THE 15TH GLOBAL SUMMIT ON REGULATORY SCIENCE (GSRS25)
ANNUAL CONFERENCE

SwissTech Convention Center, Lausanne, Switzerland
September 15-17, 2025

Building a Strong Regulatory Science with Tomorrow's Technologies

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GSRS25 Program At A Glance

Theme: Building a Strong Regulatory Science with Tomorrow's Technologies

Venue: SwissTech Convention Center, Lausanne, Switzerland

Sept 15, 2025 (Monday)	Sept 16, 2025 (Tuesday)	Sept 17, 2025 (Wednesday), Parallel Tracks	
	8:00 Registration Open	8:00 Registration Open	
	MAIN CONFERENCE (Campus Level, Auditorium B)	**MAIN CONFERENCE (Campus Level, Auditorium B)**	**NANOTECHNOLOGY SESSIONS (Garden Level, Room 1BC)**
11:00 Registration Open	9:00 – 9:10 WELCOME REMARKS • Swissmedic • GCRSR Chair	9:00 – 10:40 SESSION 4 *Theme: AI in Chemical Science* • 20min/talk; 5 talks	9:00 – 10:40 NANO-SESSION 1 *Theme: Advanced Materials, SSBD In The Context Of Nanomaterials* • 20min/talk; 4 talks + Panel
	9:10 – 10:50 KEYNOTE PRESENTATIONS • 25min/talk; 4 talks	10:40 – 11:10 *BREAK*	
	10:50 – 11:10 *BREAK*	11:10 – 12:30 SESSION 5 *Theme: The Role of Generative AI in Regulatory Science* • 20min/talk; 4 talks	11:10 – 12:30 NANO-SESSION 2 *Theme: Measurement Methods For Real World Micro(nano)plastics* • 20min/talk; 3 talks + Panel
	11:10 – 12:30 PM SESSION 1 *Theme: AI as a NAM* • 20min/talk; 4 talks		
	12:30 – 14:00 *BREAK*	12:30 – 14:00 *BREAK*	
13:00 – 16:30 Pre-conference Workshop (Garden Level, Room 2ABC) *Innovations in Retrospective Validation of NAM Evidence: Lessons Learned from Systematic Review*	14:00 – 15:20 SESSION 2 *Theme: AI in Medicine: From Molecules to Population* • 20min/talk; 4 talks	14:00 – 15:20 SESSION 6 *Theme: From Data to Action: Advancing Regulatory Science with Emerging Approaches* • 20min/talk; 4 talks	14:00 – 15:20 NANO-SESSION 3 *Theme: Nanomedicines: Progress In Regulatory Science* • 20min/talk; 4 talks
	15:20 – 15:50 *BREAK*	15:20 – 15:50 *BREAK*	
	15:50-17:30 SESSION 3 *Theme: Interactive Discussion on Regulatory Transformation: Cultural and Organizational Barriers* (Moderated discussion)	15:50-17:10 SESSION 7 *Theme: International Efforts in Digital Science* • 20min/talk; 4 talks	15:50-17:10 NANO-SESSION 4 *Theme: Nanomedicines: Emerging Applications* • 20min/talk; 3 talks + Panel
	17:30-19:30 POSTER SESSION (Drinks and hors d'oeuvres)	17:10-17:30 CLOSING REMARKS & ANNOUCEMENT OF GSRS26	

CONFERENCE PROGRAM

All times are in local time

Day 0 — Monday, 15 September 2025 | Garden Level, Room 2ABC

11:00–18:00	**REGISTRATION**
13:00–16:30	**PRE-CONFERENCE WORKSHOP:** **INNOVATIONS IN RETROSPECTIVE VALIDATION OF NAM EVIDENCE: LESSONS LEARNED FROM SYSTEMATIC REVIEW**

Instructors

- Gro Haarklou Mathisen, PhD. Norwegian Scientific Committee for Food and Environment
- Paul Whaley, PhD. Evidence-Based Toxicology Collaboration
- Angela Bearth, PhD. HF Partners

Learning objectives

Through a series of lectures and practical exercises, participants will develop an understanding of the concept of “internal validity” (systematic error arising from how a study is conducted), how to assess the internal validity of NAM studies in the context of systematic review (“retrospective validation”), and second-order skills relating to how to develop and select appropriate tools for assessing the internal validity of scientific studies.

