Sunday, September 1st, 2013

09.00 – 17.00

Satellite Symposium on "New Advances in Risk Assessment"

Chair: Herman Autrup, Denmark
Room: Theatre Room
Sponsored and organised by the Bo Helmstedt Memorial Foundation – BHMF

The symposium will integrate the latest scientific knowledge and methodology into the development of a new paradigm of human health risk assessment from hazard to exposure driven. This work is currently ongoing in both the US (EPA) and EU (DG Sanco).
The symposium will be based upon two sessions, one focusing on exposure assessment and the second one focusing on hazard assessment supplemented by a lecture on integration of non-chemical stressors into chemical risk assessment. A panel discussion with representatives from EPA, DG Sanco, academia and industrial stakeholders will conclude the symposium.

09.00 – 09.10
Welcome: Herman Autrup, Denmark

09.10 – 09.40
System biology – exposure assessment: John Wambough, USA

09.40 – 10.10
Exposomes: Paolo Vineis, UK

10.30 – 11.00
GIS-based monitoring and chip technologies: Dennis Sargiannis, Greece

11.00 – 11.30
Toxicokinetics – internal dose and in vitro vs in vivo: Emanuela Testai, Italy

11.30 – 12.00
Identifying important life stages for monitoring and assessing risks from exposures to environmental contaminants: results of a World Health Organization review: Thea de Wet, South Africa

13.00 – 13.30
Mode of action: Alan Boobis, UK

13.30 – 14.00
Incorporating new technologies into toxicity testing and chemical risk assessment: moving from 21st Century vision to a data-driven framework: Rusty Thomas, USA

14.00 – 14.30
Computational toxicology – read across: Chihae Yang, USA

14.30 – 15.00
Probabilistic risk assessment: Wout Slob, The Netherlands

15.20 – 17.00
Panel discussion: DGSANCO, ECHA, US EPA, (ICCA), RISK21 (academia)

10.00 – 16.40

CEC 1: Dietary exposure assessments – current scenario and emerging issues

Chair: David Tennant, UK
Room: Congress Hall
Organised and supported by the International Life Sciences Institute (ILSI Europe)

Dietary exposure assessment is a key component of any risk-benefit assessment, yet it is clear that there is a lack of reliable methodology in this area for assessing consumer exposures to both food constituents and non-food products. Dietary exposure assessment is needed for substance groups of varying chemistries, functions and concentration levels in foods. Assessment guidance is available for individual types of substances, but guidance and practicalities of assessment vary among substance types.
This course aims to raise awareness on key aspects of dietary exposure assessment across different substance types, including emerging issues in methodology, availability of food consumption data, and EU-wide efforts to compile harmonised food consumption data. Modelling of dietary exposure will be demonstrated using case studies on deterministic and probabilistic assessment as well as acute and chronic dietary exposure, for different types of chemicals. Uncertainties in this modelling will be discussed and methods to quantify uncertainty will be lined out.
Participants will finally be introduced to the GUIDEA website as a tool to find up-to-date guidance on dietary exposure assessments. GUIDEA uses a Wikimedia platform which will be an important reference source for stakeholders, providing concise guidance on the planning, conduct, reporting and interpretation of exposure assessments.

1 Session background and overview: Diána Bánáti, ILSI Europe, Belgium
2 Emerging/developing issues in conducting dietary exposure/intake assessment: Jürgen Koenig, Austria
3 Dietary exposure modelling of chemicals: Polly Boon, The Netherlands
4 Refinement of dietary assessment methods: Davide Arcella, Italy
5 Quantification of uncertainties: Marc Kennedy, UK
6 Assessing uncertainties in dietary exposure analysis – improving confidence in results: Susanne Kettler, Belgium
7 GUIDEA – guidance for dietary intake exposure assessment – e-learning tool: David Tennant, UK

09.30 – 16.30

CEC 2: New methods to assess contact sensitizing potential of chemicals

Chairs: Emanuela Corsini, Italy and Raymond Pieters, The Netherlands
Room: Grimsel 1+2
Organized by the EUROTOX Immunotoxicology and
Chemical Allergens Specialty Section

Allergic contact dermatitis (ACD) is to a considerable extent a preventable disease. A correct detection of skin sensitizers, the characterization of potency, the understanding of human skin exposure, and the application of adequate risk assessment and management strategies can all contribute to a reduction of ACD.
From March 2013 onward the ban on animal use to assess repeated dose toxicity, including sensitizing potential, of cosmetic ingredients is definitive. Due to the new European policy on chemicals (REACH), in vitro methods are also likely to play a major role in the near future. Growing political and practical resistance to toxicity testing in animals has driven the development of animal-free methods for screening and prioritization of toxicants, including those causing allergic hypersensitivity. Over the last decade, incredible progress has been achieved and several in vitro methods have been proposed both from academia and industries to identify the potential of chemicals to induce skin sensitization.
The SENS-IT-IV project is one of the important projects sponsored by the EU to promote the development of alternative testing to animals. The SENS-IT-IV project has provided many mechanism-based assays, which together may provide a strategy to address the issue of contact sensitization. This CEC aims to provide the up-to-date status to inform all stakeholders interested in this subject.

Course introduction: Raymond Pieters, The Netherlands

1 Pathogenesis of contact sensitization induction: Erwin Roggen, Denmark
2 QSAR and peptide binding assay: Jean Pierre Lepoittevin, France
3 Skin absorption and keratinocyte models: Emanuela Corsini, Italy
4 Skin models and DC migration: Sue Gibbs, The Netherlands
5 T cell priming assays for contact sensitization: Stefan Martin, Germany
6 Tiered approach to test contact sensitizers: Marc Teunis, Netherlands
7 Colipa (Cosmetics Europe) strategy to assess contact sensitizing potential of chemicals: Kerstin Reisinger, Germany

10.00 – 16.00

CEC 3: Alternative test methods: challenges and regulatory application

Chair: David Bell, Finland
Room: Brünig 1–3
Organised and supported by the European Chemicals Agency

Alternative test methods to traditional animal testing, and non-test methods, offer the prospect of numerous potential benefits, including reduced costs, increased coverage of chemical space, higher throughput and ethical benefits. These test methods are also of growing interest to regulators, for example with the cosmetics directive. However, it is important to be able to understand the scientific basis for these tests, and the application of that science within specific regulatory frameworks. This course aims to elucidate key scientific and regulatory principles underlying the application of these test methods. The session will open with examining the challenges for regulatory acceptance and recognition of test methods, and explaining how recently developed policies are aimed at dealing with these challenges. The following three presentations set out scientific areas which have regulatory applications. The fifth presentation will provide a status report of areas where testing is and is not feasible, and explain future prospects for their development. Finally, the last speaker will explain with the example of 'read-across' how an alternative method is applied in a regulatory setting. Students will have the opportunity to interact with speakers through a question and answer session.
At the end of the session, participants will have developed an understanding of the status quo for alternative methods, the scientific concepts and constraints that underpin alternative test methods, the concepts associated with acceptance and recognition of test methods, and the application of these test methods within a regulatory context.

Course introduction: David Bell, Finland

1 EURL ECVAM recommendations – a new tool towards regulatory acceptance of alternative test methods: Claudius Griesinger, Italy
2 The application of QSARs in regulatory toxicology: Mark Cronin, UK
3 In vitro- in vivo extrapolation for toxicity and use in PBPK: Amin Rostami, UK
4 In vitro tests for irritation and corrosion – a continuing success story: Laura Rossi, Finland
5 The EC report on "Alternative (non-animal) methods for cosmetics testing: current status and future prospects – 2010": Valerie Zuang, Italy
6 Regulatory application of non-test methods; the example of read-across in REACH: Karel de Raat, Netherlands

Panel discussion; Questions & Answers

09.30 – 16.30

CEC 4: 3d cell models in drug safety: with better tools to better drugs?

