Extractables And Leachables Services Intertek

Liver Carcinogenesis
Genotoxic Impurities
Inhaled Medicines
WHO Expert Committee on Specifications for Pharmaceutical Preparations
Pharmaceutical Quality
Radiation Sterilization for Health Care Products
Filtration and Purification in the Biopharmaceutical Industry
Lipidomics
Translational Toxicology
2019 Planner: Confetti Annual Week to a Page Organizer, Diary, Notebook, Appointment Book and Time Management Planner
Rays of Positive Electricity and Their Application to Chemical Analyses
Update on Undertaking Extractable and Leachable Testing
Handbook of Solid Phase Microextraction
Practical Gas Chromatography
Extractables and Leachables
Engineering Polymer Systems for Improved Drug Delivery
WHO Global Model Regulatory Framework for Medical Devices Including in Vitro Diagnostic Medical Devices
Mass Spectrometry of Polymers
Chiral Analysis
Fundamentals of Modern Bioprocessing
Additives for Polyolefins
Pharmaceutical Auditing
Safety Evaluation of Medical Devices
Formulation and Process Development Strategies for Manufacturing Biopharmaceuticals
Biological Test Method
The Effect of a Monocular Helmet-mounted Display on Aircrew Health
Harry's Cosmeticology
To Love and Let Go
Leachables and Extractables Handbook
Introduction to Genetic Toxicology
Identifying and Controlling Pulmonary Toxicants
Disposable Bioprocessing Systems
Essential Chemistry for Formulators of Semisolid and Liquid Dosages
New TSCA
HPLC and UHPLC for Practicing Scientists
siRNA and miRNA Gene Silencing
Delivering Essential Medicines
Clinical Toxicology Testing
Emerging Nanotechnologies for Diagnostics, Drug Delivery and Medical Devices
ICH Quality Guidelines

GRANT PAOLA

Liver Carcinogenesis Humana Press
Emerging Nanotechnologies for Diagnostics, Drug Delivery and Medical Devices covers the modern micro and nanotechnologies used for diagnosis, drug delivery, and theranostics using micro, nano, and implantable systems. In-depth coverage of all aspects of disease treatment is included. In addition, the book covers cutting-edge research and technology that will help readers gain knowledge of novel approaches and their applications to improve drug/agent specificity for diagnosis and efficient disease treatment. It is a comprehensive guide for medical specialists, the pharmaceutical-industry, and academic researchers discussing the impact of nanotechnology on diagnosis, drug delivery, and theranostics. Gives readers working in immunology, drug delivery, and medicine a greater awareness on how novel nanotechnology orientated methods can help improve treatment Provides readers with backgrounds in nanotechnology, chemistry, and materials science an understanding on how nanotechnology is used in immunology and drug delivery Includes focused coverage of the use of nanodevices in diagnostics, therapeutics, and theranostics not offered by other books
Genotoxic Impurities Humana Press
Chiral Analysis covers an important area of analytical chemistry of relevance to a wide variety of scientific professionals. The target audience is scientific professionals with an undergraduate background in chemistry or a related discipline, specifically organic chemists, researchers in drug discovery, pharmaceutical researchers involved with process analysis or combinatorial libraries, and graduate students in chemistry. Chapters have been written with the nonspecialist in mind so as to be self-contained. * Broad coverage - spectroscopic and separation methods covered in a single volume * Up-to-date and detailed review of the various techniques available and/or under development in this field * Contributions from leading experts in the field
Inhaled Medicines Chatham House (Formerly Riia)
Making essential medicines available in developing countries is a pressing international problem. Behind the humanitarian urgency lie longer-term economic, cultural and even geopolitical

