Speakers biosketches - Handbook 2021 Workshop

In this guide

Professor Alan Boobis OBE

Alan Boobis is emeritus Professor of Toxicology, Imperial College London. He retired from his position at the College as Professor of Biochemical Pharmacology ad Director of Public Health England/Department of Health-supported Toxicology Unit in June 2017, after over 40 years. His main research interests lie in in mechanistic toxicology, drug metabolism, mode of action and chemical risk assessment. He has over 470 publications (H-factor 80). He is or has been a member of several national and international advisory committees; including former member of the UK Committee on Carcinogenicity, vice-chair of the EFSA Panel on Plant Protection Products and their Residues, and member of the EFSA

Panel on Contaminants; current chair of the UK Committee on Toxicity, member of the UK Committee on Medical Effects of Air Pollutants, member of the WHO Study group on Tobacco Product Regulation (TobReg), member and sometime chair of FAO/WHO JECFA (veterinary residues) and member and sometime chair of FAO/WHO JMPR (pesticide residues). He is a member and previous chair of the Board of Trustees of ILSI (International Life Sciences Institutes), member and previous president of ILSI Europe and a member and previous chair of the HESI Board of Trustees. He is involved in several ILSI Europe projects. He has been elected fellow of several learned societies, including honorary fellow of the British Toxicology Society (BTS) and has received a number of awards recognising his contributions to toxicological sciences, including the BTS John Barnes Prize Lectureship, Royal Society of Chemistry Toxicology Award, the Arnold J Lehman Award of the US Society of Toxicology, the EuroTox Merit Award, the Toxicology Forum Philippe Shubik Distinguished Scientist Award and the civilian award of Officer of the British Empire (OBE).

Dr Melvin Ernest Andersen PhD, CIH, DABT, ATS

Now semi-retired, Dr Andersen (Mel) is Senior Fellow at ScitoVation LLC, Durham, NC. He has worked in toxicology and risk assessment since 1971. His career has primarily focused on developing biologically realistic models of the uptake, distribution, metabolism, and biological effects of various chemicals and applying these models in safety assessments and quantitative health risk assessments. His primary area of work was physiologically based pharmacokinetic modeling (PBPK). Over his career, he has worked with a remarkably capable group of colleagues and collaborators and with them has produced over 500 papers and book chapters. He has received two career achievement awards - the Mildred S. Christian Award (Academy of Toxicological Sciences, 2016) and the Merit Award (2016) from the Society of Toxicology. From 2004 through 2007, he was a member of a US National Academy of Sciences Committee on toxicity testing of environmental agents, outlining future directions to move to testing based on new alternative methods (NAMs) rather than reliance on intact animal models. Mel still pursues research using gene expression analysis and pharmacokinetics to better understand modes of action of compounds both in intact animals and in cells *in vitro*.

Professor Mark Cronin

Mark Cronin is Professor of Predictive Toxicology at the School of Pharmacy and Biomolecular Sciences, Liverpool John Moores University, Liverpool. He has over

30 years' experience in the application of *in silico* approaches to predict the toxicity and fate of chemicals; in addition to development of strategies to develop alternatives to whole animal testing for toxicity. His current research includes the application of chemical grouping and read-across to assess human health and environmental endpoints, particularly the linking of Adverse Outcome Pathways (AOPs) to category information. This research effort has resulted in four books and over 270 publications in all areas of the use of (Q)SARs, expert systems and read-across to predict toxicity. He has worked in numerous projects in this area including more than ten EU framework projects, as well as assisting in the uptake of *in silico* methods for regulatory purposes.

Professor Amin Rostami-Hodjegan PhD, FCP, FAAPS, FJSSX

Amin is the Director of the Centre for Applied Pharmacokinetic Research (CAPKR) at the University of Manchester and a Professor of Systems Pharmacology with an active program of training PhD students in proteomics, PBPK, clinical PKPD and precision dosing. Graduates from his team hold positions in the pharmaceutical industry or academia.

Professor Rostami has authored/co-authored over 280 highly cited articles (>15,500 citations, H-Factor = 68). In 2017, he was listed by ISI as one of the world's most highly cited researchers (under 'Pharmacology & Toxicology'). He was a founding editor of Pharmacometrics and System Pharmacology and serves on the Editorial Boards of several other journals (e.g. BDD, CDM, CPDD, DMPK). Professor Rostami is renowned for his contribution to translational modelling (e.g. PBPK) and has been an invited speaker at over 200 international and national meetings, in addition to leading numerous workshops in the area of IVIVE- PBPK linked models.

Amin is also the Senior Vice President of Research & Development and Chief Scientific Officer at Certara, where he ensures that various pharmaceutical companies incorporate the latest scientific advances in the field of biosimulation into their drug development efforts.

Dr Alexander J. Stevens BSc, MSc, PhD

Alex Steven's roles in industry have focused on establishing concentration-effect relationships *via* the application of pharmacokinetics (and where possible integrated pharamacodynamic studies) to aid in the translation to the human situation to better inform on human health risk assessments. His expertise was developed and applied within preclinical and clinical drug development settings

and also within the agrochemical industry where he has worked for Syngenta for the past 11 years.

