Pda Journal Of Pharmaceutical Science And Technology

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List of Journals Indexed in Index Medicus Elsevier
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 also proposes 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
Practical Pharmaceutics John Wiley & Sons
Process Simulation Testing for Sterile Bulk Pharmaceutical ChemicalsQuality risk management for aseptic processesValidation of column-based chromatography processes for the purification of proteinsVirus filtrationPDA Technical Report No. 42Biological Indicators for Gas and Vapor-phase Decontamination ProcessesSterilizing Filtration of GasesPDA Technical Report No. 45Principles and Practices of Lyophilization in Product Development and ManufacturingSpringer
Drying Technologies for Biotechnology and Pharmaceutical Applications Elsevier
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.
Biocontamination Control for Pharmaceuticals and Healthcare John Wiley & Sons
Gathering information of critical importance for professionals in the pharmaceutical and medical device industries, this guide provides a comprehensive overview of key resources, such as databases, on-line directories, reports, and periodicals-providing at-a-glance guidance and collection development tools for information professionals in this field. Each chapter corresponds to a key stage or component of the drug development processin a typical pharmaceutical company and covers the types of information typically required at that particular phase.
Parenteral Medications, Fourth Edition Cuvillier Verlag
A comprehensive overview of the demands on pharmaceutical products and manufacturing processes. It describes in detail the requirements for pharmaceutical production plants, production processes, equipment and machinery, as well as the accompanying qualification and validation measures. Suitable for both engineers in the pharmaceutical industry and in related sectors, as well as for researchers and students in chemical, pharmaceutical, biotechnological and technical courses.
Principles and Practices of Lyophilization in Product Development and Manufacturing CRC Press
Validierung als Eignungsnachweis für die Qualität der Analytik wird heute von jedem Auftraggeber und Kunden erwartet. Damit stehen Laborleitung und Qualtitätsmanagement vor den Fragen wie: - Was muß unbedingt validiert werden und welche Aussagekraft haben Validierungsdaten? - Was wird von wem vorgegeben und wo sind wir frei? - Wie können wir schnell und kostengünstig, aber richtig validieren? Die Antworten lassen sich jetzt mit diesem Handbuch finden. Es bietet neben einer Einführung in die Grundsätze und Praxis der Validierung insbesondere: - Eine Anleitung zum ökonomischen Umgang mit der Validierung, um Kosten zu senken - Anerkannte Alternativen zur Validierung - Praktische Fallbeispiele von erfahrenen Fachleuten aus den Bereichen Spektroskopie, Chromatographie, Titrimetrie, Probenvorbereitung und Mikrobiologie sowie Software und computerisierte Analysensysteme. Das Buch enthält zahlreiche Tabellen, Checklisten und Fließschemata. Es wird abgerundet mit einem Glossar, nützlichen Adressen, Namen relevanter Organisationen und einem Software- und Literaturüberblick. Es ist die erweiterte Fassung der praktischen Einführung "Validierung in der Analytik" vom selben Autor.
PDA Technical Report No. 45 CRC Press
Relying on practical examples from the authors’ experience, this book provides a thorough and modern approach to controlling and monitoring microbial contaminations during the manufacturing of non-sterile pharmaceuticals. Offers a comprehensive guidance for non-sterile pharmaceuticals microbiological QA/QC Presents the latest developments in both regulatory expectations and technical advancements Provides guidance on statistical tools for risk assessment and trending of microbiological data Describes strategy and practical examples from the authors’ experience in globalized pharmaceutical companies and expert networks Offers a comprehensive guidance for non-sterile pharmaceuticals microbiological QA/QC Presents the latest developments in both regulatory expectations and technical advancements Provides guidance on statistical tools for risk assessment and trending of microbiological data Describes strategy and practical examples from the authors’ experience in globalized pharmaceutical companies and expert networks
Index Medicus John Wiley & Sons
Drug development is an iterative process. The recent publications of regulatory guidelines further entail a lifecycle approach. Blending data from disparate sources, the Bayesian approach provides a flexible framework for drug development. Despite its advantages, the uptake of Bayesian methodologies is lagging behind in the field of pharmaceutical development. Written specifically for pharmaceutical practitioners, Bayesian Analysis with R for Drug Development: Concepts, Algorithms, and Case Studies, describes a wide range of Bayesian applications to problems throughout pre-clinical, clinical, and Chemistry, Manufacturing, and Control (CMC) development. Authored by two seasoned statisticians in the pharmaceutical industry, the book provides detailed Bayesian solutions to a broad array of pharmaceutical problems. Features Provides a single source of information on Bayesian statistics for drug development Covers a wide spectrum of pre-clinical, clinical, and CMC topics Demonstrates proper Bayesian applications using real-life examples Includes easy-to-follow R code with Bayesian Markov Chain Monte Carlo performed in both JAGS and Stan Bayesian software

