



Good Pharmaceutical Manufacturing Practice: Rationale and Compliance

John Sharp

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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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