



Global Summit on Regulatory Science 2019
Nanotechnology and Nanoplastics

24 - 26
September
2019

Lago Maggiore
Italy

**CONFERENCE
AGENDA**

Optional meetings, training and
lab tours on 27 September

#GSRS19

Global Summit on Regulatory Science 2019

Nanotechnology and Nanoplastics

Lago Maggiore, Italy

24-26 September 2019

The **Global Summit on Regulatory Science 2019** (GSRS19) on **Nanotechnology and Nanoplastics** is co-organised by the European Commission's Joint Research Centre (JRC) and the Global Coalition for Regulatory Science Research (GCRSR).

The **GSRS19** brings together scientists from government, industry, and academic research communities from around the world for addressing regulatory-research questions concerning Nanotechnology and Nanoplastics. The conference provides a platform where regulators, policy makers, and bench scientists can exchange views on innovative methodologies and regulatory assessments, as well as harmonising strategy via global collaboration.

Global Coalition for Regulatory Science Research (GCRSR) Co-Chairs

William Slikker, Ph.D., U.S. Food and Drug Administration (FDA, USA)

Marta Hugas, Ph.D., European Food Safety Authority (EFSA, EU)

Scientific Programme Committee

Anil K. Patri, Ph.D., U.S. Food and Drug Administration (FDA, USA) (Co-chair)

Birgit Sokull-Kluettgen, Ph.D., European Commission Joint Research Centre (EC JRC, EU) (Co-chair)

Susanne Bremer-Hoffmann, Ph.D., European Commission Joint Research Centre (EC JRC, EU)

Marta Hugas, Ph.D., European Food Safety Authority (EFSA, EU)

Reinhilde Schoonjans, Ph.D., European Food Safety Authority (EFSA, EU)

Dolores Hernán Pérez de la Ossa, Ph.D., European Medicines Agency (EMA, EU)

Michael Johnston, Ph.D., Health Canada (HC, Canada)

Deborah Moir, Ph.D., Canadian Food Inspection Agency (CFIA, Canada)

Neil Vary, B.Sc., Canadian Food Inspection Agency (CFIA, Canada)

Nick Fletcher, Ph.D., Food Standards Australia New Zealand (FSANZ, Australia New Zealand)

Xingchao Geng, Ph.D., National Institute for Food and Drug Control (NIFDC, China)

Conference Topics

- Global regulatory science perspectives on nanotechnology and nanoplastics
- Regulatory research needs for new and follow-on nanomedicines
- Safety assessment of nanomaterials
- Nanotechnology in the agri/food/feed sector
- Documentary standards and reference materials
- Challenges concerning nanoplastics

Optional satellite meetings, training, and visits to the JRC laboratories will be held at the [JRC in Ispra](#) on 24 and 27 September 2019.

QUICK REFERENCE

GSRs 2019						Optional visits and training opportunities								
Tuesday 24 September Joint Research Centre, Ispra		Wednesday 25 September Hotel La Palma, Stresa		Thursday 26 September		Friday 27 September Joint Research Centre, Ispra								
08:00		Registration						08:00						
08:30		Global regulatory science perspectives on nanotechnology and nanoplastics		Documentary standards and reference materials	Nanotechnology in the agri/food/feed sector			08:30						
09:00								09:00						
09:30								09:30						
10:00						Break 10:10 - 10:25	Break 10:15 - 10:40				10:00			
10:30	IPRP Nanomedicines WG Building 101	Determining size distributions of nanomaterials Building 101	Global regulatory science perspectives on nanotechnology and nanoplastics		Documentary standards and reference materials	Nanotechnology in the agri/food/feed sector	Visit to JRC Laboratories: Nanobiotechnology, EURL-ECVAM, EURL-FCM, EURL-GMFF, Visitors' Centre	Use of Reference Materials and the estimation of measurement uncertainty Building 28F	ASTM International Committee E56 Workshop on standards for regulatory science Building 101	10:30				
11:00													11:00	
11:30														11:30
12:00														12:00
12:30	Lunch Break	Lunch Break	Photo opportunity (11:45) Lunch Break		Lunch Break				Lunch Break	12:30				
13:00											13:00			
13:30												13:30		
14:00	GCRSR Executive Meeting Building 101	Determining size distributions of nanomaterials Building 101	Regulatory research needs for new and follow-on nanomedicines	Safety assessment of nanomaterials	Challenges concerning nanoplastics		Visit to JRC Nanobiotechnology Laboratory, EURL-ECVAM (EU Reference Laboratory for Alternative to Animal Testing), EURL-FCM (EU Reference Laboratory for Food Contact Materials), EURL-GMFF (EU Reference Laboratory for Genetically Modified Food & Feed), Visitors' Centre			14:00				
14:30												14:30		
15:00											15:00			
15:30											15:30			
16:00			Break 15:15 - 15:40		Break 15:25 - 15:50					16:00				
16:30			Regulatory research needs for new and follow-on nanomedicines	Safety assessment of nanomaterials	Challenges concerning nanoplastics					16:30				
17:00											17:00			
17:30	Apericena, JRC Clubhouse		Poster Session 17:30 - 19:00		Aperitivo, La Palma					17:30				
18:00									18:00					
18:30									18:30					
19:00									19:00					
19:30			Annual Meeting of the EFSA Nano Network (closed meeting, for members only) 18:15 - 19:15							19:30				
20:00			Social dinner, La Palma							20:00				

