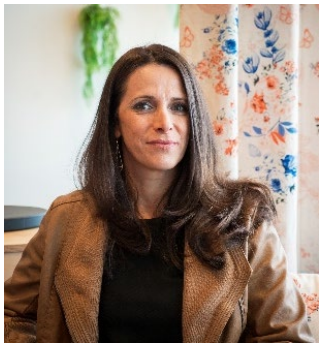
Short Bio of Speakers/Chairs/Moderator

Public Conference:

Advancing the 3Rs for Regulatory Testing of Medicines

Antwerp, 31st January 2024

SONJA BEKEN



Sonja Beken holds a Master in Biological Sciences and Applied Toxicology and a PhD in Pharmaceutical Sciences. She is a European Registered Toxicologist.

Sonja is the Coordinator of the Unit of non-clinical assessors at the Belgian Federal Agency for Medicines and Health Products (FAMHP). This Unit is responsible for the evaluation of non-clinical data submitted to support all phases of drug development

Sonja Beken is Chair of the 3Rs Working Party and Member of the Non-Clinical Working Party at the European Medicines Agency (EMA). She acted as ICH Rapporteur for the revision of the S5(R2) Guideline.

Over the years, Sonja Beken has contributed to the direct identification of opportunities for regulatory implementation of 3R testing paradigms through her active involvement in large-scale international initiatives.

SARA RAFAEL-ALMEIDA

Sara Rafael Almeida is a Policy Officer in the Medicines: policy, authorisation and monitoring Unit of DG SANTE at the European Commission. Sara is a member of the Pharmaceutical Strategy team responsible for the evaluation and review of the general pharmaceutical legislation. She is responsible for the digitisation files of the unit, including the electronic product information (ePI) initiative and the activities in the area of real-world evidence.

Before joining SANTE, she was a Policy Analyst at the Foresight and Behavioural Insights Unit of the Joint Research Centre, European Commission. Sara started her career in the European Commission in DG SANCO working on big data at the eHealth and Health Technology Assessment Unit, having previously worked in research at the Rotterdam School of Management.

Sara studied law at Nova University Lisbon, and health economics, policy and law at Erasmus University Rotterdam.

KAREN VAN MALDEREN

Karen has degrees in Pharmaceutical Sciences and Applied Toxicology and is a European Registered Toxicologist. She started her career in the field of chemical risk assessment and was a member of ECHA's Committee for Risk Assessment (RAC) for 4 years.

Since 2011, she works as a Non-Clinical Assessor at the Belgian Medicines Agency where she is involved in the evaluation of marketing authorisations, clinical trial applications, and scientific advice procedures with particular focus on paediatric medicines.

At the European Medicines Agency (EMA), she is a member of the Paediatric Committee (PDCO) and the vice-chair of the Non-Clinical Working Party. She has also contributed as EU regulatory expert to the drafting of the ICH S11 guideline.

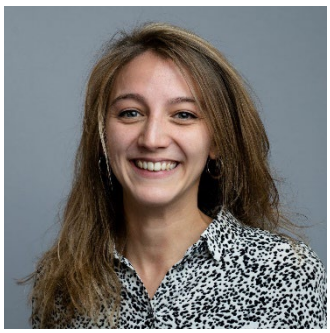
CLAIRE BEUNEU

Claire Beuneu holds a PhD in Biology (Paris XI University, France, 2001) with research in the field of inflammation and immunity. After her PhD, she worked as a research associate in the Institute for Medical Immunology (Pr. Michel Goldman, ULB, Brussels) in the field of islet transplantation.

Since 2008, Dr Beuneu is a non-clinical assessor within the DG PRE Registration Department of the Belgian Federal Agency for Medicines and Health Products (FAMHP). She is responsible for the evaluation of non-clinical data (pharmacology, pharmacokinetics and toxicology) for the purpose of clinical trial approval and drug registration for national and European registration procedures. She also provides EU and national scientific advice during non-clinical drug development phases.

Since 2009 Dr Beuneu is member of the Committee for Advanced Therapies (CAT) at the EMA.

MORGANE FLORENS



Dr. Florens is a scientist in the QVBP (quality of vaccines and blood products) service at Sciensano, Brussels. She is part of the team in charge of in vivo/ELISA testing and responsible for batch release of Human vaccines.

She holds a PhD (2019) in biomedical sciences from the University of Leuven and a MSc (2014) in biochemistry and cellular & molecular biology from the University of Brussels.

