Food and Drug Administration regulations, international regulations, good manufacturing practices, and process analytical technology, this handbook offers complete coverage of the regulations and quality control issues that

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govern pharmaceutical manufacturing. In addition, the book discusses quality assurance and validation, drug stability, and contamination control, all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines. The team of expert authors offer you advice based on their own firsthand experience in all phases of pharmaceutical manufacturing.

The third volume in the six-volume Handbook of Pharmaceutical Manufacturing Formulations, this book covers liquid drugs, which include formulations of non-sterile drugs administered by any route in the form of solutions (monomeric and multimeric), suspensions (powder and liquid), drops, extracts, elixirs, tinctures, paints, sprays, colloidons, emul

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