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Biologics, A History of Agents Made From Living Organisms in the Twentieth Century Springer Science & Business Media Handbook of Modern Pharmaceutical Analysis, Second Edition, synthesizes the complex research and recent changes in the field,

while covering the techniques and technology required for today's laboratories. The work integrates strategy, case studies, methodologies, and implications of new regulatory structures, providing complete coverage of quality assurance from the point of discovery to the point of use. Treats pharmaceutical analysis (PA) as an integral partner to the drug development process rather than as a service to it Covers method development, validation, selection, testing, modeling, and simulation studies combined with advanced exploration of assays, impurity testing, biomolecules, and chiral separations Features detailed coverage of QA, ethics, and regulatory guidance (quality by design, good manufacturing practice), as well as high-tech methodologies and technologies from "lab-on-a-chip" to LC-MS, LC-NMR, and LC-NMR-MS

Life Extension

CRC Press

Process Validation in Manufacturing of Biopharmaceuticals, Third Edition delves into the key aspects and current practices of process validation. It includes discussion on the final version of the FDA 2011 Guidance for

Industry on Process Validation Principles and Practices, commonly referred to as the Process Validation Guidance or PVG, issued in final form on January 24, 2011. The book also provides guidelines and current practices, as well as industrial case studies illustrating the different approaches that can be taken for successful validation of biopharmaceutical processes. Case studies include Process validation for membrane chromatography Leveraging multivariate analysis tools to qualify scale-down models A matrix approach for process validation of a multivalent bacterial vaccine Purification validation for a therapeutic monoclonal antibody expressed and secreted by Chinese Hamster Ovary (CHO) cells Viral clearance validation studies for a product produced in a human cell line A much-needed resource, this book presents process characterization techniques for scaling down unit operations in biopharmaceutical manufacturing, including chromatography, chemical modification reactions, ultrafiltration, and microfiltration. It also provides practical methods to test raw materials and in-process samples. Stressing the importance of taking a risk-based approach towards computerized system compliance, this book will help you and your team ascertain process validation is carried out and exceeds expectations.

Short Textbook of Preventative and

Social Medicine

CRC Press

This easy-to-read reference book provides a practical approach for dealing with the legal and regulatory compliance issues involved in human research. Covering a broad range of topics, such as consent, confidentiality, subject recruitment and selection, the role of the investigator and Institutional Review Board, it offers timely and useful strategies for achieving regulatory compliance while reducing liability. In addition, insurance, quality management, accreditation, and risk management are topics examined in the book. The practical insights found in this volume are not found in other books on the subject. Clinical Trials and Human Research is a practical tool to help anyone involved in clinical research.

Handbook of Biomarkers and Precision Medicine

CRC Press

Drug discovery and development is a challenging, expensive and time consuming field of research, requiring contributions from chemists, pharmacologists, toxicologists, clinicians, and practitioners. The ultimate goal is to generate a safe and biologically active drug which can stall, or even reverse, the pathological events that cause the disease condition. But in the search for the drug a host of tests and trials must be applied to evaluate the efficiency and safety of the newly developed molecule in the biological system. These trials or "screening methods" are critical. On their basis, the new molecule either becomes accepted for usage, or is discarded forever. Advances in drug research have forced the need for quicker, more automated screening methods, using molecular

techniques applied in vitro, in vivo and in clinical systems. Researchers need to know the latest developments outside their own speciality. With this book, Professor Gupta has brought together in one coherent volume the most up to date developments of consolidated screening methods for biological systems. By paying attention to the practical techniques used in academia and the commercial pharmaceutical industry, "Drug Screening Methods" will enjoy a broad readership, serving both the professional community and the student of pharmacology.

A Textbook of Pharmaceutical Analysis PHI Learning Pvt. Ltd.

