# Wednesday, October 15

## Continuing Education Course

**October 15 | 10:00–12:00 | Guojin Hall**

### CEC01: Advancing Scientific Excellence and Increasing Confidence in NAMs through Good In Vitro Method Practices (GIVIMP)

***Chairs:***
- *Robert Landsiedel, BASF SE, Germany*
- *Amanda Ulrey, Institute for In Vitro Sciences, Inc., USA*

**Summary:**
The landscape of pre-clinical testing is shifting with the introduction of novel test systems like microphysiological systems and other cell-based models, instead of relying on animal models. In response to regulatory imperatives for transitioning to these human-relevant models, scientists are turning to the development and routine use of New Approach Methodologies (NAMs). This continuing education course is designed to acquaint professionals with the principles and practices outlined in the OECD guidance document 286 – Good In Vitro Method Practices (GIVIMP). Starting with an exploration of the foundational principles shaping GIVIMP, the course emphasizes its role not only in ensuring high standards for study performance but also in influencing the design and development of NAMs. Participants will be presented with a summary of topics such as roles and responsibilities; facility design; apparatus, materials, and reagents; test systems; standard operating procedures; and the recording and reporting of results. The course illustrates the integration of GIVIMP recommendations into a variety of laboratory settings through the use of several case studies. The overarching goal is to empower scientists with the knowledge and tools essential for navigating the intricacies of in vitro methods, thereby upholding the highest standards of quality and reliability across diverse laboratory settings.

**Schedule:**

10:00–10:20 **Founding Principles of GIVIMP**
*Erin Hill, International Collaboration on Cosmetics Safety (ICCS), USA*

10:20–10:50 **Good In Vitro Method Practices (GIVIMP) Overview**
*Amanda Ulrey, Institute for In Vitro Sciences, Inc., USA*

10:50–11:10 **Test System Strategies: Applying GIVIMP to Improve NAMs**
*Samuel Constant, Epithelix, Switzerland*

11:10–11:40 **Taking Advantage of GIVIMP During Method Development**
*Robert Landsiedel, BASF SE, Germany*

11:40–12:00 **Application of GIVIMP Principles to a Laboratory in China**
*Jing Sang, Zhejiang Institute for Food and Drug Control, China*

12:00–12:20 **Impact of Increased Confidence in NAMs on Acceptance in China and Beyond**
*Quanshun Zhang, Institute for In Vitro Sciences, Inc., China*

**October 15 | 10:00–12:00 | Guoxiu Hall**

## CEC02: From the Past to the Present: Does Particle Toxicology Really Change?

***Chairs:*** ● *Flemming R. Cassee, Institute for Risk Assessment Sciences, Utrecht University & National Institute for Public Health and the Environment (RIVM), The Netherlands*

**Summary:**
Particle toxicology investigates the harmful effects of particles and fibres on living organisms, primarily human health. These materials originate from diverse sources, including industrial processes, pollution, construction, and natural environments. Understanding their toxicological properties is essential for risk assessment, regulatory development, and protective measures. Particles are found in air, food, water, and other matrices, leading to various exposure routes. Airborne particles, classified by size, can be coarse (2.5-10 µm), fine (<2.5 µm), or ultrafine (<0.1 µm). The latter two are particularly concerning due to their ability to penetrate deep into the respiratory system. Fibers, elongated particles, can be natural (e.g., asbestos) or synthetic (e.g., carbon nanotubes). Certain fibres are linked to severe health conditions, such as lung cancer. Particles and fibres induce toxic effects depending on their physicochemical characteristics, exposure concentration, and dose. Adverse health effects include respiratory and gastrointestinal problems, cardiovascular diseases, cancer, and neurological disorders. This course aims to provide up-to-date information on critical aspects of particle toxicology, including sample preparation, dosimetry, biodistribution, and toxicity at the port of entry and secondary organs. By understanding these aspects, we can develop effective risk management strategies and promote human health.

