To facilitate the development of novel drug delivery systems and biotechnology-oriented drugs, the need for new excipients to be developed and approved continues to increase. Excipient Development for Pharmaceutical, Biotechnology, and Drug Delivery Systems serves as a comprehensive source to improve understanding of excipients and forge new avenues.

Artificial intelligence (AI) is a field within computer science that is attempting to build enhanced intelligence into computer systems. This book traces the history of the subject, from the early dreams of eighteenth-century (and earlier) pioneers to the more successful work of today's AI engineers. AI is becoming more and more a part of everyone's life. The technology is already embedded in face-recognizing cameras, speech-recognition software, Internet search engines, and health-care robots, among other applications. The book's many diagrams and easy-to-understand descriptions of AI programs will help the casual reader gain an understanding of how these and other AI systems actually work. Its thorough (but unobtrusive) end-of-chapter notes containing citations to important source materials will be of great use to AI scholars and researchers. This book promises to be the definitive history of a field that has captivated the imaginations of scientists, philosophers, and writers for centuries.

In recent years, the field of pharmaceutical microbiology has experienced numerous technological advances, accompanied by the publication of new and harmonized compendial methods. It is therefore imperative for those who are responsible for monitoring the microbial quality of pharmaceutical/biopharmaceutical products to keep abreast of the latest changes. Microbial Limit and Bioburden Tests: Validation Approaches and Global Requirements guides readers through the various microbiological methods listed in the compendia with easy-to-follow diagrams and approaches to...
validations of such test methodologies. Includes New and Updated Material. Now in its second edition, this work is the culmination of research and discussions with technical experts, as well as USP and FDA representatives on various topics of interest to the pharmaceutical microbiologist and those responsible for the microbial quality of products, materials, equipment, and manufacturing facilities. New in this edition is an entire chapter dedicated to the topic of biofilms and their impact on pharmaceutical and biopharmaceutical operations. The subject of rapid methods in microbiology has been expanded and includes a discussion on the validation of alternative microbiological methods and a case study on microbial identification in support of a product contamination investigation. Substantially updated and revised, this book assists readers in understanding the fundamental issues associated with pharmaceutical microbiology and provides them with tools to create effective microbial contamination control and microbial testing programs for the areas under their responsibility.

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 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

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Pharmaceutics is one of the most diverse subject areas in all of pharmaceutical science. In brief, it is concerned with the scientific and technological aspects of the design and manufacture of dosage forms or medicines. An understanding of pharmaceutics is therefore vital for all pharmacists and those pharmaceutical scientists who are involved with converting a drug or a potential drug into a medicine that can be delivered safely, effectively and conveniently to the patient. Now in its fourth edition, this best-selling textbook in pharmaceutics has been brought completely up to date to reflect the rapid advances in delivery methodologies by eye and injection, advances in drug formulations and delivery methods for special groups (such as children and the elderly), nanomedicine, and pharmacognosy. At the same time the editors have striven to maintain the accessibility of the text for students of pharmacy, preserving the balance between being a suitably pitched introductory text and a clear reflection of the state of the art.

Provides a logical, comprehensive account of drug design and manufacture includes the science of formulation and drug delivery designed and written for newcomers to the design of dosage forms

New to this edition New editor: Kevin Taylor, Professor of Clinical Pharmaceutics, School of Pharmacy, University of London. Twenty-two new contributors. Six new chapters covering parenteral and ocular delivery; design and administration of medicines for the children and elderly; the latest in plant medicines; nanotechnology and nanomedicines, and the delivery of biopharmaceuticals. Thoroughly revised and updated throughout.

Part I: Process design -- Introduction to design -- Process flowsheet development -- Utilities and energy efficient design -- Process simulation -- Instrumentation and process control -- Materials of construction -- Capital cost estimating -- Estimating revenues and production costs -- Economic evaluation of projects -- Safety and loss prevention -- General site considerations -- Optimization in design -- Part II: Plant design -- Equipment selection, specification and design -- Design of pressure vessels -- Design of reactors and mixers -- Separation of fluids -- Separation columns (distillation, absorption and extraction) -- Specification and
The book aims to address the major aspects of future drug product development and therapy for older adults, giving practical guidance for the rational product and clinical development and prescribing of drug products to this ever-growing segment of the population. With authors coming from key aging markets such as Europe, the USA, China, and Japan, the book will provide valuable information for students, scientists, regulators, practitioners, and other healthcare professionals from academia, industry, and regulatory bodies.

