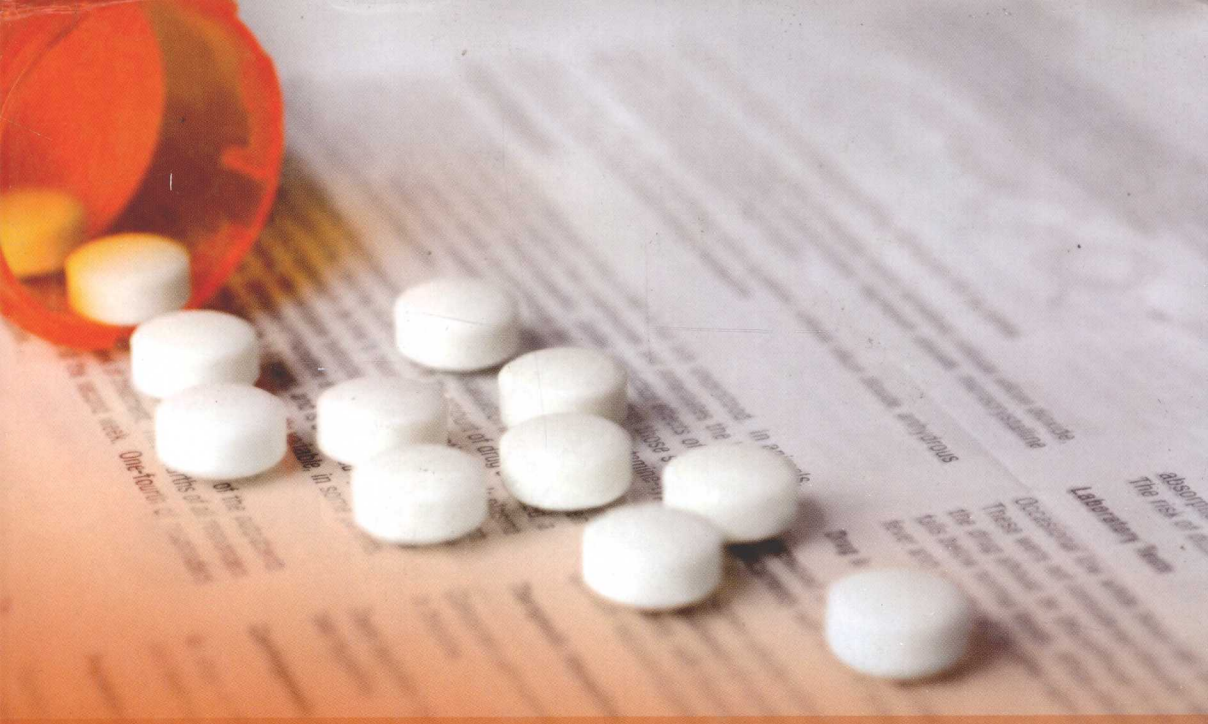

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A Guide to International Pharmaceutical Regulations

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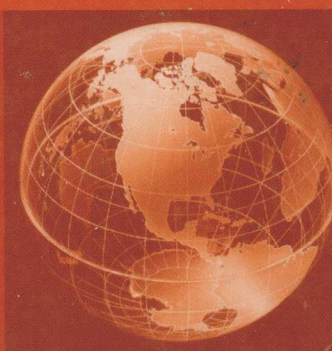

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Preface

This book, *Nonclinical Safety Assessment: A Guide to International Pharmaceutical Regulations*, was conceived as an update to the Alder and Zbinden text on international nonclinical testing regulations. This out-of-print text was published in 1988 prior to ICH but, at the time, represented a reasonably complete description of the testing requirements for pharmaceuticals. Since that time, the pharmaceutical industry has seen the implementation of ICH, development of new guidance and guidelines from FDA and the EU (CHMP), a new regulatory process in China and other regions, implementation of FDAMA, and so on. It is hoped that this book provides a practical description of nonclinical drug development regulations in the major market regions although we do recognize that this is not a static but a dynamic process that continues to evolve almost on a daily or weekly basis. Although we attempted to capture the state-of-the-art in regulatory toxicology development, we also recognize that certain aspects will change even during the publishing process. Not all regions are covered in this edition of the book. However, with the evolution of ICH, it is likely that all pharmaceutical regions will adopt the ICH concept with minimal alternatives in the testing strategy.

Regardless, the objective of this text is to provide a guide for those involved in nonclinical drug development. As you will see from the layout of the book, the initial section discusses the legislative and regulations for different regions. This is followed by specific chapters on the conduct, interpretation and regulatory considerations of nonclinical studies. The final section of the book describes biotechnology-derived products, vaccines, and so on and the nonclinical challenges and solutions for the clinical development of these sometimes difficult therapeutics.

This text is intended for those actively involved in the clinical development of a pharmaceutical product, whether as a toxicologist, pharmacologist, clinician, project manager, and other functional responsibilities. The approaches and methodologies described throughout this book provide a useful and scientifically valid means to drug approval.

We hope you find this a very useful resource.

The Editors
December 2012

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