Chapter 4 Aseptic Processing Equipment And Systems

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Aseptic Processing and Packaging of Food and Beverages Academic Press
A self-contained and practical book providing step-by-step guidance to the design and construction of cleanrooms, appropriate testing methodologies, and operation for the minimization of contamination... This second edition has been comprehensively revised and includes extensive updates to the two chapters that contain information on cleanroom standards and guidelines. The chapter on risk management has been extensively revised, especially the section on risk assessment. Other new subjects that have been added to the various chapters are those on clean-build, determination of air supply volumes for non-unidirectional airflow cleanrooms, RABS (Restricted Access Barrier Systems), contamination recovery test methods, entry of large items into a cleanroom, glove allergy problems, and how to develop a cleanroom cleaning programme. Used for in-house training and a textbook in colleges, this volume is for cleanroom personnel at all levels. It provides novices with an introduction to the state-of-the-art technology and professionals with an accessible reference to the current practices. It is particularly useful in the semiconductor, pharmaceutical, biotechnology and life sciences industries. William Whyte is an international authority in cleanrooms, with over 45 years experience in research, teaching and consulting in the electronic, healthcare and pharmaceutical industries. He is a member of British and International standards committees writing the International Cleanroom standards, and has received numerous awards for his work in Cleanroom Technology. A comment on the first edition: "...extremely useful and helpful...very well-written, highly organized, easy to understand and follow..." (Environmental Geology, 2003)

Good Design Practices for GMP Pharmaceutical Facilities, Second Edition Academic Press
Sterile Pharmaceutical Products: Process Engineering Applications addresses the key concepts and applications of the sterile pharmaceutical manufacturing industry. It covers elements of the design, installation, validation, and usage of critical processes associated with sterile product manufacture. From water systems to clean-in-place systems, to sterile powder handling and robotic applications in sterile production environments, this book addresses the issues of system implementation, integration, and operations. Written by recognized experts and peer reviewed for accuracy, all chapters include references to supplemental resources and numerous illustrations.

Guidelines for Preparation of Human Milk and Formula in Health Care Facilities CRC Press
While introducing the principles and processes of industrial-level food canning, the volume clarifies the effects of microorganisms, their ecology, fate, and prevention in canning operations, as well as in other thermal processing techniques, such as aseptic packaging. It covers microbial spoilage and detection for vegetables, fruits, milk, meat and seafood from the raw food materials through individual unit operations, facility sanitation, and packaging. It thus offers a practical introduction to understanding, preventing and destroying microbe-based hazards in food plants that use thermal processes to preserve and package foods. The text surveys major spoilage and pathogenic microbes of interest, explaining their toxicity, product and safety effects, and the conditions of their destruction by heat treatment. From the Foreword "Not only does this volume contain up-to-date information regarding the types of microbes of interest in heat-treated foods, but it also provides, as a complete resource, details of many aspects of the food chain and processing environment that influences the microflora of thermally-processed foods. This is what I find separates this book from ... (other) treatises on heat-processed foods."

Regulations, Processes, and Guidelines Routledge
FROM THE PREFACE The purpose of this laboratory manual is to facilitate the understanding of the most relevant unit operations in food engineering. The first chapter presents information on how to approach laboratory experiments; topics covered include safety, preparing for a laboratory exercise, effectively performing an experiment, properly documenting data, and preparation of laboratory reports. The following eleven chapters cover unit operations centered on food applications: dehydration . . . . , thermal processing, friction losses in pipes, freezing, extrusion, evaporation, and physical separations. These chapters are systematically organized to include the most relevant theoretical background pertaining to each unit operation, the objectives of the laboratory exercise, materials and methods . . ., expected results, examples, questions, and references. The experiments presented have been designed for use with generic equipment to facilitate the adoption of this manual . . . .

Compounding Sterile Preparations Elsevier Health Sciences
This comprehensive overview of the fundamentals, design, testing and operation of cleanroom systems provides novices with an introduction to this state-of-the-art technology and professionals with an accessible reference to current standards.