Achieving operational excellence is a challenge for the pharmaceutical industry, with many companies setting successful examples time and again. This book presents such leading practices for managing operational excellence throughout the pharmaceutical industry. Based on the St. Gallen OPEX Model, the authors describe the current status of OPEX and the future challenges that have to be dealt with. The ample theoretical background is complemented hand-in-hand by case studies contributed by authors from leading pharmaceutical companies. Readers will find this book to be the most comprehensive source on pharmaceutical dosage forms and drug delivery systems. Physical Pharmacy Capsules highlight key concepts with boxes, providing easy reference. Reflecting traditional pharmaceutics pedagogy, the new edition is organized by dosage form rather than by route of administration.
The book covers a wide range of topics, including: biomedical signal processing, medical physics, biomedical imaging and radiation protection, biosensors and bioinstrumentation, bio-micro/nano technologies, biomaterials, biomechanics, robotics and minimally invasive surgery, and cardiovascular, respiratory and endocrine systems engineering. Further topics include bioinformatics and computational biology, clinical engineering and health technology assessment, health informatics, e-health and telemedicine, artificial intelligence and machine learning in healthcare, as well as pharmaceutical and genetic engineering. Given its scope, the book provides academic researchers, clinical researchers and professionals alike with a timely reference guide to measures for improving the quality of life and healthcare.

Completely updated and enlarged to three volumes (originally published as two volumes), the Second Edition of Pharmaceutical Dosage Forms: Parenteral Medications examines every important aspect of sterile drug products. This volume offers comprehensive coverage of medical devices, quality assurance and regulatory issues. It discusses regulatory requirements in record-keeping based on the US Food and Drug Administration's (FDA) Current Good Manufacturing Practices; places special emphasis on methods of detecting, counting and sizing particles; offers new perspectives on contemporary validation concepts and how they affect the validation process; explains current FDA enforcement activities, the voluntary compliance policy, select court cases, and how these relate to parenterals; provides recent materials on the use of audits as a means of verifying the efficacy of manufacturing control systems; highlights new US regulations for medical devices; and examines quality assurance, including new information on biological control tests for medical device materials. With the contributions of leading experts, volume 3 of Pharmaceutical Dosage Forms: Parenteral Medications is intended as a day-to-day reference and text.

This book serves as a reference text for regulatory, industry and academic statisticians and also a handy manual for entry level Statisticians. Additionally it aims to stimulate academic interest in the field of Nonclinical Statistics and promote this as an important discipline in its own right. This text brings together for the first time in a single volume a comprehensive survey of methods important to the nonclinical science areas within the pharmaceutical and biotechnology industries. Specifically the Discovery and Translational sciences, the Safety/Toxicology sciences, and the Chemistry, Manufacturing and Controls sciences.

Drug discovery and development is a long and costly process. Most decisions in the drug development process are made with incomplete information. The data is rife with uncertainties and hence risky by nature. This is therefore the purview of Statistics. As such, this book aims to introduce readers to important statistical thinking and its application in these nonclinical areas. The chapters provide as appropriate, a scientific background to the topic, relevant regulatory guidance, current statistical practice, and further research directions.

For a decade and a half, Biopharmaceutics and Clinical Pharmacokinetics has been used in the classrooms around the world as an introductory textbook on biopharmaceutics and pharmacokinetics. Now, the new Fourth Edition, Revised and Expanded further enhances the preceding editions’ proven features, introducing significant advances in clinical pharmacokinetics, pharmacokinetic design of drugs and dosage forms, and model-independent analyses. Still usable without prior knowledge of calculus or kinetics, this successfully implemented workbook maintains a carefully graduated “building block” presentation, incorporating sample problems and exercises.

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Biopharmaceutics and Clinical Pharmacokinetics features a growth-oriented format that systematically develops and interrelates all subject matter. It introduces basic theory and fields of application, emphasizes model-independent pharmacokinetic analyses, presents biopharmaceutical aspects of product design and evaluation, offers a unique approach to teaching dosage regimen design and individualization, and considers structural modification of drug molecules for problems associated with pharmacokinetics. As a comprehensive coverage of the basic principles and the recent achievements in the field, no other textbook does as much for students of pharmacy, pharmacology, medicinal chemistry, and medicine, or for scientists who desire a simple but thorough introduction to theory and application.