**Schedule:**

10:00–10:30 **From Reactionary to Anticipatory Toxicology, We Have Come a Long Way**
*Johan Øvrevik, Norwegian Institute of Public Health (NIPH) & University of Oslo, Norway*

10:30–11:00 **From Exposure to Dose: The Use of Dosimetry Models for In Vivo and In Vitro Studies and Information on Biodistribution Upon Inhalation**
*Flemming R. Cassee, Institute for Risk Assessment Sciences, Utrecht University & National Institute for Public Health and the Environment (RIVM), The Netherlands*

11:00–11:30 **Toxicology of Ingested Particles**
*Roel P.F. Schins, Department of Pharmacology and Toxicology, School for Nutrition and Translational Research in Metabolism (NUTRIM), Maastricht University, The Netherlands*

11:30–12:00 **Developmental Toxicity of (Nano)Particles: The State of the Science**
*Luisa Campagnolo, University of Rome Tor Vergata, Italy*

**October 15 | 10:00–12:00 | Guocui Hall**

## CEC03: Utilizing Computational Methods and Tools for Inferring and Predicting Reference Dose (RfD) in Chemical Risk Assessment

***Chairs:*** ● *Kan Shao, Indiana University School of Public Health, USA*
● *Chao Ji, Office of Innovation and Analytics, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, USA*

**Summary:**
Computational methods are increasingly vital in modern chemical risk assessment, offering innovative approaches to infer dose-response relationships. The next-generation chemical risk assessment paradigm seeks to supplement and eventually supplant traditional animal-based toxicity testing

through New Approach Methodologies (NAMs). This continuing education course session highlights recent advancements in leveraging computational tools to improve chemical safety evaluation. The first presentation introduces a mode of action (MOA)-based probabilistic dose-response modeling framework that integrates data from multiple sources to estimate reference doses (RfDs). The second presentation demonstrates the application of quantitative in vitro-in vivo extrapolation (IVIVE) to translate in vitro data into in vivo equivalent doses using the Integrated Chemical Environment (ICE) tool. The third presentation explores Bayesian benchmark dose (BMD) estimation of toxicogenomics data, providing insights into deriving genomic points of departure. The final presentation showcases mechanistic modeling of complex toxicity endpoints by organizing high-throughput screening (HTS) data into adverse outcome pathway (AOP) models. Together, these presentations illustrate how computational methods enhance chemical risk assessment by integrating diverse data streams, improving dose-response modeling, and addressing uncertainty and variability.

**Schedule:**

10:00–10:30 **An MOA-Based Dose-Response Modeling Framework to Integrate Data from Multiple Sources for Reference Dose (RfD) Estimation**
*Kan Shao, Indiana University School of Public Health, USA*

10:30–11:00 **Application of Quantitative In Vitro-In Vivo Extrapolation (IVIVE) to Estimate Reference Doses from NAM Data**
*Xiaoqing Chang, Integrated Laboratory Systems, LLC, USA*

11:00–11:30 **Bayesian Benchmark Dose Estimation of Genomic Data**
*Chao Ji, Office of Innovation and Analytics, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, USA*

11:30–12:00 **Mechanistic Modeling of Complex Toxicity Endpoints Using Public Concentration-Response Metadata**
*Hao Zhu, Tulane University, USA*

**October 15 | 13:00–15:00 | Guojin Hall**

## CEC04: Episkin Academy Training

***Chairs:*** ● *Lizao Chen, L'Oréal Research and Innovation Center, China*
● *Tairan Xing, L'Oréal Research and Innovation Center, China*

**Summary:**

Episkin Academy Training is a course that gives attendees a tour of reconstructed tissue models and covers the best ways to use them in applications and validated methods. Attendees will have the opportunity to realize by themselves skin and eye irritation tests with unknown products. The course is taught by highly experienced scientists from L'OREAL and includes lectures (inspired by OECD guidelines (TG431, TG439, TG492), SOPs) and hands-on exercises that provide real-world experience. It will also integrate an introduction on next-generation risk assessment process (NGRA), which is an exposure-led, hypothesis-driven risk assessment approach that integrates existing knowledge with in silico, in chemico, and in vitro approaches. Participants will have an overview of each step of the next-generation risk assessment process (NGRA) applied on cosmetics safety.

**Schedule:**

13:00–13:40 **The Integration of New Methods and Approaches in the Safety Assessment of Cosmetic Ingredients in Europe in the Context of Animal Testing Ban**
*Fabrice Nesslany, L'Oréal Research and Innovation Center, France*

13:40–14:10 **Overview of Integrated Approaches to Testing and Assessment (IATA) Process and Its**

**Application in Regulatory Toxicology**
*Xiaofeng Fang, L'Oréal Research and Innovation Center, China*

14:10–14:40 **Introduction of SkinEthic™ RHE Skin Irritation Method and the Stand-Alone New Approach Methodology for Eye Hazard Identification Validated by OECD**
*Chunmei Ding, L'Oréal Research and Innovation Center,China*

14:40–15:00 **On Site Operation Demonstration and Hands-on Training of SkinEthic™ RHE Irritation & Corrosion Testing and SkinEthic™ HCE Eye Irritation Testing**
*Lizao Chen, L'Oréal Research and Innovation Center, China*