He currently works in Crop Protection Research providing Product Safety input (both human and environmental safety) as part of multidisciplinary Research Portfolio Teams who manage and guide the research projects to bring forward candidate compounds for development. Prior to this, he was responsible for the ADME and Toxicokinetics skillset working in support of discovery and regulatory projects across the research portfolios. Previous positions held include: over 8 years at GlaxosmithKline in pre-clinical DMPK within the Immunoinflammation and the Neurology & Gastrointestinal Centres of Excellence for Drug Discovery and 3 years as a pharmacokineticist at Medeval Ltd. where he was responsible for primary pharmacokinetic, adverse event and statistical analysis of Phase I Clinical Studies for the pharmaceutical industry. This was preceded by 6 years in the pharmacokinetics group in the Department of Pharmacy, University of Manchester where he obtained MSc and PhD degrees and 3 years as a clinical biochemist at Glenfield General Hospital, Leicester where he was involved in therapeutic drug monitoring. All of the above was built upon the foundation provided by a BSc degree in Pharmacology obtained from Sunderland Polytechnic graduating in 1986.

Dr Sheila Annie Peters

Sheila Annie Peters is currently the Head of Translational Quantitative Pharmacology Group at Merck KGaA, Darmstadt, where she has contributed to the R&D strategy 2023 at Merck and is currently part of the strategy implementation team. Her areas of expertise include physiologically-based pharmacokinetic (PBPK) drug absorption, translational PK/PD, clinical pharmacology and drug-drug interactions. She is the European Federation of Pharmaceutical Industries and Associations (EFPIA) Topic leader for the ICH (International Council for Harmonisation) M12 group focused on harmonising drug- drug interaction (DDI) guidelines.

Previously, she worked for AstraZeneca, Mölndal, where she has developed a generic whole-body PBPK model in MATLAB® which she used to support several drug discovery and early development projects across different R&D sites with innovative approaches to identifying potential limitations to drug disposition. She successfully implemented Model- based drug discovery (MBDDx) strategy in Respiratory Inflammation and Autoimmunity iMed through cross-functional collaborations. She wone the 2013 IMED (Innovative Medicines) Science Award at

AstraZeneca for the “Design and Development of LungSim Simulation tool for Inhalation PK modelling”.

She has published several papers in high impact journals as well as a book on PBPK modelling. As part of the IQ Consortium, she co-authored a White Paper on PBPK and continues to work with the on various topics of interest in DMPK and Clinical Pharmacology.

Dr George Loizou PhD

George Loizou is a computational toxicologist with over 36 years’ experience in quantitative, mechanistic, chemical toxicology. For the past 23 years, George has been engaged in strategic research for the Health & Safety Executive (HSE) and external customers investigating whether computational tools can be designed to exploit new technologies and mathematical modelling to provide a biologically based, quantitative chemical risk assessment.

This work had focused on the use of physiologically-based pharmacokinetic (PBPK) modelling to analyse, quantify and explain toxicological data with the ultimate aim of replacing the current slow, inefficient and expensive animal-based chemical risk assessment paradigm. For the past 4 years, George had also been investigating developments of personalised medicine where data obtained in people may potentially be appropriate for occupational and environmental toxicology. The use of gene expression (transcriptomics), metabolite (metabolomics) data and bioinformatics could lead to the development of a ‘next generation’ approach to chemical risk assessment based on human data.

Dr Judith Madden

Dr Judith Madden is a Reader in Molecular Design in the School of Pharmacy and Biomolecular Sciences at Liverpool John Moores University (LJMU, UK). She undertook a Ph D in computer-aided drug development (at LJMU) and post-doctoral research in the area of pharmacokinetics (University of Manchester). Her research interests are in the application of *in silico* methods to predict the effects of chemicals, on humans and environmental species. Research is directed towards predicting, both the interaction of a chemical with its biological target and the potential of a chemical to reach site of action.

Hence, her research encompasses the use and evaluation of *in silico* tools (such as (quantitative) structure-activity relationships ((Q)SARS) and read-across to predict biological activity/toxicity, pharmacokinetic/toxicokinetic-relevant

properties and methods to inform the development of physiologically based kinetic (PBK) models.

Dr Harvey J. Clewell III PhD, DABT, FATS

Harvey Clewell is currently a Principal Consultant with Ramboll US Consulting, Inc. He was previously the Director of the Center for Human Health Assessment at The Hamner Institutes for Health Sciences. He received a master's degree in chemistry from Washington University, St. Louis, and a PhD in Toxicology from the University of Utrecht, the Netherlands. He is a Diplomate of the American Board of Toxicology and a Fellow of the Academy of Toxicological Sciences. He has more than forty-five years of research experience in environmental transport, toxicology and chemical risk assessment, and has authored more than 200 peer-reviewed scientific publications and book chapters. He played a seminal role in the incorporation of pharmacokinetic and mode of action information in chemical risk assessments, having contributed to the first applications of physiologically based pharmacokinetic (PBPK) modeling in risk assessments by the USEPA, USFDA, ATSDR, OSHA and Health Canada. In 2007, the Society of Toxicology recognized Clewell with the Arnold J. Lehman Award for his major contributions to chemical safety and risk assessment. Dr Clewell is currently a member of the Chemical Assessment Advisory Committee of the USEPA's Scientific Advisory Board. He also served as a member of the ECVAM Scientific Advisory Committee from 2012 to 2016.