She has been extensively involved in preclinical and clinical studies focusing on neuro-immune interactions in the gut, mainly in the context of IBS (irritable bowel syndrome). This experience allowed her to become familiar with numerous in vivo techniques, mostly performed in mice. She has contributed to several scientific papers in renown journals and participated to international and national conferences.

PIETER VAN DE VIJVER

Pieter Van de Vijver is a non-clinical assessor at the Belgian Federal Agency for Medicines and Health Products. Pieter studied pharmaceutical sciences and has a PhD in pharmaceutical sciences (KULeuven, Belgium). He is mainly involved in the assessment of non-clinical aspects of clinical trial applications (medicinal products) and clinical investigation applications (medical devices).

Other responsibilities include ancillary medicinal substance consultation, scientific advice procedures and review of medical device technical files as part of notified body oversight.

Additionally, he is also a scientific support expert member of the ICH Q3E Expert Working Group on Extractables and Leachables.

Specific areas of expertise include combination products, toxicology, biological safety and biocompatibility of medical devices.

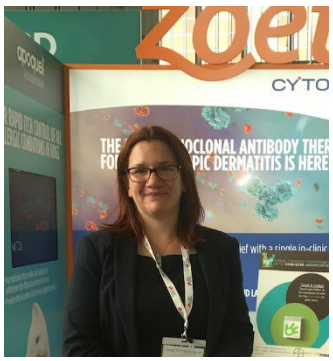
KIRSTY REID

Kirsty Reid is the Director for Science Policy at EFPIA, the European Federation of pharmaceutical industries and associations. She holds a PhD in biology.

For the past 18 years she has worked closely on research, EU public and regulatory affairs. She covers topics on alternatives to animal testing, environment, health, safety and sustainability issues.

She has been engaged in animal welfare and the 3Rs in many fora including the EPAA, World Congresses and as a stakeholder in Commission meetings and the Innovative Medicines Initiative (now innovative health initiative). She has organised numerous webinars on industry initiatives on the 3Rs in close collaboration with animal welfare NGOs..

CAT STIRLING



Dr Catrina (Cat) Stirling graduated from the University of Edinburgh with a degree in Virology before doing a PhD in Veterinary Immunology at the Pirbright Institute/University of Sussex.

She then spent 4 years as a post-doc at Pirbright working on DNA vaccines for FMDV and ASFV immunology before joining the UK Veterinary Medicines Directorate (VMD). After 2 years at VMD she moved to Pfizer Animal Health, now Zoetis focusing on regulatory affairs, she is currently Director of Regulatory affairs focusing on companion animal vaccines and biologicals.

She is an expert on immunological and biological product development and registration as well as 3Rs aspects of vaccine release.

TINA STIBBE

Dr Tina Stibbe advises the PETA Science Consortium International e.V. on science policy issues.

She holds an undergraduate degree in molecular life science and a master's degree in biochemistry. After working as a medical writer for several years, she became the CEO of a small contract research organisation for clinical research in neurology and psychiatry in Leipzig, Germany. Simultaneously, she received her doctorate in psychiatric clinical research from the University of Leipzig and later, she studied health management and was awarded a Master of Health Business Administration from the University of Erlangen-Nuremberg.

Dr Stibbe has several years of experience in conducting and managing international clinical research in humans and advises the Science Consortium on non-animal testing policies in the EU, with a primary focus on Germany.

CHRISTIAN DESAINTES

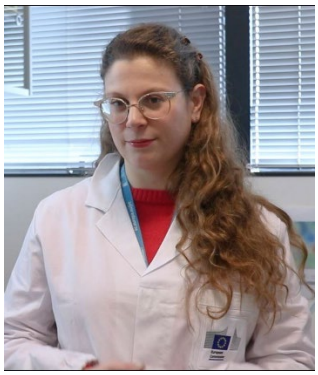
Dr. Desaintes has worked for the Directorate-General for Research and Innovation at the European Commission since 2001.

He is currently in charge of the Horizon 2020 and Horizon Europe research portfolio on human health and safety. At the Commission, Dr Desaintes has participated in the development and implementation of European research programmes (FP4-FP7, Horizon 2020, Horizon Europe) in various fields, including radiation protection, systems biology, stem cells, animal models, infectious diseases and alternatives to animal testing.

Dr Desaintes has been involved in the conception and setting up of several strategic international alliances for large-scale collaborative research programmes, such as the International Human Microbiome Consortium.

With university degrees of Graduate Agronomist Engineer and Ph.D. in Molecular Biology, Dr Desaintes has performed biomedical and radiation research at various European research institutions. Dr Desaintes' research work has focused mainly on understanding the molecular pathways regulated by the oncogenic human papillomaviruses and by ionizing radiation.

