



Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing

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Sets forth tested and proven risk management practices in drug manufacturing

Risk management is essential for safe and efficient pharmaceutical and biopharmaceutical manufacturing, control, and distribution. With this book as their guide, readers involved in all facets of drug manufacturing have a single, expertly written, and organized resource to guide them through all facets of risk management and analysis. It sets forth a solid foundation in risk management concepts and then explains how these concepts are applied to drug manufacturing.

Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing features contributions from leading international experts in risk management and drug manufacturing. These contributions reflect the latest research, practices, and industry standards as well as the authors' firsthand experience. Readers can turn to the book for:

- Basic foundation of risk management principles, practices, and applications
- Tested and proven tools and methods for managing risk in pharmaceutical and biopharmaceutical product manufacturing processes
- Recent FDA guidelines, EU regulations, and international standards governing the application of risk management to drug manufacturing
- Case studies and detailed examples demonstrating the use and results of applying risk management principles to drug product manufacturing
- Bibliography and extensive references leading to the literature and helpful resources in the field

With its unique focus on the application of risk management to biopharmaceutical and pharmaceutical manufacturing, this book is an essential resource for pharmaceutical and process engineers as well as safety and compliance professionals involved in drug manufacturing.

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