platforms Offers sufficient background for each problem and detailed description of solutions suitable for practitioners with limited Bayesian knowledge Harry Yang, Ph.D., is Senior Director and Head of Statistical Sciences at AstraZeneca. He has 24 years of experience across all aspects of drug research and development and extensive global regulatory experiences. He has published 6 statistical books, 15 book chapters, and over 90 peer-reviewed papers on diverse scientific and statistical subjects, including 15 joint statistical works with Dr. Novick. He is a frequent invited speaker at national and international conferences. He also developed statistical courses and conducted training at the FDA and USP as well as Peking University. Steven Novick, Ph.D., is Director of Statistical Sciences at AstraZeneca. He has extensively contributed statistical methods to the biopharmaceutical literature. Novick is a skilled Bayesian computer programmer and is frequently invited to speak at conferences, having developed and taught courses in several areas, including drug-combination analysis and Bayesian methods in clinical areas. Novick served on IPAC-RS and has chaired several national statistical conferences.

Sterility, Sterilisation and Sterility Assurance for Pharmaceuticals Process Simulation Testing for Sterile Bulk Pharmaceutical ChemicalsQuality risk management for aseptic processesValidation of column-based chromatography processes for the purification of proteinsVirus filtrationPDA Technical Report No. 42Biological Indicators for Gas and Vapor-phase Decontamination ProcessesSterilizing Filtration of GasesPDA Technical Report No. 45Principles and Practices of Lyophilization in Product Development and Manufacturing

The biotechnology/biopharmaceutical sector has tremendously grown which led to the invention of engineered antibodies such as Antibody Drug Conjugates (ADCs), Bispecific T cell engager (BITES), Dual Variable Domain (DVD), Chimeric Antigen Receptor - Modified Tcells (CART) that are currently being used as therapeutic agents for immunology and oncology disease conditions. In addition to other pharmaceuticals and biopharmaceuticals, all these novel formats are fragile with respect to their stability/structure under processing conditions meaning marginal stability in the liquid state and often require lyophilization to enhance their stability and shelf-life. This book contains chapters/topics that will describe every aspect of the lyophilization process and product development and manufacturing starting from the overview of lyophilization process, equipment required, characterization of the material, design and development of the formulation and lyophilization process, various techniques for characterization of the product, scale-up/tech-transfer and validation. It also describes the application of CFD coupled with mathematical modeling in the lyophilization process and product development, scale-up, and manufacturing. Additionally, Principles and Practice of Lyophilization Process and Product Development contains an entire dedicated section on “Preservation of Biologicals” comprised of nine chapters written by experts and including case studies.