MONICA PIERGIOVANNI



Monica Piergiovanni is a biomedical engineering, graduated at Politecnico di Milano, where she obtained a PhD in bioengineering working at the Laboratory of Biological Structure Mechanics (LaBS).

During her years of university research at Politecnico di Milano and ETH Zurich, she grew interest in the design and development of organ on chip platforms for patient-specific drug screening.

She is now working for the Joint Research Centre of the European Commission, in the unit for Safety Toxiclogy, that hosts the EURL ECVAM. Here, she is focusing on standardisation and regulatory acceptance of emerging technologies, including Organ-on-Chip and High Content Imaging.

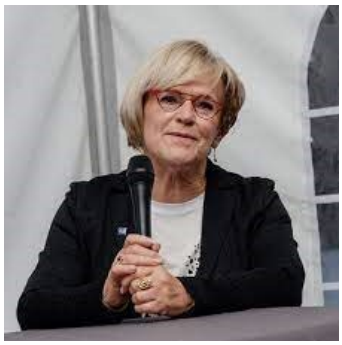
BIRGIT MERTENS

Birgit Mertens obtained her Master's in Pharmaceutical Sciences and PhD in Neuropharmacology from the Vrije Universiteit Brussel in Belgium.

She joined Sciensano in 2010 and is currently a senior toxicologist and team leader of the Risk and Health Impact Assessment service. She coordinates and participates in multiple (inter)national research projects and activities on the genotoxicity of physical and chemical agents, focusing on food contaminants and developing and applying new approach methodologies.

She is the National Coordinator of the Test Methods Programme both at the European and OECD level and the Belgian contact point for the Preliminary Assessment of the Regulatory Relevance of Alternative Methods (PARERE) network. She is also a member of the OECD genotoxicity expert group. She participates in different (inter)national working groups and scientific committees on hazard and risk assessment and is the current president of the Belgian Environmental Mutagenesis Society. She is also a guest lecturer in the toxicology courses of different Belgian universities.

VERA ROGIERS



After many years of leading the department of In Vitro Toxicology and Dermato-Cosmetology at the VUB in a successful way, Emeritus professor in Toxicology Vera Rogiers is actually still teaching dermato-cosmetics at the VUB and the University of Ghent. She also gives a limited number of lessons to the University of Namur. She yearly organizes international courses on Cosmetics and Risk Assessment.

She is the Director of the Innovation Centre-3Rs (IC-3Rs) at the VUB with focus on replacing experimental animals by novel technologies. At the EU level, she is co-chair of the Scientific Committee on Consumer Safety (SCCS).

Her main research activity was many years situated in the development of in vitro models as an alternative to the use of experimental animals. Actual focus is on the differentiation of human skin-derived stem cells to functional hepatic cells and their application for drug discovery and the detection of drug-induced liver injury. She has been promoter of 33 doctoral theses, is author or co-author of >425 publications in international peer reviewed scientific journals and is editor of several scientific books. She is an often-invited (inter)national speaker (>400) and participated in the organization of more than 60 international congresses.

She has coordinated 2 EU research projects and was/is partner in several FP6, FP7 EU, COST, Horizon 2020, PARC research projects concerned with in vitro methodology development. Of the obtained scientific results, several patents have been filed. Throughout her carrier she received several international scientific awards for her pioneering role in in vitro Experimental Toxicology.

H-index= 55; 12 678 citations.

AXELLE COOREMAN

Axelle Cooreman studied pharmaceutical sciences at the Vrije Universiteit Brussel. After obtaining her master degree, she pursued her academic career by enrolling in a doctoral thesis project entitled 'the role of connexins and their channels in cholestasis' at the entity of In vitro Toxicology and Dermato-Cosmetology (IVTD) within the Faculty of Medicine and Pharmacy of the VUB under promotorship of Prof. Mathieu Vinken. This doctoral thesis project was set up as a joint PhD initiative together with the research group Drug Delivery and Disposition within the Faculty of Pharmaceutical Sciences of the KU Leuven under promotorship of Prof. Pieter Annaert. Axelle successfully defended her PhD in October 2023.

Since November 2023 she has been employed as a postdoctoral scientific collaborator at the entity of In Vitro Toxicology and Dermato-Cosmetology (IVTD) of the VUB, working for IC-3Rs.

