Extractables Leachables Risk Based Assessment Of

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Practical Guide to Single-use Technology - Adriana G Lopes 2016-08-31
Single-use technology (SUT) is now available for all processing operations within the biopharmaceutical industry. It has the potential to reduce capital costs, improve plant throughput and reduce the risk of cross-contamination. However, there are no clear guidelines to aid the end-user on implementation of these technologies into a validated, good manufacturing practice (GMP) environment. This book is the first comprehensive publication of practical considerations for each stage of the implementation process of SUT, and covers the selection, specification, design and qualification of systems to meet end-user requirements.Serving as an

introduction and practical reference to this growing area of application within the biopharmaceutical industry, this handbook presents:An approach for SUT implementation within an end-users facility with examples for bioreactors, tangential-flow filtration and fill-finish systems;SUT within the context of regulatory guidance, such as ICH Q8, Q9, Q10 and GMP;Strategy for standardisation of single-use bag systems and assessment of extractables and leachables;Specifications of user requirements and design of specific SUT alongside process descriptions and flow diagrams;Strategies and tools to evaluate risk with examples of risk assessments applicable to design, processing and product quality; andQualification approach for different SUT types.With the information presented in this book, engineers, researchers and professionals involved in biopharmaceuticals will be better prepared to plan and make effective decisions to design and implement SUT.

Process Control, Intensification, and Digitalisation in Continuous Biomanufacturing - Ganapathy Subramanian 2021-12-15

Process Control, Intensification, and Digitalisation in Continuous Biomanufacturing Explore new trends in continuous biomanufacturing with contributions from leading practitioners in the field With the increasingly widespread acceptance and investment in the ??technology, the last decade has demonstrated the utility of continuous ??processing in the pharmaceutical industry. In Process Control, Intensification, and Digitalisation in Continuous Biomanufacturing, distinguished biotechnologist Dr. Ganapathy Subramanian delivers a comprehensive exploration of the potential of the continuous processing of biological products and discussions of future directions in advancing continuous

processing to meet new challenges and demands in the manufacture of therapeutic products. A stand-alone follow-up to the editor's Continuous Biomanufacturing: Innovative Technologies and Methods published in 2017, this new edited volume focuses on critical aspects of process intensification, process control, and the digital transformation of biopharmaceutical processes. In addition to topics like the use of multivariant data analysis, regulatory concerns, and automation processes, the book also includes: Thorough introductions to capacitance sensors to control feeding strategies and the continuous production of viral vaccines Comprehensive explorations of strategies for the continuous upstream processing of induced microbial systems Practical discussions of preparative hydrophobic interaction chromatography and the design of modern protein-A-resins for continuous biomanufacturing In-depth examinations of bioprocess intensification approaches and the benefits of single use for process intensification Perfect for biotechnologists, bioengineers, pharmaceutical engineers, and process engineers, Process Control, Intensification, and Digitalisation in Continuous Biomanufacturing is also an indispensable resource for chemical engineers seeking a one-stop reference on continuous biomanufacturing.

Process Validation in Manufacturing of Biopharmaceuticals, Third Edition - Anurag S. Rathore 2012-05-09

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.

Specification of Drug Substances and Products - Christopher M. Riley 2020-07-23

Specification of Drug Substances and Products: Development and Validation of Analytical Methods, Second Edition, presents a comprehensive and critical analysis of the requirements and approaches to setting specifications for new pharmaceutical products, with an emphasis on phase-appropriate development, validation of analytical methods, and their application in practice. This thoroughly revised second edition covers topics not covered or not substantially covered in the first edition, including method development and validation in the clinical phase, method transfer, process analytical

technology, analytical life cycle management, special challenges with generic drugs, genotoxic impurities, topical products, nasal sprays and inhalation products, and biotechnology products. The book's authors have been carefully selected as former members of the ICH Expert Working Groups charged with developing the ICH guidelines, and/or subject-matter experts in the industry, academia and in government laboratories. Presents a critical assessment of the application of ICH guidelines on method validation and specification setting Written by subject-matter experts involved in the development and application of the guidelines Provides a comprehensive treatment of the analytical methodologies used in the analysis, control and specification of new drug substances and products Covers the latest statistical approaches (including analytical quality by design) in the development of specifications, method validation and shelf-life prediction

Filtration and Purification in the Biopharmaceutical Industry, Third Edition - Maik W. Jornitz 2019-06-26