Concise Encyclopedia of High Performance Silicones John Wiley & Sons

Failure to adequately control any microbial challenge associated within process or product by robust sterilisation will result in a contaminated marketed product, with potential harm to the patient. Sterilisation is therefore of great importance to healthcare and the manufacturers of medical devices and pharmaceuticals. Sterility, sterilisation and sterility assurance for pharmaceuticals examines different means of rendering a product sterile by providing an overview of sterilisation methods including heat, radiation and filtration. The book outlines and discusses sterilisation technology and the biopharmaceutical manufacturing process, including aseptic filling, as well as aspects of the design of containers and packaging, as well as addressing the cleanroom environments in which products are prepared. Consisting of 18 chapters, the book comprehensively covers sterility, sterilisation and microorganisms; pyrogenicity and bacterial endotoxins; regulatory requirements and good manufacturing practices; and gamma radiation. Later chapters discuss e-beam; dry heat sterilisation; steam sterilisation; sterilisation by gas; vapour sterilisation; and sterile filtration, before final chapters analyse depyrogenation; cleanrooms; aseptic processing; media simulation; biological indicators; sterility testing; auditing; and new sterilisation techniques. Covers the main sterilisation methods of physical removal, physical alteration and inactivation Includes discussion of medical devices, aseptically filled products and terminally sterilised products Describes bacterial, pyrogenic, and endotoxin risks to devices and products

Data Integrity in Pharmaceutical and Medical Devices Regulation Operations Springer

Biocontamination Control for Pharmaceuticals and Healthcare outlines a biocontamination strategy that tracks bio-burden control and reduction at each transition in classified areas of a facility. The first edition of the book covered many of the aspects of the strategy, but the new official guidance signals that a roadmap is required to fully comply with its requirements. Completely updated with the newest version of the EU-GPM (EN17141) the new edition expands the coverage of quality risk management and new complete examples to help professionals bridge the gap between regulation and implementation. Biocontamination Control for Pharmaceuticals and Healthcare offers professionals in pharma quality control and related areas guidance on building a complete biocontamination strategy. Includes the most current regulations Contains three new chapters, including Application of Quality Risk Management and its Application in Biocontamination Control, Designing an Environmental Monitoring Programme, and Synthesis: An Anatomy of a Contamination Control Strategy Offers practical guidance on building a complete biocontamination strategy

Handbook of Validation in Pharmaceutical Processes, Fourth Edition John Wiley & Sons

The encyclopedia will be an invaluable source of information for researchers and students from diverse backgrounds including physics, chemistry, materials science and surface engineering, biotechnology, pharmacy, medical science, and biomedical engineering.

Influence of Microplastics on Environmental and Human Health John Wiley & Sons

Nonionic Surfactants, Sugar-Based Surfactants, Alkylpolyglucosides, Protein Formulations

Bayesian Analysis with R for Drug Development Newnes

Die pharmazeutische Mikrobiologie hat sich in den letzten Jahrzehnten von einer hochspezialisierten Wissenschaft zu einer Querschnittdisziplin entwickelt, die für Pharmazeuten, Mikrobiologen, aber auch Mediziner und Qualitätssicherungsbeauftragte von fundamentaler Bedeutung ist. Michael Rieth, promovierter Mikrobiologe mit langjähriger Erfahrung in mikrobiologischer Qualitätsprüfung in der pharmazeutischen Industrie, stellt in diesem Buch umfassend alle unterschiedlichen Aktivitäten, Entwicklungen und Technologien dieses dynamischen Gebiets zusammen. Immer aus dem Blickwinkel der pharmazeutischen Praxis, liegt hier das erste deutschsprachige Buch vor, das den wachsenden Anforderungen an Arzneimittelsicherheit und -qualität Rechnung trägt und selbstverständlich Erfordernisse nationaler und internationaler (FDA) Kontroll- und Regulierungsbehörden berücksichtigt. Aus dem Inhalt: *Desinfektion, Sterilisation und aseptische Herstellung *mikrobiologisches und physikalisches Monitoring in der Sterilproduktion *Prozessvalidierungen *Auswertung von Bioindikatoren * mikrobiologische Schnellmethoden, z. B. über Fluoreszenz und Biolumineszenz *Identifizierung von Mikroorganismen (u. a. PCR, Gaschromatographie und MALDI-TOF Massenspektrometrie)

Quality risk management for aseptic processes CRC Press

Issues for 1977-1979 include also Special List journals being indexed in cooperation with other institutions. Citations from these journals appear in other MEDLARS bibliographies and in MEDLING, but not in Index medicus.