Agenda

13:00-13:10 | Introduction to the workshop and the instructors

13:10-13:25 | Refresher on systematic review and the need for assessing bias

13:25-13:45 | How to assess internal validity, using the new INVITES-IN tool (beta version)

13:45-13:55 | How INVITES-IN was developed, with lessons for tool development in general

14:00-14:15 | Break

14:15-14:45 | Breakout session #1, familiarisation with INVITES-IN

14:45-15:05 | Q&A session, group discussion of INVITES-IN approach

15:05:15:20 | Coffee Break

15:20-16:10 | Breakout session #2, applying INVITES-IN to selected NAM studies

16:10-16:25 | Group discussion of results of assessing the selected studies

16:25-16:30 | Close

Day 1 — Tuesday, 16 September 2025 | Campus Level, Auditorium B

8:00	**Registration Open**
09:00–09:10	**WELCOME REMARKS** • Michael Renaudin, Swissmedic • Dr. Weida Tong, U.S. Food and Drug Administration (FDA), GCRSR Chair
09:10–10:50	**KEYNOTE PRESENTATIONS** Co-Chairs: Katherine Serrano, U.S. Food and Drug Administration (FDA), Belgium; Dr. Tucker Patterson, U.S. Food and Drug Administration (FDA), USA
09:10–09:35	**The Regulator as Strategic Asset: A Swiss Perspective** Dr. Philippe Girard, Deputy Executive Director, Swissmedic, Switzerland
09:35–10:00	**FDA's AI Programs: Challenges and Opportunities** Dr. Tucker Patterson, Director, National Center for Toxicological Research, U.S. Food and Drug Administration (FDA), USA
10:00–10:25	**Regulatory Science and Innovation: A Perspective from the European Medicines Agency** Dr. Emmanuel Cormier, Head of the Regulatory Science and Innovation Task Force, European Medicines Agency (EMA), Netherlands
10:25–10:50	**Risk Assessment and Regulatory Sciences in Times of Accelerated Change – How Can We Keep Up the Pace?** Dr. Carlos Das Neves, Chief Scientist, European Food Safety Authority (EFSA), Italy
10:50–11:10	**Break**
11:10–12:30	**SESSION 1: AI AS A NAM** Co-Chairs: Didier Verloo, European Food Safety Authority (EFSA), Italy; Maurice Whelan, European Commission, Joint Research Centre (JRC), Italy
11:10–11:30	**Are We There Yet? AI as a NAM to Replace Conventional Toxicity Testing in Pharma** Dr. Elisabeth Klenke, Head of Nonclinical Assessment and GLP Inspectorate, Swissmedic, Switzerland
11:30–11:50	**From Animals to Algorithms: AI in DILI Risk Evaluation** Dr. Weida Tong, Director, Division of Bioinformatics and Biostatistics, National Center for Toxicological Research, U.S. Food and Drug Administration (FDA), USA
11:50–12:10	**Recent, Current and Future Case Studies of AI in Safety Evaluation: Can AI Become "Regulatory-Grade"?** Dr. Billy Amzal, Head of Strategic Consulting, Phastar, France
12:10–12:30	**In Silico NAMs for Systemic and Topical Toxicity (STopTox) Assessment** Dr. Alex Tropsha, K.H. Lee Distinguished Professor, Division of Chemical Biology and Medicinal Chemistry, University of North Carolina at Chapel Hill, USA
12:30–14:20	**Break**
14:20–15:20	**SESSION 2: AI IN MEDICINE: FROM MOLECULES TO POPULATION** Co-Chairs: Dr. Masahiro Tohkin, Food Safety Commission of Japan (FSCJ), Japan; Dr. Zhan Yuin Ong, Singapore Food Agency (SFA), Singapore
14:20–14:40	**Identification of Genomic Biomarkers of Liver Toxicity Risk Using Formal Concept Analysis of UK Biobank Data** Dr. Federico Goodsaid, SVP Regulatory, Ariana Pharma, France