Since sterile filtration and purification steps are becoming more prevalent and critical within medicinal drug manufacturing, the third edition of Filtration and Purification in the Biopharmaceutical Industry greatly expands its focus with extensive new material on the critical role of purification and advances in filtration science and technology. It provides state-of-the-science information on all aspects of bioprocessing including the current methods, processes, technologies and equipment. It also covers industry standards and regulatory requirements for the pharmaceutical and biopharmaceutical industries. The book is an essential, comprehensive source for all involved in filtration and purification practices, training and compliance. It describes such technologies as viral retentive filters, membrane

chromatography, downstream processing, cell harvesting, and sterile filtration. Features: Addresses recent biotechnology-related processes and advanced technologies such as viral retentive filters, membrane chromatography, downstream processing, cell harvesting, and sterile filtration of medium, buffer and end product Presents detailed updates on the latest FDA and EMA regulatory requirements involving filtration and purification practices, as well as discussions on best practises in filter integrity testing Describes current industry quality standards and validation requirements and provides guidance for compliance, not just from an end-user perspective, but also supplier requirement It discusses the advantages of single-use process technologies and the qualification needs Sterilizing grade filtration qualification and process validation is presented in detail to gain the understanding of the regulatory needs The book has been compilated by highly experienced contributors in the field of pharmaceutical and biopharmaceutical processing. Each specific topic has been thoroughly examined by a subject matter expert.

Advances in Biotechnology Research and Application: 2011 Edition - 2012-01-09

Advances in Biotechnology Research and Application: 2011 Edition is a ScholarlyEditions™ eBook that delivers timely, authoritative, and comprehensive information about Biotechnology. The editors have built Advances in Biotechnology Research and Application: 2011 Edition on the vast information databases of ScholarlyNews.™ You can expect the information about Biotechnology in this eBook to be deeper than what you can access anywhere else, as well as consistently reliable, authoritative, informed, and relevant. The content of Advances in Biotechnology Research and Application: 2011 Edition has been produced by the world's leading scientists, engineers,

analysts, research institutions, and companies. All of the content is from peer-reviewed sources, and all of it is written, assembled, and edited by the editors at ScholarlyEditions™ and available exclusively from us. You now have a source you can cite with authority, confidence, and credibility. More information is available at http://www.ScholarlyEditions.com/.

Practical Toxicology - David Woolley 2017-03-16

Practical Toxicology: Evaluation, Prediction, and Risk, Third Edition shows how to conduct a program of safety evaluation and testing and then to interpret and apply the resulting data and information in the real world, beginning with the basic concepts in toxicology and progressing to the interpretation of the resulting data. Revised and updated chapters on risk assessment guide the reader to setting the foundations necessary for submission to regulatory authorities. In addition, a new chapter in the book reviews the errors in toxicology, mistakes, misuse, mismanagement, and misunderstanding with a view to avoiding these in the future. New Chapters in the Third Edition: Toxicology in silico Errors in Toxicology Safety Assessment of Extractables and Leachables. This new edition follows a practical sequence from introducing the basics of toxicology (including the vital concept of normality in controls) to describing a test program and then interpreting the data and translating that to risk assessment that can be used in a number of real world situations where safety and secure risk assessment are essential. Although written primarily from the perspective of pharmaceutical development, the test designs and toxicological problems encountered in that field are entirely relevant to those with other classes of chemicals, the only difference being the regulatory context. Toxicology is an international discipline and the book has been written to take into account some of

the differences in regulatory nuance between the main regions of the world. Completely revised and written in an easily accessible style, the text address several audiences—from students and post-graduates coming to the subject for the first time to established professionals who find themselves needing to learn about toxicology, toxicity testing, interpretation of the results, and risk assessment. It is intended primarily as a textbook, with case studies and information on where to go to ask questions, but can also be used as a practical reference book. It covers all the basics of toxicology and the main aspects of safety evaluation testing and risk assessment while reviewing critically the current state of the discipline. It also provides a foundation for those seeking registration or certification.

Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing - Hamid Mollah 2013-03-18

Sets forth tested and proven risk management practices in drug manufacturing Risk management is essential for safe and efficient pharmaceutical and biopharmaceutical manufacturing, control, and distribution. With this book as their guide, readers involved in all facets of drug manufacturing have a single, expertly written, and organized resource to guide them through all facets of risk management and analysis. It sets forth a solid foundation in risk management concepts and then explains how these concepts are applied to drug manufacturing. Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing features contributions from leading international experts in risk management and drug manufacturing. These contributions reflect the latest research, practices, and industry standards as well as the authors' firsthand experience. Readers can turn to the book for: Basic

foundation of risk management principles, practices, and applications Tested and proven tools and methods for managing risk in pharmaceutical and biopharmaceutical product manufacturing processes Recent FDA guidelines, EU regulations, and international standards governing the application of risk management to drug manufacturing Case studies and detailed examples demonstrating the use and results of applying risk management principles to drug product manufacturing Bibliography and extensive references leading to the literature and helpful resources in the field With its unique focus on the application of risk management to biopharmaceutical and pharmaceutical manufacturing, this book is an essential resource for pharmaceutical and process engineers as well as safety and compliance professionals involved in drug manufacturing.

