DESCRIPTION

A reference on drug metabolism and metabolite safety in the development phase, this book reviews the analytical techniques and experimental designs critical for metabolite studies. It features case studies of lessons learned and real world examples, along with regulatory perspectives from the US FDA and EMA.

- Reviews the analytical techniques and experimental designs critical for metabolite studies
- Covers methods including chirality, species differences, mass spectrometry, radiolabels, and in vitro / in vivo correlation
- Discusses target pharmacology, in vitro systems aligned to toxicity tests, and drug-drug interactions
- Includes perspectives from authors with firsthand involvement in industry and the study of drug metabolites, including viewpoints that have influenced regulatory guidelines

ABOUT THE AUTHOR

Suzanne L. Iverson, PhD, ERT, earned her PhD studying reactive drug metabolites and idiosyncratic drug reactions (University of Toronto, Dr. Jack Uetrecht supervisor) and has worked in the pharmaceutical industry for over 14 years as principal scientist and manager of development in vitro/in vivo metabolism and distribution imaging as well as functional project leader for both DMPK
and safety assessment functions. Since 2011, she has served on the management committee of the Drug Metabolism Discussion Group, UK, and the Board of the PK–Metabolism subcommittee of the Swedish Pharmaceutical Society.

**Dennis A. Smith, PhD,** currently holds part-time advisory and academic positions and, previously, worked in the pharmaceutical industry for 32 years. He has coauthored over 150 publications, including *Attrition in the Pharmaceutical Industry* (Wiley, 2016), *Reactive Drug Metabolites* (Wiley, 2012), and three editions of the book *Pharmacokinetics and Metabolism in Drug Design* (Wiley, 2012).

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