challenges. Following up on The Economics of Essential Medicines (2002), this volume extends the debate on the best practical ways of improving access to health care and the delivery of health services. While there have been encouraging signs of increased attention to these issues by public policy-makers in rich countries - such as the recent EU initiative to allow the export of generic drugs to poor countries - huge unsolved problems remain. These are addressed by a wide range of contributors - academics and policy-makers from both rich and poor countries, alongside representatives of NGOs and the pharmaceutical sector. Through a combination of detailed thematic and case studies, this volume aims to show the most promising ways forward to ensure essential medicines become accessible to all.
WHO Expert Committee on Specifications for Pharmaceutical Preparations CRC Press
Examining the implications and practical implementation of multi-disciplinary International Conference on Harmonization (ICH) topics, this book gives an integrated view of how the guidelines inform drug development strategic planning and decision-making. • Addresses a consistent need for interpretation, training, and implementation examples of ICH guidelines via case studies • Offers a primary reference point for practitioners addressing the dual challenge of interpretation and practical implementation of ICH guidelines • Uses case studies to help readers understand and apply ICH guidelines • Provides valuable insights into guidelines development, with chapters by authors involved in generating or with experience implementing the guidelines • Includes coverage of stability testing, analytical method validation, impurities, biotechnology drugs and products, and good manufacturing practice (GMP)
Pharmaceutical Quality Gallery Books
The relatively new technique of solid phase microextraction (SPME) is an important tool to prepare samples both in the lab and on-site. SPME is a "green" technology because it eliminates organic solvents from analytical laboratory and can be used in environmental, food and fragrance, and forensic and drug analysis. This handbook offers a thorough background of the theory and practical implementation of SPME. SPME protocols are presented outlining each stage of the method and providing useful tips and potential pitfalls. In addition, devices and fiber coatings, automated SPME systems, SPME method development, and In Vivo applications are discussed. This handbook is essential for its discussion of the latest SPME developments as well as its in depth information on the history, theory, and practical application of the method. Practical application of Solid Phase Microextraction methods including detailed steps Provides history of extraction methods to better understand the process Suitable for all levels, from beginning student to experienced practitioner
Radiation Sterilization for Health Care Products John Wiley & Sons
Filtration and Purification in the Biopharmaceutical Industry, First Edition greatly expands its focus with extensive new material on the critical role of purification and the significant advances in filtration science and technology. This new edition provides state-of-the-science information on all aspects of filtration and purification, in
Filtration and Purification in the Biopharmaceutical Industry Springer
EXTRACTABLES AND LEACHABLES Learn to address the safety aspects of packaged drug products and medical devices Pharmaceutical drug products and medical devices are expected to be effective and safe to use. This includes minimizing patient, user or product exposure to impurities leached from these items when the drug product is administered or when the medical device is used. Clearly, patient or user exposure to leachables must not adversely impact their health and safety. Furthermore, these impurities must not adversely affect key quality attributes of the drug product or medical device, including its manufacturability, stability, efficacy, appearance, shelf-life and conformance to standards. Extractables and leachables are derived from the drug product's packaging, manufacturing systems and/or delivery systems or from the medical device's materials of construction. It is imperative to understand and quantify the release of extractables from these items, the accumulation of leachables in drug products and the release of leachables from medical devices. Once extractables and leachables have been discovered, identified and quantified, their effect on the key product or device quality attributes, including safety, must be systematically and scientifically established according to recognized, rigorous and relevant regulatory and compendial standards and industry-driven best practices. In Extractables and Leachables, the chemical compatibility (including safe use) of drugs (and their containers, delivery devices and manufacturing systems) and medical devices is examined at length, focusing particularly on how trace-level extractables and leachables affect the quality and safety of a medical product and how to assess the magnitude of the effect. This is accomplished by addressing the two critical activities required to develop, register and commercialize safe, effective and affordable clinical therapies; measuring extractables and leachables (chemical characterization) and assessing their impact (for example, toxicological safety risk assessment). Each of these activities is addressed in-depth, based on the existing and developing international regulations and guidelines, current published literature and the author's extensive personal experience. Written by a key contributor to standards, guidelines, recommended practices and the scientific literature, the book provides "insider" insights beyond those gained by merely reading the relevant texts. Given that the rapidly evolving extractables and leachables landscape, this book provides the most current and crucial information on new and forthcoming regulations and best practices. Extractables and Leachables readers will also find: A thorough summary of regulatory and compendial guidelines and the steps required to meet them A detailed and in-depth review of essential scientific principles and recommended best practices for the design, implementation, interpretation and reporting of chemical characterization studies A practical resource for optimizing the development, registration, and commercialization of safe and effective medical products A helpful tool to maximize product development and successful regulatory outcomes Extractables and Leachables is the essential reference for pharmaceutical scientists, analytical chemists, regulatory affairs professionals, engineers, and toxicologists in areas such as product research and development, product registration and approval, regulatory affairs, analytical science, quality control, and manufacturing.
Lipidomics American Bar Association
"A comprehensive overview of clinical laboratory toxicology services and analytes"--
Translational Toxicology Office of Technology Assessment
A concise yet comprehensive reference guide on HPLC/UHPLC that focuses on its fundamentals, latest developments, and best practices in the pharmaceutical and biotechnology industries Written for practitioners by an expert practitioner, this new edition of HPLC and UHPLC for Practicing Scientists adds numerous updates to its coverage of high-performance liquid chromatography, including comprehensive information on UHPLC (ultra-high-pressure liquid chromatography) and the continuing migration of HPLC to UHPLC, the modern standard platform. In addition to introducing readers to HPLC's fundamentals, applications, and developments, the book describes basic theory