Pharmaceutical Dosage Forms - Parenteral Medications - Sandeep Nema 2016-04-19

This three-volume set of Pharmaceutical Dosage Forms: Parenteral Medications is an authoritative, comprehensive reference work on the formulation and manufacture of parenteral dosage forms, effectively balancing theoretical considerations with the practical aspects of their development. As such, it is recommended for scientists and engineers in the

Parenteral Medications, Fourth Edition - Sandeep Nema 2019-07-19

Parenteral Medications is an authoritative, comprehensive reference work on the formulation and manufacturing of parenteral dosage forms, effectively balancing theoretical considerations with practical aspects of their development. Previously published as a three-volume set, all volumes have been combined into one comprehensive publication that addresses the plethora of changes in the science and considerable advances in the technology associated with

these products and routes of administration. Key Features: Provides a comprehensive reference work on the formulation and manufacturing of parenteral dosage forms Addresses changes in the science and advances in the technology associated with parenteral medications and routes of administration Includes 13 new chapters and updated chapters throughout Contains the contributors of leading researchers in the field of parenteral medications Uses full color detailed illustrations, enhancing the learning process The fourth edition not only reflects enhanced content in all the chapters but also highlights the rapidly advancing formulation, processing, manufacturing parenteral technology including advanced delivery and cell therapies. The book is divided into seven sectionss: Section 1 - Parenteral Drug Administration and Delivery Devices; Section 2 - Formulation Design and Development; Section 3 - Specialized Drug Delivery Systems; Section 4 - Primary Packaging and Container Closure Integrity; Section 5 - Facility Design and Environmental Control; Section 6 - Sterilization and Pharmaceutical Processing; Section 7 - Quality Testing and Regulatory Requirements

Plastics in Medical Devices - Vinny R. Sastri 2021-10-01

Plastics in Medical Devices: Properties, Requirements, and Applications, Third Edition provides a comprehensive overview on the main types of plastics used in medical device applications. The book focuses on the applications and properties that are most important in medical device design, such as chemical resistance, sterilization capability and biocompatibility. The roles of additives, stabilizers and fillers as well as the synthesis and production of polymers are covered and backed up with a wealth of data tables. The book also covers other key aspects in detail, including regulations, compliance, purchasing controls and supplier controls, and process validation. This

updated edition has been thoroughly revised with regard to new plastic materials, applications and requirements. This is a valuable resource for engineers, scientists and managers involved in the design and manufacture of medical devices. Presents detailed coverage of commercially available plastics used in medical device applications, organized by polymer type and supported by data Includes up-to-date regulatory requirements and practical information on purchasing and supplier controls, process validation and risk management Supports the development, marketing and commercialization of medical devices and materials for use in medical devices

Pharmaceutical Formulation Development of Peptides and Proteins - Lars Hovgaard 2012-11-14

The rapid advances in recombinant DNA technology and the increasing availability of peptides and proteins with therapeutic potential are a challenge for pharmaceutical scientists who have to formulate these compounds as drug products. Pharmaceutical Formulation Development of Peptides and Proteins, Second Edition discusses the development of therap

Nanostructured Biomaterials for Regenerative Medicine - Vincenzo Guarino 2019-10-05

Nanostructured Biomaterials for Regenerative Medicine focuses on the definition of new trends for the design of biomaterials for biomedical applications. It includes the ex novo synthesis as well as technological strategies to manipulate them into appropriate two-dimensional (2D) and three-dimensional (3D) forms, in order to impart all the main physical, chemical, structural and biological properties requested to achieve desired clinical efficacy. This book aims at offering a concise overview of innovative platforms based on nanostructured biomaterials as a function of their chemical nature - established by a consolidated material

classification i.e., polymer, ceramics and metals. For each class, emerging bioinspired systems with rapid expansion in the biomedical research area and fabricated via new enabling technologies will be proposed for the use in tissue repair/regeneration and nanomedicine. This book is an essential resource for researchers, academics and professionals interested in the potential of nanostructured biomaterials for regenerative medicine. Classifies materials into three classes for comprehensive discussion Discusses design techniques to create innovative nanostructured biomaterials Looks at enabling technologies and strategies for emerging applications

Biopharmaceutical Production Technology - Ganapathy Subramanian 2012-05-14

Cost-effective manufacturing of biopharmaceutical products is rapidly gaining in importance, while healthcare systems across the globe are looking to contain costs and improve efficiency. To adapt to these changes, industries need to review and streamline their manufacturing processes. This two volume handbook systematically addresses the key steps and challenges in the production process and provides valuable information for medium to large scale producers of biopharmaceuticals. It is divided into seven major parts: - Upstream Technologies - Protein Recovery - Advances in Process Development - Analytical Technologies - Quality Control - Process Design and Management - Changing Face of Processing With contributions by around 40 experts from academia as well as small and large biopharmaceutical companies, this unique handbook is full of first-hand knowledge on how to produce biopharmaceuticals in a cost-effective and quality-controlled manner.