"The field of Biomarkers and Precision Medicine in drug development is rapidly evolving and this book presents a snapshot of exciting new approaches. By presenting a wide range of biomarker applications, discussed by knowledgeable and experienced scientists, readers will develop an appreciation of the scope and breadth of biomarker knowledge and find examples that will help them in their own work." -Maria Freire, Foundation for the National Institutes of Health Handbook of Biomarkers and Precision Medicine provides comprehensive insights into biomarker discovery and development which has driven the new era of Precision

Medicine. A wide variety of renowned experts from government, academia, teaching hospitals, biotechnology and pharmaceutical companies share best practices, examples and exciting new developments. The handbook aims to provide in-depth knowledge to research scientists, students and decision makers engaged in Biomarker and Precision Medicine-centric drug development. Features: Detailed insights into biomarker discovery, validation and diagnostic development with implementation strategies Lessons-learned from successful Precision Medicine case studies A variety of exciting and emerging biomarker technologies The next frontiers and future challenges of biomarkers in Precision Medicine Claudio Carini, Mark Fidock and Alain van Gool are internationally recognized as scientific leaders in Biomarkers and Precision Medicine. They have worked for decades in academia and pharmaceutical industry in EU, USA and Asia. Currently, Dr. Carini is Honorary Faculty at Kings ' s College School of Medicine,

London, UK. Dr. Fidock is Vice President of Precision Medicine Laboratories at AstraZeneca, Cambridge, UK. Prof.dr. van Gool is Head Translational Metabolic Laboratory at Radboud university medical school, Nijmegen, NL.

The Life Extension Companion CRC Press

A key text for all those involved in pharmacovigilance. Detection of new adverse drug reactions is fundamental to the protection of patients from harm that may occur as a result of medication. This book explores the methods used to investigate new adverse drug reactions, discussing all elements from the scientific background and animal toxicology through to worldwide regulatory and ethical issues. Stephens' Detection of New Adverse Drug Reactions provides comprehensive and up-to-date coverage of material fundamentally important to all those active in the field, whether they work in the pharmaceutical industry, drug regulatory authorities or in academia. The fifth edition of this classic reference work includes new chapters on: vaccine safety surveillance managing drug safety issues with marketed products operational aspects of drug safety function safety of biotechnology products future of pharmacovigilance Reviews of

previous editions: "This book surpasses all its educational aims. Not only is the subject matter covered comprehensively but the material is presented in a very user-friendly manner. The editors have succeeded in producing a highly-specific, definitive reference book which doubles as a most enjoyable read." —Commended by the 1999 BMA Medical Book Competition "For anyone entering the field of adverse reaction monitoring one could not wish for a better primer" —International Journal of Risk and Safety in Medicine Pharmaceutical Process Development World Scientific Very Good,No Highlights or Markup,all pages are intact. *Pharmaceutical Stress Testing* John Wiley & Sons In this era of increased pharmaceutical industry competition, success for generic drug companies is dependent on their ability to manufacture the rapeutic-equivalent drug products in an economical and timely manner, while also being cognizant of patent infringement and other legal and regulatory concerns.Generic Drug Product Development: Solid Oral Handbook of Modern Pharmaceutical Analysis John Wiley & Sons Pharmaceutical process research and development is an exacting, multidisciplinary effort but a somewhat neglected discipline in the

chemical curriculum. This book presents an overview of the many facets of process development and how recent advances in synthetic organic chemistry, process technology and chemical engineering have impacted on the manufacture of pharmaceuticals. In 15 concise chapters the book covers such diverse subjects as route selection and economics, the interface with medicinal chemistry, the impact of green chemistry, safety, the crucial role of physical organic measurements in gaining a deeper understanding of chemical behaviour, the role of the analyst, new tools and innovations in reactor design, purification and separation, solid state chemistry and its role in formulation. The book ends with an assessment of future trends and challenges. The book provides a valuable overview of: both early and late stage chemical development, how safe and scaleable synthetic routes are designed, selected and developed, the importance of the chemical engineering, analytical and manufacturing interfaces, the key enabling technologies, including catalysis and biocatalysis, the importance of the green chemical perspective and solid form issues. The book, written and edited by experts in the field, is a contemporary, holistic treatise,

with a logical sequence for process development and mini-case histories within the chapters to bring alive different aspects of the process. It is completely pharmaceutical themed, encompassing all essential aspects, from route and reagent selection to manufacture of the active compound. The book is aimed at both graduates and postgraduates interested in a career in the pharmaceutical industry. It informs them about the breadth of the work carried out in chemical research and development departments, and gives them a feel for the challenges involved in the job. The book is also of value to academics who often understand the drug discovery arena, but have far less appreciation of the drug development area, and are thus unable to advise their students about the relative merits of careers in chemical development versus discovery.