**October 15 | 13:00–15:00 | Guoxiu Hall**

CEC

## CEC05: The Emerging Psychoactive Drugs: Epidemiology, Consumption Modes, and Toxicities

***Chair:*** • *Bruno Mégarbane, European Association of Poisons Centres and Clinical Toxicologists (EAPCCT), France*

**Summary:**
The panorama of the new psychoactive drugs is enriched day by day with emerging toxicities and novel mechanisms of drug action. Some come from the diversion of drugs sold in pharmacies and others come directly from chemical synthesis carried out in clandestine laboratories. The opioid overdose epidemic alone killed 120,000 people in the United States in 2023. But other similarly dangerous substances are spreading worldwide despite surveillance and restrictive legislation. The objective of this CEC is to make an updated review of these new psychoactive substances, the involved chemistry structures and toxic consequences of their use. Scientists and clinical toxicologists need to adopt novel ways of capturing data on the epidemiology of use and potentials for toxicity related these novel substances. This session will be focused on a translational approach covering areas from mechanistic and epidemiological studies through to clinical data from poisoned patients. We will give an overview of the approaches used to investigate the patterns of toxicity of these molecules sweeping the spectrum of the novel stimulant, sedative and hallucinogenic drugs.

**Schedule:**

13:00–13:20 **The Synthetic Cathinones**
*Davide Lonati, Poison Control Centre and National Toxicology Information Centre – Laboratory of Clinical & Experimental Toxicology, Toxicology Unit, Istituti Clinici Scientifici Maugeri IRCCS, Maugeri Hospital, Italy*

13:20–13:40 **The Synthetic Cannabinoids**
*Knut Erik Hovda, Department of Acute Medicine, Oslo University Hospital; Institute of Clinical Medicine, University of Oslo; Norwegian Poisons Information Centre, National Institute of Health, Norway*

13:40–14:00 **The NBOMe and New Hallucinogenic Designer Drugs**
*Jones Chan, Poison Treatment Centre, Prince of Wales Hospital, Hospital Authority, Hong Kong SAR*

14:00–14:20 Gamma-Hydroxybutyrate and Analogues
*Shaun Greene, Victorian Poisons Information Centre, Australia*

14:20–14:40 **The Fentanyloids and Non-Fentanyl Synthetic Opioids**
*Bruno Megarbane, Paris Cité University, Department of Medical and Toxicological Critical Care, Lariboisière Hospital, France*

14:40–15:00 **Ketamine and the Novel Arycyclohexamines**
*Paul I. Dargan, Guy's and St Thomas' NHS Foundation Trust and King's College London, UK*

**October 15 | 13:00–15:45 | Guocui Hall**

## CEC06: Advanced Toxicological Topics for Study Directors of Nonclinical Studies

***Chairs:*** ● *William J. Brock, American College of Toxicology, USA*
● *Alan Hoberman, American College of Toxicology, USA*

**Summary:**
An introductory study director course was held in China in 2019 and was developed to provide continuing education for Study Directors with up to five years of experience. Study Directors are conducting more complex studies with new modalities and with new methodologies that include gene or cell therapies, complex biological products, oligonucleotides, drug conjugates, etc. The outcome of nonclinical studies requires the Study Director to have an in-depth knowledge of the complexity of these drugs and drug products as well as the biological response to the administration of these substances. The tentative topics to be covered include nonclinical testing for biologics, gene and cell therapies, developmental and reproductive toxicology, carcinogenicity and advanced topics for study directors at all levels. Although this course is directed towards toxicologists and related professional in toxicological testing laboratories, this course would be valuable to a broad range of nonclinical, clinical, management and regulatory personnel across all industrial and governmental sectors. Regulatory and managerial personnel will gain a thorough working knowledge of preclinical development to facilitate planning, project management and development nonclinical regulatory strategies. The course will cover practical topics that apply to the interpretation, summarization and reporting of study results for any data collected and will include a separate lecture on the requirements of the Chinese FDA. If time permits, a panel discussion will be convened at the end of the session.

