
Preface

The primary objective of this book series is to provide readers with practical guidance on the application of pharmacokinetics as a drug development science. Our goal has been, and continues to be, to provide the link between the theoretical and the applied. We ask every author to write their chapter with this question in the back of their mind: “If you were training someone new to industry, what about this topic should they know?” In the first two volumes, topics were chosen specifically for their relative “stability” and they represented the core what we do as a profession. Though the approaches and technologies may have advanced, the practical considerations for topics like bioavailability study designs, analysis procedures for absorption data or dose-proportionality, or the role of pharmacokinetics in early development have remained relatively consistent over time. Some of the topics, however, have changed and some become more prominent over time. With this volume, we begin to address the more “adaptable” issues facing pharmacokineticists and pharmacologists supporting new compound development.

The topics chosen for this volume were selected because they are some of the current development or technological issues facing drug development project teams. They regard the practical considerations for the assessment of selected special development populations. For example, they include characterization of drug disposition in pregnant subjects, for measuring arrhythmic potential, for analysis of tumor growth modeling, and for disease progression modeling. Practical considerations for metabolite safety testing, transporter assessments, Phase 0 testing, and development and execution of drug interaction programs reflect current regulatory topics meant to address enhancement of both safety assessment and early decision-making during new candidate selection. Important technologies like whole body autoradiography, digital imaging and dried blood spot sample collection methods are introduced, as both have begun to take a more visible role in pharmacokinetic departments throughout the industry.

We are very pleased to extend the goals of the series to this newest volume. We remain committed to the aim of publishing material to fill the gap between the academic sciences and the practical application of that knowledge in drug development. Our grateful thanks goes out to the authors who contributed their time (and more importantly) their opinions, thoughts, authorship, and most of all, *patience* to this project. Without their hard work, expertise, and keen knowledge of the subjects presented, it would not be possible to have reached our shared goal.

We would like to dedicate this book to the editors and authors' families – whose love for us and understanding for our obsession make it possible for us to happily wander through the maze of our scientific dreams.

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