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Ispe Good Practice Guide Cold

Christian Drosten



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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 require 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 Design Practices for GMP Pharmaceutical Facilities** Terry Jacobs,Andrew A. Signore,2016-08-19 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

TEXT BOOK OF INDUSTRIAL PHARMACY-II Dr. Ritesh Kumar, Dr. Devendra Kumar Bhopte, Dr. D. Akila Devi, Anjali Naharwal, Dr. Vivekanand Katare, 2025-06-21 The Textbook of Industrial Pharmacy II provides a comprehensive and structured insight into the critical aspects of industrial pharmaceutical practices It begins with pilot plant scale up techniques highlighting the importance of scaling formulations from laboratory to production scale covering personnel space raw materials and regulatory documentation Special attention is given to scale up processes for various dosage forms such as solids liquid orals and semisolids including compliance with SUPAC Scale Up and Post Approval Changes guidelines and the emerging role of platform technologies The second unit Technology Development and Transfer TT outlines WHO protocols for transferring pharmaceutical technologies from R D to manufacturing It details the roles of quality risk management analytical method transfer and validation Important components such as API excipients packaging and documentation are discussed alongside legal frameworks including confidentiality agreements licensing and MoUs The section also explores Indian TT agencies like APCTD NRDC and BCIL Regulatory Affairs forms the third section offering a historical perspective and an overview of global regulatory bodies It emphasizes the function and responsibilities of regulatory professionals and the importance of their involvement across product lifecycle stages The fourth chapter details the regulatory requirements for drug approval addressing components such as INDs NDAs investigator brochures non clinical pharmacology toxicology and biostatistics It also explains the management and design of clinical protocols BE studies and data presentation for FDA submissions In the fifth section Quality Management Systems are discussed extensively Topics include Total Quality Management TQM Quality by Design QbD Six Sigma Out of Specification OOS handling change control and compliance with ISO standards 9000 and 14000 series NABL and GLP practices This ensures students understand how to maintain and evaluate quality at every stage of product development and manufacturing Lastly the textbook addresses Indian Regulatory Requirements with a focus on the Central Drug Standard Control Organization CDSCO and State Licensing Authorities It covers their structure responsibilities and role in issuing Certificates of Pharmaceutical Product COPP along with procedures for new drug approval in India This well organized content makes the textbook a valuable resource for students educators and professionals bridging academic knowledge and industrial application

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