Pharmaceutical Dosage Forms - Sandeep Nema 2010-08-26

Pharmaceutical Dosage Forms: Parenteral Medications explores the administration of medications through other than

the enteral route. First published in 1984 (as two volumes) and then last revised in 1993, this three-volume set presents the plethora of changes in the science and considerable advances in the technology associated with these products

Update on Undertaking Extractable and Leachable Testing - Andrew Feilden 2011-03-31

The assessment of all materials - and especially elastomeric and plastic components - for the presence of leachable and extractable components, forms an important part of the submission for approval of a new drug system or medical device. This Update gives a detailed, state-of-the-art review of the selection of techniques, available to the analyst, to perform a controlled extraction study for leachables and extractables, with an overview of the factors to consider when selecting the extraction technique. This book will be of interest to Chemists and R&D managers.

Leachables and Extractables Handbook - Douglas J. Ball 2012-01-24

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.

Leachables and Extractables Handbook - Douglas J. Ball 2012-02-08

A practical and science-based approach for addressingtoxicological concerns related to leachables and extractablesassociated with inhalation drug products Packaging and device components of Orally Inhaled and Nasal DrugProducts (OINDP)—such as metered dose inhalers, dry powderinhalers, and nasal sprays—pose potential safety risks fromleachables and extractables, chemicals that can be released ormigrate from these components into the drug product. Addressing theconcepts, background, historical use, and development of safetythresholds and their utility for qualifying leachables andextractables in OINDP, the Leachables and Extractables Handbooktakes a practical approach to familiarize readers with the recentrecommendations for safety and risk assessment established througha joint effort of scientists from the FDA, academia, and industry.Coverage includes best practices for the chemical evaluation andmanagement of leachables and extractables

throughout thepharmaceutical product life cycle, as well as: Guidance for pharmaceutical professionals to qualify andrisk-assess container closure system leachables and extractables indrug products Principles for defining toxicological safety thresholds that areapplicable to OINDP and potentially applicable to other drugproducts Regulatory perspectives, along with an appendix of key terms anddefinitions, case studies, and sample protocols Analytical chemists, packaging and device engineers, formulationdevelopment scientists, component suppliers, regulatory affairsspecialists, and toxicologists will all benefit from the wealth ofinformation offered in this important text.

Influence of Microplastics on Environmental and Human Health - Yvonne Lang 2022-03-14

Microplastics have received increased attention in the research world over the last ten years. A number of significant publications by the World Health Organisation, European Union, SAPEA, and GESAMP have highlighted this growing environmental and health emergency. This book provides an accessible introduction to the microplastic problem and details its potential impact both on nature and human health. Filled with the latest developments in the field, it attempts to address the gaps in our knowledge of microplastics and will also propose additional areas of research and impact to be considered to resolve this crisis. It will be of interest to researchers and academics working in the areas of microplastic pollution, microplastic detection, and the impact of microplastics on environmental and human health. It will also be of use to undergraduate students of environmental programmes, analytical programmes, and public health programmes. Key Features: Chapters describe the impact of our reliance on plastics in certain sectors and how they relate to microplastic pollution Investigates emerging

solutions to the microplastic pollution Presents a multi-disciplinary perspective, covering topics such as analytical techniques, quantitative techniques, environmental monitoring, and human health monitoring

Compatibility of Pharmaceutical Solutions and Contact Materials - Dennis Jenke 2013-02-26