14:40–15:00	**Insight to Standard: ML Prediction Models and LLMs for Omics Data Reanalysis and Standardization** Dr. Wenjun Bao, Chief Scientist and Director of Advanced Analytics R&D, JMP Statistical Discovery, SAS Institute Inc, USA
15:00–15:20	**Exploiting AI in the Development of Adverse Outcome Pathways and Their Use in New Approaches to Safety Assessment** Clemens Wittwehr, Group Leader, European Commission, Joint Research Centre (JRC), Italy
15:20–15:50	**Break**
15:50–17:30	**SESSION 3**: **INTERACTIVE DISCUSSION ON REGULATORY TRANSFORMATION: CULTURAL AND ORGANIZATIONAL BARRIERS** Moderators: Michael Renaudin, Swissmedic, Switzerland; Dr. Lilliam Rosario, Formerly U.S. Food and Drug Administration (FDA), USA • Drs. Lixian Schmid and Grzegorz (Greg) Podrygajlo, CSL Behring, Switzerland • Didier Verloo, European Food Safety Authority (EFSA), Italy • Dr. Henric Taavola-Gustafsson, Uppsala Monitoring Centre (UMC), Sweden
17:30–19:30	**POSTER PRESENTATIONS & WELCOME RECEPTION (Campus Level, Entrance Hall)**

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Day 2 — Wednesday, 17 September 2025 | Parallel Tracks

Main Conference | Campus Level, Auditorium B

8:00	**Registration Open**
09:00–10:40	**SESSION 4: AI IN CHEMICAL SCIENCE** Co-Chairs: Dr. Yoko Hirabayashi, National Institute of Health Sciences (NIHS), Japan; Dr. Alex Tropsha, University of North Carolina, USA
09:00–09:20	**AI-Augmented Chemical Research using Language Models** Prof. Philippe Schwaller, Assistant Professor, Laboratory of Artificial Chemical Intelligence (LIAC), Swiss Federal Technology Institute of Lausanne (EPFL), Switzerland
09:20–09:40	**Beyond QSARs – Quantitative Knowledge-Activity Relationships (QKARs) for Toxicity Prediction** Dr. Dongying Li, Research Scientist, Division of Bioinformatics and Biostatistics, National Center for Toxicological Research, U.S. Food and Drug Administration (FDA), USA
09:40–10:00	**Language-Driven Organ Lesion Prediction in Large-Scale Toxicology** Dr. Tommaso Furlanello, HK3 Lab, Italy
10:00–10:20	**Current Status of Understanding and Application of AI for Handling Chemical Structures** Dr. Tadahaya Mizuno, Assistant Professor, University of Tokyo and Institute of Statistical Mathematics, Japan
10:20–10:40	**Artificial Intelligence in Chemical Safety Assessment: Current Status, Perspectives, and Challenges** Dr. Predrag Kukic, Computational Science Leader, Safety, Environmental and Regulatory Science (SERS), Unilever, United Kingdom
10:40–11:10	**Break**
11:10–12:30	**SESSION 5: THE ROLE OF GENERATIVE AI IN REGULATORY SCIENCE** Co-Chairs: Dr. Philippe Girard, Swissmedic, Switzerland; Dr. Dongying Li, U.S. Food and Drug Administration (FDA), USA
11:10–11:30	**Evaluating the Black Box: How to Think About Generative AI in Medicine** Dr. Henric Taavola-Gustafsson, Senior Data Scientist, Uppsala Monitoring Centre (UMC), Sweden
11:30–11:50	**In 5 years from ChatGPT to Super-Intelligence? Reflection on Our Current Moment in AI** Prof. Marcel Salathé, Co-Director of AI Center, Swiss Federal Technologyta Institute of Lausanne (EPFL), Switzerland
11:50–12:10	**Adopting Large Language Models for Regulatory Review** Dr. Joshua Xu, R2R Branch Chief, Division of Bioinformatics and Biostatistics, National Center for Toxicological Research, U.S. Food and Drug Administration (FDA), USA
12:10–12:30	**LLMs Task Force: Past, Present, and Future** Michael Renaudin, Lead Swissmedic 4.0, Swissmedic, Switzerland
12:30–14:00	**Break**
14:00–15:20	**SESSION 6: FROM DATA TO ACTION: ADVANCING REGULATORY SCIENCE WITH EMERGING APPROACHES** Co-Chairs: Dr. Weida Tong, U.S. Food and Drug Administration (FDA), USA; Dr. Tammy Collins, Burroughs Wellcome Fund (BWF), USA
14:00–14:20	**Experiments with AI in the Regulatory Assessment of Marketing Authorisation Applications** Dr. Philipp Weyermann, Head of Unit, Regulatory Assessment 2, Swissmedic, Switzerland