Endotoxin Detection and Control in Pharma, Limulus, and Mammalian Systems Springer

Der Coatingprozess einer 3,5 kg Charge im Laborcoater wurde mit Hilfe der Ramanspektroskopie anhand von inline Messungen verfolgt. Dabei wurde mit der multivariaten Datenanalyse ein Modell erstellt, um den Coatingfortschritt zu beschreiben. Im Gegensatz zu der univariaten Regression werden bei der multivariaten Datenanalyse geeignete spektrale Bereiche zur Modellerstellung verwendet, wodurch man mehr Informationen aus den erhaltenen Messdaten gewinnt, die mit dem Coatingverlauf in Zusammenhang gebracht werden können. Dabei stellen die Auswahl des spektralen Wellenzahlbereiches, Anzahl der Hauptkomponenten und die Datenvorbehandlung wichtige Parameter dar, welche die Qualität des Modells entscheidend beeinflussen. Die mit der Ramanspektroskopie entwickelte Methode wurde in Übereinstimmung mit der ICH Guideline Q2 validiert. Dabei wurden die charakteristischen Validierungselemente in Hinblick auf die Übertragung für inline Messungen untersucht. Im Gegensatz zur Trommeldrehzahl, die nicht signifikant die Vorhersage des Modells beeinflusst, kommt dem Messabstand eine wichtige Bedeutung zu. Aber bedingt durch die große Tiefenschärfe der PhAT-Sonde ist ein Spielraum für im Prozess auftretende Veränderungen im Sondenabstand zur Tablettenoberfläche gegeben. Mit Hilfe des erstellten multivariaten Modells war es möglich, anhand der inline Messungen den Prozessverlauf beim Wirkstoffcoating mit dem Modellarzneistoff Diprophyllin auf Placebotabletten zu verfolgen. Die Ramanspektren enthalten chemische Informationen über das Coatingmaterial, womit die im Laufe des Prozesses erfolgten Veränderungen in den Spektren im direkten Zusammenhang mit dem Coatingfortschritt stehen. Weiterhin war es auch möglich, bei genügend hoher Konzentration des Diprophyllins in der Sprühflüssigkeit bzw. bei genügend aufgetragener Menge den Auftrag auf Diprophyllintabletten zu verfolgen. Aufgrund der Eindringtiefe von ungefähr 2 mm des Laserspots der PhAT-Sonde konnte auch nach dem Prozess der Kern ausreichend detektiert werden. Da sich die Zusammensetzung der Sprühflüssigkeit und der Diprophyllintabletten voneinander unterscheiden, kann der Prozess auch durch die inline Messungen verfolgt werden, wenn die Konzentration des Diprophyllins in der Sprühflüssigkeit stark erniedrigt wird. Die Veränderungen in den Spektren, die im Laufe des Prozesses durch die anderen Komponenten der Sprühflüssigkeit herbeigeführt werden, können verwendet werden, den Prozess zu verfolgen. Mit Scale up Versuchen konnte gezeigt werden, dass die aufgetragene Diprophyllinmenge auf Placebotabletten auch beim Coating einer 30 kg Charge in einem größeren Coater durch die inline Messungen vorhergesagt werden konnten. Die inline Messung beim Coating wird dadurch limitiert, dass jede erfolgte Messung im Prozess einen Durchschnittswert von mehreren Tabletten darstellt, wodurch eine Detektion von Coatinginhomogenitäten zwischen Tabletten unmöglich wird. Selbst im vereinfachten Vorversuch mit der Drehscheibe war es schwierig, die Coating Uniformity zwischen sich bewegenden Tabletten mit Hilfe der Ramanspektroskopie zu untersuchen. Um die Coatinginhomogenität annähernd detektieren zu können, muss die Messzeit drastisch verkürzt werden, wobei aufgrund des Signal/Rausch Verhältnisses die Verkürzung der Messzeit limitiert ist. Beim funktionellen Coaten zur Modifizierung der Freisetzung war es nicht möglich, den gesamten Prozess anhand der inline Messungen zu verfolgen. Im Vergleich zum Wirkstoffcoating erhält man keinen stetigen Anstieg des zu quantifizierenden Analyten. Die Hauptinformation in den Spektren steckt in der Signalabschwächung des Kerns und einem verhältnismäßig kleinen Anstieg der für das Polymer charakteristischen Peaks. Weiterhin steht die anhand der inline Messung ermittelte aufgetragene Polymermenge nicht in einem direkten Zusammenhang mit dem gesuchten Referenzwert. Die mit Hilfe der Terahertzspektroskopie ermittelten Coatingdicken zeigen, dass am Prozessanfang die Filme noch zu dünn sind und starke Coatinginhomogenitäten zwischen den Tabletten bestehen. Dies kann zum Filmriss und damit zur Abweichung vom gewünschten Freisetzungsverhalten führen. Erst bei ausreichender Coatingdicke steht die durch die Ramanmessung ermittelte aufgetragene Polymermenge im direkten Zusammenhang mit der mittleren Auflösungszeit. Dadurch kann der Prozess erst nach einer bestimmten Coatingzeit gut verfolgt werden, wodurch es aber möglich war, den Endpunkt des Prozesses zu detektieren.