Chairs: David Kaplan, USA and Linda Griffith, USA
Room: Harder 1+2
Sponsored by the Bo Holmstedt Memorial Foundation (BHMF)

Selection of drug candidates early on in development has become increasingly important to minimize use of animals and to avoid costly failures of drugs later on. In vitro systems to predict and assess organ toxicity have been of limited value so far due to difficulties in re-capitulating in vivo-relevant toxicity on a cell culture level. To overcome the limitations of single cell type monolayer cultures and short-lived primary cell preparations, researchers have created novel 3-dimensional culture systems which appear to more closely resemble in vivo biology. These may become key for drug industry in the evaluation of drug candidates, yet, the value and acceptance of those new models in standard drug safety applications needs to be demonstrated. The sessions aims to give an overview of different approaches undertaken in the field of pre-clinical safety assessment and in particular organ toxicity.

Opening remarks & introduction to the course: Session Chairs

1 Development of advanced tissue models for in vitro toxicity testing: ZhanFeng Cui, UK
2 Kidney injury and disease modelling in silk based 3d in vitro systems: David Kaplan, USA
3 3d cardiac models: Jens Kelm, Switzerland
4 Long-term 3d culture systems to detect human-specific liver toxicants
Adrian Roth: Switzerland
5 Human organo-typical (HOT) co-cultures for functional substance screening
Manfred Schmolz: Germany
6 Human 3d tissue cultures to assess metabolism of drugs: Tommy Andersson, Sweden
7 Integration of systems biology and tissue engineering for drug development:
Linda Griffith, USA

9.30 – 16.30

CEC 5: Statistical evaluation in toxicology

Chairs: Ludwig A. Hothorn, Germany, Christian Ritz, Denmark and Thomas Jaki, UK
Room: Susten

This practical course is designed for toxicologists who have the need to generate or interpret data in toxicology. Special emphasis is placed on hands-on application using R-software and real data without use of complex mathematical formulae. In the first session the principles for multiple comparisons are explained for the analysis of normally distributed as well as skewed endpoints. In part ii) the related evaluation of mutagenicity assays is explained: count or proportions as endpoints, using a k-fold relevance criteria, and taking possible downturn effect at high doses into account. In part iii), the basic concepts of dose-response modelling are introduced: commonly used models (e.g., log-logistic /Hill-slope model) and their toxicological interpretation. The principles of ECxx and benchmark dose estimation are explained. The second session starts with exercises using R for the first session. A number of case studies using the R packages bmd and drc demonstrate how to carry out dose-response analysis for standard assays. In part ii), we will discuss the estimation of the AUC in sparse sampling situations, discuss the role of the AUC in toxicokinetic studies and illustrate the use of the R package PK for that purpose. In the third session, the proof-of-safety approach "significant toxicity" (Denton et al. Environ. Tox. Chem, 2011,30,1117-1126) will be discussed. Finally, practical exercise sessions will allow you perform the analysis of real toxicity data using the R packages multcomp, mratios, MCPAN, nparcomp, PK and drc. The data examples (as xls and txt files), the program code and a short user guide to R will be provided in advance of the course. We recommend that participants bring their own notebook – with installed R and selected packages – to the course.

1 Principles and analysis of repeated toxicity studies: Ludwig A. Hothorn, Germany
2 Evaluation of mutagenicity assays: Ludwig A. Hothorn, Germany
3 Dose-response modeling: Christian Ritz, Denmark
4 Exercise I using R
5 Toxicokinetics: Thomas Jaki, UK
6 Exercise II using R
7 Signicant toxicity approach: Ludwig A. Hothorn, Germany
Final discussion

EUROTOX 2013 – Opening Ceremony

Chair: Ruth Roberts, President of EUROTOX, UK
Room: Auditorium

18.00 – 18.45 Opening Ceremony

- Welcome address by Thomas Weiser
  President of the EUROTOX 2013 congress, Basel, Switzerland
- Welcome address by Pascal Strupler
  Director of the Federal Office of Public Health, Bern, Switzerland
- Welcome address by Urs Graf
  Mayor of the city of Interlaken, Switzerland
- Opening of EUROTOX 2013 by Ruth Roberts
  President of EUROTOX, Macclesfield, United Kingdom

18.45 – 19.00 EUROTOX Merit Award Ceremony

- Awarded Scientist (tbd)
  Chair: Ruth Roberts
  President of EUROTOX, Macclesfield, United Kingdom

19.00 – 19.30 Keynote Lecture

- „From room odorizers, bath salts and plant food – New psychoactive substances on the rise“
  Thomas Kraemer
  Institute of Legal Medicine, University of Zürich, Switzerland

Monday, September 2nd, 2013

08.30 – 09.30

Keynote Lecture 1: Public health impact of food; quantity, quality, supplements and appetites

Prof. Sir Colin Berry, Prof. Emeritus of Pathology, Queen Mary University of London, UK
Chair: Werner Kobel, Switzerland
Room: Auditorium

10.00 – 12.00

Symposium 1: Early safety assessment: considerations and strategies in drug discovery

Chair: Thomas Hartung, USA
Room: Ball Room

10.00 – 10.20
Fail early and learn fast – how early safety testing impacts drug attrition: Susanne Mohr, Switzerland

10.25 – 10.45
Early off-target assessments for the prediction of safety liabilities – case studies: Andreas Hartmann, Switzerland

10.50 – 11.10
Structure-based assessment of potentially mutagenic impurities – processes aligned to ICH M7 step 2 document at Bayer HealthCare: Andreas Sutter, Germany

11.15 – 11.35
Leveraging early pharmacology studies and animal models of human disease to learn about toxicity: Eckart Krupp, Germany

11.40 – 12.00
Early safety assessment of biologicals: Jennifer Sims, Switzerland

10.00 – 12.00

Symposium 2: Recent developments in risk assessment of nanomaterials and nano safety science

Chairs: Yasuo Yoshioka, Japan and Akihiko Hirose, Japan
Room: Congress Hall
This Symposium is sponsored by the Bo Holmstedt Memorial Foundation (BHMF).

10.00 – 10.20
Nanomaterials as a potential cause of lung disease: James C. Bonner, USA

10.25 – 10.45
Safety consideration of nanomaterials for biomedical applications: Chunying Chen, China

10.50 – 11.10
Nanoparticles as an emerging environmental and occupational hazard: Anna A. Shvedova, USA

11.15 – 11.35
Dosimetry of nanomaterials after different routes of exposure: Wolfgang Kreyling, Germany

11.40 – 12.00
Nanotoxicity and nano safety science in various exposure scenarios: Akihiko Hirose, Japan

10.00 – 12.00

Symposium 3: Profiling the toxicity of new drugs: a non animal-based approach integrating toxicodynamics and biokinetics

Chairs: Armin Wolf, Switzerland and Stefan Müller, Germany
Room: Theatre Room
This Symposium is sponsored by ACEA Bio.

