

GOOD PRACTICE GUIDE:
Cold Chain
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Facility Requirements

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Josip Stjepandić, Georg Rock, Cees Bil



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ISPE Good Practice Guide, 2011 Good Quality Practice (GQP) in Pharmaceutical Manufacturing: A Handbook Jordi Botet, 2015-09-28 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.

Guidelines for the international packaging and shipping of vaccines, 2020-12-22

International shipping of vaccines is the first leg of the complex journey that vaccines undertake to reach the end users in a country. Particular challenges include the size and weight of packages, implementation of quality control checks at reception, ensuring environmental sustainability and maintaining required temperatures during the journey. Although there are many possibilities of transport e.g. sea freight and terrestrial transportation, air freight currently remains the most widely used means of transport for vaccines. In recognition of this fact, these guidelines apply predominantly to the air freighting of vaccines. Transportation of vaccines from the manufacturing facility to the airport facility requires the use of ground transportation and reference is also made to the qualification of refrigerated road vehicles as well. The objective of these guidelines is to provide technical guidance to help ensure the quality of vaccines during all stages of the international air transportation process. These guidelines are applicable to all persons and institutions involved in international air shipment of vaccines from the premises of the product manufacturer to the recipient country. This includes all parties involved in shipment: vaccine manufacturers, logistics service providers, LSPs, freight forwarders, carriers and their employees. The relevant sections of these guidelines should also be considered for implementation by UN procurement agencies and other international procurement organizations, countries, donor agencies and certifying bodies.

Good Manufacturing

Practices for Pharmaceuticals, Seventh Edition Graham P. Bunn, 2019-02-04 This book provides insight into the world of

pharmaceutical quality systems and the key elements that must be in place to change the business and organizational dynamics from task oriented procedure based cultures to truly integrated quality business systems that are self detecting and correcting Chapter flow has been changed to adopt a quality systems organization approach and supporting chapters have been updated based on current hot topics including the impact of the worldwide supply chain complexity and current regulatory trends Key Features Presents insight into the world of pharmaceutical quality systems Analyzes regulatory trends and expectations Includes approaches and practices used in the industry to comply with regulatory requirements Discusses recent worldwide supply chain issues Delivers valuable information to a worldwide audience regarding the current GMP practices in the industry *Pharmaceutical Computer Systems Validation* Guy Wingate,2016-04-19 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 regulations of pharmaceuticals healthcare products blood processing medical devices clinical systems and biotechnology Ensuring that organizations transition smoothly to the new system this guide explains how to implement the new GMP paradigm while maintaining continuity with current practices In addition all 24 case studies from the previous edition have been revised to reflect the new system

Health Care Management and the Law Hammaker,Thomas M. Knadig,2017-03-02 Health Care Management and the Law 2nd Edition is a comprehensive practical health law text relevant to students seeking the basic management skills required to work in health care organizations as well as students currently working in health care organizations This text is also relevant to those general health care consumers who are simply attempting to navigate the complex American health care system Every attempt is made within the text to support health law and management theory with practical applications to current issues

ICH Quality Guidelines Andrew Teasdale,David Elder,Raymond W. Nims,2017-09-29 Examining the implications and practical implementation of multi disciplinary International Conference on Harmonization ICH topics this book gives an integrated view of how the guidelines inform drug development strategic planning and decision making Addresses a consistent need for interpretation training and implementation examples of ICH guidelines via case studies Offers a primary reference point for practitioners addressing the dual challenge of interpretation and practical implementation of ICH guidelines Uses case studies to help readers understand and apply ICH guidelines Provides valuable insights into guidelines development with chapters by authors involved in generating or with experience implementing the guidelines Includes coverage of stability testing analytical method validation impurities biotechnology drugs and products and good manufacturing practice GMP

