SOT FDA Colloquia on Emerging Toxicological Science
Integrated Approaches to Testing and Assessment:
The Future of Regulatory Toxicology Assessment

Speaker Biographies

Lidia Ceriani, MSc; Colloquium Chair

Lidia Ceriani is a Regulatory Science Advisor at Humane Society International, with a background in computational toxicology and regulation. She has experience of QSAR modeling, and chemical hazard and risk assessment. Lidia has worked for the Italian International Centre for Pesticides and Health Risk Prevention (ICPS), and for the European Joint Research Centre (JRC) in Ispra, Italy, where her main duties where assessing the environmental fate and behavior of Plant Protection Products, and also performing environmental risk assessment for several different classes of substances under the European Water Framework Directive (WFD). Through her working experience at the English company wca environment limited, a chemical risk assessment and environment consultancy, she also gained further experience in data review and assessment, robust summary preparation for IUCLID dossiers, EQS derivation, and support to technical projects. As a research scientist in the computational toxicology team of the Italian consulting company S-IN Soluzioni Informatiche, Ms. Ceriani performed chemical hazard assessments using *in silico* (Q)SAR predictions and read-across. She also carried out key activities in the EFSA's project "Further Development and Update of EFSA's Chemical Hazards Database," and in the ECHA's project "Curation of Systemic Toxicity Endpoint Study Records in the REACH Registration Database." She joined Humane Society International in June 2019, with the aim of promoting and supporting the development and the implementation of new approach methodologies (NAMs) in regulatory chemical safety decisions. She holds a BSc in Biotechnology (Biomedical curriculum), and an MSc in Biology.

Andrea-Nicole Richarz, PhD

Andrea Richarz holds a diploma and PhD in Chemistry from the Technical University Berlin. She has managed two large international European Union research projects in the area of computational toxicology and new approaches for chemical safety assessment. These are related to REACH chemicals and cosmetics substances and were at the Helmholtz Centre for Environmental Research (UFZ), Leipzig, Germany, and Liverpool John Moores University, UK. She has also conducted nanosafety project research. As Scientific Officer at the European Commission Joint Research Centre in Ispra, Italy, she worked in the area of predictive toxicology, *in silico* methods, and read-across. Her special interest was in integrated chemical safety assessment approaches as well as combined exposure to chemicals, including uncertainties of, and confidence in, the approaches in view of their regulatory acceptance. She joined the European Chemicals Agency in Helsinki in 2019.

Susanne Hougaard Bennekou, PhD

Dr. Susanne Hougaard Bennekou works currently as a senior advisor at the National Food Institute, the Danish Technical University, which involves giving scientific advice to the Danish EPA and the Danish Food and Veterinary Administration on chemical safety, mainly in the area of pesticides. She is also involved in work for the European Food Safety Authority (EFSA) acting as vice-chair for the Scientific Committee and being member of several working groups over the years. Her research activities are in regulatory toxicology and the area of new approach methodologies in the context of the H2020-funded "EU-ToxRisk–An Integrated European 'Flagship' Programme Driving Mechanism-Based Toxicity Testing and Risk Assessment for the 21st Century"

and also the OECD project “Developing an OECD Guidance on the Application and Interpretation of *In Vitro* Developmental Neurotoxicity Assays and Definition of a Tiered Approach to Testing and Assessment.” Previously for nearly twenty years she worked as a senior advisor in regulatory toxicology at the Pesticide Division of the Danish EPA, also involving regulation of biocides and REACH regulated chemicals. During this time, in the context of EFSA, she has been involved in the development of several pesticide risk assessment guidelines and scientific opinions. She was appointed member of the working group/SAPEA, supporting the “Scientific Advise Mechanism (EU Commission) High Level Group Opinion on Authorisation Process for Plant Protection Product (PPPs) in Europe from a Scientific View,” drafting the evidence review 2018. This opinion gives specific advice to the EU Commission for applying New Approach Methods in safety and risk assessment of pesticides. She was appointed a member of the ad hoc ECHA/EFSA Endocrine Disruptor Consultation Group. Dr. Hougaard Bennekou holds a BS in veterinary science from The Royal Veterinary University of Denmark, Copenhagen (Denmark); a MS in human biology from the University of Copenhagen, Denmark; and a PhD in molecular cancer biology, University of Copenhagen, Denmark.

