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Physiologically based pharmacokinetics: From academia to application



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For many years a predominantly academic subject, the application of physiologically-based pharmacokinetic modelling (PBPK) has come of age in drug development and regulation, reflecting significant advances in recent years in the predictability of key PK parameters from a combination of human in vitro data, drug physicochemical information, and the availability of dedicated software platforms and associated data bases. The complexity of the resulting model depends on the intended application. PBPK is now helping to predict the first-inhuman PK, and has the facility to be updated in the light of Phase 1 data. Some of the specific advances and contemporary challenges with respect to predicting the quantitative extent of PK-based drug-drug interactions and the impact of age, genetics, disease and formulation are considered in the context of academia, industry and regulation.

CURRICULUM VITAE

Malcolm Rowland is Professor Emeritus and former Dean, School of Pharmacy and Pharmaceutical Sciences, and member and former director (1996-2000), Centre for Applied Pharmacokinetic Research, University of Manchester. He is Adjunct Professor, Department of Bioengineering and Therapeutic Sciences, Schools of Pharmacy and Medicine, University of California San Francisco (UCSF) and Founder Member, NDA Partners. He was President, EUFEPS (1996-2000); VP FIP (International Pharmaceutical Federation, 2001-2009); Board Member, National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs, 2004-2008); Member, Governing Board, EU Network of Excellence in Biosimulation (Biosim, 2004-2009), Advisor, PhRMA initiative in prediction of human pharmacokinetics, and Scientific Advisor, EUMAPP (European Union Microdose AMS Partnership Programme, 2006-2010). He received his degrees in Pharmacy and PhD, University of London, and was on faculty, School of Pharmacy, UCSF (1967-75) before taking up a professorship at Manchester (1975-2004).

He has been awarded honorary doctorate degrees from the Universities of Athens (Greece), Poitiers (France), and Uppsala (Sweden), and Honorary Membership, Royal College of Physicians (London). He received the 2012 Sheiner-Beal Award in Pharmacometrics, American Society of Clinical Pharmacology and Therapeutics; the 2011 Host Madsen Award, FIP; 2007 ACCP Distinguished Investigator Award; the Millennial Pharmaceutical Scientist Award (FIP BPS, 2000), and the 1994 AAPS Research Achievement Award in Pharmacokinetics, Pharmacodynamics and Drug Metabolism. He has been awarded fellowship of the Academy of Medical Sciences, the American College of Clinical Pharmacology (Hon), the Royal Pharmaceutical Society of Great Britain, AAPS, and the Institute of Mathematics. In 2002 he was rated among the top 200 most cited pharmacologists worldwide by the Institute of Scientific Information.

His main research interest is physiologically based pharmacokinetics and its application to drug discovery, development and use. Author of over 300 scientific articles, and co-author, with Dr. TN Tozer, of *Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications*, and *Introduction to Pharmacokinetics and Pharmacodynamics*. He was editor of the Journal of Pharmacokinetics and Pharmacodynamics (1973-2007), and since 1977 has organised regular residential workshops in pharmacokinetics.