**Schedule:**

13:00–13:15 **Introduction to Study Director Course**
*Lijie Fu, Breakthrough Pharmaceuticals, China*

13:15–13:45 **Complex Study Director Issues and Resolution**
*John Kapeghian, Frontage Labs, USA*

13:45–14:15 **Extrapolation: The Use and Application of In Vivo, In Vitro and In Silico Models, Artificial Intelligence and ICH S1B**
*William J. Brock, Brock Scientific Consulting, LLC, USA*

14:15–14:45 **The Use and Application of In Vivo, In Vitro and In Silico Models, Artificial Intelligence and ICH S1B**
*David Woolley, ForthTox, UK*

14:45–15:15 **Complex Methods and Study Designs for Developmental and Reproductive Toxicology**
*Alan Hoberman, Charles River Laboratories, USA*

15:15–15:45 **Scientifically Sound Data Interpretation and Report Writing for Toxicology Studies**
*Charles Wang, InnoCare Pharma Tech Co. Ltd, China*

# WuXi / Elsevier Seminars

**October 15 | 10:00–12:00 | Guohua Hall**

## SS01: WuXi Seminar – Changing Drug Development Landscape with New Modalities Such as ADC

***Chair:*** ● *Xuanjia Peng, WuXi AppTec, China*

**Schedule:**

10:00–10:20 **Kickoff: Changing Drug Development Landscape with New Modalities Such as ADC**
*Xuanjia Peng, Senior Vice President, WuXi AppTec, China*

10:20–10:40 **Overall Introduction and ADC Background**
*Leo Pan, PhD, Senior Director, Toxicology, WuXi AppTec, China*

10:40–11:00 **Regulatory-Compliant Genetic and In Vitro Toxicology Assessment for ADCs**
*Liwen Gao, MS, Med, DABT, DCST, ERT, Director, Genetic and In Vitro Toxicology, WuXi AppTec, China*

11:00–11:20 **Overcoming the Challenges for Detecting the Antibody in ADC Drugs: Using Ligand Binding Assay and LC-MS/MS Assays for Different Cases**
*Nan Jia, PhD, Preclinical SME, WuXi AppTec, China*

11:20–11:40 **Pathology, Off-Target and On-Target Effects**
*Rongrong Li, BAgr (Vet Med), MAgr (Vet Med), DCCVP, Senior Pathologist, WuXi AppTec, China*

**October 15 | 13:00–15:05 | Guohua Hall**

## SS02: Elsevier Seminar – Gen AI in Scientific Publishing

***Chairs:*** ● *Jagna Gent-Aalén, Senior Publisher, Toxicology Journals, Elsevier, The Netherlands*
● *Xi Han, Publisher, Toxicology and Pharmacology Journals, Elsevier, China*

**Summary:**
Generative AI (GenAI) is playing a transformative role in scientific publishing and the entire research process, reshaping knowledge discovery and innovation. As researchers increasingly adopt GenAI tools to sift through vast amounts of literature, summarize findings and analyze complex datasets, the technology enables them to enhance research efficiency, facilitate knowledge discovery and communications, and foster interdisciplinary and cross-sector collaboration, paving the way for innovative insights. It is also widely utilized in editorial workflows, such as recommending reviewers, matching suitable journals, performing technical checks, and detecting plagiarism.
However, the rapid adoption of GenAI also raises unprecedented ethical questions. It is essential to promote the responsible use of AI and raise awareness of the associated policies to ensure transparency and accountability, thereby upholding research integrity. A joint commitment from the research community and key stakeholders will be crucial in mitigating potential risks, ensuring that AI serves as a reliable technology. There is a pressing need for reliable AI-powered tools based on advanced technologies but also trustworthy content to help ensure that knowledge discovery remains rigorous and reliable. With a better understanding of the challenges, opportunities, and resources in AI adoption, we can together explore how to fully realize the benefits of this powerful technology to drive scientific progress.

**Schedule:**

13:30–13:35 **Welcome, Opening, Introduction**
*Jagna Gent-Aalén, Senior Publisher Toxicology Journals, Elsevier, The Netherlands*

13:35–13:55 **Knowledge Discovery and Scholarly Publishing in the AI Era: Harnessing Tools and Navigating Responsibilities**
*Yinhui Wu, Customer Success Director, Elsevier, China*

13:55–14:15 **Knowledge Discovery and Scholarly Publishing in the AI Era: Harnessing Tools and Navigating Responsibilities**
*Wenwen Zheng, Head of Research Integrity Group, Scientometrics and Evaluation*

*Research Center, Institute of Scientific and Technical Information of China, China*

14:15–15:00 **Panel Discussion Including Q&A**

*José Manautou, Co-Editor-in-Chief of Current Opinion in Toxicology and President of IUTOX, USA*

*Xiaoling Kang, Academic Relations Director, Elsevier, China*

*Xi Han, Publisher Toxicology and Pharmacology Journals, Elsevier, China*

15:00–15:05 **Closing**

*Jagna Gent-Aalén, Senior Publisher Toxicology Journals, Elsevier, The Netherlands*