MIEKE VAN MULDERS

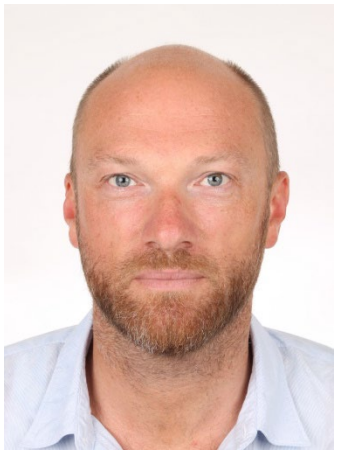
Mieke Van Mulders obtained her Master's degree in Biomedical Sciences, with a major in Nutrition and Metabolism, from the University of Ghent (2014). Mieke started her career as a consultant in the pharmaceutical industry where she was in charge of several projects in the Departments of Regulatory Affairs and Quality Assurance.

Since 2017, Mieke is fully dedicated to the RE-Place project, a joint research collaboration between Sciensano and the Vrije Universiteit Brussel (VUB). She has been responsible for the development of the RE-Place platform and currently works on its further optimization. The RE-Place project focuses on increasing knowledge sharing on alternative methods to animal testing, also known as 'New Approach Methodologies' (NAMs) and fosters collaborations across life sciences sectors/stakeholders.

Mieke is also involved in the activities of the Belgian 'Network for Preliminary Assessment of Regulatory Relevance (PARERE)', which provides EURL ECVAM with upstream input and preliminary views on potential regulatory relevance of methods or approaches submitted for validation and/or peer review.

Furthermore, Mieke is a steering committee member of the Belgian Society of Toxicology and Ecotoxicology (BelTox), where she improves the communications strategy with fellow steering committee members. She is also an active member of the Flemish and Brussels animal testing committees in Belgium.

STEVEN VAN CRUCHTEN



Steven Van Cruchten is veterinarian, reproductive toxicologist and professor in the Department of Veterinary Sciences within the Faculty of Pharmaceutical, Biomedical and Veterinary Sciences of the University of Antwerp. His research is focused on predicting exposure and potential safety issues of medication in pregnant women and the pediatric population by investigating, developing and validating translational models (i.e. animal models (i.c. the Göttingen minipig) and alternatives to animal testing). He is currently President of the Belgian Society of Toxicology and Ecotoxicology.

After obtaining the degree of DVM at the Faculty of Veterinary Medicine (Ghent University) in 1999, Steven Van Cruchten started his PhD research in reproductive morphology at the same university. After his PhD defense (July 2004), he was recruited as a reproductive toxicologist by Janssen Pharmaceutica in Beerse, Belgium. In this function, he elaborated his knowledge on teratogenicity, fertility and peri- and postnatal development issues with pharmaceutical compounds in preclinical models. He also became involved into the field of juvenile toxicology. During this time, S. Van Cruchten also joined the international societies in the field of reproductive toxicology, i.e. the European Teratology Society and BDRP, formerly called Teratology Society. In January 2008, he took the opportunity to join another pharmaceutical company, i.e. AstraZeneca in Sweden, as a Toxicology Project Leader, overviewing the complete preclinical development of several compounds, while keeping his scientific role in reproductive and juvenile toxicology. S. Van Cruchten returned to Belgium in January 2011 to start at the University of Antwerp and he is currently as full-time tenured professor supervising a group of 5 PhD students, 1 postdoctoral fellow and 1 project coordinator. He was Vice-President (2020-2021) and President (2022-2023) of the European Teratology Society. He is Associate Editor of the journals Reproductive Toxicology, Frontiers in Toxicology (DART section) and Animals. Besides his research activities, he is responsible for several courses within the bachelor program of Veterinary Medicine, the master program of Pharmaceutical Sciences and the bachelor and master of Biomedical Sciences. He is currently vice-chair of the department of veterinary sciences at UAntwerp and is member of several institutional boards and (inter-)university committees.

For a full list of publications and projects see https://www.uantwerpen.be/en/staff/steven-vancruchten/research/.

EVELINE ROOSE

Holding a master's degree in international politics, Eveline began her professional journey in 2008 with the Flemish Department of Environment.

During her initial years, Eveline dedicated herself to the integration of environmental sustainability into the policies of local governments, universities, and various other stakeholders. Following the sixth state reform, animal welfare transitioned into a regional topic under the purview of the Department of Environment. Drawing on her passion for animal welfare and her experience in policy work, Eveline seamlessly joined the Animal Welfare service. Since 2017, Eveline has served as a policy officer animal welfare, focusing on the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes.

Her work reflects her commitment to animal welfare within research and finding alternatives to animal testing.