Principles of Microbiological Troubleshooting in the Industrial Food Processing Environment CRC Press
This textbook is a comprehensive overview of the development of cell-based biopharmaceuticals. Beginning with the underlying biology of stem cell and cell-based products, it traces the long and complex journey from preclinical concept to initiation of a pivotal clinical trial and the potential business model behind it.The book also takes into consideration the different regulatory landscapes and their continuous evolution in Europe, North America and other parts of the world. The authors describe a path to manufacture a clinical grade therapeutic that passes all necessary quality measures as a robust and marketable product including an outlook on next generation products and innovative strategies.This reference book is a must-have guide for any professional already active in biopharmaceuticals and anyone interested in getting involved in a scientific, medical or business capacity.

Advances In Pharmaceutical Cell Therapy: Principles Of Cell-based Biopharmaceuticals ASHP
Assurance of Sterility for Sensitive Combination Products and Materials: New Paradigms for the Next Generation of Medical Devices and Pharmaceuticals discusses the medical device industry and existing challenges regarding the exciting new world of sensitive combination products (SCPs) and their terminal sterilization. This book reassesses the current assumptions to assure the patient’s best interests are met in the development of increasingly rigorous sterilization methods used to counteract MRSA and other 'super-bugs'. In addition, the book discusses the special challenges faced with implantable medical devices, sterilization requirements and further methods needed for material selection and the design process. This book is unique in taking a holistic, end-to-end approach to sterilization, with a particular focus on materials selection and product design. Introduces sterilization principles at the material selection and design stages Addresses the industry need for new sterilization processes for new medical devices and biomaterials Provides guidance to select the appropriate sterilization technique for newly developed sensitive combination products Examines forward thinking tactics for matching new developments in material compatibility with possible regulatory and QSR strategies

Quality Assurance of Aseptic Preparation Services Standards Handbook John Wiley & Sons
Biotechnology brings together many fields of expertise including engineering, chemistry, microbiology to mention a few. This paperback book provides a overview of the key themes and requirements of Aseptic processing and sterile manufacturing. It is written in a simple and plain style and provides a practical approach under standing the technologies used within the industry. Chapter 1: Facilities Chapter 2: Clean Utilities Chapter 3: Sterile Manufacturing Operations Chapter 4: Depyrogenation Chapter 5: Cleaning and Disinfection Chapter 6: Process Development Chapter 7: Physical Processes Chapter 8: Equipment Validation Chapter 9: Performance Qualification Chapter 10: GMP Basics Chapter 11: Data Integrity Glossary

