Ispe Good Engineering Practice

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.

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

Delivering an encompassing overview of the factors, varieties, and applications determining product containment, this concise reference provides authoritative information on containment processes. It reviews the historical context, definition, evolution, and application of containment technology, analyzes a variety of containment techniques in new

Configuration management (CM) is frequently misunderstood. This discipline is growing in popularity because it allows project participants to better identify potential problems, manage change, and efficiently track the progress of a software project. This book gives the reader a practical understanding of the

complexity and comprehensiveness of the discipline.

This book explains the decision-making processes for the management of instrumented protective systems (IPS) throughout a project's life cycle. It uses the new IEC 61511 standard as a basis for the work processes used to achieve safe and reliable process operation. By walking the reader through a project's life cycle, engineering, maintenance, and operations, the information allows users to easily focus on their responsibilities and duties. Using this approach, the book is useful as a primer, guidelines reference, and resource manual. Examples provide the added "real-world" experience applications.

ISPE Good Practice GuideGood Engineering PracticeISPE Good Practice GuideTechnology TransferISPE Good Practice GuideMaintenanceISPE Good Practice GuideProcess GasesGAMP 5A Risk-based Approach to Compliant GxP Computerized SystemsIspe HeadquartersGood Quality Practice (GQP) in Pharmaceutical Manufacturing: A HandbookBentham Science Publishers

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.

This book details the foundations, new developments and methods, applications, and current challenges of systems engineering (SE). It provides key insights into SE as a concept and as an approach based on the holistic view on the entire lifecycle (requirements, design, production, and exploitation) of complex engineering systems, such as spacecraft, aircraft, power plants, and ships. Written by leading international experts, the book describes the achievements of the holistic, transdisciplinary approach of SE as state of the art both in research and practice using case study examples from originating at universities and companies such as Airbus, BAE Systems, BMW, Boeing, and COMAC. The reader obtains a comprehensive insight into the still existing challenges of the concept of SE today and the various forms in which SE is applied in a variety of areas.

This book covers all aspects of containment technology in depth and the latest developments in this exciting field are introduced. This book is a key publication to planning engineers, production managers and those interested in getting a picture of the different applications of the isolator technology. References on literature, laws, norms and guidelines will support the reader to become acquainted with the containment technology.

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

This revised publication serves as a handy and current reference for professionals engaged in planning, designing, building, validating and maintaining modern cGMP pharmaceutical manufacturing facilities in the U.S. and internationally. The new edition expands on facility planning, with a focus on the ever-growing need to modify existing legacy facilities, and on current trends in pharmaceutical manufacturing which include strategies for sustainability and LEED building ratings. All chapters have been re-examined with a fresh outlook on current good design practices.

This second volume offers numerous approaches to using Chinese medicine for the prevention and treatment of various diseases in medical practice. It brings the concepts and theories learned in the first volume and applies them in clinical settings with real patient examples. It goes over the four natures and five flavors of herbal drugs, and covers the different techniques of acupuncture. The book considers how the advancements in modern technology have shaped Traditional Chinese Medicine (TCM), and discusses the revolutionary innovations that are occurring in the Chinese medicine industry today and how they will shape the future.

The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for the quality assurance of medicines. Standards are developed by the Committee through worldwide consultation and an international consensus-building process. The following new guidelines were adopted and recommended for use: Procedure for development of the WHO medicines quality assurance guidelines; Guidelines on Good Manufacturing Practices (GMP) for heating, ventilation and air-conditioning systems (HVAC) illustrative part; Guidance on GMP for Validation, including the general main text, analytical procedure validation, validation of computerized systems and qualification; in the area of interchangeability of multisource medicines: the Protocol to conduct equilibrium solubility experiments for the purpose of biopharmaceutics classification systembased classification of active pharmaceutical ingredients for biowaiver; Guidelines on Import Procedures for pharmaceutical products; and the Good Practice Guidance document on implementing the collaborative procedures. All of the above are included in this report and recommended for implementation.

Medicines from Animal Cell Culture focuses on the use of animal cell culture, which has been used to produce human and veterinary vaccines, interferon, monoclonal

antibodies and genetically engineered products such as tPA and erythropoietin. It also addresses the recent dramatic expansion in cell-based therapies, including the use of live cells for tissue regeneration and the culture of stem cells. Medicines from Animal Cell Culture: Provides comprehensive descriptions of methods for cell culture and nutrition as well as the technologies for the preservation and characterisation of both the cells and the derived products Describes the preparation of stem cells and others for use in cell-based therapies – an area of burgeoning research Includes experimental examples to indicate expected results Covers regulatory issues from the UK, the EU and the USA and reviews how these are developing around the world Addresses the key issues of standardisation and validation with chapters on GLP and GMP for cell culture processes Delivering insight into the exciting world of biological medicines and directions for further investigation into specific topics, Medicines from Animal Cell Culture is an essential resource for researchers and technicians at all levels using cell culture within the pharmaceutical, biotechnology and biomedical industries. It is of value to laboratory managers in these industries and to all those interested in this topic alike.
Concurrent Engineering (CE) is based on the premise that different phases of a product's lifecycle should be conducted concurrently and initiated as early as possible within the Product Creation Process (PCP). It has become the substantive basic methodology in many industries, including automotive, aerospace, machinery, shipbuilding, consumer goods, process industry and environmental engineering. CE aims to increase the efficiency of the PCP and reduce errors in later phases while incorporating considerations for full lifecycle and through-life operations. This book presents the proceedings of the 22nd ISPE Inc. (International Society for Productivity Enhancement) International Conference on Concurrent Engineering (CE2015) entitled 'Transdisciplinary Lifecycle Analysis of Systems', and held in Delft, the Netherlands, in July 2015. It is the second in the series 'Advances in Transdisciplinary Engineering'. The book includes 63 peer reviewed papers and 2 keynote speeches arranged in 10 sections: keynote speeches; systems engineering; customization and variability management; production oriented design, maintenance and repair; design methods and knowledge-based engineering; multidisciplinary product management; sustainable product development; service oriented design; product lifecycle management; and trends in CE. Containing papers ranging from the theoretical and conceptual to the highly pragmatic, this book will be of interest to all engineering professionals and practitioners; researchers, designers and educators.
The World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations advises the Director-General of WHO in the area of medicines quality assurance. It provides independent expert recommendations and guidance to ensure that medicines meet standards of quality, safety and efficacy in all WHO Member States. Its advice is developed through a broad consensus-building process and covers all areas of quality assurance of medicines, from their development to their distribution to patients. In the area of quality control, the Expert Committee reviewed new and revised specifications and general texts for inclusion in The International Pharmacopoeia, and received the annual report of the European Directorate for the Quality of Medicines & HealthCare (EDQM), the custodian centre for International Chemical Reference Substances (ICRS). The Committee adopted a number of monographs, general texts and ICRS. It noted the report on Phase 6 of the