10.00 – 10.20
Predict-IV project overview (EU grant 202222): non animal-based toxicity profiling by integrating toxico-dynamics and biokinetics: Armin Wolf, Switzerland

10.25 – 10.45
An integrated 'omics' approach to characterise nephrotoxin induced stress responses in renal epithelial cells: Paul Jennings, Austria

10.50 – 11.10
The relevance of toxicokinetics in in vitro studies: Emanuela Testai, Italy

11.15–11.35
Integrating Toxicokinetics and Toxicodynamics to predict toxic responses in vivo: Frédéric Bois, France

11.40–12.00
The virtual liver: possibilities to simulate mechanisms of toxicity and predict drug targets: Jan Hengstler, Germany

10.00–12.00

Workshop 1: Immunotoxicants: modes of action and pathways to toxicity

Chair: Raymond Pieters, The Netherlands
Room: Brünig 1–3

10.00–10.25
Application of 'omics' to immunotoxicology: from mechanisms of action to alternative methods: Oscar Volger, The Netherlands

10.30–10.55
Aryl hydrocarbon receptor activation: new insides on TCDD immunotoxicity: Raymond Pieters, The Netherlands

11.00–11.25
Signal transduction pathways activated by contact allergens: in vitro opportunities for the identification of chemical allergens: Andreas Natsch, Switzerland

11.30–11.55
Glucocorticoid receptor and signal transduction pathway associated with immune cell activation: Marco Racchi, Italy

10.00–12.00

Workshop 2: Pesticide exposure and risk assessment by field measurements and model approaches

Chairs: Claudio Colosio, Italy and Aristidis Tsatsakis, Greece
Room: Auditorium

10.00–10.20
Pesticide exposure of agricultural workers in Greece. Biomarkers diversity and variability: Aristidis Tsatsakis, Greece

10.25–10.45
Typical exposure levels in Europe and in tropical countries: Francisco Javier Egea González, Spain & Richard Glass, UK

10.50 – 11.10
Definition of AOEL-based provisional BEIs for pesticide exposure monitoring: a proposed approach for the protection of farmer's health: Claudio Colosio, Italy

11.15 – 11.35
Pesticide and biocide exposures in the UK: John Cocker, UK

11.40 – 12.00
The PESTEXPO program: results of pesticide measurements in vinegrowing and development of exposure algorithms: Isabelle Baldi, France

10.00 – 12.00

Oral Session 1: Computational toxicology & Endocrine disruption

Chair: Alex Odermatt, Switzerland
Room: Harder 1+2

10.00 – 10.15
Generalized workflow for generating high quality in-silico models for off-target mediated toxicity: Lennart T. Anger, Germany

10.15 – 10.30
Multi-scale modeling for individualized spatiotemporal prediction of drug effects: Juan G. Diaz-Ochoa, Germany

10.30 – 10.45
Pharmacophore-based virtual screening as a prioritization tool to assess mechanism-based cardiotoxic effects of small organic molecules: Daniela Schuster, Austria

10.45 – 11.00
Pharmacophore-based virtual screening in the search for endocrine disrupting chemicals – successful case studies: Anna Vuorinen, Austria

11.00 – 11.15
Endocrine modulatory effects of cadmium and the molecular mechanism of action: Ali Imran, Sweden

11.15 – 11.30
Overview of the existing regulations and testing programs for endocrine active chemicals: Simon Warren, USA

11.30 – 11.45
Determination of Bisphenol A exposure in rural and urban area populations in Mersin City: Turkey: Dilek Battal, Turkey

11.45 – 12.00
A case study of risk assessment in Malaysia: Letchumi Thannimalay, Malaysia

10.00 – 11.00

Exhibitor-hosted Session

Room: Grimsel 1+2
How do I get into Phase 1 Trials with my compound?
Scott Boley, MPI Research, USA
For details see page 62

12.00 – 13.00

ILSI/HESI Lecture
Emerging needs for chemical safety and risk assessment in Europe

David R. Bell, European Chemicals Agency, Finland
Chair: Syril D. Pettit, HESI Executive Director, USA
Room: Auditorium

13.00 – 14.00

Keynote Lecture 2: Reliability of toxicology without experimental animals? Possibilities and limitations since the ban of animal experiments with cosmetics

Prof. Franz Oesch, University of Mainz, Germany
Chair: Michael Arand, Switzerland
Room: Auditorium

13.00 – 14.00

Sponsor-hosted Session

Room: Grimsel 1+2
Evidence-based Toxicology Collaboration
Chair: Thomas Hartung, USA
For details see page 62

13.00 – 13.45

Informative Session

Room: Brünig 1–3
The WHO chemical risk assessment network: A new global collaborative approach to human health risk assessment
Chair: Carolyn Vickers, World Health Organization, Geneva, Switzerland

13.00 – 13.15
Background and rationale for a global chemical risk assessment network: Martin Wilks, Switzerland

13.15 – 13.30
Objectives, setup and ways of working for the WHO Chemical Risk Assessment Network: Carolyn Vickers, Switzerland

13.30 – 13.45
Current and planned projects of the WHO Chemical Risk Assessment Network: Alan Boobis, UK

13.00 – 14.00

Exhibitor-hosted Session

Room: Harder 1+2
Pathology evaluation involved in the development of ATMPs
Klaus Weber and colleagues, AnaPath GmbH, BSL Bioservices Scientific Laboratories GmbH and collaboration groups
For details see page 63

14.00 – 16.00

Symposium 4: Stem cell derived tissues in safety assessment

Chair: Kyle Kolaja, USA
Room: Auditorium

14.00 – 14.20
Safety issues in human pluripotent stem cells: Nissim Benvenisty, Israel

14.25 – 14.45
The use of stem cells in discovery and toxicology: Heinz Ruffner, Switzerland

14.50 – 15.10
Realizing the potential of IPS cells and derived tissues – from banking to improved safety assessment to microphysiological systems: Kyle Kolaja, USA

15.15 – 15.35
Stem cell derived cardiomyocytes – application review: Stefan Braam, The Netherlands

15.40 – 16.00
Novel iPSC-derived hepatic model systems for investigating mechanisms of idiosyncratic Drug-Induced Liver Injury (DILI): Ed LeCluyse, USA

14.00 – 16.00

Symposium 5: Renal toxicology – epidemiology, mechanisms and risk assessment

Chairs: Angelika Tritscher, Switzerland and Felix Carvalho, Spain
Room: Congress Hall

14.00 – 14.20
Epidemiology and causation of human renal disease; the case of aristolochic acid nephropathy: Volker Arlt, UK

14.25 – 14.45
Nephrotoxicity of melamine, cyanuric acid, and their combination: Gonçalo Gamboa, USA

14.50 – 15.10
Mechanisms of renal disease – Ochratoxin A: Angela Mally, Germany

15.15 – 15.35
Renal toxicology in drug attrition: Magnus Söderberg, Sweden

15.40 – 16.00
Integration of epidemiological and toxicological information into risk assessment – the melamine example: Angelika Tritscher, Switzerland

14.00 – 16.00

Workshop 3: Carcinogenicity testing for pharmaceuticals

Chairs: Paul Baldrick, UK and Peter Heining, Switzerland
Room: Harder 1+2

14.00 – 14.25
Carcinogenicity testing for pharmaceuticals – an update: Paul Baldrick, UK

14.30 – 14.55
Practical considerations when setting up and conducting a carcinogenicity study: Guy Healing, UK

15.00–15.25
Transgenic versus conventional carcinogenicity testing: David Jones, UK

15.30–15.55
Case studies or how to deal with 'difficult' results: Martin Bopst, Switzerland

14.00–16.00

Workshop 4: Advances in the application of the Threshold of Toxicological Concern (TTC) as a pragmatic risk assessment tool for cosmetics

Chair: Alan Boobis, UK and Co-Chair: Heli Hollnagel, Switzerland
Room: Ball Room
This Symposium is sponsored by ILSI EUROPE.