and terminology for the novice, and reviews relevant concepts, best practices, and modern trends for the experienced practitioner. HPLC and UHPLC for Practicing Scientists, Second Edition offers three new chapters. One is a standalone chapter on UHPLC, covering concepts, benefits, practices, and potential issues. Another examines liquid chromatography/mass spectrometry (LC/MS). The third reviews at the analysis of recombinant biologics, particularly monoclonal antibodies (mAbs), used as therapeutics. While all chapters are revised in the new edition, five chapters are essentially rewritten (HPLC columns, instrumentation, pharmaceutical analysis, method development, and regulatory aspects). The book also includes problem and answer sections at the end of each chapter. Overviews fundamentals of HPLC to UHPLC, including theories, columns, and instruments with an abundance of tables, figures, and key references Features brand new chapters on UHPLC, LC/MS, and analysis of recombinant biologics Presents updated information on the best practices in method development, validation, operation, troubleshooting, and maintaining regulatory compliance for both HPLC and UHPLC Contains major revisions to all chapters of the first edition and substantial rewrites of chapters on HPLC columns, instrumentation, pharmaceutical analysis, method development, and regulatory aspects Includes end-of-chapter quizzes as assessment and learning aids Offers a reference guide to graduate students and practicing scientists in pharmaceutical, biotechnology, and other industries Filled with intuitive explanations, case studies, and clear figures, HPLC and UHPLC for Practicing Scientists, Second Edition is an essential resource for practitioners of all levels who need to understand and utilize this versatile analytical technology. It will be a great benefit to every busy laboratory analyst and researcher.

2019 Planner: Confetti Annual Week to a Page Organizer, Diary, Notebook, Appointment Book and Time Management Planner CRC Press

RNA interference has become a key method in the suppression of gene expression and the development of therapeutic agents, yet there is still the problem of delivery, stability, and the danger of off-target effects such as the silencing of unwanted genes and activation of innate immunity. In siRNA and miRNA Gene Silencing: From Bench to Bedside, expert researchers explore the most recent advances in siRNA design, expression, delivery, in vivo imaging, and methods to minimize siRNA’s unwanted effects and promote successful use in patients. As part of the highly successful Methods in Molecular BiologyTM series, the chapters focus on their respective subjects with easy-to-use, up-to-date information, including several step-by-step laboratory protocols on topics such as new delivery formulations and strategies with promising applications in vitro and in vivo, validated therapeutic target genes, and components of miRNA function, biogenesis, and interference with virus infection. Comprehensive and cutting-edge, siRNA and miRNA Gene Silencing: From Bench to Bedside offers an excellent collection of chapters to aid all those with an interest in RNAi, gene regulation, and new therapies.

Rays of Positive Electricity and Their Application to Chemical Analyses John Wiley & Sons

A real-world guide to the production and manufacturing of biopharmaceuticals While much has been written about the science of biopharmaceuticals, there is a need for practical, up-to-date information on key issues at all stages of developing and manufacturing commercially viable biopharmaceutical drug products. This book helps fill the gap in the field, examining all areas of biopharmaceuticals manufacturing, from development and formulation to production and packaging. Written by a group of experts from industry and academia, the book focuses on real-world methods for maintaining product integrity throughout the commercialization process, clearly explaining the fundamentals and essential pathways for all development stages. Coverage includes: Research and early development phase appropriate approaches for ensuring product stability Development of commercially viable formulations for liquid and lyophilized dosage forms Optimal storage, packaging, and shipping methods Case studies relating to therapeutic monoclonal antibodies, recombinant proteins, and plasma fractions Useful analysis of successful and failed products Formulation and Process Development Strategies for Manufacturing Biopharma-ceuticals is an essential resource for scientists and engineers in the pharmaceutical and biotech industries, for government and regulatory agencies, and for anyone with an interest in the latest developments in the field.

