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eCoursesWebinarsePosters

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Job SeekersEmployers & RecruitersAAPS Career FairNBC Career ResourcesProfessional DevelopmentContinuing EducationAAPS Salary Survey and Calculator Publications

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Business OverviewAdvertisers, Exhibitors, and SponsorsMember DemographicsList RentalMedia Kit and Editorial CalendarBuyers' Guide

You are Here: Home > Publications
Publications
AAPS NewsmagazineAAPS Journals

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Pharmacokinetics in Drug Development: Regulatory and Development Paradigms, Volume 2

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Edited by Peter Bonate and Danny Howard

Development Paradigms warne 2

In Volume 2, the authors' attentions turn toward key regulatory and development paradigms where pharmacokinetics supplements decision-making during drug development. Pharmacokinetics' association with toxicologic assessments, bioanalysis targets and objectives, and application in preclinical programs are discussed. General discussions for rational development and knowledge discovery schemes are presented. Specific areas of recent regulatory interest are reviewed for exposure-response relationships, and detailed overviews of regulatory considerations and review are presented for pharmacokinetic studies and clinical trial simulations. Also included in Volume 2 are reviews of topics of special development consideration for pharmacokinetics oncology, controlled release, transdermal, ocular, parenteral, chiral, and biologic products. See also the table of contents.

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