14.00–14.20
Chemical risk assessment in absence of adequate toxicological data: Benoît Schilter, Switzerland

14.25–14.45
TTC Task Force: Development of a cosmetics database to support application of TTC to cosmetic ingredients (EU Cosmos project): Heli Hollnagel, Switzerland

14.50–15.10
Threshold of toxicological concern (TTC) task force: a strategy to support application of TTC to dermally applied cosmetic ingredients: Faith M. Williams, UK

15.15–15.35
Risk assessment of genotoxic carcinogens task force. Use of TTC for contaminants with potential genotoxic hazard: Alan Boobis, UK

15.40–16.00
Future directions for TTC: Heli Hollnagel, Switzerland

14.00–16.00

Workshop 5: Closing the gap between academic research and regulatory risk assessment of chemicals

Chairs: Christina Ruden, Sweden and Marlene Agerstrand, Sweden
Room: Theatre Room

14.00–14.20
Risk to all or none? The Bisphenol A risk controversy: Anna Beronius, Sweden

14.25 – 14.45
Ensuring reliability and relevance of academic research for regulatory assessments – some practical considerations: Sharon Munn, Italy

14.50 – 15.10
How is new science used in regulatory approaches for dealing with endocrine disrupters? Andreas Kortenkamp, UK

15.15 – 15.35
Editors' and Reviewers' roles in promoting quality publications: James Kehrer, Canada

15.40 – 16.00
Discussion: What is needed to close the gap between science and regulatory risk assessment? All speakers

14.00 – 16.00

Oral Session 2: Models for assessing organ toxicity

Chair: Jan G. Hengstler, Germany and Co-Chair: Dieter Schrenk, Germany
Room: Brünig 1–3

14.00 – 14.15
Determination of liver specific toxicities in rat hepatocytes by High Content Imaging during 2-week multiple treatment: Davide Germano, Switzerland

14.15 – 14.30
3d hepatocyte cultures: a useful tool in the study of Nevirapine bioactivation and toxicity: Joana P. Miranda, Portugal

14.30 – 14.45
A physiologically relevant HepG2 cell based 3D cell culture model for high throughput toxicity studies: Sreenivasa Ramaiahgari, The Netherlands

14.45 – 15.00
A 4D lung multi-culture system mimicking alveolar cellular organization to study the toxic potential of airborne particles: Tommaso Serchi, Luxemburg

15.00 – 15.15
Predictive human kidney-specific in vitro models: Yao Li, Singapore

15.15 – 15.30
An in vitro model of the renal proximal tubule composed of small intestinal submucosa (SIS) and human kidney-derived cells (hKDCs): Anke Hoppensack, Germany

15.30 – 15.45
Microgravity spheroids as a reliable, long-term tool for predictive toxicology: Stephen Fey, Denmark

15.45 – 16.00
A novel zebrafish model to predict organ toxicities in mammals: Philip Ingham, Singapore

16.30 – 18.30

Symposium 6: Challenges with immunogenicity of biologics

Chair: Valerie Quarmby, USA
Room: Congress Hall

16.30 – 16.50
Challenges with immunogenicity of biologics: Cecilia Tami, USA

16.55 – 17.15
Update on new regulatory guidelines on immunogenicity: Gaby Reichmann, Germany

17.20 – 17.40
IMI project ABIRISK: Anti-biopharmaceutical immunization: prediction and analysis of clinical relevance to minimize the risk: Marc Pallardy, France

17.45 – 18.05
Drug hypersensitivity and stimulation of the immune system: beyond the hapten concept: Werner Pichler, Switzerland

18.10 – 18.30
Assessing immunogenicity of therapeutic antibodies in transgenic mice: Antonio Iglesias, Switzerland

16.30 – 18.30

Symposium 7: RISK21: Novel thinking for 21st century risk assessment

Chair: Alan Boobis, UK
Room: Auditorium
This Symposium is sponsored by ILSI / HESI USA.

16.30 – 16.50
The HESI RISK21 project: Alan Boobis, UK

16.55 – 17.15
Optimizing the use of exposure information: Herman Autrup, Denmark

17.20 – 17.40
Incorporation of mode-of-action information into dose-response assessment: the Quantitative Key Events / Dose-Response Framework (Q-KEDRF): Richard Currie, UK

17.45 – 18.05
In vitro to in vivo extrapolation (IVIVE) for human health risk assessment:
Rory B. Conolly, USA

18.10 – 18.30
Assessing cumulative risk to multiple stressors: Angelo Moretto, Italy

16.30–18.30

Symposium 8: New challenges for risk assessment: how innovation can make the difference

Chair: Tuomo Karjalainen, Belgium
Room: Theatre Room
This Symposium is sponsored by European Commission, Research and Innovation Directorate-General, Environment Directorate.

16.30–16.40
Introductory remarks: Tuomo Karjalainen, Belgium

16.40–17.00
Challenges in risk assessment of chemicals: DG Environment point of view: Peter Korytar, Belgium

17.00–17.25
Advances in toxigenomics: use for risk assessment: Jos Kleinjans, The Netherlands

17.25–17.45
Developmental origins of diseases: Challenge for risk assessment of chemicals: Philippe Grandjean, Denmark

17.45–18.10
Biomarkers of exposure and effect, where are we going? Greet Schoeters, Belgium

18.10–18.30
Questions and comments from the audience

16.30–18.30

Workshop 6: Preclinical safety assessment: evolution of science-based decision making

Chair: Ruth Roberts, UK
Room: Ball Room
This Symposium is sponsored by NC3R (UK).

16.30–16.50
Strategies in preclinical safety: target organ toxicities, recovery assessment and significance for clinical development: Ruth Roberts, UK

16.55–17.15
Assessment of dependence potential and suicidality liabilities: how non–clinical data help: Andreas Hartmann, Switzerland

17.20–17.40
Science-based approaches to carcinogenicity risk assessment for large molecules: Ron Steigerwalt, USA

17.45–18.05
Significance of species and study design in pre-clinical testing of biologics: challenges and opportunities: Kathryn Chapman, UK

18.10–18.30
A prospective view towards investigative safety assessment: Richard Weaver, France

A Culture of Collaboration

At Novartis Institutes for BioMedical Research (NIBR), the global research organization of Novartis, our ambition is to transform drug discovery and develop breakthrough medicines that change patient treatment. Our culture of science is open and entrepreneurial; we are focused on clearly sharing our views and opinions while listening to the views of others. By hiring the best academic, biotech, and pharmaceutical-trained scientists, we have fostered an atmosphere for drug discovery where creativity thrives. Our research is driven by rigorous science and unmet medical need, not the market size. We have created a dynamic and flexible culture that values each associate's diverse background, unique style and wealth of experience.

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16.30–18.30

Workshop 7: Connexin-based cellular signaling and its relevance to toxicology

Chair: Mathieu Vinken, Belgium
Room: Brünig 1–3

16.30–16.55
The role of connexins and their channels in toxicity: Mathieu Vinken, Belgium

17.00–17.25
Mechanisms underlying connexin-mediated bystander cell death: Elke Decrock, Belgium

17.30–17.55
The role of connexins and their channels in carcinogenesis: Marc Mesnil, France

18.00–18.25
Connexins and benzene toxicity: Edgar Rivedal, Norway

16.30–18.30

Roundtable Discussion: Risk versus hazard in Europe

Chairs: Christine Lorez and Martin Wilks, Switzerland
Room: Harder 1+2
This Symposium is sponsored by ECPA.