Applications for the 1990s John Wiley & Sons

Aseptic Processing and Packaging of Food and BeveragesDesktop Reference for Food Industry PractionersCRC Press
Food Engineering Laboratory Manual Academic Press
Aseptic Processing and Packaging of Food explains how aseptic processing and packaging first began and traces its fascinating progression over the last fifty years. It explores current technologies, discusses why they are used today, and explains why certain basic approaches to critical operations, such as pumping, heat exchange, fluid flow, and controls, must be applied. Commercially used heating and holding concepts are also explained, with emphasis on avoiding problems. This unique book states the technique and method of choice for accurate flow control (timing). It includes an explanation of secondary flow and describes its use to solve many of the heat exchange and fluid flow problems associated with particle-containing products. It also discusses the manufacturers of aseptic packaging equipment, exploring the types of products they produce and the advantages and disadvantages of their product design. Aseptic Processing and Packaging of Food fills in many of the information gaps left by other sources - a must-have reference for anyone working in this area.
Createspace Independent Publishing Platform
This book highlights key ideas and factors to coach and guide professionals involved in learning about Sterile Manufacturing and operational requirements. It covers regulations and guidelines instituted by the FDA, ISPE, EMA, MHRA, and ICH, emphasizing good manufacturing practice and inspection requirements in the manufacturing of medicinal products. Additionally, this book provides the fundamentals of aseptic techniques, quality by design, risk assessment, and management in support of sterile operations applications. It creates a link to the implementation of business practices in drug manufacturing and healthcare and forms a correlation between design strategies including a step-by-step process to ensure reliability, safety, and efficacy of healthcare products for human and animal use. The book also provides a connection between drug production and regulated applications by offering a review of the basic elements of sterile processing, and how to remain viable with solid strategic planning. The book is a concise reference for professionals and learners in the field of sterile operations that governs primarily, pharmaceutical and medical device space, but can also extend to food and cosmetics that require clean (aseptic) manufacturing applications. It also helps compounding pharmacists and GMP inspectors and auditors.
Engineering Practice, Validation, and Compliance in Regulated Environments CRC Press
Welcome to the leading text in surgical technology the most up-to-date, the most trusted, and the most comprehensive. SURGICAL TECHNOLOGY FOR THE SURGICAL TECHNOLOGIST: A POSITIVE CARE APPROACH, Fourth Edition is your trusted source for comprehensive foundational surgical technology information. This streamlined new edition gets right to the essential topics such as equipment and supplies, operative preparation, practical and technical considerations, and postoperative considerations. With updated real-life scenarios, medical artwork, live surgery images, and numerous tools to support learning, this text is the ultimate resource for helping students anticipate the patient's and surgeon's needs before, during, and after a surgical procedure. Full coverage of essential procedures, this text provides students with the information needed to successfully apply the guidelines found in the Sixth Edition Core Curriculum for Surgical Technology, published by the Association of Surgical Technologists. Important Notice: Media content referenced within the product description or the product text may not be available in the ebook version.
Bacteriological Analytical Manual John Wiley & Sons
Principles of Parenteral Solution Validation: A Practical Lifecycle Approach covers all aspects involved in the development and process validation of a parenteral product. By using a lifecycle approach, this book discusses the latest technology, compliance developments, and regulatory considerations and trends, from process design, to divesting. As part of the Expertise in Pharmaceutical Process Technology series edited by Michael Levin, this book incorporates numerous case studies and real-world examples that address timely problems and offer solutions to the daily challenges facing practitioners in this area. Discusses international and domestic regulatory considerations in every section Features callout boxes that contain points-of-interest for each segment of the audience so readers can quickly find their interests and needs Contains important topics, including risk management, the preparation and execution of properly designed studies, scale-up and technology transfer activities, problem-solving, and more
Principles of Parenteral Solution Validation Purdue University Press
Biotechnology brings together many fields of expertise including engineering, chemistry, microbiology to mention a few. This paperback book provides a overview of the key themes and requirements of Aseptic processing and sterile manufacturing. It is written in a simple and plain style and provides a practical approach under standing the technologies used within the industry. Chapter 1: Facilities Chapter 2: Clean Utilities Chapter 3: Sterile Manufacturing Operations Chapter 4: Depyrogenation Chapter 5: Cleaning and Disinfection Chapter 6: Process Development Chapter 7: Physical Processes Chapter 8: Equipment Validation Chapter 9: Performance Qualification Chapter 10: GMP Basics Chapter 11: Data Integrity Glossary
Regulations and Quality Academic Press
Therapeutic protein drug products provides a comprehensive overview of therapeutic protein drug products, with an emphasis on formulation beginning in the laboratory, followed by manufacturing and administration in the clinic. A list of many commercial therapeutic drug products are described and include the product name, dosages, active concentration, buffer, excipients, Ph, container type and route of administration. The laboratory formulation sections focus on the most common buffers, excipients, and Ph ranges that are commonly tested in addition to systematic approaches. A brief section on biophysical and analytical analysis is also provided. Properties of therapeutic protein formulations are described and include opalescence, phase separation, color, and subvisible particles. An emphasis is placed on material and process testing to ensure success during manufacturing. The drug product manufacturing process, which includes the process of compounding to filling, is also covered. Methods of delivery in the clinic are addressed, as well as delivery strategies. Finally, a perspective on the regulatory requirements for therapeutic protein formulations is discussed. Provides a list and description of commercially available therapeutic drug products and their formulations A comprehensive and practical overview of protein formulation in the laboratory, manufacturing, and the clinic Discusses recent topics including high protein concentration, phase separation, opalescence, and subvisible particles