14:20–14:40	**Navigating the Future in the NAMs ecosystem: Scientific Advances Driving Non-Animal Approaches in Toxicology and Drug Development** Dr. Madhu Nag, Chief Scientific Officer, InSphero, USA
14:40–15:00	**The Sample-to-Reference Ratio (SRR) Framework: Ensuring Reproducibility of Quantitative Multiomics Data for Standardization and Regulatory Decision-Making** Dr. Leming Shi, Professor, School of Life Sciences and Shanghai Cancer Center, Fudan University; Director, International Human Phenome Institutes (Shanghai), China
15:00–15:20	**Persistent Agentic Tasks for Regulatory Toxicology: From Property Inference to Hazard Surveillance** Dr. Thomas Luechtefeld, CEO, Insilica, USA
15:20–15:50	**Break**
15:50–17:10	**SESSION 7: INTERNATIONAL EFFORTS IN DIGITAL SCIENCE** Co-Chairs: Dr. Supriya Sharma, Health Canada (HC), Canada; Dr. Carlos Das Neves, European Food Safety Authority (EFSA), Italy
15:50–16:10	**From Closed Source to Open Source – Why Transparency is the Future of Regulatory AI** Alexander Horst, Data Scientist, Veanu, Switzerland
16:10–16:30	**Beyond Big Data Analysis: Learn from the 2nd AMES/QSAR International Challenge Project** Dr. Ayako Furuhama, National Institute of Health Sciences (NIHS), Japan
16:30–16:50	**Cutting Edge Technology in Regulatory Science – Who is doing what? A Landscape View of New Technologies Worldwide** Dr. Nicolas Löffler-Pérez, Data Scientist, Swissmedic, Switzerland
16:50–17:10	**NAMs Without Borders: The 3Rs Collaborative Drives Global Awareness & Harmonization in Translational Science** Dr. Megan R. LaFollette, Executive Director, The 3Rs Collaborative, USA
17:10–17:30	**CLOSING REMARKS & ANNOUNCEMENT OF GSRS26**