Virus filtration Elsevier

Endotoxin detection and control is a dynamic area of applied science that touches a vast number of complex subjects. The intersection of test activities includes the use of an ancient blood system from an odd “living fossil” (Limulus). It is used to detect remnants of the most primitive and destructive forms of life (prokaryotes) as contaminants of complex modern systems (mammalian and Pharma). Recent challenges in the field include those associated with the application of traditional methods to new types of molecules and manufacturing processes. The advent of “at will” production of biologics in lieu of harvesting animal proteins has revolutionized the treatment of disease. While the fruits of the biotechnology revolution are widely acknowledged, the realization of the differences in the means of production and changes in the manner of control of potential impurities and contaminants in regard to the new versus the old are less widely appreciated. Endotoxin as an ancient, dynamic interface between lifeforms, provides a singular perspective from which to view the parallel development of ancient and modern organisms as well as the progress of man in deciphering the complexity of their interactions in his efforts to overcome disease.

Process Simulation Testing for Sterile Bulk Pharmaceutical Chemicals CRC Press

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

Sterilizing Filtration of Gases Springer

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

Sugar-Based Surfactants for Pharmaceutical Protein Formulations Cuvillier Verlag

This book contains essential knowledge on the preparation, control, logistics, dispensing and use of medicines. It features chapters written by experienced pharmacists working in hospitals and academia throughout Europe, complete with practical examples as well as information on current EU-legislation. From prescription to production, from usage instructions to procurement and the impact of medicines on the environment, the book provides step-by-step coverage that will help a wide range of readers. It offers product knowledge for all pharmacists working directly with patients and it will enable them to make the appropriate medicine available, to store medicines properly, to adapt medicines if necessary and to dispense medicines with the appropriate information to inform patients and caregivers about product care and how to maintain their quality. This basic knowledge will also be of help to industrial pharmacists to remind and focus them on the application of the medicines manufactured. The basic and practical knowledge on the design, preparation and quality management of medicines can directly be applied by the pharmacists whose main duty is production in community and hospital pharmacies and industries. Undergraduate as well as graduate pharmacy students will find knowledge and backgrounds in a fully coherent way and fully supported with examples.