Compatibility of Pharmaceutical Products and Contact Materials Dennis Jenke Important safety aspects of compatibility for therapeuticproducts and their manufacturing systems, delivery devices, andcontainers Compatibility of Pharmaceutical Products and ContactMaterials helps pharmaceutical, toxicology, analytical, andregulatory affairs professionals assess the safety of leachable andextractable chemicals associated with drug product packaging,manufacturing systems, and devices. The most comprehensive resourceavailable, its coverage includes the strategies, tactics, andregulatory requirements for performing safety assessments, alongwith the means for interpreting results. Structured around a logical framework for an extractables andleachables safety assessment and closely linked to thepharmaceutical product development process, Compatibility ofPharmaceutical Products and Contact Materials directlyaddresses the fundamental questions of "what activities need to beperformed to completely, efficiently, and effectively address theissue of product safety from an extractables and leachablesperspective?" and "when do the various required activities need tobe performed?" Specifically, the chapters describe: Pertinent regulations and practical ways to meetguidelines Coordinating manufacturing, storage, and delivery systemsdevelopment and qualification with therapeutic productdevelopment Materials characterization and the materials screeningprocess Component and/or system qualification (illustrated by

severalcase studies) Performing validation/migration studies and interpreting andreporting the results Creating a product registration dossier and putting it throughregulatory review Product maintenance (Change Control) from an extractables andleachables perspective Likely future developments in extractables and leachablesassessment Additionally, the book's appendix provides a database, includingCAS registry numbers, chemical formulas and molecular weights ofextractable/leachable substances that have been reported in thechemical literature. Detailing the interconnected roles played by analyticalchemistry, biological science, toxicology, and regulatory science,Compatibility of Pharmaceutical Products and ContactMaterials supplies a much-needed, comprehensive resource to allthose in pharmaceutical product or medical device development.

Practical Toxicology - David Woolley 2017-03-16

Practical Toxicology: Evaluation, Prediction, and Risk, Third Edition shows how to conduct a program of safety evaluation and testing and then to interpret and apply the resulting data and information in the real world, beginning with the basic concepts in toxicology and progressing to the interpretation of the resulting data. Revised and updated chapters on risk assessment guide the reader to setting the foundations necessary for submission to regulatory authorities. In addition, a new chapter in the book reviews the errors in toxicology, mistakes, misuse, mismanagement, and misunderstanding with a view to avoiding these in the future. New Chapters in the Third Edition: Toxicology in silico Errors in Toxicology Safety Assessment of Extractables and Leachables. This new edition follows a practical sequence from introducing the basics of toxicology (including the vital concept of normality in controls) to describing a test

program and then interpreting the data and translating that to risk assessment that can be used in a number of real world situations where safety and secure risk assessment are essential. Although written primarily from the perspective of pharmaceutical development, the test designs and toxicological problems encountered in that field are entirely relevant to those with other classes of chemicals, the only difference being the regulatory context. Toxicology is an international discipline and the book has been written to take into account some of the differences in regulatory nuance between the main regions of the world. Completely revised and written in an easily accessible style, the text address several audiences—from students and post-graduates coming to the subject for the first time to established professionals who find themselves needing to learn about toxicology, toxicity testing, interpretation of the results, and risk assessment. It is intended primarily as a textbook, with case studies and information on where to go to ask questions, but can also be used as a practical reference book. It covers all the basics of toxicology and the main aspects of safety evaluation testing and risk assessment while reviewing critically the current state of the discipline. It also provides a foundation for those seeking registration or certification.

Extractables and Leachables - Dennis Jenke 2022-07-14 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.

Pharmaceutical Industry Practices on Genotoxic Impurities - Heewon Lee 2014-08-29

A great deal of confusion and uncertainty over genotoxic impurity (GTI) identification, assessment, and control exists in the pharmaceutical industry today. Pharmaceutical Industry Practices on Genotoxic Impurities strives to facilitate scientific and systematic consensus on GTI management by presenting rationales, strategies, methods, interpretati

Compatibility of Pharmaceutical Solutions and Contact Materials - Dennis Jenke 2009-06-02

Important safety aspects of compatibility for therapeutic products and their manufacturing systems, delivery devices, and containers Compatibility of Pharmaceutical Products and

Contact Materials helps pharmaceutical, toxicology, analytical, and regulatory affairs professionals assess the safety of leachable and extractable chemicals associated with drug product packaging, manufacturing systems, and devices. The most comprehensive resource available, its coverage includes the strategies, tactics, and regulatory requirements for performing safety assessments, along with the means for interpreting results. Structured around a logical framework for an extractables and leachables safety assessment and closely linked to the pharmaceutical product development process, Compatibility of Pharmaceutical Products and Contact Materials directly addresses the fundamental questions of "what activities need to be performed to completely, efficiently, and effectively address the issue of product safety from an extractables and leachables perspective?" and "when do the various required activities need to be performed?" Specifically, the chapters describe: Pertinent regulations and practical ways to meet guidelines Coordinating manufacturing, storage, and delivery systems development and qualification with therapeutic product development Materials characterization and the materials screening process Component and/or system qualification (illustrated by several case studies) Performing validation/migration studies and interpreting and reporting the results Creating a product registration dossier and putting it through regulatory review Product maintenance (Change Control) from an extractables and leachables perspective Likely future developments in extractables and leachables assessment Additionally, the book's appendix provides a database, including CAS registry numbers, chemical formulas and molecular weights of extractable/leachable substances that have been reported in the chemical

literature. Detailing the interconnected roles played by analytical chemistry, biological science, toxicology, and regulatory science, Compatibility of Pharmaceutical Products and Contact Materials supplies a much-needed, comprehensive resource to all those in pharmaceutical product or medical device development.

