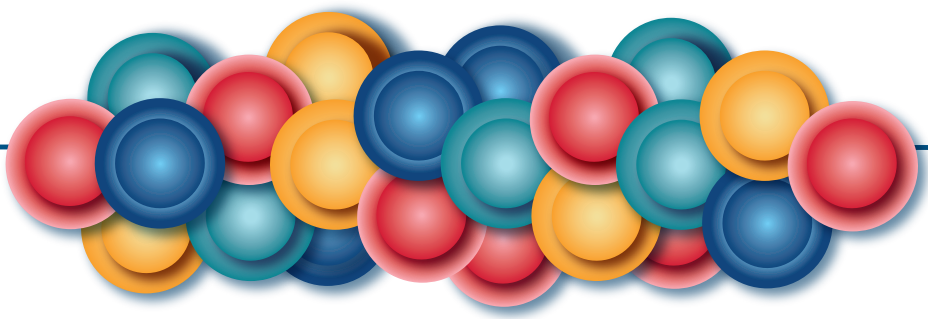
FIFTH EDITION
Revised & Expanded

GMP in Practice

Regulatory Expectations for the Pharmaceutical Industry



James L. Vesper
Tim Sandle

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Regulatory Expectations for the Pharmaceutical Industry

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Connecting People, Science and Regulation®

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James Vesper

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Tim Sandle

FOREWORD

Current practices for manufacturing medical products reflect an evolution that parallels technological advancements driven by the needs of patients and practitioners. In the US, medical product regulation grew from concerns about the safety of foods processed with impure ingredients or toxic additives. To address the safety of drugs in the US, the Pure Food and Drugs Act of 1906 became law, while the Public Health Service Act of 1912 was enacted to address vaccine regulation. Regulations resembling good manufacturing practice for drugs in the US were published in 1963, and the FDA revised drug GMPs in 1978 with an emphasis on "remaining current." Trade and marketing of drugs expanded concurrently with improvements in airfreight throughout the 1970s leading to a global market that in turn spurred a need for partnerships in the manufacturing components of the pharmaceutical industry and the regulatory bodies. In preparation for the Food and Drug Modernization Act of 1997, revisions in 1996 brought these Current Good Manufacturing Practices (CGMPs) to their current form of the "211s." Additional CGMP regulations (e.g., 212s) have been added since then, and more sections are in discussion to respond to the Drug Quality and Security Act, signed into law on November 27, 2013, that established section 503b to cover outsourcing pharmacies. Meanwhile, a continuous flow of guidance documents serve to clarify the FDA's thinking on CGMP regulations.

While standardization of regulatory policies by consensus organizations (WHO, ISO, and ICH) have been of immense help, there remain regional differences among the global authorities. These incremental changes and disparate requirements demonstrate the need to remain aware of developments in regulatory and technical expectations. Distinguishing the appropriate criteria and procedures for manufacturing and distribution in each region is a geopolitical challenge complicated by frequently changing technical requirements.

Jim Vesper and Tim Sandle have teamed-up in the fifth edition of *GMP in Practice*. Jim's understanding of US expectations are presented in a fashion that only an accomplished educator could offer. Tim's participation adds expert international perspectives needed to operate in the global market. In addition, the fifth edition provides important insights and detail about the emerging expectations for data integrity.

These critical and dynamic elements make the fifth edition of *GMP in Practice* an important contribution to a greater understanding GMPs now and where they are heading. This edition will be an essential instructional aid for beginning and experienced production personnel and a valuable reference for quality managers and process developers in the industry.

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