15:05–15:30 **Post Meeting Communication; Demo and Trial of Scopus AI, SD AI**

## Opening Ceremony

**October 15 | 16:00–16:40 | Guobin Hall**

OW **Opening Welcome**

**October 15 | 16:40–17:30 | Guobin Hall**

IAL **ICT2025 Award Lecture: New Pollutants Study in China: History, Progress and Challenges**

- *Guibin Jiang, Research Center for Eco-Environmental Sciences, Chinese Academy of Sciences, China*

**Abstract:**

The governance of new pollutants has become the primary policy for environmental protection in China. New pollutant is an emerging scientific term, in analogy to contaminants of emerging concern, which refers to any synthetic or naturally occurring chemical or micro-organism that can cause significant known, or suspected toxic effects and health hazards when deposited in the environment. At present, the new pollutant analogues of extensive concern include persistent organic pollutants, endocrine disruptor compounds, and antibiotics. In general, the rapid growth in the use of synthetic chemicals is the underlying cause of the new pollutant issue. A significant number of chemical substances that are environmentally persistent, bio-accumulative and toxic are becoming a potential threat to the ecosystem and public health. International scientific research on New Pollutants has been developing rapidly in the 2000s, and it is well recognized that the rapid development of analytical instrumentation and analytical techniques has been an intrinsic driving force. As quoted from a presentative review article (Science, 2020, 367, 388): “Along with the increased use of chemicals in commerce and the advances in analytical methodology, rising attention is being paid to a variety of chemicals that have not been detected and are thereby not regulated”. It is also linked with the research on traditional environment pollutants, uniting the efforts of Chinese scholars for decades. For instance, the studies on screening and control for environmental endocrine disruptors were funded by the National 863 Program since 1999. A prospective exploration of the pollution characteristics, interfacial behavior, and health effects of emerging pollutants (i.e., PBDEs, PFAS and SCCP) has been realized with the financial support of the National 973 Program during 2003-2018. Basic research is a systemic endeavor that could be a key underpinning of the New Pollutants governance initiative. Many topics of this international toxicology conference, such as analytical toxicology, computational toxicology, biochemical and molecular toxicology, epigenetic toxicology, drug and food safety and risk assessment, as well as alternative approaches in toxicology, are elements that should be focused on for support in basic science research on New Pollutants. Along with the development of new approach methodologies such as machine learning and big data analytics, high-throughput toxicology testing, quantitative structure-property relationship modeling, and stem cell research will play a critical role. Future challenges also lie in a number of areas, for instance, the identification of key toxicants from complex matrices, the scientific assessment of the effects and

mechanisms of combined exposures, the population exposure levels and safety thresholds for new pollutants, and the causal links between environmental exposures and ecological/health risks.

**October 15 | 17:30–18:20 | Guobin Hall**

DL

## Deichmann Lecture: Toxicology – The Now, The New and The Next


- *Thomas Hartung, Johns Hopkins University, USA & University of Konstanz, Germany*



**Abstract:**

Toxicology stands at a historic inflection point. In the wake of technological innovation, mounting societal demands, and a pressing need for human relevance, the discipline is undergoing a profound transformation. This keynote will reflect on the Now—the current state of toxicological science, still heavily reliant on animal testing, fragmented data, and limited human predictivity. It will then pivot to the New—emerging paradigms that redefine toxicology through new approach methodologies (NAMs), including organoid(-on-chip) systems, integrated omics, high-content imaging, and artificial intelligence. These tools are already reshaping regulatory frameworks and enabling evidence-based assessments rooted in mechanistic insights and human biology. Building trust into them and their formal validation, however, represent major challenges. Finally, the Next will be outlined: a bold vision for a predictive, preventive, and personalized toxicology. This includes the integration of microphysiological systems (MPS), exposomics, and agentic AI into a global infrastructure for health risk assessment—aiming ultimately at a Human Exposome Project and Green Toxicology, i.e., benign-by-design chemicals and early testing in product development. Emphasis will be placed on establishing reproducibility standards (e.g., GCCP 2.0, GIVReSt), trust-building in AI applications, and a shift toward probabilistic, systems-based assessments. The keynote will also highlight the organizational and cultural shifts needed to accelerate this transition—from validation bottlenecks to transdisciplinary collaboration and public-private partnerships. By connecting scientific innovation with regulatory foresight, toxicology can lead the way toward a truly 21st-century biomedical and environmental health science.