Biocompatibility and Performance of Medical Devices - Jean-Pierre Boutrand 2019-11-21

Biocompatibility and Performance of Medical Devices, Second Edition, provides an understanding of the biocompatibility and performance tests for ensuring that biomaterials and medical devices are safe and will perform as expected in the biological environment. Sections cover key concepts and challenges faced in relation to biocompatibility in medical devices, discuss the evaluation and characterization of biocompatibility in medical devices, describe preclinical performance studies for bone, dental and soft tissue implants, and provide information on the regulation of medical devices in the European Union, Japan and China. The book concludes with a review of histopathology principles for biocompatibility and performance studies. Presents diverse insights from experts in government, industry and academia Delivers a comprehensive overview of testing and interpreting medical device performance Expanded to include new information, including sections on managing extractables, accelerating and simplifying medical device development through screening and alternative biocompatibility methods, and quality strategies which fasten device access to market

Continuous Biomanufacturing - Ganapathy Subramanian 2017-12-26

This is the most comprehensive treatise of this topic available, providing invaluable information on the technological and economic benefits to be gained from implementing continuous

processes in the biopharmaceutical industry. Top experts from industry and academia cover the latest technical developments in the field, describing the use of single-use technologies alongside perfusion production platforms and downstream operations. Special emphasis is given to process control and monitoring, including such topics as 'quality by design' and automation. The book is supplemented by case studies that highlight the enormous potential of continuous manufacturing for biopharmaceutical production facilities.

Comprehensive Medicinal Chemistry III - 2017-06-03

Comprehensive Medicinal Chemistry III provides a contemporary and forward-looking critical analysis and summary of recent developments, emerging trends, and recently identified new areas where medicinal chemistry is having an impact. The discipline of medicinal chemistry continues to evolve as it adapts to new opportunities and strives to solve new challenges. These include drug targeting, biomolecular therapeutics, development of chemical biology tools, data collection and analysis, in silico models as predictors for biological properties, identification and validation of new targets, approaches to quantify target engagement, new methods for synthesis of drug candidates such as green chemistry, development of novel scaffolds for drug discovery, and the role of regulatory agencies in drug discovery. Reviews the strategies, technologies, principles, and applications of modern medicinal chemistry Provides a global and current perspective of today's drug discovery process and discusses the major therapeutic classes and targets Includes a unique collection of case studies and personal assays reviewing the discovery and development of key drugs

Biosimilars and Interchangeable Biologics - Sarfaraz K. Niazi 2016-01-05

What’s the Deal with

Biosimilars? Biosimilars are gaining momentum as new protein therapeutic candidates that can help fill a vital need in the healthcare industry. The biological drugs are produced by recombinant DNA technology that allows for large-scale production and an overall reduction time in costs and development. Part of a two-volume set that covers varying aspects of biosimilars, Biosimilars and Interchangeable Biologics: Tactical Elements explores the development and manufacturing of biosimilars and targets challenges surrounding the creation of these products. This includes manufacturing, production costs, and intellectual property barriers, particularly in regulated markets (regulatory agencies are still in the process of developing guidelines). It addresses the complexity of biological drugs, and it discusses specific structural elements vital to the functionality, immunogenicity, and safety of biosimilar products. Of specific interest to practitioners, researchers, and scientists in the biopharmaceutical industry, this volume provides an overall understanding of the hurdles, difficulties, and practicalities of developing a strong plan. It introduces a step-by-step approach for creating a strategy that helps develop and manufacture a biosimilar product while reducing overall production costs and meeting the requirements of biosimilarity based on analytical and functional, pharmacokinetic, pharmacodynamic (where applicable), and nonclinical toxicology or toxicokinetic similarity (where appropriate) while remaining competitive in the market.