16.30–16.50
Hazard-based regulation in Europe: status of impact in risk assessments: Albert Bergmann, Austria

16.50–17.10
Hazard classification or risk assessment: Ulla Hass, Denmark

17.10–17.30
Using hazard characterization in chemical classification. Potency as a key discriminator: Dick Lewis, Belgium

17.30–17.50
Risk and hazard: perspective of a regulatory agency: Roland Solecki, Germany

17.50–18.30
Discussion, all speakers

Tuesday, September 3rd, 2013

08.30–09.30

Bo Holmstedt Memorial Foundation (BHMF) lecture: The developing brain: Neurotoxic insults and their long term impact

Sandra Ceccatelli, Sweden
Chair: Herman Autrup, Denmark
Room: Auditorium

10.00–12.00

Symposium 9: Assessment and control of genotoxic drug impurities

Chairs: Lutz Müller, Switzerland and Dieter Schrenk, Germany
Room: Auditorium

10.00–10.20
Development of genotoxic impurities guidelines and their impact on regulatory review: Elisabeth Klenke, Switzerland

10.25–10.45
The staged TTC concept in the evaluation of genotoxic impurities in drugs: Lutz Müller, Switzerland

10.50–11.10
Genotoxic impurities in drugs – 'paper chemistry' or analytical data? Alexander Amberg, Germany

11.15–11.35
Genotoxic impurities – a quality perspective on analysis and control: Rolf Schulte Oestrich, Switzerland

11.40–12.00
How to apply impurity control procedures to complex mixtures such as herbal medicines: Olavi Pelkonen, Finland

10.00 – 12.00

Symposium 10: Genetic susceptibility: relevance to toxicology

Chairs: Hans Ketelslegers, Belgium and Ruth Roberts, UK
Room: Congress Hall

10.00 – 10.25
Genetic susceptibility: relevance to toxicology: Hans Ketelslegers, Belgium

10.30 – 10.55
Epigenome changes induced by environmental factors and cancer: Zdenko Herceg, France

11.00 – 11.25
In vitro screening for population variability in chemical toxicity: Ivan Rusyn, USA

11.30 – 11.55
Genetic susceptibly: relevance to adverse drug reactions: Ruth Roberts, UK

10.00 – 12.00

Workshop 8: Risk perception and communication

Chairs: Hanspeter Naegeli, Switzerland and Mojmir Mach, Slovakia
Room: Brünig 1–3

10.00 – 10.20
Proper communication of compound-inherent risks: the scientists dilemma: Michael Arand, Switzerland

10.25 – 10.45
Human functioning in the context of risk: Heinz Gutscher, Switzerland

10.50 – 11.10
Quality criteria in professional risk communication – the editors view: Jan Georg Hengstler, Germany

11.15 – 11.35
Risk assessment – the needs of an expert panel: Andrea Hartwig, Germany

11.40 – 12.00
Round table discussion

10.00 – 12.00

Workshop 9: The toxicology of drug delivery systems

Chairs: Heather Wallace, UK and Nursen Basaran, Turkey
Room: Ball Room

10.00 – 10.20
Modifying the risk-benefit ratio using drug delivery systems: Peter Newham, UK

10.25 – 10.45
Drug delivery using endogenous transport systems: Heather Wallace, UK

10.50 – 11.10
Understanding the behavior of nanoparticulate drug delivery systems in vivo: particle disposition patterns, toxicologic implications and effective drug development: Richard Kirsh, UK

11.15 – 11.35
Pharmacokinetics and toxicology of nanoparticles in drug delivery: Raymond Yang, USA

11.40 – 12.00
Safety of therapeutic monoclonal antibody conjugates: Nicholas Buss, UK

10.00 – 12.00

Workshop 10: Mechanism-based safety biomarkers

Chair: Dominique Brees, Switzerland
Room: Theatre Room

10.00 – 10.20
Emerging trends in hemostasis biomarkers: David Ledieu, Switzerland

10.25 – 10.45
Current status and future perspectives of renal safety biomarkers: Mark Pinches, UK

10.50 – 11.10
Preclinical (epi)genomics – identifying safety biomarkers for the prediction of non-genotoxic carcinogenesis: Remi Terranova, Switzerland

11.15 – 11.35
Clinical utility of novel mechanistic biomarkers of drug-induced liver injury: Daniel Antoine, UK

11.40 – 12.00
Roundtable discussion: Using non-validated safety biomarkers in clinical studies
Moderated by session chairs

10.00 – 11.45

Oral Session 3: Nanotoxicology, Immunotoxicology & Dermatoxicology

Chair: Ioannis Trantakis, Switzerland
Room: Harder 1+2

10.00 – 10.15
Transfer of engineered nanoparticles across the human placenta: Stefanie Grafmüller, Switzerland

10.15 – 10.30
Use of 'same donor' endothelial cells and PBMC in co-culture to detect cytokine storm reactions to a TGN1412-like anti-CD28 antibody: A novel assay for biologic drug safety screening: Daniel Reed, UK

10.30 – 10.45
HLA haplotype determines hapten or p-i T cell reactivity to flucloxacillin: Werner J. Pichler, Switzerland

10.45 – 11.00
Use of cytotoxicity-based assays in the in vitro diagnosis of patients with Sevens-Johnson syndrome: Tatjana Pecaric Pekovic, Switzerland

11.00 – 11.15
A modified oral UV-LLNA in Balb/c mice to investigate phototoxicity mechanisms and pharmacokinetic properties in skin: Stéphanie Boudon, Switzerland

11.15 – 11.30
Relevance of in-vitro methods for the evaluation of eye and skin irritation/corrosion potential of aliphatic tertiary amines: Qiang Li, Germany

11.30 – 11.45
Animal-free studies in cosmetic ingredient industry: Perspective and strategy after a 10-year experience: Herve Ficheux, UK

10.00 – 11.00

Exhibitor-hosted Session

Room: Grimsel 1+2
Using the xCELLigence RTCA Cardio System for Assessment of Preclinical Cardiac Safety Assessment
Yama Abassi, ACEA Biosciences, Inc., USA
For details see page 64

12.00–13.00

Exhibitor-hosted Session

Room: Brünig 1–3
3Rs: refinement techniques for Primates and their effect on data quality
Helen Palmer, Huntington Life Sciences, UK
For details see page 65

12.15–13.15

EUROTOX – SOT Debate: In the near foreseeable future, much of toxicity testing can be replaced by computational approaches

EUROTOX Debater: George Loizou, UK
SOT Debater: Rory B. Conolly, USA
Chair: Aristidis Tsatsakis, Greece, President Elect EUROTOX and Co-chair: Norbert E. Kaminski, USA, President Elect SOT
Room: Auditorium

13.30–15.30

Symposium 11: The Extended One Generation Reproductive Toxicity (EOGRT) assay – scientific challenges and regulatory implementation

Chairs: Helen Håkansson, Sweden and Richard Vogel, Germany
Room: Auditorium

13.30–13.50
Practical experience of the EOGRTS protocol in use: Steffen Schneider, Germany

13.55–14.15
Analysis of immune toxicity in the extended one-generation reproduction toxicity study: Aldert Piersma, The Netherlands

14.20–14.40
Analysis of developmental neurotoxicity: Sandra Allen, UK

14.45–15.05
Developmental toxicity in reproductive organs: Geertje Lewin, Germany

15.10–15.30
Epigenetics: how genes and environment interact: Randy Jirtle, USA

13.30–15.30

Symposium 12: Integration of human and environmental risk assessment – is it the future?