First multi-year cumulation covers six years: 1965-70. The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for the quality assurance of medicines. Standards are developed by the Committee through worldwide consultation and an international consensus-building process. The following new guidelines were adopted and recommended for use: Procedure for development of the WHO medicines quality assurance guidelines; Guidelines on Good Manufacturing Practices (GMP) for heating, ventilation and air-conditioning systems (HVAC) illustrative part; Guidance on GMP for Validation, including the general main text, analytical procedure validation, validation of computerized systems and qualification; in the area of interchangeability of multisource medicines: the Protocol to conduct equilibrium solubility experiments for the purpose of biopharmaceutics classification system based classification of active pharmaceutical ingredients for biowaiver; Guidelines on Import Procedures for pharmaceutical products; and the Good Practice Guidance document on implementing the collaborative procedures. All of the above are included in this report.
This edited volume brings together the expertise of numerous specialists on the topic of particles—their physical, chemical, pharmacological and toxicological characteristics when they are a component of pharmaceutical products and formulations. The book discusses in detail properties such as the composition, size, shape, surface properties and porosity of particles with respect to how they impact the formulations and products in which they are used and the effective delivery of pharmaceutical active ingredients. It considers all dosage forms of pharmaceuticals involving particles, from powders to tablets, creams to ointments, and solutions to dry-powder inhalers, also including the latest nanomedicine products. Further, it discusses examples of particle toxicity, as well as the important subject of pharmaceutical industry regulations, guidelines and legislation. The book is of interest to researchers and practitioners who work on testing and developing pharmaceutical dosage and delivery systems.

The Tableting Specification Manual covers every facet of tablet manufacturing: tooling and tablet design, tooling steels, maximum compression forces, tooling inspection and maintenance, and troubleshooting of tablet and tool production problems. This reference helps users increase tablet quality and production rate, extend tooling life, prevent damage to presses, and avoid costly work stoppages.
Until now, books addressing Halal issues have focused on helping Muslim consumers decide what to eat and what to avoid among products currently on the marketplace. There was no resource that the food industry could refer to that provided the guidelines necessary to meet the Halal requirements of Muslim consumers in the U.S. and abroad. Halal

A practical summary of the technical and technological as well as nutritional and physiological properties attained through the targeted selection of raw materials and the corresponding production processes. The two authors come from the world’s leading gelatine company and adopt here an international approach, enabling their knowledge to be transferred between the various application areas on a global scale. Following an introduction to and the history of gelatine, the text surveys the
global industry and current trends, before going on to analyze the basic physical, chemical and technological properties of gelatine. Manufacturing, including quality and safety and the processing of powder, instant gelatine and hydrolysate are dealt with next, prior to an in-depth review of applications in beverages and foodstuffs, pharmaceuticals, health and osteoarthritis, among others. The whole is rounded off by future visions and a useful glossary. Aimed at all gelatine users, heads and technicians in production and quality control, product developers, students of food science and pharmacy as well as marketing experts within the industry and patent lawyers.

Describes tradename products and generic chemicals and materials, available from worldwide manufacturers, that function as pharmaceutical additives. Entries include chemical description, uses, regulatory, properties, and storage.

The authors had five objectives in preparing this book: (i) to bring together relevant information on many raw materials used in the manufacture of sweets and chocolate; (ii) to describe the principles involved and to relate them to production with maximum economy but maintaining high quality; (iii) to describe both traditional and modern production processes, in particular those continuous methods which are finding increasing application; (iv) to give basic recipes and methods, set out in a form for easy reference, for producing a large variety of sweets, and capable of easy modification to suit the raw materials and plant available; (v) to explain the elementary calculations most likely to be required. The various check lists and charts, showing the more likely faults and how to eliminate them, reflect the fact that art still plays no small part in this industry. To help users all over the world, whatever units they employ, most formulations are given in parts by weight, but tables of conversion factors are provided at the end of the book. There also will be found a collection of other general reference data in tabular form; while the Glossary explains a number of technical terms, many of them peculiar to the industry.
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.

An internationally acclaimed reference work recognized as one of the most authoritative and comprehensive sources of information on excipients used in pharmaceutical formulation with this new edition providing 340 excipient monographs. Incorporates information on the uses, and chemical and physical properties of excipients systematically collated from a variety of international sources including: pharmacopeias, patents, primary and secondary literature, websites, and manufacturers' data; extensive data provided on the applications, licensing, and safety of excipients; comprehensively cross-referenced and indexed, with many additional excipients described as related substances and an international supplier's directory and detailed information on trade names and specific grades or types of excipients commercially available.