Global Summit on Regulatory Science 2019
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Lago Maggiore, Stresa (VB), Italy
Wednesday, 25 September

08:00 Registration

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Plenary Session (1)

Global regulatory science perspectives on nanotechnology and nanoplastics

Co-chairs: Anil K. Patri and Birgit Sokull-Kluettgen

- 08:30 William Slikker and Marta Hugas (GCRSR Co-chairs)
Opening remarks
- 08:40 Elke Anklam (EC JRC, EU)
Welcome address
- 09:00 Anil K. Patri (FDA, USA)
Nanotechnology regulatory science at US FDA
- 09:20 Marta Hugas (EFSA, EU)
The importance of collaboration and research in regulatory science
- 09:40 Mauro Ferrari (University of St. Thomas, USA)
On the clinical translation of nanomedicines
-
- 10:00 **Break**
-
- 10:25 Primal Silva (CFIA, Canada)
The current research and regulatory approach for nanomaterials and nanoplastics in Canada
- 10:45 Lisa Friedersdorf (National Nanotechnology Coordination Office, USA)
Leveraging advances in nanotechnology and international collaboration to address emerging contaminants
- 11:05 Carlos Eduardo Lima da Cunha (EC DG RTD, EU)
Safe by design: creating nanomaterials of tomorrow
- 11:25 Haruhiro Okuda (NIHS, Japan)
Progress of regulatory science in Japan
-
- 11:45 **Photo opportunity**
-
- 12:00 **Lunch Break**

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Parallel Session (2)

Regulatory research needs for new and follow-on nanomedicines

Co-chairs: Susanne Bremer-Hoffmann, Dolores Hernán Pérez de la Ossa and Michael Johnston

- 13:30 Co-chairs, **Introduction into session**
- 13:35 Katherine Tyner (FDA, USA)
Regulatory research supporting the development of drug products containing nanomaterials: A US-FDA perspective
- 13:55 Amit K. Dinda (AIIMS, India)
Development of Indian guideline for nanopharmaceuticals: The challenges
- 14:15 Dolores Hernán Pérez de la Ossa (EMA, EU) and Susanne Bremer-Hoffmann (EC JRC, EU)
Nanomedicines: EU regulatory experience, challenges and regulatory research work
- 14:35 Matthias Wacker (National University of Singapore)
Translational nanomedicine – How to predict clinical performance?
- 14:55 Sven Even Borgos (SINTEF, Norway)
Joining transatlantic forces - EU-US Communities of Research and the EU-NCL
-
- 15:15 **Break**
-
- 15:40 Pieter Cullis (National Centre of Excellence in Nanomedicines, Canada)
Lipid nanoparticle systems for enabling gene therapies
- 16:00 Jon de Vlieger (Lygature)
Science-based regulations for non-biological complex drugs, nanomedicines and their similars
- 16:20 Agnès Pottier (Nanobiotix)
NBTXR3, a first-in-class hafnium oxide nanoparticle radioenhancer: Journey from concept to clinical application
- 16:40 Michael Johnston (HC, Canada)
The IPRP nanomedicines working group: current and potential future activities
- 17:00 Panel discussion - All speakers
Regulatory research needs for new and follow-on nanomedicines
-
- 17:30 **Poster Session** (until 19:00)
-
- 18:15 Annual Meeting of the EFSA Nano Network (closed meeting, for members only)
-
- 20:00 **Social Dinner**

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Parallel Session (3)

