Title:
Pharmaceutical Good Manufacturing Practices*: Principles, Compliance and Applications*
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Pharmaceutical Good Manufacturing Practices: Principles, Compliance and Applications

Good Manufacturing Practices (GMP) are fundamental to pharmaceutical production, ensuring that medicines are consistently produced and controlled to meet established quality standards. While numerous international guidelines exist, their dispersion and technical complexity impede effective implementation. This book addresses this challenge by bringing together these guidelines in a single, comprehensive, and accessible resource with a strong emphasis on practical interpretation and implementation in pharmaceutical manufacturing. It integrates academic knowledge with industrial application to support effective GMP compliance.

This text focuses on applying Quality Risk Management tools to enable the systematic identification, evaluation, and control of risks throughout pharmaceutical manufacturing processes. It emphasizes Root Cause Analysis and Corrective and Preventive Actions as essential elements of deviation management and continuous quality improvement. The book provides a comprehensive overview of the production cycle and examines the Quality System, Quality Assurance, Quality Control, documentation, data integrity, and core GMP concepts, including the Five Ps: People, Premises, Processes, Procedures, and Products. WHO-GMP compliance requirements and strategies to prevent contamination, mix-ups, and errors are discussed in depth, with practical illustrations to support effective application.

GMP defines what must be achieved but does not prescribe how it should be implemented. This book addresses this gap by providing illustrative examples of standard operating procedures, deviation reports, user requirement specifications, and inspection checklists to demonstrate practical and compliant implementation. Overall, this book is intended to provide students and practitioners with the foundational knowledge, applied understanding, and professional competencies necessary to systematically incorporate quality into pharmaceutical products and to ensure consistent manufacturing performance and regulatory compliance. It further interprets regulatory requirements and presents them as practical guidance for effective implementation. Leading pharmaceutical professionals have endorsed this book, stating:

In an era of stringent regulations and globalized pharmaceutical manufacturing, a clear, practical grasp of GMP is essential for students, educators, and professionals. Given my background as a GMP administrator, Head of Manufacturing of Health Products and Technologies, and researcher, I regard this book as an indispensable resource for both students and professionals, as it offers comprehensive foundational knowledge, rigorous academic exposition, and practical guidance to support the maintenance of GMP compliance. *Dr. James Kimotho, PhD. Head of Innovation and Technology Transfer Division, Kenya Medical Research Institute (KEMRI), Nairobi - Kenya.*

This volume on GMPs is a timely and authoritative guide from one of Kenya's pioneers in industrial pharmacy. Bridging policy and the plant floor, the book aligns quality systems, regulatory expectations, and everyday practice. At a pivotal moment, as our sector advances toward WHO ML3 maturity and strives for self-sufficiency in local manufacturing of essential medicines, it provides both a roadmap and inspiration to elevate capability, embed a culture of quality, and strengthen regional competitiveness. *Dr. Simon Muigai, Company Pharmacist, Laboratory & Allied Limited, Nairobi.*

Based firmly on established GMP guidelines, this book links regulatory compliance and scientific principles to the practical execution of pharmaceutical manufacturing. A valuable reference for students and professionals, since manufacturing capability has become a priority in Africa. *Dr. Wilberforce O. Wanyanga, Executive Director, PharmaQ Limited, Nairobi - Kenya.*

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