GLOBAL SUMMIT ON REGULATORY SCIENCE 2023

EFSA premises, Parma (IT), 27 & 28 September 2023

Draft agenda

Day 1

08:30-09:00	**Registration**	
OPENING CEREMONY		
09:00-09:30	**Welcome and introduction to the event by the EFSA Chief Scientist**	Carlos das Neves, EFSA
	Recorded message from the Food and Drug Administration Commissioner	Robert M. Califf M.D., FDA (US)
	Welcome from FDA	Tucker Patterson, FDA (US)
SESSION 1 | NAMs Global Landscape **Co-chairs: Tucker Patterson, National Center for Toxicological Research (NTCR, FDA) (US) & Georges Kass, EFSA**		
09:30-09:40	**Opening Remarks**	Co-chairs
09:40-10:10	**Technology for future smart food** Q&A	Kristi Muldoon Jacobs, FDA (US)
10:10-10:40	**ToxAIcology – AI is the future of toxicology** Q&A	Thomas Hartung, Center for Alternatives to Animal Testing (CAAT) (US)
10:40-11:10	**Coffee/Tea break**	
11:10-11:40	**Bridging the divide between scientific development and regulatory application** Q&A	Maurice Whelan, European Commission (EC, JRC)
11:40-12:10	**The Scientific Progress of Drug Regulation in China and its Regulatory Science Development** Q&A	Junning Zhao, National Medical Products

		Administration (NMPA) (CN)
12:10-12:40	**NIHS 150th Anniversary and Regulatory Sciences** Q&A	Masamitsu Honma, National Institute of Health Sciences (NIHS) (JP)
12:40-14:00	**Networking lunch**	
SESSION 2 | NAMs: Regulatory implementations **Co-chairs: Suzanne Fitzpatrick, FDA (US) & Calvin Yeo, Singapore Food Agency (SFA) (SG)**		
14:00-14:10	**Opening Remarks**	Co-chairs
14:10-14:30	**Implementation of the 3RS at the EMA: past, present and future** Q&A	Sonja Beken, FAGG/AFMPS & Chair 3Rs Working Party, European Medicines Agency (EMA)
14:30-14:50	**Toxicokinetics Modeling** Q&A	James Chan, A*STAR, Singapore Institute of Food and Biotechnology Innovation (SG)
14:50-15:10	**Activities of the Japanese Center for the Validation of Alternative Methods (JaCVAM), NIHS: Development of new toxicity tests using NAM and their use in regulations** Q&A	Yoko Hirabayashi, National Institute of Health Sciences (NIHS) (JP)
15:10-15:30	**Regulatory landscape and critical Needs for NAMs in the Hazard assessment of industrial chemicals** Q&A	Mounir Bouhifd, European Chemicals Agency (ECHA)
15:30-15:50	**Emerging technologies for protein safety** Q&A	Anna Lanzoni, EFSA
15:50-16:10	**Coffee/Tea break**	
SESSION 3 | Regulatory Apps **Co-chairs: Joanne Chan, Singapore Food Agency (SFA) (SG) & Catherine Carrillo, Canadian Food Inspection Agency (CFIA) (CA)**		
16:10-16:20	**Opening Remarks**	Co-chairs
16:20-16:40	**Evaluation for developmental toxicity using human iPS cells** Q&A	Yusuke Okubo, National Institute of Health Sciences (NIHS) (JP)

16:40-17:00	**Quality attributes and standards for mRNA-based and Lipid-based therapeutics** Q&A	Luigi Calzolai, European Commission (EC, JRC)
17:00-17:20	**How to handle human variability in risk assessment** Q&A	Bob van der Water, University of Leiden (NL)
17:20-17:40	**Case studies on refining risk assessment of food-related substances with NAMs** Q&A	Takashi Yamada, National Institute of Health Sciences (NIHS) (JP)
17:40-18:00	**FDALabel: A tool to facilitate regulatory application of drug labeling at FDA** Q&A	Hong Fang, NCTR, FDA (US)
18:00-18:15	**Wrap-up of day 1**	Guilhem de Seze
18:15-20:15	**Poster session & Networking cocktail**	

