Good pharmaceutical manufacturing practice : rationale and compliance

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URI: http://hdl.handle.net/123456789/505
Date: 2005

Abstract:

With over twenty different official regulatory statements worldwide on Good Manufacturing Practice (GMP) for pharmaceutical, drug, or medicinal products, two stand out as being the most influential and most frequently referenced.Bridging the gap between U.S. regulations and European Good Manufacturing Practice guidelines, Good Pharmaceutical Manufacturing Practice: Rationale and Compliance gleans the most important substance from the U.S. Current Good Manufacturing Practice, parts 210 and 211 (US cGMPs, 2002) and the European Guide to Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use (EU GMP guide, 2002). The author uses his 40+ years of experience in technical management, production, quality assurance, and distribution within the pharmaceutical industry, offering a hands-on guide to better understand and implement optimal pharmaceutical practices.This book also compares the principle requirements of GMP, and explores the reasoning behind these requirements and ways to comply with them. Relevant topics include personnel, documentation, premises and equipment, production, quality control, self-inspection, recalls, and more. This is an essential guidebook for those who wish to expand their pharmaceutical business in any international capacity.

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Good Manufacturing Practice (GMP) is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. GMP covers all aspects of production from the starting materials, premises, and equipment to the training and personal hygiene of staff. Detailed written procedures are essential for each process that could affect the quality of the finished product. There must be systems to provide documented proof that correct GMP certificates, non-compliance statements and manufacturing authorisations. Inspection coordination. Data integrity (New August 2016). It is normal practice for companies to use a bulk batch number that is different from the finished product batch when the bulk is packaged as several sub-batches. There is normally an element in the numbering format common to the bulk batch and finished product batches that clearly ties these together. Current Good Manufacturing Practice for Phase 1 Investigational Drugs (I) Investigating Out of Specification (OOS) Test Results for Pharmaceutical Production (I) Media Fills for Validation of Aseptic Preparations for Positron Emission Tomography PET Drugs — Current Good Manu ... Mr. Shiv Kumar is the Author and founder of pharmaceutical guidance, he is a pharmaceutical Professional from India having more than 14 years of rich experience in pharmaceutical field. During his career, he work in quality assurance