---------- Continued on next page: Day-2 Agenda for Nanotechnology Sessions

Day 2 — Wednesday, 17 September 2025 | Parallel Tracks

Nanotechnology Sessions | Garden Level, Room 1BC

8:00	**Registration Open**
09:00–10:40	**NANO-SESSION 1: ADVANCED MATERIALS, SSBD IN THE CONTEXT OF NANOMATERIALS** Co-Chairs: Dr. Birgit Sokull Kluettgen, European Commission, Joint Research Centre (JRC), Italy; Dr. Anil K. Patri, U.S. Food and Drug Administration (FDA), USA
09:00–09:20	**OECD Working Party on Manufactured Nanomaterials – Important Achievements and Future Directions** Mar Gonzalez, Organization for Economic Cooperation and Development (OECD)
09:20–09:40	**Safe-and-Sustainable-by-Design Drives Innovation Towards Safer and More Sustainable Nanomaterials** Drs. Hubert Rauscher & Irantzu Garmendia Aguirre, European Commission, Joint Research Centre (JRC), Italy
09:40–10:00	**EFSA's Approach to Risk Assessment of Nanomaterials and Materials Containing Small/Nanoparticles in the Food and Feed Chain** Irene Cattaneo, European Food Safety Authority (EFSA), Italy
10:00–10:20	**Standardisation Efforts and Upcoming Challenges for Nanomedicines** Dr. Caterina Minelli, National Physical Laboratory, United Kingdom
10:20–10:40	**Panel Discussion**
10:40–11:10	**Break**
11:10–12:30	**NANO-SESSION 2: MEASUREMENT METHODS FOR REAL WORLD MICRO(NANO)PLASTICS** Co-Chairs: Dr. Birgit Sokull Kluettgen, European Commission, Joint Research Centre (JRC), Italy; Dr. Anil K. Patri, U.S. Food and Drug Administration (FDA), USA
11:10–11:30	**Challenges in Developing Methodologies for Legislative Monitoring of Micro(Nano)Plastics** Dr. Douglas Gilliland, European Commission, Joint Research Centre (JRC), Italy
11:30–11:50	**Microplastics and Nanoplastics Monitoring in Water and Food: Analytical Advances to Support Risk Assessment** Dr. Zhan Yuin Ong, National Centre for Food Science, Singapore Food Agency (SFA), Singapore
11:50–12:10	**The POLYRISK Risk Assessment Framework for Micro- and Nanoplastic Particles (MNPs) and Its Application in Selected Case Studies** Dr. Andrea Haase, German Federal Institute for Risk Assessment (BfR), Germany
12:10–12:30	**Panel Discussion**
12:30–14:00	**Break**
14:00–15:20	**NANO-SESSION 3: NANOMEDICINES: PROGRESS IN REGULATORY SCIENCE** Co-Chairs: Dr. Michael Johnston, Health Canada, Canada; Dr. Birgit Sokull-Kluettgen, European Commission, Joint Research Centre (JRC), Italy
14:00–14:20	**Progress and Challenges with Nanotechnology/Nanomedicines** Dr. Anil K. Patri, U.S. Food and Drug Administration (FDA), USA
14:20–14:40	**Work of the European Pharmacopeia (EDQM) on mRNA Vaccines** Prof. Gerrit Borchard, University of Geneva & EDQM, Switzerland

14:40–15:00	**Quality Attributes for LNP-RNA Therapeutics: A New Generation of Medicines** Dr. Luigi Calzolai, European Commission, Joint Research Centre (JRC), Italy
15:00–15:20	**Development of Prototype LNP Lyme Disease Vaccine** Dr. Michael Johnston, Health Canada, Canada
15:20–15:50	**Break**
15:50–17:10	**NANO-SESSION 4: NANOMEDICINES: EMERGING APPLICATIONS** Co-Chairs: Dr. Michael Johnston, Health Canada, Canada; Dr. Anil K. Patri, U.S. Food and Drug Administration (FDA), USA
15:50–16:10	**Advanced Continuous Manufacturing to Accelerate Production of LNPs** Prof. Diane J. Burgess, University of Connecticut, USA
16:10–16:30	**Regulatory and Research Progress on Nanomedicines in China** Dr. Xingchao Geng, National Institute for Food and Drug Control (NIFDC), China
16:30–16:50	**Innovating Quality Characterization of Lipid-Based Nanomedicines: Advancing AFM and Cryo-EM Applications in Regulatory Science** Dr. Yuki Haraya, National Institute of Health Sciences (NIHS), Japan
16:50–17:10	**Panel Discussion**
17:10–17:30	**CLOSING REMARKS & ANNOUNCEMENT OF GSRS26**