Supply Chain Management in the Drug Industry Hedley Rees,2011-04-06 This book bridges the gap between practitioners of supply chain management and pharmaceutical industry experts It aims to help both these groups understand the different worlds they live in and how to jointly contribute to meaningful improvements in supply

chains within the globally important pharmaceutical sector Scientific and technical staff must work closely with supply chain practitioners and other relevant parties to help secure responsive cost effective and risk mitigated supply chains to compete on a world stage This should not wait until a drug has been registered but should start as early as possible in the development process and before registration or clinical trials The author suggests that CMC chemistry manufacturing controls drug development must reset the line of sight from supply of drug to the clinic and gaining a registration to the building of a patient value stream Capable processes and suppliers streamlined logistics flexible plant and equipment shorter cycle times effective flow of information and reduced waste All these factors can and should be addressed at the CMC development stage

Pharmaceutical Anti-Counterfeiting Mark Davison,2011-08-04 This book overviews and integrates the business and technical issues that pharmaceutical companies need to know in order to combat the major global problem of counterfeit medicines In addition to discussion of the problems the author Davison addresses analytical techniques scientists use to detect counterfeits and presents some possible solutions to the threat of counterfeit medical products Coverage moves from basic overview of the problem costs risks to consumers toxic products mistrust of drug companies and business revenue loss public trust government oversight and regulation authentication strategies packaging analytical techniques product tracking and supply chain and case studies from around the globe

Understanding Pharmaceutical Standards and Regulations Navneet Sharma,Vikesh Kumar Shukla,Sandeep Arora,2025-06-24 This unique resource provides a comprehensive guide to the evolving regulations and standards which govern the international pharmaceutical industry Featuring clear explanations of the latest regulations as well as insights and strategies to maintain compliance the book covers the key principles of best practice for laboratory research manufacturing and distribution It also offers strategies to navigate the intricacies of different regulatory environments so that pharmaceutical companies can operate internationally avoiding the potentially costly risk of violations Detailed and holistic the book is an essential resource to pharmaceutical researchers and manufacturers as well as an important resource for students and scholars in the field

Drug Products for Clinical Trials Donald Monkhouse,Charles F. Carney,Jim Clark,Peter Brun,2005-11-09 Addressing issues at the forefront of interest for the Clinical Trial Materials Professional CTMP this Second Edition highlights the most critical concepts related to the planning manufacturing packaging labeling distribution reconciliation and quality and regulatory control of clinical trial materials offering an authoritative selection of chapters on the current and evolving state of clinical supplies operations by esteemed researchers and consultants in industry

20th ISPE International Conference on Concurrent Engineering C. Bil,J. Mo,J. Stjepandić,2013-09-12 As a concept Concurrent Engineering CE initiates processes with the goal of improving product quality production efficiency and overall customer satisfaction Services are becoming increasingly important to the economy with more than 60% of the GDP in Japan the USA Germany and Russia deriving from service based activities The definition of a product has evolved from the manufacturing and supplying of goods only to providing goods with added value

to eventually promoting a complete service business solution with support from introduction into service and from operations to decommissioning This book presents the proceedings of the 20th ISPE International Conference on Concurrent Engineering held in Melbourne Australia in September 2013 The conference had as its theme Product and Service Engineering in a Dynamic World and the papers explore research results new concepts and insights covering a number of topics including service engineering cloud computing and digital manufacturing knowledge based engineering and sustainability in concurrent engineering

Enhancing compliance to good manufacturing practices and pharmaceutical quality system requirements in vaccine production World Health Organization,2024-06-25

Collaborative Product and Service Life Cycle Management for a Sustainable World Richard Curran,Shuo-Yan Chou,Amy J. C. Trappey,2008-08-31 Collaborative Product and Service Life Cycle Management for a Sustainable World gathers together papers from the 15th ISPE International Conference on Concurrent Engineering CE2008 to stimulate the new thinking that is so crucial to our sustained productivity enhancement and quality of life It is already evident in this new century that the desire for sustainable development is increasingly driving the market to reach for new and innovative solutions that more effectively utilize the resources we have inherited from previous generations with the obvious responsibility to future generations Human productivity and progress can be positively engineered and managed in harmony with the provision and needs of our natural environment One century on from the industrial revolution this is now the time of the sustainable revolution requiring holistic technological process and people integrated solutions to sustained socio economic enhancement