Chairs: Inge Werner, Switzerland and Lothar Aicher, Switzerland
Room: Theatre Room
This Symposium is sponsered by the Swiss Centre for Applied Human Toxicology and the Swiss Centre for Applied Ecotoxicology.

13.30–13.50
HEROIC – an integrated European approach to the coordination of human and environmental risk assessment: Martin Wilks, Switzerland

13.55–14.15
Environmental and drinking water risk assessment of substances which are toxic to humans or aquatic organisms – examples and options: Robert Kase, Switzerland

14.20–14.40
Human risk assessment of drinking water residues from pharmaceuticals: environmental pathways, pharmacological potency and toxicity: Reinhard Länge, Germany

14.45–15.05
Decision-making in human and environmental risk assessment using a weight of evidence approach: Philippe Ciffroy, France

15.10–15.30
Application of probabilistic modelling techniques in human and environmental risk assessment: Ad Ragas, The Netherlands

13.30–15.30

Workshop 11: New approaches to unravel toxicities based on compound activity observed in zebrafish

Chair: Carles Callol, Spain
Room: Ball Room

13.30–13.50
Locomotor activity in zebrafish embryo and larva: alternative assays to evaluate the developmental neurotoxic potential of chemicals and drugs: Hilda Witters, Belgium

13.55–14.15
Resolving the neuropharmacology of zebrafish sleep: Jason Rihel, UK

14.20–14.40
The utility of the zebrafish for drug safety assessment: an industry perspective: Matthew Winter, UK

14.45–15.05
Predicting drug-induced hepatotoxicity in zebrafish larvae: Natalie Mesens, Belgium

15.10–15.30
New approach to a predictive toxicity evaluation with a zebrafish assay: Ainhoa Alzualde, Spain

13.30–15.30

Workshop 12: Identifying, assessing and managing allergens in food

Chair: Yong Joo Chung, Switzerland
Room: Brünig 1–3

13.30–13.50
Trends in food allergy and impact on public health: Jonathan Hourihane, Ireland

13.55–14.15
A regulator's approach to risk assessment of food allergens: Sue Hattersley, UK

14.20–14.40
Identification of new food allergens of public health relevance: Geert Houben, The Netherlands

14.45–15.05
Experimental approaches to predict allergenic potential of novel food: Charlotte Madsen, Denmark

15.10–15.30
Impact of processing on the allergenic potential of food: Clare Mills, UK

13.30–15.15

Oral Session 4: Environmental toxicology, Food toxicology & Novel analytical techniques

Chair: Rex FitzGerald, Switzerland
Room: Harder 1+2

13.30–13.45
Toxicogenomics to group environmental chemicals in vitro? Alessa Ignarski, Switzerland

13.45–14.00
Toxicity of microcystin-deficient Planktothrix strains due to chlorine and sulfate containing aeruginosins: Esther Kohler, Switzerland

14.00–14.15
Toxicological risk assessment in carbon capture and storage technology: Marcus Hillebrand, Germany

14.15–14.30
Evidence for lipid signaling molecules in glycated protein preparations being responsible for the stimulation of inflammatory signaling in RAGE expressing cells – potential role of lysophosphatidic acid: Timo Buetler, Switzerland

14.30–14.45
Liquid chromatographic determination of histamine in traditionally salted, smoked and frozen fish with relation to microbial load: Mohamed Mahmoud Deabes, Egypt

14.45–15.00
A refined surgical technique for telemetry in group housed macaques (M. fascicularis): Jörg Luft, Germany

15.00–15.15
Less is more: Better toxicity data from fewer rodents using plasma microsampling: Anne Eichinger-Chapelon, Switzerland

16.00–18.00

Symposium 13: Toxic injury to the lung: mechanisms and consequences

Chairs: Martin Wilks, Switzerland and Daniela Pelclová, Czech Republic
Room: Auditorium

16.00–16.20
Toxic lung injury associated with fever: mechanisms and outcome: Daniela Pelclová, Czech Republic

16.25–16.45
Emerging occupational lung disorders caused by inhaled chemical agents: Benoit Nemery, Belgium

16.50–17.10
Pulmonary consequences of drug use: Bruno Mégarbane, France

17.15–17.35
Pulmonary consequences of chemical warfare agent: Sulphur Mustard: Reza Afshari, Iran

17.40–18.00
New insights in the management of toxic acute lung injury: Dylan de Lange, The Netherlands

16.00 – 18.00

Symposium 14: Cardiovascular toxicity in drug discovery and development

Chair: Jean-Pierre Valentin, UK
Room: Theatre Room

16.00 – 16.20
Cardiovascular toxicity: understanding the issues, challenges and opportunities: Rashmi R. Shah, UK

16.25 – 16.45
Hazard identification and elimination: designing safe medicines: Laszlo Urban, USA

16.50 – 17.10
Integrated cardiovascular risk assessment: a balancing act between risks and benefits: Tim Hammond, UK

17.15 – 17.35
Mitigating and managing clinical cardiovascular risks: preserving effective medicines: Paul Volders, The Netherlands

17.40 – 18.00
Translational cardiovascular toxicity: from animal to man and back: Jean-Pierre Valentin, UK

16.00 – 18.00

Workshop 13: miRNAs: mechanisms and safety issues

Chairs: Nancy Claude, France and Catherine de la Moureyre-Spire, France
Room: Ball Room

16.00 – 16.20
Non-coding RNA mechanisms and biomarkers of toxicity: from tissue to circulation: Jonathan Moggs, Switzerland

16.25 – 16.45
Analysis of the expression, maturation and functioning of microRNAs in cancer: Jörg Hoheisel, Germany

16.50 – 17.10
MicroRNAs as markers of drug-induced tissue perturbation and adaptation: Christopher Goldring, UK

17.15 – 17.35
The role of microRNAs in the response to toxic insult: Martin Bushell, UK

17.40 – 18.00
The HESI inter-laboratory miRNA Project: Catherine de la Moureyre-Spire, France

16.00 – 18.00

Workshop 14: Addressing safety in the immature organism: about children's safety and risk-assessment

Chairs: Jacqueline Carleer, Belgium and Georg Schmitt, Switzerland
Room: Brünig 1–3
This Workshop is co-sponsered by Sequani Limited, UK.

16.00 – 16.25
Introduction to the immature organism: Georg Schmitt, Switzerland

16.30 – 16.55
Non-clinical safety in paediatric drug development: Jim Ridings, UK

17.00 – 17.25
Juvenile safety testing for chemicals and pesticides: Aldert Piersma, The Netherlands

17.30 – 17.55
Value of studies in juvenile animals for human risk assessment: John DeSesso, USA

16.00 – 17.30

Oral Session 5: Genotoxicity, Carcinogenicity & Mechanisms in Toxicology

Chair: Shana Sturla, Switzerland
Room: Harder 1+2

16.00 – 16.15
Dose-response of alkylation-induced colorectal carcinogenesis in MGMT-proficient and -deficient mice: Jörg Fahrer, Germany

16.15 – 16.30
Breast cancer in danish women: A prospective case-control study on breast cancer risk upon exposure to perfluorinated compounds: Eva Cecilie Bonefeld-Jorgensen, Denmark

16.30 – 16.45
The ToxTracker assay: Unveiling the carcinogenic properties of chemicals: Giel Hendriks, The Netherlands

16.45 – 17.00
Noncanonical activation of ATR-p53 axis by DNA-protein crosslinks controls cell death responses to formaldehyde: Anatoly Zhitkovich, USA

17.00 – 17.15
The role of rat and human CYP enzymes in okadaic acid-associated toxicity: Franziska Kolrep, Germany

17.15 – 17.30
FRET-based analysis of the interaction between mEH and CYP: Anette Orjuela, Switzerland

Wednesday, September 4th, 2013

08.30 – 10.30

Symposium 15: Tiered approaches to assess complex mixtures

Chairs: Heli Hollnagel, Switzerland and Martin van den Berg, The Netherlands
Room: Auditorium
This Symposium is sponsored by ECETOC.