Safety assessment of Nanomaterials

Co-chairs: Peter Goering and Juan Riego Sintes

- 13:30 Co-chairs, **Introduction into session**
- 13:35 Robert Burgess (EPA, USA)
Overview of ecological studies on the fate and effects of nanomaterials in the marine environment
- 13:55 Abdel Sumrein (ECHA, EU)
Safety assessment of nanomaterials under REACH
- 14:15 Wim H. de Jong (EC SCCS, EU)
Safety assessment of nanomaterials as ingredients for cosmetic products
- 14:35 Kumiko Ogawa (NIHS, Japan)
Size-dependent toxicity of silver nanoparticles
- 14:55 Ritu Nalubola (FDA - Europe Office, USA)
FDA - Europe Office – Our role and how you can engage with us
-
- 15:15 **Break**
-
- 15:40 Peter L. Goering, (FDA, USA)
Nanotechnology and medical devices: A regulatory science approach involving research, standards, and risk assessment
- 16:00 Nadim Akhtar (AstraZeneca)
CMC challenges in developing commercial nanomedicines
- 16:20 Jan Simak (FDA, USA)
Investigation of blood and endothelial toxicity of engineered nanoparticles using a PAMAM dendrimer model
- 16:40 Luis Velasquez Cumplido (I3CBSEK, Universidad SEK, Chile)
International review of micro and nanoplastic regulations in marine environments and their potential impact on Chilean aquaculture
- 17:00 Panel discussion - All speakers
Safety assessment of Nanomaterials
-
- 17:30 **Poster Session** (until 19:00)
-
- 18:15 Annual Meeting of the EFSA Nano Network (closed meeting, for members only)
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- 20:00 **Social Dinner**

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Parallel Session (4)
Nanotechnology in the agri/food/feed sector

Co-chairs: Primal Silva and Reinhilde Schoonjans

- 08:30 Co-chairs, **Introduction into session**
- 08:35 **Guilhem de Sèze** (EFSA, EU)
Nanomaterials in food and feed - Experience and perspective from the European Food Safety Authority
- 08:55 **Frank Herzberg** (BfR, Germany)
Towards grouping of nanomaterials: lessons learnt and remaining challenges
- 09:15 **Ralf Greiner** (Max Rubner-Institut (MRI), Germany)
Nano-sized delivery systems for food application
- 09:35 **Ken Bosnick** (National Research Council, Canada)
Nanomaterials for reducing food-related waste
- 09:55 **Valérie Fessard** (ANSES, France)
Genotoxicity of aluminium nanoparticles
-
- 10:15 **Break**
-
- 10:40 **Katrin Löschner** (National Food Institute, Denmark)
Analysis of inorganic nanoparticles in food and biological matrices
- 11:00 **Melanie Kah** (University of Auckland, New Zealand)
Nanopesticides: deliberate application in agriculture
- 11:20 **Hongda Chen** (DA, USA)
Observations of nano-agrochemicals and nanoplastics in food and agriculture research
- 11:40 **Agnes Oomen** (RIVM, The Netherlands)
Nanobiotechnology – an exploration
- 12:00 Panel discussion - All speakers & Josefa Barrero Moreno (EC JRC, EU)
Nanotechnology in the agri/food/feed sector
-
- 12:30 **Lunch Break**

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Parallel Session (5)
Documentary standards and reference materials

Co-chairs: Debra Kaiser and Andrea Held

- 08:30 Co-chairs, **Introduction into session**
- 08:35 Debra Kaiser (NIST, USA)
Nanotechnology standards: Progress on GRS16 needs and ASTM International
- 08:55 Andrea Held (EC JRC, EU)
Reference materials supporting legislation
- 09:15 Mar Gonzalez (OECD)
OECD work supporting the regulation of nanomaterials
- 09:35 Denis Koltsov (ISO TC229, Nanotechnologies)
Nanotechnology standards for industry, regulators and other stakeholders
- 09:55 Vincent A. Hackley (NIST, USA)
Challenges in standardising methods for the analysis of nano-enabled drugs
-
- 10:15 **Break**
-
- 10:40 Charles Clifford (NPL, UK)
Normative and pre-normative activities for nanomaterials measurement and characterisation
- 11:00 Liming Xie (NCNST, China)
Standards and evaluations of nanomedical devices in China
- 11:20 Wenlei Jiang (FDA, USA)
Regulating generic nanotechnology drug products: Guidances and standards
- 11:40 Shan Zou (NRC, Canada)
Characterisation of nanomaterials and their cytotoxicity assessment
- 12:00 Panel discussion - All speakers & Kirsten Rasmussen (EC JRC, EU)
Documentary standards and reference materials
-
- 12:30 **Lunch Break**