Quality Risk Management in the FDA-Regulated Industry José Rodríguez-Pérez,2017-02-21 The purpose of this new edition is to offer an updated view of the risk management field as it applies to medical products Since the publication of the first edition 2012 the emphasis on risk based processes has growth exponentially across all sectors and risk management is now considered as significant as quality management ISO 9001 was revised and now requires that top management promote the use of risk based thinking ISO 13485 2016 which specifies the requirements for a quality management system specific to the medical devices industry also now shows a greater emphasis on risk management and risk based decision making In addition the FDA Food Safety Modernization Act FSMA is the most important reform of U S food safety laws in more than 70 years This indispensable book presents a systematic and comprehensive approach to quality risk management It will assist medical and food product manufacturers with the integration of a risk management system or risk management principles and activities into their existing quality management system by providing practical explanations and examples The appropriate use of quality risk management can facilitate compliance with regulatory requirements such as good manufacturing practice or good laboratory practice All chapters have been updated and revised and a new chapter has been added to discuss some of the most common pitfalls and misunderstandings regarding risk management specifically those related to the use of FMEA as the only element of risk management programs One of the appendices includes 12 case studies

and the companion CD ROM contains dozens of U S FDA and European guidance documents as well as international harmonization documents ICH and GHTF IMDRF related to risk management activities as well as a 30 question exam with answers on the material discussed in the book Best Practices for Online Procurement Auctions Parente, Diane H.,2007-12-31 Offers a systematic approach to the examination of online procurement auctions Growth in online auctions reinforces the need for understanding the factors important in auctions and the caveats that both researchers and practitioners need to know in order to effectively study and use the auction tool Moving Integrated Product Development to Service Clouds in the Global Economy J. Stjepandić,2014-09-23 The theory of concurrent engineering is based on the concept that the different phases of a product lifecycle should be conducted concurrently and initiated as early as possible within the product creation process Concurrent engineering is important in many industries including automotive aerospace shipbuilding consumer goods and environmental engineering as well as in the development of new services and service support This book presents the proceedings of the 21st ISPE Inc International Conference on Concurrent Engineering held at Beijing Jiaotong University China in September 2014 It is the first volume of a new book series Advances in Transdisciplinary Engineering The title of the CE2014 conference is Moving Integrated Product Development to Service Clouds in the Global Economy which reflects the variety of processes and methods which influence modern product creation After an initial first section presenting the keynote papers the remainder of the book is divided into 11 further sections with peer reviewed papers product lifecycle management PLM knowledge based engineering KBE cloud approaches 3 D printing applications design methods educational methods and achievements simulation of complex systems systems engineering services as innovation and science sustainability and recent research on open innovation in concurrent engineering The book will be of interest to CE researchers practitioners from industry and public bodies and educators alike *Concurrent Engineering Approaches for Sustainable Product Development in a Multi-Disciplinary Environment* Josip Stjepandić,Georg Rock,Cees Bil,2012-08-10 The CE Conference series is organized annually by the International Society for Productivity Enhancement ISPE and constitutes an important forum for international scientific exchange on concurrent and collaborative enterprise engineering These international conferences attract a significant number of researchers industrialists and students as well as government representatives who are interested in the recent advances in concurrent engineering research and applications Concurrent Engineering Approaches for Sustainable Product Development in a Multi Disciplinary Environment Proceedings of the 19th ISPE International Conference on Concurrent Engineering contains papers accepted peer reviewed and presented at the annual conference held at the University of Applied Sciences in Trier Germany from 3rd 7th of September 2012 This covers a wide range of cutting edge topics including Systems Engineering and Innovation Design for Sustainability Knowledge Engineering and Management Managing product variety Product Life Cycle Management and Service Engineering Value Engineering *Transdisciplinary Lifecycle Analysis of Systems* R. Curran,N. Wognum,M.

Borsato,2015-07-15 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 **Transdisciplinary Engineering**

Methods for Social Innovation of Industry 4.0 M. Peruzzini,M. Pellicciari,C. Bil,2018-09-14 The concept of concurrent engineering CE was first developed in the 1980s Now often referred to as transdisciplinary 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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