Update on Undertaking Extractable and Leachable Testing William Andrew

A practical and science-based approach for addressing toxicological concerns related to leachables and extractables associated with inhalation drug products Packaging and device components of Orally Inhaled and Nasal Drug Products (OINDP) such as metered dose inhalers, dry powder inhalers, and nasal sprays pose potential safety risks from leachables and extractables, chemicals that can be released or migrate from these components into the drug product. Addressing the concepts, background, historical use, and development of safety thresholds and their utility for qualifying leachables and extractables in OINDP, the Leachables and Extractables Handbook takes a practical approach to familiarize readers with the recent recommendations for safety and risk assessment established through a joint effort of scientists from the FDA, academia, and industry. Coverage includes best practices for the chemical evaluation and management of leachables and extractables throughout the pharmaceutical product life cycle, as well as: Guidance for pharmaceutical professionals to qualify and risk-assess container closure system leachables and extractables in drug products Principles for defining toxicological safety thresholds that are applicable to OINDP and potentially applicable to other drug products Regulatory perspectives, along with an appendix of key terms and definitions, case studies, and sample protocols Analytical chemists, packaging and device engineers, formulation development scientists, component suppliers, regulatory affairs specialists, and toxicologists will all benefit from the wealth of information offered in this important text.

Handbook of Solid Phase Microextraction John Wiley & Sons

Genetic Toxicology as a discipline examines the short and long-term effects of all physical and chemical agents in the environment on the human genetic system. It is a relatively new, but now fast-growing field of research as more and more substances are found to have unexpected long-term genetic side-effects. This short introduction includes in one volume various methodologies for assessing toxicity; a classification of potential mutagenic pollutants according to their danger to man, and finally some possible solutions to genetic toxicology problems. This material has been amended and substantially updated for the English edition."

Practical Gas Chromatography Academic Press

“Rachel beautifully illustrates that loving fiercely and grieving deeply are often two halves of the same whole. Her story will break you down and lift you up.” —Glennon Doyle, author of the #1 New York Times bestseller Love Warrior and founder of Together Rising While on her way to teach a yoga retreat in March 2014, Rachel Brathen collapses at an airport, brought to her knees by excruciating stomach pains. She is rushed to the hospital on the tiny island of Bonaire, and hours later forced to undergo surgery. When she wakes up from anesthesia, her

boyfriend is weeping at her bedside. While Rachel was struck down with seemingly mysterious pain, her best friend, Andrea, sustained fatal injuries as a result of a car accident. Rachel and Andrea had a magical friendship. Though they looked nothing alike—one girl tall, blond, and Swedish, the other short, brunette, and Colombian—everyone called them gemelas: twins. Over the three years following Andrea's death, at what might appear from the outside to be the happiest time—with her engagement to the man she loves and a blossoming career that takes her all over the world—Rachel faces a series of trials that have the potential to define her life. Unresolved grief and trauma from her childhood make the weight of her sadness unbearable. At each turn, she is confronted again and again with a choice: Will she lose it all, succumb to grief, and grasp for control that's beyond her reach? Or can she move through the loss and let go? When Rachel and her husband conceive a child, pregnancy becomes a time to heal and an opportunity to be reborn herself. As she recounts this transformative period, Rachel shares her hard-won wisdom about life and death, love and fear, what it means to be a mother and a daughter, and how to become someone who walks through the fire of adversity with the never-ending practice of loving hard and letting go.

Extractables and Leachables John Wiley & Sons

Biological drug and vaccine manufacturing has quickly become one of the highest-value fields of bioprocess engineering, and many bioprocess engineers are now finding job opportunities that have traditionally gone to chemical engineers. Fundamentals of Modern Bioprocessing addresses this growing demand. Written by experts well-established in the field, this book connects the principles and applications of bioprocessing engineering to healthcare product manufacturing and expands on areas of opportunity for qualified bioprocess engineers and students. The book is divided into two sections: the first half centers on the engineering fundamentals of bioprocessing; while the second half serves as a handbook offering advice and practical applications. Focused on the fundamental principles at the core of this discipline, this work outlines every facet of design, component selection, and regulatory concerns. It discusses the purpose of bioprocessing (to produce products suitable for human use), describes the manufacturing technologies related to bioprocessing, and explores the rapid expansion of bioprocess engineering applications relevant to health care product manufacturing. It also considers the future of bioprocessing—the use of disposable components (which is the fastest growing area in the field of bioprocessing) to replace traditional stainless steel. In addition, this text: Discusses the many types of genetically modified organisms Outlines laboratory techniques Includes the most recent developments Serves as a reference and contains an extensive bibliography Emphasizes biological manufacturing using recombinant processing, which begins with creating a genetically modified organism using recombinant techniques Fundamentals of Modern Bioprocessing outlines both the principles and applications of bioprocessing engineering related to healthcare product manufacturing. It lays out the basic concepts, definitions, methods and applications of bioprocessing. A single volume comprehensive reference developed to meet the needs of students with a bioprocessing background; it can also be used as a source for professionals in the field.