External Quality Assurance Assessment Scheme (EQAAS) and on new approaches to ensure sustainability of this scheme through user fees. The Committee further acknowledged the progress of good pharmacopoeial practices (GPhP), and adopted the document on GPhP which was prepared by the consecutive international meetings of world pharmacopoeias. In the various quality assurance-related areas the Expert Committee was presented with a number of new and revised guidelines related to good manufacturing practices (GMP), distribution and trade of pharmaceuticals and regulatory practice. It adopted 10 guidelines as listed below as well as 22 new specifications and general texts for inclusion in The International Pharmacopoeia. The Committee took note of ongoing work to promote collaboration and information exchange through the good regulatory practice project and welcomed the development of a comprehensive set of guidelines for all national regulatory authorities through this project.

The Pharmaceutical Engineering Series is a comprehensive reference for the pharmaceutical professional covering all aspects from quality, documentation and validation through manufacturing processes to facility design and management. In 'Quality', Dr Kate McCormick provides the reader with comprehensive coverage of this vital subject, including the quality life cycle, management and cost of quality, GMP, auditing and inspections. This book with the others in the series will become a unique source of reference and educational material for the readership. Case studies and examples make the book of direct practical relevance to the professional in the pharmaceutical industry Find the answers you are looking for quickly and easily with clear indexing and referencing Reference to international standards and practice mean this book will be useful wherever you are working

This book addresses the rapidly emerging field of Knowledge Management in the pharmaceutical, medical devices and medical diagnostics industries. In particular, it explores the role that Knowledge Management can play in ensuring the delivery of safe and effective products to patients. The book also provides good practice examples of how the effective use of an organisation’s knowledge assets can provide a path towards business excellence.

Thoroughly revised to include the latest industry developments, the Second Edition presents a comprehensive overview of computer validation and verification principles and how to put them into practice. To provide the current best practice and guidance on identifying and implementing improvements for computer systems, the text extensively reviews r

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.
Pharmaceutical manufacturing can be viewed as a supply chain which spans from the production and purchase of the starting and packaging materials through the manufacture of dosage forms until the safe reception of the finished product by the patient. The entire chain comprises of several processes: auditing, materials purchase (procurement), production, storage, distribution, quality control, and quality assurance. The quality standard for pharmaceutical production is ‘current good manufacturing practice (CGMP)’‘, which is applied within the frame of a pharmaceutical quality system (PQS). This implementation, however, requires a scientific approach and has to take into account several elements such as risk assessment, life cycle, patient protection, among other factors. Hence, pharmaceutical manufacturing is a complex subject in terms of regulation, given the technical and managerial requirements. This comprehensive handbook describes CGMP for new professionals who want to understand and apply the elements which build up pharmaceutical quality assurance. The book gives details about basic quality control requirements (such as risk management, quality hazards and management systems, documentation, clean environments, personnel training) and gives guidelines on regulatory aspects. This is an ideal handbook for undergraduates studying pharmaceutical or industrial manufacturing and supply chains as well for entrepreneurs and quality control professionals seeking to learn about CGMP standards and implementing quality assurance systems in the pharmaceutical sector.
The concept of concurrent engineering (CE) was first developed in the 1980s. Now often referred to as transdiciplinary engineering, it is based on the idea that different phases of a product life cycle should be conducted concurrently and initiated as early as possible within the Product Creation Process (PCP). The main goal of CE is to increase the efficiency and effectiveness of the PCP and reduce errors in later phases, as well as incorporating considerations – including environmental implications – for the full lifecycle of the product. It has become a substantive methodology in many industries, and has also been adopted in the development of new services and service support. This book presents the proceedings of the 25th ISPE Inc. International Conference on Transdisciplinary Engineering, held in Modena, Italy, in July 2018. This international conference attracts researchers, industry experts, students, and government representatives interested in recent transdisciplinary engineering research, advancements and applications. The book contains 120 peer-reviewed papers, selected from 259 submissions from all continents of the world, ranging from the theoretical and conceptual to papers addressing industrial best practice, and is divided into 11 sections reflecting the themes addressed in the conference program and addressing topics as diverse as industry 4.0 and smart manufacturing; human-centered design; modeling, simulation and virtual design; and knowledge and data management among others. With an overview of the latest research results, product creation processes and related methodologies, this book will be of

interest to researchers, design practitioners and educators alike.
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