Gladys Ouédraogo, PhD

Dr. Ouédraogo has 19 years’ experience in developing predictive methods for toxicity, leading research initiatives with external partners, primarily on repeated dose systemic toxicity and genotoxicity. She has been a scientific officer at L’Oréal Research & Innovation in Aulnay sous bois, France, since 2013, where she leads research collaboration with external partners mainly on repeated dose systemic toxicity and genotoxicity. Dr. Ouédraogo began in the Safety Research Department, L’Oréal Advanced Research, in 2003 where she developed *in vitro* genotoxicity and *in vitro* cell transformation assays. She became head of the genotoxicity and cancer group in 2006 and lead several projects on *in vitro* genotoxicity and in silico approaches (covering different endpoints). Beginning in 2010 as head of the predictive methods development group, she managed a team of scientists working on different endpoints like skin sensitization, systemic toxicity, phototoxicity, and genotoxicity. She represents the company in different working groups, such as HESI (Genetic Toxicology Technical Committee), Cosmetics Europe (Genotoxicity taskforce, Systemic Toxicity taskforce), OECD (Extended Advisory Group on Molecular Screening and Toxicogenomics), HTPC (Humane Toxicology Project Consortium), and is on the Toxicology Education Foundation (board member since 2014). Dr. Ouédraogo received her Dr in Pharmacy (University of Padova), a PhD in Photobiology (Natural History Museum of Paris), and then was a postdoctoral fellow at the Wellman Center for Medicine, Harvard Medical School (Boston).

Nicole C. Kleinstreuer, PhD

Dr. Nicole Kleinstreuer is the acting director of the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), leading domestic and international efforts to develop novel testing and analysis strategies that provide more rapid, mechanistic, and human-relevant predictions of potential environmental chemical hazards. She has a secondary appointment in the NIEHS Division of Intramural Research Biostatistics and Computational Biology Branch, and adjunct faculty positions in the Yale School of Public Health and the Eshelman School of Pharmacy at University of North Carolina-Chapel Hill. Dr. Kleinstreuer’ s research focuses on mathematical and computational modeling of biological systems and their susceptibility to perturbations that result in adverse health outcomes. She is the recipient of numerous prestigious awards, including the 2019 Society of Toxicology Achievement Award. Prior to joining NTP, she worked for Integrated Laboratory Systems, Inc., as a senior staff computational toxicologist and director of the ILS computational toxicology group supporting NICEATM. Dr. Kleinstreuer received her PhD in bioengineering from the University of Canterbury in Christchurch, New Zealand, and BS degrees in mathematics and biomedical engineering from the University of North Carolina at Chapel Hill. Her postdoctoral training was at the EPA National Center for Computational Toxicology.

Reyk Horland, PhD

Reyk studied Medical Biotechnology at the Technische Universität Berlin with a focus on tissue engineering concepts. Over the course of his academic career at the German Arthritis Research Center and the TU Berlin in the group of Prof. Roland Lauster, he has pursued the development of tissue models that can mimic human biology *in vitro*. The group especially focused on emulating the critical development steps during organ neogenesis employing the innate self-assembly processes of human organs and tissues. Utilizing this approach, he successfully developed a complex hair follicle model that can be used for *in vitro* screening purposes as well as for cell therapy-based hair restoration strategies. In addition, he investigated the use of novel bioreactor systems to scale up production of tissue engineered skin models for use in transplant surgeries.

Since 2010 Reyk is actively involved in the development of TissUse's Multi-Organ-Chip platform for culture analysis of drug candidates, cosmetics, chemicals, and consumer products. Here he led the efforts to establish and characterize a chip-based vascular model in an interdisciplinary team of engineers, computational modelers, and biologists. He currently holds the position of Head of Business Development at TissUse.