Cobert's Manual Of Drug Safety And Pharmacovigilance (Third Edition) Royal Society of Chemistry

Leading scientists offer detailed profiles of ten protein drugs currently in development. The case histories of these important new compounds are described from the perspective of their formulation, characterization, and stability. This ready reference also features recent data and an abundance of previously unpublished information. The

in-depth coverage includes a highly useful compendium of degradation sites occurring in over 70 proteins. An invaluable aid in the rapid identification of potential `hot spots' in proteins, this accessible compilation allows for inspection of the protein's primary structure and preparation of a hydroflex plot.

Pharmaceutical Marketing in India Jones & Bartlett Publishers

Pharmaceutical Marketing in India: For Today and Tomorrow is the go-to guide for anyone interested in the pharmaceutical industry in India. With its comprehensive coverage of the sector, this book is a must-read for students, practitioners, and researchers alike. In this updated 25th Anniversary Edition, readers will find new content that covers the latest trends and initiatives in the industry. The book provides a thorough introduction to the changes taking place in first-world markets and the incremental steps being taken by Indian drug majors and their MNC counterparts in India. This book contains seventy-seven cases that highlight the best practices of successful practitioners of Pharma marketing in India. These cases showcase how they have positioned their products, launched and promoted their brands, and defended their therapeutic segments. The insights provided by these cases are incredibly valuable to both practitioners and

students of pharmaceutical marketing. The new edition of the book includes information on changing detailing practices such as e-Detailing, iPad detailing, and tablet detailing, digital marketing strategies, social media strategies for the pharmaceutical industry, multichannel marketing, closed-loop marketing, and more. It also covers the latest ways of engaging and building meaningful relationships with physicians, including medical sales liaisons (MSL), key opinion leader (KOL) management, and key account management (KAM). The primary purpose of this edition is to make it not only relevant for today but also for tomorrow. In other words, to make it as future-proof as possible. This book is a vital resource for anyone interested in the pharmaceutical industry and is a must-read for those looking to stay ahead of the curve in this ever-evolving field. Contents: Part One: The Big Picture 1. The Indian Pharmaceutical Industry: An Overview 2. The Pharmaceutical Market Part Two: Ten 'P's 3. The Product 4. The Price 5. The Place 6. The Promotion 7. Personal selling 8. The Prescription 9. The Policy 10. Public Relations 11. The Power 12. The Patient Part Three: Key Success Factors 13. Managing New Products 14. The Winning Game Plans 15. Towards

Excellence in Marketing 16. The Winning Edge 17. Corporate Scoreboard 18. GMP

Topics in Pharmaceutical Sciences CRC Press

With the advent of the new pharmaceutical practice paradigm, critical changes are occurring in pharmacy education and practice. Pharmaceutical Care Practice is authored by the key leaders in the development of this new practice model, which features an increased focus on patient-oriented care. This book explains these changes in comprehensive detail. This text provides all the implementation strategies in step-by-step detail to operate in this new environment. Its versatility and depth enable it to be used as a basis for improvements in the pharmacy curriculum and throughout clinical practice.

Quantitative Drug Design CRC Press

The use of biologics – drugs made from living organisms – has raised specific scientific, industrial, medical and legal issues. The essays contained in this collection each deal with a case study of a biologic substance, or group of biologics, and its use during the twentieth century.

