Quality by Design
Putting Theory into Practice

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PREFACE

The global pharmaceutical industry has experienced great advances in development and control of pharmaceutical products in the recent past. Quality by Design (QbD) has been at the forefront of this effort. The QbD concept became widely known during the 2000s and has evolved to emphasize and clarify the most important elements of new product development. QbD emphasizes product and process understanding with technical focus based on risk analysis. QbD has integrated established and reliable methods (e.g., DOE) with newer concepts such as design space, critical quality attributes (CQAs), critical process parameters (CPPs), and critical material attributes (CMAs). QbD has encouraged a proactive approach to identification and control of variation. The QbD initiative has successfully organized and structured these methods and applied them throughout the entire product lifecycle in a logical systematic approach.

The pharmaceutical scientific community has responded to the QbD initiative through professional association collaborations and as individuals in publishing conceptual approaches, methods, and research. This effort has resulted in clarified QbD approaches, more sophisticated new product development, and technical innovations. QbD has facilitated implementation of technology that is now commonplace in the pharmaceutical manufacturing environment. The QbD approach has evolved from origins in small molecule dosage form development to applications far beyond its original scope. Opinion leaders now espouse the QbD approach to small molecule and biotech API manufacturing, analytical

methods, pharmaceutical microbiology, computer systems, and various quality system compliance applications. Such widespread application clearly demonstrates that QbD has evolved and is accepted as a proven strategic methodology.

The publication of *Quality By Design — Putting Theory into Practice* by Dr. Siegfried Schmitt and coauthors is appropriate, relevant, and timely. Many of the initial questions and concerns raised with QbD have been resolved. Several pilot development programs with regulatory submissions have been completed. Experiences have been communicated at international forums. The industry is now poised for increasing implementation of QbD methods. A compilation of the background, regulatory guidances, strategies and approaches, experiences, and applications of QbD will be a useful and relevant resource in support of this next phase of QbD implementation.

Quality By Design — Putting Theory into Practice is a comprehensive reference on QbD useful to new and experienced professionals in regulated industries. Further, it is a "how-to" book with useful and practical advice. This book provides a thorough and complete treatise on the subject including potential applications beyond the original scope of QbD. The regulatory basis of QbD including international guidance documents are discussed. Several chapters discuss various aspects of implementation including organizational considerations, business issues, connection to associated disciplines, and related concerns are presented. An organizational decision to implement QbD is a significant undertaking; these chapters provide practical direction. Chapters on applications of QbD principles to the bioprocess development, analytical laboratory and analytical methods, and to pharmaceutical microbiology demonstrate the utility of the QbD methodology. Aspects of QbD in CTD regulatory submissions are discussed. The volume ends with discussion of the role of the university in teaching QbD and associated content.

Readers of *Quality By Design — Putting Theory into Practice* will find this book to be greatly valuable. This book provides comprehensive information that is clearly written and well-referenced. Chapter authors are knowledgeable and experienced. Readers will learn the philosophy and fundamentals of QbD, know its history, understand regulatory status, appreciate the scope of implementation, develop a lifecycle perspective, and see many possible applications in their organizations. Discussion topics providing author experiences are extremely useful. Readers of this book will be well-prepared for the future direction of the development, manufacturing, quality, regulatory, and associated areas in the global pharmaceutical industry.

Siegfried Schmitt