Engineering Polymer Systems for Improved Drug Delivery Elsevier

Gas chromatography continues to be one of the most widely used analytical techniques, since its applications today expand into fields such as biomarker research or metabolomics. This new practical textbook enables the reader to make full use of gas chromatography. Essential fundamentals and their implications for the practical work at the instrument are provided, as well as details on the instrumentation such as inlet systems, columns and detectors. Specialized techniques from all aspects of GC are introduced ranging from sample preparation, solvent-free injection techniques, and pyrolysis GC, to separation including fast GC and comprehensive GCxGC and finally detection, such as GC-MS and element-specific detection. Various fields of application such as enantiomer, food, flavor and fragrance analysis, physicochemical measurements, forensic toxicology, and clinical analysis are discussed as well as cutting-edge application in metabolomics is covered.

WHO Global Model Regulatory Framework for Medical Devices Including in Vitro Diagnostic Medical Devices CRC Press

Bringing together a distinguished interdisciplinary team of contributors, this volume provides a comprehensive exploration of translational toxicology—a systematic approach to developing therapeutic interventions that can protect against, mitigate, or reverse the effects of exposures. In particular, the book addresses modes of action and biomarkers, developmental risks of exposures, and potential translational toxicology therapeutics. The result is a compelling application of developmental toxicology in a new therapeutic discipline that is destined to become part of standard medical practice. Translational Toxicology: Defining a New Therapeutic Discipline is an essential text for regulatory authorities, scientists, and physicians who are concerned with environmental exposures, public health, nutrition, and pharmaceutical research and development. Basic science, epidemiological, and clinical investigators will also find this book a significant resource.

Mass Spectrometry of Polymers Independently Published

Written by a researcher with experience designing, establishing, and validating biological manufacturing facilities worldwide, this is the first comprehensive introduction to disposable systems for biological drug manufacturing. It reviews the current state of the industry; tackles questions about safety, costs, regulations, and waste disposal; and guides readers to choose disposable components that meet their needs. This practical manual covers disposable containers, mixing systems, bioreactors, connectors and transfers, controls and sensors, downstream processing systems, filling and finishing systems, and filters. The author also shares his predictions for the future, calling disposable bioprocessing technology a "game changer."

Chiral Analysis John Wiley & Sons

Focusing on the practical applications, this user-oriented guide presents current technologies and strategies for systems-level lipid analysis, going beyond basic research to concentrate on commercial uses of lipidomics in biomarker and diagnostic development, as well as within pharmaceutical drug discovery and development. The editor and authors have experience of the most recent analytical instruments and techniques, allowing them to provide here first-hand practical experience for newcomers to the field. The first half of the book covers current methodologies, ranging from global to targeted lipidomics and shotgun approaches, while the second part discusses the role of lipidomics in biomedical and pharmaceutical research, covering such diverse fields as inflammation, metabolic syndrome, cardiovascular and neurological disease. Both small and large-scale, high-throughput approaches are discussed, resulting in an invaluable source for academic and industrial research and development.

Fundamentals of Modern Bioprocessing Academic Press

"This practical reference examines the implications of biological and chemical interactions of medical devices with human tissue - offering comprehensive coverage on the evaluation of safety in

specialty devices, medical and surgical supplies, imaging systems, in vitro diagnostics, and health information systems." "Discussing preapproval and ongoing test requirements necessary for the development of new products, Safety Evaluation of Medical Devices shows how to select individual materials, components, or devices for testing and how to prepare the samples selected...explains cytotoxicity testing for the determination of biocompatibility using mammalian cell cultures...details the evaluation of hemocompatibility and the potential adverse effects of medical devices on the immune system...addresses studies for both short- and long-term implantable devices...delineates possible genotoxic effects of device materials...presents appropriate models for clinical studies of medical devices...describes specialized studies for cardiovascular prostheses, contact lenses and solutions, and tampons as well as the "mouse safety" systemic injection test...and much more."--BOOK JACKET.Title Summary field provided by Blackwell North America, Inc. All Rights Reserved