The application of risk management to the processes within the healthcare industry is not just good practice, but an essential must do for any competitive and compliant enterprise. Whereas the ICH Q9 guideline “Quality Risk Management” describes the fundamental concepts, additional information is needed to further describe how risk management can and should be applied to the regulated healthcare environment. Although many publications exist on the subject, none cover it from the perspective of the entire drug lifecycle. The “Risk-based Compliance Handbook” now fills this gap.
This publication puts into context the various risk assessment methodologies with the business needs at the various stages of the life cycle. The emphasis is on implementing and achieving competitive compliance through the application of risk management.

In this book you will find crucial information on:

- An introduction to the various risk methodologies and their terminology
- Selecting the best method for a particular stage in the drug lifecycle
- Building risk management into the Quality Management System
- Many practical examples from real industry applications, including PAT
- The application of risk management for optimising the benefit / risk ratios

This book has been written by several authors who are experts in their field. It covers all stages of the drug lifecycle from R&D, to the clinical phases, the launch and pharmacovigilance stages, and the discontinuation step. It is written for the practitioner in the operational part of the organisation, who wishes to select from practical examples, and it will be equally of interest to those working in quality assurance / compliance, who wish to learn more about implementing risk management as a quality concept.

Siegfried Schmitt
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Risk Based Compliance Handbook

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