08.30 – 08.50
Current concepts in mixture toxicology and risk assessment: Herman Autrup, Denmark

08.55 – 09.15
Testing mixtures in vivo at human-relevant exposure levels: Steffen Schneider, Germany

09.20 – 09.40
Application of the combined decision tree to surface water data from Switzerland, UK, and other EU countries: Marion Junghans, Switzerland

09.45 – 10.05
Application of the decision tree methodology to human health endpoints for multi-constituent chemical formulations: Heli Hollnagel, Switzerland

10.10 – 10.30
Grouping approaches and the development of mechanism of action information for use in the decision tree: Angelo Moretto, Italy

8.30 – 10.30

Symposium 16: New developments in "omics" for use in risk assessment

Chairs: Michael Schwarz, Germany and Bennard van Ravenzwaay, Germany
Room: Theatre Room
This Symposium is sponsored by ECETOC and ECPA.

08.30 – 08.50
The challenges and opportunities to identify modes of action using toxicogenomics: Richard Currie, UK

08.55 – 09.15
Integrating genomics into the AOP framework: Chris Corton, USA

09.20 – 09.40
The use of toxicogenomics for cancer risk identification and assessment, Jos Kleinjans, The Netherlands

09.45 – 10.05
Metabolomics & REACH: quantitative biological activity relationships: Bennard van Ravenzwaay, Germany

10.10 – 10.30
Qualitative and quantitative aspects of omics data: can we improve our risk assessment using these technologies ? Saskia van der Vies, The Netherlands

8.30 – 10.30

Workshop 15: Translational imaging in non-clinical safety applications

Chair: Markus Stephan-Gueldner, Switzerland
Room: Brünig 1–3

08.30 – 08.50
Magnetic resonance histology: Cool images – but who cares? Allan Johnson, USA

08.55 – 09.15
Towards PET imaging of Kupffer cell activity: Erik de Vries, The Netherlands

09.20 – 09.40
Echocardiography in non-clinical safety studies: adding value, and increasing acceptance and application: Robert W. Coatney, USA

09.45 – 10.05
Potential of in-vivo imaging for DART assessment in primates: Gerhard Weinbauer, Germany

10.10 – 10.30
Revolutionizing biomedical optical imaging with multispectral optoacoustic tomography (MSOT): Vasilis Ntziachristos, Germany

8.30 – 10.30

Workshop 16: Predicting chronic toxicity to establish level of safety concern in absence of toxicological data

Chairs: Elena Lo Piparo, Switzerland and Benoît Schilter, Switzerland
Room: Grimsel 1+2

08.30 – 08.50
Integration of in silico models to establish safety concern of food chemicals: the ILSI-Europe proposal: Benoît Schilter, Switzerland

08.55 – 09.15
Applying read-across for quantitative chronic toxicity prediction: Mark Cronin, UK

09.20 – 09.40
QSAR approach to predict chronic toxicity and carcinogenicity potency: state of the art: Elena Lo Piparo, Switzerland

09.45 – 10.05
VirtualToxLab – In silico prediction of the toxic potential of drugs and chemicals: Angelo Vedani, Switzerland

10.10 – 10.30
Potential of short-term biological assays to quantitatively predict chronic toxicity: Alexander Tropsha, USA

11.00 – 13.00

Symposium 17: Reactive metabolites and drug toxicity: contribution, mechanisms and novel approaches

Chairs: Nico Vermeulen, The Netherlands and Hilmi Orhan, Turkey
Room: Auditorium

11.00 – 11.25
Target organs and cellular reactivity of drug metabolites: Hilmi Orhan, Turkey

11.30 – 11.55
Reactive metabolites in drug discovery and development: approaches to risk mitigation: Thomas Baillie, USA

12.00 – 12.25
Translational strategies for identifying chemically reactive metabolites as cause for Adverse Drug Reactions: Nico Vermeulen, The Netherlands

12.30 – 12.55
Clinical relevance of drug bioactivation: Kevin Park, UK

11.00–13.00

Symposium 18: Nuclear receptors integrate metabolic and environmental signals to regulate cell fate

Chairs: Ronald Tjalkens, USA and Eva Cecilie Bonefeld-Jørgensen, Denmark
Room: Theatre Room

11.00–11.25
Aryl Hydrocarbon receptor (AhR) regulation of inflammation and cancer: Michael Platten, Germany

11.30–11.55
The orphan receptor NR4A1 (TR3/Nur77) as a drug target for cancer chemotherapy: Stephen Safe, USA

12.00–12.25
Non-genomic responses of nuclear receptors to environmental signals: Xiao-kun Zhang, China

12.30–12.55
Neuroinflammatory injury and NR4A receptors: Ronald Tjalkens, USA

11.00–13.00

Workshop 17: Assessment of azo dyes and aromatic amines in food additives, cosmetics and consumer products

Chairs: Thomas Platzek, Germany and Rex FitzGerald, Switzerland
Room: Harder 1+2

11.00–11.20
Overview on toxicity and exposure to azo dyes and aromatic amines: Thomas Platzek, Germany

11.25–11.45
Re-evaluation of azo dyes as food additives: problems encountered: Iona Pratt, Ireland

11.50–12.10
Allergies and hair dyes: Wolfgang Uter, Germany

12.15–12.35
Metabolism of oxidative hair dyes in the skin and the organism: Gerhard Nohynek, France

12.40–13.00
Toxicity of non-regulated aromatic amines from azo dyes in textiles: knowns and unknowns: Beat Brüschweiler, Switzerland

11.00–13.00

Workshop 18: Ecological risk assessment in the 21st century: taking into account mechanistic data

Chairs: Claus Svendsen, UK and Jean-Lou Dorne, Italy
Room: Brünig 1–3

11.00–11.20
Using OMICS in ecological risk assessment: where do we stand? Peter Kille, UK

11.25–11.45
The promise of ecotoxicogenomics for detecting adverse contaminant effects in non-model species: Inge Werner, Switzerland

11.50–12.10
Functional toxicogenomics in bees: recent advances towards mechanism-based risk assessment: Reed M. Johnson, USA

12.15–12.35
Using OMICS technologies to unravel mechanisms of toxicity from endocrine disruptors in aquatic species: Nancy Denslow, USA

12.40–13.00
Toxicokinetic interactions of chemical mixtures in ecotoxicology: critical issues: Jean-Lou Dorne, Italy

11.00–13.00

Oral Session 6: Neurotoxicology, Developmental Toxicology & miRNAs

Chair: Michael Arand, Switzerland
Room: Grimsel 1+2

11.00–11.15
Enhanced intranasal delivery of Gemcitabine to the central nervous system: Mansi Krishan, USA

11.15–11.30
“Ecstasy” impairs mitochondrial trafficking in hippocampal neurons by a Tau phosphorylation-dependent mechanism involving GSK3ß: Félix Carvalho, Portugal