Paediatric Formulation - Nunzio Denora 2021-09-02

The development of paediatric medicines can be challenging since this is a different patient population with specific needs. A medicine designed for use in paediatric patients must consider the following aspects: patient population variability; the need for dose flexibility;

route of administration; patient compliance; excipient tolerability. For example, the toxicity of excipients may differ in children compared to adults and children have different taste preferences. Globally, about 75% of drugs do not carry regulatory approval for use in children; worldwide, many medications prescribed for the treatment of paediatric diseases are used off-label, and less than 20% of package inserts have sufficient information for treating children. This book provides an update on both state-of-the-art methodology and operational challenges in paediatric formulation design and development. It aims at re-evaluating what is needed for more progress in the design and development of age-appropriate treatments for paediatric diseases, focusing on: formulation development; drug delivery design; efficacy, safety, and tolerability of drugs and excipients.

Handbook of Validation in Pharmaceutical Processes, Fourth Edition - James Agalloco 2021-10-28

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 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

Biopharmaceutical Processing - Gunter Jagschies 2018-01-18

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 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

Disposable Bioreactors - Regine Eibl 2009-12-02

Over the past five years, the immense financial pressure on the development and manufacturing of biopharmaceuticals has

resulted in the increasing use and acce- ance of disposables, which are discarded after harvest and therefore intended only for single use. In fact, such disposables are implemented in all the main bioprocess production stages today and an even higher growth than those in the biopharmac- tical market is predicted (reaching double figures). Alongside disposable filter capsules, membrane chromatography units, tubing, connectors, flexible containers processing or containing fluids, freezer systems, mixers and pumps, and fully c- trolled disposable bioreactors of up to 2,000 L culture volume are already available on the market. Numerous studies highlight the advantages of disposable bioreactors and reveal their potential for simple, safe and fast seed inoculum production, process devel- ment and small as well as middle volume production (e.g. bioactive substances, viruses for vaccines and gene therapies etc.). They suggest that such disposable bioreactors (typically characterized by the cultivation chamber or bag from plastic materials) may be advantageous for plant, animal and microbial cells. Running industrial activities such as CFD-modelling, development of single-use process monitoring and control technology, and standardized film formulations are attempting to resolve the limitations of the current disposable bioreactors. These achievements, along with substantial improvements in product yield, will reduce the use of stainless steel in the biomanufacturing facilities of the future.

Biomaterials Science - Buddy D. Ratner 2012-12-31

The revised edition of this renowned and bestselling title is the most comprehensive single text on all aspects of biomaterials science. It provides a balanced, insightful approach to both the learning of the science and technology of biomaterials and acts as the key reference for practitioners who are involved in the applications of materials in

medicine. Over 29,000 copies sold, this is the most comprehensive coverage of principles and applications of all classes of biomaterials: "the only such text that currently covers this area comprehensively" - Materials Today Edited by four of the best-known figures in the biomaterials field today; fully endorsed and supported by the Society for Biomaterials Fully revised and expanded, key new topics include of tissue engineering, drug delivery systems, and new clinical applications, with new teaching and learning material throughout, case studies and a downloadable image bank

Comprehensive Biotechnology - 2019-07-17

Comprehensive Biotechnology, Third Edition unifies, in a single source, a huge amount of information in this growing field. The book covers scientific fundamentals, along with engineering considerations and applications in industry, agriculture, medicine, the environment and socio-economics, including the related government regulatory overviews. This new edition builds on the solid basis provided by previous editions, incorporating all recent advances in the field since the second edition was published in 2011. Offers researchers a one-stop shop for information on the subject of biotechnology Provides in-depth treatment of relevant topics from recognized authorities, including the contributions of a Nobel laureate Presents the perspective of researchers in different fields, such as biochemistry, agriculture, engineering, biomedicine and environmental science

Fundamentals of Modern Bioprocessing - Sarfaraz K. Niazi 2017-07-27

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.

Single-Use Technology in

Biopharmaceutical Manufacture - Regine Eibl 2019-07-18
Authoritative guide to the principles, characteristics, engineering aspects, economics, and applications of disposables in the manufacture of biopharmaceuticals The revised and updated second edition of Single-Use Technology in Biopharmaceutical Manufacture offers a comprehensive examination of the most-commonly used disposables in the manufacture of biopharmaceuticals. The authors—noted experts on the topic—provide the essential information on the principles, characteristics, engineering aspects, economics, and applications. This authoritative guide contains the basic knowledge and information about disposable equipment. The author also discusses biopharmaceuticals' applications through the lens of case studies that clearly illustrate the role of manufacturing, quality assurance, and environmental influences. This updated second edition revises existing information with recent developments that have taken place since the first edition was published. The book also presents the latest advances in the field of single-use technology and explores topics including applying single-use devices for microorganisms, human mesenchymal stem cells, and T-cells. This important book: • Contains an updated and end-to-end view of the development and manufacturing of single-use biologics • Helps in the identification of appropriate disposables and relevant vendors • Offers illustrative case studies that examine manufacturing, quality assurance, and environmental influences • Includes updated coverage on cross-functional/transversal dependencies, significant improvements made by suppliers, and the successful application of the single-use technologies Written for biopharmaceutical manufacturers, process

developers, and biological and chemical engineers, Single-Use Technology in Biopharmaceutical Manufacture, 2nd Edition provides the information needed for professionals to come to an easier decision for or against disposable alternatives and to choose the appropriate system.