Thermal Food Engineering Operations World Scientific
Since publication of the first edition of this book, Aseptic Processing and Packaging of Food, significant changes have taken place in several aseptic processing and packaging areas. These include changes in aseptic filling of nutritional beverages in plastic bottles; the popularity of value-added commodity products such as juice, concentrate, and
Infant Feedings Elsevier
Describes the methodologies and best practices of the sterile manufacture of drug products Thoroughly trained personnel and carefully designed, operated, and maintained facilities and equipment are vital for the sterile manufacture of medicinal products using aseptic processing. Professionals in pharmaceutical and biopharmaceutical manufacturing facilities must have a clear understanding of current good manufacturing practice (cGMP) and preapproval inspection (PAI) requirements. Sterile Processing of Pharmaceutical Products: Engineering Practice, Validation, and Compliance in Regulated Environments provides up-to-date coverage of aseptic processing techniques and sterilization methods. Written by a recognized expert with more than 20 years of industry experience in aseptic manufacturing, this practical resource illustrates a comprehensive approach to sterile manufacturing engineering that can achieve drug manufacturing objectives and goals. Topics include sanitary piping and equipment, cleaning and manufacturing process validation, computerized automated systems, personal protective equipment (PPE), clean-in-place (CIP) systems, barriers and isolators, and guidelines for statistical procedure. Offering authoritative guidance on the key aspects of sterile manufacturing engineering, this volume: Covers fundamentals of aseptic techniques, quality by design, risk assessment and management, and operational requirements Addresses various regulations and guidelines instituted by the FDA, ISPE, EMA, MHRA, and ICH Provides techniques for systematic process optimization and good manufacturing practice Emphasizes the importance of attention to detail in process development and validation Features real-world examples highlighting different aspects of drug manufacturing Sterile Processing of Pharmaceutical Products: Engineering Practice, Validation, and Compliance in Regulated Environments is an indispensable reference and guide for all chemists, chemical engineers, pharmaceutical professionals and engineers, and other professionals working in pharmaceutical sciences and manufacturing.
Desktop Reference for Food Industry Practioners Springer Science & Business Media
Publications in food technology proliferate; however, noticeable by its absence of coverage is the subject of processing and packaging of particulates in foods. Recent years have seen significant advances which will almost certainly result in substitution of existing and conventional retorting. In addition, when com bined with high temperature/short time (HTST) processing, we can expect substantial further growth, reflecting quality and convenience advantages over products processed from yesterday's technologies. The anticipated growth in particulates is driven by both materials and packaging advances and only requires modest marketing of the organoleptic advantages to establish their place on menu options. The directions taken in packaging developments, especially those interfacing with the latest and established methods of processing, are increasingly influ enced by the need to design packaging on a cradle-to-grave basis. Time was when multi-laminated films on board satisfied the total needs of consumers of aseptic products. The problems of recycling combustible, i.e. energy generating mate rials laminated with aluminium foil, are becoming sensitive issues in a world preoccupied with recycling, and are creating openings for alternative and envi ronmentally friendly material combinations. This book brings together advanced technologies in the field, to provide information for professionals with interests in aseptic processing on how to go about selecting a system appropriate to their commercial needs and constraints.
Assurance of Sterility for Sensitive Combination Products and Materials American Dietetic Associati
In aseptic processing, food is stored at ambient temperatures in sterilized containers free of spoilage organisms and pathogens. The results of this food technology come in all shapes and sizes, from the consumer packages of milk on the shelves of the supermarket to the huge containers full of orange juice transported around the world by cargo ships. Over the last couple of decades, aseptic bulk storage and distribution has revolutionized the global food trade. For example, more than 90 percent of the approximately 24 million tons of fresh tomatoes harvested globally each year are aseptically processed and packaged for year-round remanufacture into various food products. The technology has also been applied to bring potable water and emergency food aid to survivors of the 2004 tsunami in Southeast Asia and the victims of Hurricane Katrina in 2005, as well as to other crisis situations worldwide. The construction of new aseptic facilities continues around the world, and an up-to-date understanding of the technology is essential for a new generation of food scientists and engineers alike. The contributors to this important textbook discuss all aspects of aseptic processing and packaging, focusing on the areas that most influence the success or failure of the process. Fully updated, this new edition covers all areas of chemistry, microbiology, engineering, packaging, and regulations as they relate to aseptic processing.
Practical Approaches to formulation in the Laboratory, Manufacturing, and the Clinic DEStech Publications, Inc
Research and development into biological products for therapeutic use has increased dramatically over the last 10 years. With this, strict regulatory requirements have been imposed by authorities such as the U.S. Food & Drug Administration, so that today validation has become a key issue in the biopharmaceutical industry. This concise book addresses validation issues in the chromatography of biotherapeutics. It covers process design, qualification and validation, including an overview of analytical techniques commonly used in the validation of processes. A concluding section comments on product changeover and presents four case studies.

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