Advanced Toxicology at the interface of Science & Practise

Meeting Future Challenges in Risk Assessment

22-24 October 2008 University of Surrey

22 October '08
BEST PRACTICE IN RISK ASSESSMENT

23 October '08
REACH AND ITS IMPACT ON INDUSTRY

24 October '08
RECENT ADVANCES IN SAFETY PHARMACOLOGY

Seminar speakers are leaders in their field recruited from the Pharmaceutical and Chemical Industry, Government Agencies and Academia.

The meeting has been awarded CPD points by the Royal College of Pathologists.

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RSC | Advancing the Chemical Sciences

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BEST PRACTICE IN RISK ASSESSMENT 22 October '08

General Introduction and Principles, Professor Len Levy

Challenges and Strategy for Risk Assessment from the Chemical Industry Perspective, Dr David Farrar

Case Studies: Computer-Assisted Workshop on Modelling in Practise, Dr George Loizou

Challenges and Strategy for Drug Registration, Dr Henry Stemplewski

Challenges and Strategy in Ecotoxicology, Dr Paul Whitehouse

Concluding discussion including 'Case problems' raised by participants. Chaired by Professor Len Levy

REACH AND ITS IMPACT ON INDUSTRY 23 October '08

Overview of the impact of REACH, Mr Alan Ritchie

Complexities of REACH – Scope and Guidance, Dr Steffen Erler

The Operation of SIEF's and Consortia, Dr Graham Lloyd

Registration, Safety Data, IULID 5 dossiers and CSR's, Dr Derek Knight

Authorisation and Substitution, Dr Paul Illing

Workshop on the Toxicological and Risk Assessment aspects of registration dossiers, Dr Derek Knight and Dr Paul Illing

Discussion and Concluding remarks chaired by Dr Derek Knight and Dr Paul Illing

RECENT ADVANCES IN SAFETY PHARMACOLOGY 24 October '08

Safety Pharmacology Overview, Dr Jean Pierre Valentin

Core battery, follow-up studies; Cardiovascular, Respiratory, Nervous Systems, Dr Mark Holbrook and (Speaker to be confirmed)

Supplementary studies: GI tract, Renal and Immune functions, Dr Mark Holbrook

Syndicate work highlighting the Impact of Safety Pharmacoology Data in Drug Discovery and Development, Dr Jean Pierre Valentin, Dr Mark Holbrook and (Speaker to be confirmed)

Emerging Trends and Future Challenges for Safety Pharmacology chaired by Dr Jean Pierre Valentin

QUOTES FROM DELEGATES ON OUR PAST COLLABORATIVE COURSES

"Excellent programme – very thought provoking!" (February 2008)

"A good group of talks which linked together well – very enjoyable and informative" (June 2007)

"Excellent session; very well organised; brilliant speakers" (February 2008)

SPEAKER PROFILES

Dr Steffen Erler is Director of REACH Services at Smithers Rapra Technology. Steffen has followed REACH since working with the OECD Existing Chemicals Programme 10 years ago. His academic experience is in chemistry and toxicology and his practical knowledge of regulation includes work on REACH at the European Commission. Since 2003, Steffen has worked as a researcher and consultant for companies, investors and regulators preparing for REACH. Through various mechanisms and as a Stakeholder Expert, he has been involved in drafting and designing parts of the REACH Implementation Projects.

Dr David Farrar is Occupational Health Manager at Ineos Chlor where he provides health hazard and risk assessment advice for Ineos and external clients, and contributes to their multi-disciplinary approach to SHE matters. He serves on industry committees in CEFIC and ECETOC and contributes to EU chemical hazard classification and risk assessment, including REACH, and work with CIA, CEFIC, HSE, DEFRA and the Environment Agency. He is an Independent Expert on the UK Advisory Committee on Toxic Substances (ACTS) and Working Group on Action to Control Chemicals (WATCH). David has published on occupational and industrial toxicology and health risk assessment and is a member of the British Toxicological Society. He was awarded an OBE for his services to occupational health.