Day 2

08:00-08:30	**Registration**	
SESSION 4 | Emerging Technologies **Co-chairs: Laila Mouawad, Brazilian Health Regulatory Agency (Anvisa) (BR) & Yoko Hirabayashi, National Institute of Health Sciences (NIHS) (JP)**		
08:30-08:40	**Opening Remarks**	Co-chairs
08:40-09:00	**Non-Targeted Analysis** Q&A	Dingyi Yu, Singapore Food Agency (SFA) (SG)
09:00-09:20	**Emerging technologies in vaccines** Q&A	Manuela Mura, European Medicines Agency (EMA)
09:20-09:40	**Advancing Regulatory Science thru Innovation-Microphysiological Systems** Q&A	Suzanne Fitzpatrick, FDA (US)
09:40-10:00	**The Ascent of AI: Predicting Drug-Induced Liver Injury (DILI)** Q&A	Weida Tong, FDA (US)
10:00-10:20	**Safety assessment of cell-based therapeutic products derived from iPS cells** Q&A	Satoshi Yasuda, National Institute of Health Sciences (NIHS) (JP)
10:20-10:40	**Coffee/Tea break**	
SESSION 5| Artificial Intelligence /Machine Learning **Co-chairs: Maurice Whelan, European Commission (EC, JRC) & Weida Tong, FDA (US)**		
10:40-10:50	**Opening Remarks**	Co-chairs
10:50-11:10	**Newly developed artificial intelligence (AI) based bioimaging inspection system for lymph-node granuloma lesions in high-speed line slaughter plants** Q&A	Annamalai Manickavasagan, Bioimaging

		Research Solutions (CA)
11:10-11:30	**Of Mice and Machines: Augmented Intelligence for Improving Chemical Safety Assessments** Q&A	Nicole Kleinstreuer, NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) (US)
11:30-11:50	**GCRSR Interagency LLMs Taskforce: the Progress Report and Beyond** Q&A	Joshua Xu, FDA (US)
11:50-12:10	**AskYourDocs: harnessing the power of LLMs for a working cross-agency prototype on Information Retrieval from PDFs** Q&A	Nicolas Löffler-Pérez, Swissmedic (CH)
12:10-12:30	**Molecular Representation for Drug Safety Assessment** Q&A	Djork-Arné Clevert, Pfizer (DE)
12:30-13:30	**Networking lunch**	
SESSION 6 | Horizon scanning I **Co-chairs: Supriya Sharma, Health Canada (CA)& Bo Li, National Institutes for Food and Drug Control (NIFDC) (CN)**		
13:30-13:40	**Opening Remarks**	Co-chairs
13:40-14:00	**Structural analysis of therapeutic antibodies using CRYO EM** Q&A	Masato Kiyoshi, National Institute of Health Sciences (NIHS) (JP)
14:00-14:20	**An evidence pathway for trustworthy AI innovations: bridging the gap between developer and user communities** Q&A	Claudius Griesinger (EC, JRC)
14:20-14:40	**TK Plate, an open access platform for TK and TD modelling** Q&A	Jean Lou Dorne, EFSA

14:40-15:00	**Navigating Regulatory Genomics: Applications, Strengths, and Limitations in Monitoring Threats in the Food Supply Chain** Q&A	Catherine Carrillo, Canadian Food Inspection Agency (CIFA) (CA)
15:00-15:15	**Short Coffee/Tea break**	
SESSION 7 | Horizon scanning II **Co-chairs: Marta Hugas, former Chief Scientist, EFSA & Bill Slikker, former Director, NCTR, FDA (US)**		
15:15-15:25	**Opening Remarks**	Co-chairs
15:25-15:45	**Innovation in Regulatory Science Awards at Burroughs Wellcome Fund—Preview of the Latest Technologies and Progress Towards Equitable Clinical Outcomes** Q&A	Tammy Collins, Burroughs Wellcome Fund (US)
15:45-16:05	**Toward social implementation and regulatory acceptance of MPS** Q&A	Daiju Yamazaki, National Institute of Health Sciences (NIHS) (JP)
16:05-16:25	**Development status and supervision of organoids and organ-on-a-chip in China** Q&A	Xingchao Geng, National institutes for Food and Drug Control (NIFDC), (CN)
16:25-16:45	**Closing remarks**	Georges Kass, EFSA Weida Tong, FDA, US Carlos das Neves, EFSA