Single-Use Technology - Adriana G. Lopes 2019-06-17

Single-Use Technology (SUT) is the first comprehensive publication of practical considerations for each stage of the implementation process of SUT, and covers the selection, specification, design and qualification of systems to meet end-user requirements. Having become readily available for all processing operations within the biopharmaceutical industry, SUT has the potential to reduce capital costs, improve plant throughput and reduce the risk of cross-contamination. However, there are no clear guidelines to aid the end-user on implementation of these technologies into a validated, good manufacturing practice (GMP) environment. This book presents approaches for the implementation within various end-user facilities and systems, SUT within regulatory frameworks (ICH Q8, Q9, Q10 and GMP), standardisation and assessment strategies, specifation of user requirements and SUT design, risk assessment and evaluation as well as qualification for different SUT types.

Quality by Design for Biopharmaceutical Drug Product Development - Feroz Jameel 2015-04-01

This volume explores the application of Quality by Design (QbD) to biopharmaceutical drug product development. Twenty-eight comprehensive chapters cover dosage forms, liquid and lyophilized drug products. The introductory chapters of this book define key elements of QbD and examine how these elements are integrated into drug product development. These chapters also discuss lessons learned from the FDA Office of Biotechnology

Products pilot program. Following chapters demonstrate how QbD is used for formulation development ranging from screening of formulations to developability assessment to development of lyophilized and liquid formats. The next few chapters study the use of small-scale and surrogate models as well as QbD application to drug product processes such as drug substance freezing and thawing, mixing, sterile filtration, filling, lyophilization, inspection and shipping and handling. Later chapters describe more specialized applications of QbD in the drug product realm. This includes the use of QbD in primary containers, devices and combination product development. The volume also explores QbD applied to vaccine development, automation, mathematical modeling and monitoring, and controlling processes and defining control strategies. It concludes with a discussion on the application of QbD to drug product technology transfer as well as overall regulatory considerations and lifecycle management. Quality by Design for Biopharmaceutical Drug Product Development is an authoritative resource for scientists and researchers interested in expanding their knowledge on QbD principles and uses in creating better drugs.

Integrated Safety and Risk Assessment for Medical Devices and Combination Products - Shayne C. Gad 2020-02-24

While the safety assessment ("biocompatibility") of medical devices has been focused on issues of local tissue tolerance (irritation, sensitization, cytotoxicity) and selected quantal effects (genotoxicity and acute lethality) since first being regulated in the late 1950s, this has changed as devices assumed a much more important role in healthcare and became more complex in both composition and in their design and operation. Add to this that devices now frequently serve as delivery systems for drugs, and that

drugs may be combined with devices to improve device performance, and the problems of ensuring patient safety with devices has become significantly more complex. A part of this, requirements for ensuring safety (once based on use of previously acceptable materials – largely polymers and metals) have come to requiring determining which chemical entities are potentially released from a device into patients (and how much is released). Then an appropriate and relevant (yet also conservative) risk assessment must be performed for each identified chemical structure. The challenges inherent in meeting the current requirements are multifold, and this text seeks to identify, understand, and solve all of them. • Identify and verify the most appropriate available data. • As in most cases such data is for a different route of exposure, transform it for use in assessing exposure by the route of interest. • As the duration (and rate) of exposure to moieties released from a device are most frequently different (longer) than what available data speaks to, transformation across tissue is required. • As innate and adaptive immune responses are a central part of device/patient interaction, assessing potential risks on this basis are required. • Incorporating assessments for special populations such as neonates. • Use of (Q)SAR (Quantitative Structure Activity Relationships) modeling in assessments. • Performance and presentation of integrative assessments covering all potential biologic risks. Appendices will contain summarized available biocompatibility data for commonly used device materials (polymers and metals) and safety assessments on the frequently seen moieties in extractions from devices.

Handbook for Critical Cleaning: Applications, processes, and controls - Barbara Kanegsberg 2011

"Updated, re-organized, and rewritten, this second edition of a bestseller covers cleaning processes, applications,

management, safety, and environmental concerns. A two-volume set, it discusses cleaning process applications, management, and safety and environmental concerns. International contributors give the text a global viewpoint. Color illustrations, video clips, and animations that make the information accessible are available from the website. The handbook is available for purchase individually or as the two-volume set"--