Dr Mark Holbrook is the Global Discipline Leader in the Global Safety Pharmacology department at Pfizer, where he leads Pfizer's science and technology strategy in this discipline. His focus is on ensuring that safety pharmacology can grow as a science, have maximum impact within the pharmaceutical industry, and on developing and delivering safer medicines to patients. Mark has 18 years experience in the drug industry and in all phases across discovery and development. He worked at Celltech (now UCB) developing animal models of inflammation and on the discovery of both small molecules and monoclonal antibodies. He then joined, what is now, AstraZeneca where he focussed on animal model development and chemokines as novel drug targets.

Dr Paul Illing is a consultant in toxicology and risk assessment for occupational health, environmental pollution and consumer protection and an honorary Lecturer at the Centre for Occupational and Environmental Health, University of Manchester. Paul is the current Royal Society of Chemistry representative on the UK Chemicals Stakeholders Forum (DEFRA) and represented the RSC on the EU Stakeholder Expert Group for REACH Implementation Project 3.7 (Authorisation). He is an Associate Member of IUPAC's Chemistry and Health Division Committee.

Dr Derek Knight is the Director of Regulatory Affairs at Safepharm Laboratories Ltd., a leading UK contract research organisation, specialising in safety assessments of chemicals, biocides, and agrochemical pesticides. He heads a team of regulatory affairs professionals whose registration projects cover many product types for regulatory compliance in all the key markets globally. He has gained an overall perspective into commercial issues associated with the regulation of the chemical industry. He is a Fellow of the RSC and of TOPRA. His PhD was in organosulphur chemistry.

Professor Len Levy is Professor in Environmental Health at Cranfield University. He has conducted occupational and environmental risk assessments on many substances, including particles, pesticides, metals and solvents. He is interested in occupational health cancer and has served as a working group member on 12 of the WHO's IARC Monograph evaluations. He is a member of the EU SCOEL Committee which sets occupational exposure limits for the EU and a member of the UK's Veterinary Medicines Committee, HSC's Advisory Committee on Toxic Substances and WATCH Committee. Len has published >200 papers on occupational cancer, occupational toxicology, risk assessment and risk management and the regulatory aspects of environmental and occupational air standards.

Dr. Graham Lloyd, Director of Regulatory Compliance Ltd., provides regulatory support to chemical supply companies. He has >35 years experience in the chemicals industry and >20 years in regulatory affairs. He worked in R&D for Unilever Research; as Technical Manager for Sterling Industrial and as Product Development Manager for Albright and Wilson. At Olin/Arch chemicals he led non-US regulatory compliance programmes for a range of chemicals and biocides. Graham was Vice Chairman of the Cefic European Biocides Forum and has represented industry on numerous committees eg. OECD. At Steptoe & Johnson he set up a European Consultancy and expanded the scope of regulatory activities of chemicals projects and collaborations with regulatory groups and consortia.

Dr. George Loizou is a biochemical toxicologist with >20 years experience in quantitative, mechanistic chemical toxicology. He has applied physiologically-based pharmacokinetic and pharmacodynamic modelling to toxicological data to provide a quantitative basis to chemical risk assessment in support of the UK Health and Safety Executive. His work involves the development and use of methods that incorporate human inter-individual variability and aid the interpretation of biological monitoring, risk-benefit analysis, use of *in vitro* techniques to study metabolism and mode of action of chemicals and the rapid generation of PBPK models.

Mr Alan Ritchie is a Senior Consultant with Caleb Management Services Limited. Prior to this, he was Head of Technical Services for Revlon, Regulatory Affairs Manager for Crompton (now Chemtura); Product Stewardship Manager for ISP and worked in R&D with Cadbury Schweppes. He has worked in chemicals control regulations (including REACH) for 18 years. He has represented industry on various trade groups, including 2 CTPA committees (Scientific advisory group and advertising standards working group), Additives technical Committee (ATC), WTR (rubber chemicals), and the CIA Chemical Policy Task Force.