Formulation, Characterization, and Stability of Protein Drugs McGraw-Hill Professional Publishing

The Majority Of Clinical Pharmacy

Textbooks Focus On Disease States And Applied Therapeutics. This Book Is Different. It Aims To Provide Readers With A Comprehensive Description Of The Concepts And Skills That Are The Foundation For Current Clinical Pharmacy Practice. It Seeks To Answer The Question How Do Clinical Pharmacists Practice? Rathar Than What Do Clinical Pharmacists Need To Know About Drugs And Therapeutics? The Book Is Divided Into Three Sections, And Each Chapter Is Self-Contained And Can Be Read Independently. Section I Provides An Overview Of The Current Status Of Clinical Pharmacy Practice In India And Other Countries. Section Ii Includes Chapters On The Key Concepts, Skills And Competencies Required For Effective Clinical Practice. Section Iii Covers Topics Of Interest To Graduate And Postgraduate Students, And More Experienced Clinical Pharmacists And Researchers.This Book Will Be Useful For All Students Of Pharmacy And Pharmacists Working In Hospital Pharmacy, Community Pharmacy, Drug Or Medical Information, Clinical Research, Government And Nongovernment Organisations, Teaching And Research.

Handbook Of Manufacturing

Warner Books (NY)

This Second Edition examines the mechanisms and means to establish regulatory compliance for pharmaceutical products and company practices. It focuses on major legislative revisions that impact requirements for drug safety

reviews, product regulatory approvals, and marketing practices. Written by top industry professionals, practicing attorneys, and FDA regulators, it includes policies and procedures that pharmaceutical companies need to implement regulatory compliance post-approval. New chapters cover: the marketing of unapproved new drugs and FDA efforts to keep them in regulatory compliance pharmacovigilance programs designed to prevent widespread safety issues legal issues surrounding the sourcing of foreign APIs the issues of counterfeit drugs updates on quality standards

Stephens' Detection of New Adverse Drug Reactions CRC Press

The first edition of this book was welcomed with great enthusiasm by teachers and students. It therefore seemed opportune to publish a second, revised, updated and extended edition. Unfortunately, Professor F è lix Serratosa died before he could complete this task. Some new material has been added, the more significant changes being:. The book has been restructured into two well-differentiated sections: Part A, dealing with conventional organic synthesis, and Part B, devoted exclusively to c omputer-assisted organic synthesis and

based on the former Chapter 11 and Appendices 2, 3 and 4 of the first edition. As decided in advance, Part B was to be the sole responsibility of Dr. Josep Xicart, who prepared the first versions of the CHAOS (Computerisation and Heuristics Applied to Organic Synthesis) program under the direction of Professor Serratosa.

Pharmaceutical Manufacturing Handbook Wiley-Interscience 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 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.

Selenium in Biology and Medicine Routledge Stressing the theory involved in formulating suspensions, emulsions, and colloidal drug

products, this Second Edition of a well-received reference test highlights typical formulations, the avoidance of formulation pitfalls, and compliance with established regulatory principles.

Brancas; Les Amours de Quaterquem

PharmaMed Press / BSP Books

Since the publication of the first edition, the field has changed dramatically. Scientists can now explicitly consider 3D features in quantitative structure-activity relationship (QSAR) studies and often have the 3D structure of the macromolecular target to guide the 3D QSAR. Improvements in computer hardware and software have also made the methods

Pharmaceutical Care Practice

Jossey-Bass

Completely revised and updated, Cobert's Manual of Drug Safety and Pharmacovigilance, Third Edition, is a how-to manual for those working in the fields of drug safety, clinical research, pharmacology, regulatory affairs, risk management, quality/compliance, and in government and legal professions.This comprehensive and practical guide discusses the theory and the practicalities of drug safety (also known as pharmacovigilance), and provides essential information on drug safety and

regulations in the United States, Europe Union, and more, including: recognizing, monitoring, reporting, and cataloging serious adverse drug reactions.Cobert's Manual of Drug Safety and Pharmacovigilance, Third Edition, teaches the daily practice of drug safety in industry, hospitals, the FDA and other health agencies — both in the United States and around the world — and provides critical information about what to do when confronted with a drug safety problem.