11.30–11.45
Effects of neurotoxic compounds on functional three-dimensional neural tissues derived from hESCs: Luc Stoppini, Switzerland

11.45 – 12.00
miRNomics, metabolomics and 3D neuronal differentiation of LUHMES progenitor cells as an in vitro model for DNT studies, Lena Smirnova, USA

12.00 – 12.15
MiRNA-210 modulates nickel-induced hypoxic responses by repressing the iron-sulfur cluster assembly proteins ISCU1/2: Min-Di He, China

12.15 – 12.30
miRNA profiling as a tool for developmental neurotoxicity pathway analysis in human in vitro model: Anna Price, Italy

12.30 – 12.45
Using adverse outcome pathway genes to assess developmental toxicity of compounds in a mouse stem cell system: Marc Teunis, The Netherlands

13.10 – 14.10

Closing Ceremony

Chair: Ruth Roberts, President of EUROTOX, UK
Room: Auditorium

Farewell address
Thomas Weiser, President of the EUROTOX 2013 Congress, Switzerland

Award ceremony
Ruth Roberts, President of EUROTOX, UK

Presentation of the EUROTOX 2014 Congress in Edinburgh, UK
Heather Wallace, President of the EUROTOX 2014 Congress, UK

Closing of the EUROTOX 2013 Congress
Ruth Roberts, President of EUROTOX, UK

Sponsor/Exhibitor-hosted Sessions

Monday, September 2nd, 2013

10.00 – 11.00

Exhibitor-hosted Session
MPI Research

Room: Grimsel 1+2
How Do I Get Into Phase 1 Trials With My Compound?
Scott Boley, USA

Once a company has selected their lead compound, the next phase is determining which nonclinical studies need to be conducted to support taking the lead compound into the first clinical trials. Unfortunately this question does not have a straightforward answer since the approach taken is entirely dependent on the test article type (small molecule, biopharmaceutical, device), clinical indication (life threatening, non-life threatening), and planned Phase I trial design (route and regimen). This presentation outlines the nonclinical studies that should be considered in designing a strategy to support your initial IND application. Examples from small molecules to biopharmaceuticals to botanicals, oncology to pediatric indications, will be covered. This information will provide a solid basis for understanding the numerous factors influencing the nonclinical approach needed to progress into the clinic.

13.00 – 14.00

Sponsor-hosted Session
Evidence-based Toxicology Collaboration

Room: Grimsel 1+2
Chair: Thomas Hartung, USA

Evidence-based approaches, which were pioneered in medicine, provide the means to transparently, objectively, and consistently assess the evidence bearing on questions in medicine or other fields of science. The Evidence-based Toxicology Collaboration (EBTC) was formed to translate the principles and approaches of Evidence-based Medicine/Health Care to toxicology. The EBTC comprises stakeholders in academia, industry, and government seeking to strengthen decision-making in safety sciences, and thereby enhance confidence in the process by which scientific evidence is assessed. The EBTC is primarily interested in assessing the performance of the toxicological test methods and addressing

questions about the safety of substances to human health and the environment. The EBTC's efforts are timely, as there is growing interest in applying systematic reviews in toxicology, which would be facilitated by a toxicology ontology, be as well as a growing recognition that new test assessment approaches are needed, for example in the context of composing and assessing integrated testing strategies.

13.00 – 13.20
Evidence-based Toxicology (EBT) and the EBT Collaboration: Sebastian Hoffmann, Germany

13.20 – 13.40
EBT and Integrated Testing Strategy: Thomas Hartung, USA

13.40 – 14.00
Toxicology Ontology Development supporting Evidence-based Approaches in Predictive Toxicology: Barry Hardy, Switzerland

13.00 – 14.00

Exhibitor-hosted Session

AnaPath and collaborating groups

Room: Harder 1+2
Pathology Evaluation involved in the Development of ATMPs
K. Weber, AnaPath GmbH, Oberbuchsiten, Switzerland
J. Füner, preclinics GmbH, Potsdam, Germany
S. Gähler, AnaPath GmbH, Oberbuchsiten, Switzerland
H. Hofman-Hüter, BSL Bioservice Scientific Laboratories GmbH, Planegg, Germany
O. Janke, preclinics GmbH, Potsdam, Germany
J. Lehmann, Fraunhofer Institute for Cell Therapy and Immunology, Germany
W. Riedel, BSL Bioservice Scientific Laboratories GmbH, Planegg, Germany
K. Weidemann, BSL Bioservice Scientific Laboratories GmbH, Planegg, Germany

ATMPs (Advanced Therapy Medicinal Products) consist of three major therapeutical groups including gen therapeutics, somatic cell therapeutics, and engineered tissues. A number of ATMPs are classified and listed under the 'Summaries of scientific recommendations on classification of advanced-therapy medicinal products' by the EMA. All ATMPs contain partially or consist fully of living cells or tissues. A further option is the combination of ATMPs with medical devices. Therefore, ATMPs are complex, and the preclinical testing differs in many aspects from 'classical' testing strategies.
The use of many different species including diseases models as well as the complex application of molecular biology approaches and the usage of an extended armamentarium to trace ATMPs in vivo not alone cause changes in the way of classical pathology evaluation. The presentation will show examples on strategies of pathology evaluation during the development of ATMPs.

Tuesday, September 3rd, 2013

10.00–11.00

Exhibitor-hosted Session

ACEA Biosciences, Inc.

Room: Grimsel 1+2
Using the xCELLigence RTCA Cardio System for Assessment of Preclinical Cardiac Safety Assessment
Yama Abassi, USA

Cardiac toxicity is a major concern in drug development and it is imperative that clinical candidates are thoroughly tested for adverse effects earlier in the drug discovery process. In this presentation we will discuss the utility of ACEA Biosciences xCELLigence RTCA Cardio System in conjunction with stem cell derived cardiomyocytes for assessment of compound risk in the drug discovery process. The system was validated using stem cell-derived

cardiomyocytes and primary cardiomycytes and by dose-response profiling of pharmacological compounds, including ion channel modulators, chronotropic/ionotropic agents, hERG trafficking inhibitors and drugs withdrawn due to TdP arrhythmia. Our results show this system can sensitively and quantitatively detect modulators of cardiac function, including compounds missed by electrophysiology. Our key finding is that pro-arrhythmic compounds produce signature profiles that reflect arrhythmia and can be used for identification of other pro-arrhythmic compounds. The time series data can be used to identify compounds which induce arrhythmia by complex mechanisms such as hERG trafficking inhibition. Microelectronic monitoring of stem cell derived cardiomyocyte beating provides a high throughput, quantitative and predictive assay system that can be used for assessment of cardiac liability earlier in the drug discovery process.

12.00 – 13.00

Exhibitor-hosted Session
Huntington Life Sciences

Room: Brünig 1–3
3Rs: refinement techniques for Primates and their effect on data quality
Helen Palmer, UK

There is no doubt that over the last 20 years the state of housing and husbandry for primates in research premises has improved enormously throughout Europe. In our attempts to improve the welfare and wellbeing of our animals we must constantly remind ourselves that fulfilling the scientific objectives of the study is paramount, otherwise there is no justification for use of the primate at all. In this session we will review techniques and equipment originally implemented as welfare improvements, and show how the data produced is of higher quality because of these changes. The effect of some of these welfare improvements, including group housing, positive reinforcement training, restraint free measurement techniques and microsampling will be examined with regards to safety pharmacology and toxicology studies. The state of animal welfare in laboratories is in a state of continual improvement; in this session we will discuss just how worthwhile these improvements are.