Profiles continue overleaf

Dr Henry Stemplewski assesses submissions for marketing authorisations for human medicines at the MHRA. He conducted scientific and risk assessment at the Pesticide Safety Division at MAFF. He was secretary to the Medical and Toxicological Panel of the Advisory Committee on Pesticides and conducted research at the Department of Health (DH) Toxicology unit. Henry is the MHRA assessor for DH Committees on Mutagenicity and Carcinogenicity and the MHRA representative to the FRAME toxicity and reduction committees. He is on the Steering Committee of the Interdepartmental Group on Health Risks from Chemicals and the European Medicines Agency's (EMEA) panel of experts. He was involved in the development of international EMEA guidelines on environmental risk assessment and on specification limits for residues of metal catalysts and reagents in medicines. He is the Chair of the Regulatory Toxicology Speciality Sub-section.

Dr Jean-Pierre Valentin is Director, Head of Safety Pharmacology Department at AstraZeneca. The Department supports ~60% of the AstraZeneca R&D portfolio with Safety and Secondary Pharmacology activities and the entire portfolio with in vitro cardiac electrophysiology and in vitro safety / toxicity screens. His PhD is in cardiovascular physiology and his postdoc was in cardio-renal physiology and pharmacology. As Team Leader in Cardiovascular Pharmacology at Pierre Fabre Laboratories, Jean-Pierre contributed to the discovery and development of a TP receptor antagonist as anti-thrombotic; a 5-HT1B/D receptor agonist as anti-migraine; and a mixed 5HT2A/C receptor antagonist / Na channel blocker as anti-ischemic. Jean-Pierre is on the Board of Directors of the Safety Pharmacology Society and has authored 14 patents and numerous academic publications.

Dr Paul Whitehouse manages the Environment Agency's Chemicals Science team, focussing on derivation of environmental quality standards, ecological risk assessment of industrial chemicals, pesticides, veterinary medicines and pharmaceuticals in soil and water, and factors affecting chemical bioavailability in the environment. Paul's PhD is in pesticide uptake and behaviour in target species. Before joining the Environment Agency he researched agrochemicals with Shell Research Ltd and worked as an environmental toxicologist with the environmental consultancy, WRc. His primary area of interest is the derivation and use of chemical standards for environmental protection.

Toxicology research at Birmingham and Surrey

Delegates on this programme will benefit from the experience and expertise which underpin Birmingham's (RAE 5) and Surrey's (RAE 5*) excellent research and teaching profiles in Toxicology. Substantial interactions with Industry also provide a platform to apply expertises to important human health issues and obtain feedback for future research ideas.

Both universities have a strong record of running successful, high-quality training programmes which meet the requirements of a broad range of clients.

Surrey runs a successful MSc in Toxicology and Modular Training Programme in Applied Toxicology (part-sponsored by the BBSRC MTI programme) as well as a more basic programme on the Principles of Toxicology for non-toxicologists through the Centre for Toxicology. Birmingham runs an acclaimed MSc in Toxicology and an MRes in Molecular Mechanistic Toxicology, both on a modular basis.

Both Universities have world class standing for research in Toxicology; contribute to committees of the British Toxicology Society and the International Union of Toxicology and act in advisory roles to Government Committees.

UNIVERSITY OF BIRMINGHAM

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Birmingham and Surrey's successful partnership in CPD provision

This exciting new programme has arisen from a successful partnership between The Universities of Birmingham and Surrey. We collaboratively run a thriving, BBSRC sponsored, Advanced Training Programme in Toxicology for a consortium of 6 of the leading UK companies (including pharmaceutical, household and personal health care products and contract research). Demand for this course is so high that we have had to close registration to delegates from other companies, to ensure we maintain a high-quality learning experience.

Registration deadline: 22 August '08

Fee: £400 per day including refreshments and buffet lunch.

Discounts are available for those booking multiple days: 2 days @ £375 per day and 3 days @ £350 per day and for early bird bookings (10%) received before 22/07/08.

Further information and registration forms are available from Ms. Lorraine Day L.Day@bham.ac.uk, Telephone 0121 414 5471 http://www.biosciences.bham.ac.uk/study/prodev/toxsme.htm

Terms and Conditions. The University of Birmingham and University of Surrey reserve the right to make any alterations to the stated programme and other arrangements as deemed necessary. If the organizers cancel the course, participants will be given as much notice as possible. However the Universities' liabilities will be limited to refund of the course fee.