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Plenary Session (6)
Challenges concerning Nanoplastics

Co-chairs: Anil K. Patri and Arnd Hoeveler

- 14:00 Co-chairs, **Introduction into session**
- 14:05 **Nanna B. Hartmann** (DTU, Denmark)
Risks of micro- and nanoplastics to humans and the environment – state of knowledge and highlights from the SAPEA report
- 14:25 **Julien Gigault** (CR-CNRS, France)
Nanoplastics in real world: source, presence and environmental fate
- 14:45 **Souhail Al-Abed** (EPA, USA)
Detecting nanoplastics in the environment: adapting existing methods from nanotechnology
- 15:05 **Douglas Gilliland** (EC JRC, EU)
What can the analytics of nanomaterials bring to the detection of nanoplastics?
-
- 15:25 **Break**
-
- 15:50 **Iseult Lynch** (University of Birmingham, UK)
Harmonising detection, quantification and impact assessment of micro/nanoplastics in freshwater environmental hotspots
- 16:10 **Ted Henry** (Heriot-Watt University, UK)
First results from the RealRiskNano project
- 16:30 **Alfonso Lampen** (BfR, Germany)
Micro- and nanoplastics in food: oral uptake, toxicology and initial aspects of risk assessment
- 16:50 **Sylvain Bintein** (EC DG ENV, EU)
ECHA proposal for a restriction of intentionally added micro- and nanoplastics
- 17:10 Panel discussion - All speakers
Challenges concerning Nanoplastics
-
- 17:40 **Closing remarks GRS19**
-
- 18:00 **Reception / Aperitivo**
-
- End of Meeting**

**TRAINING & VISITS
TO JRC LABORATORIES
& VISITORS' CENTRE**

Global Summit on Regulatory Science 2019

Possibility of Training

Lago Maggiore, Ispra (VA), Italy

Tuesday, 24 September

Hands-on training

Determining size distributions of nanomaterials

On 24 September 2019 (10:00-17:00), back-to-back to the **GSR519**, the **European Commission's Joint Research Centre** (JRC) offers a hands-on training on '**Determining size distributions of nanomaterials**'.

This one-day training course will include two sessions. One session will focus on particle size distribution theory, including topics such as 'What is particle size?', 'ISO standard nomenclature', 'Graphical representation of particle size distributions', and 'Transformation between number, mass and absorption weighted distributions'. This will be complemented by a practical session which will allow the participants to gain hands on experience in the use of selected nanoparticle sizing techniques, such as 'Single particle ICP-MS', 'Transmission Electron Microscopy' or 'Centrifugal Particle Sedimentation'. In alternative to the practical session, the participants can get an introduction to the regulatory relevance of identifying nanomaterials according to the European Commission's recommendation on a definition of nanomaterial and how to do this in practice with the help of a decision support framework and a handy e-tool.

Friday, 27 September

Short course

Use of Reference Materials and the Estimation of Measurement Uncertainty

On 27 September 2019 (10:00-13:00), back-to-back to the **GSR519**, the **European Commission's Joint Research Centre** (JRC) offers a short course on the '**Use of Reference Materials and the estimation of measurement uncertainty**'.

This course provides participants with the theoretical basis for the estimation of measurement uncertainty and establishment of traceability, which are essential for the evaluation of measurement results. Reference materials are key tools for achieving traceability of measurement results, proving the accuracy of methods and demonstrating the proficiency of laboratories. Examples for the proper selection and use of reference materials in the field of nanoparticle characterisation will be given.

Optional Visit to the European Commission's Joint Research Centre (JRC)

Possibility of Lab tours

Lago Maggiore, Ispra (VA), Italy

Friday, 27 September

Visit to the JRC Ispra site

On 27 September 2019, back-to-back to the **GSR519**, the **European Commission's Joint Research Centre** (JRC) offers the possibility to visit its Ispra site:

- the **Nanobiotechnology Laboratory**
- the European Union Reference Laboratory for Alternatives to Animal Testing, **EURL-ECVAM**
- the European Union Reference Laboratory for Food Contact Materials, **EURL-FCM**
- the EU Reference Laboratory for Genetically Modified Food & Feed, **EURL-GMFF**, and
- the **Visitors' Centre**.

Guided tours will be organised in the morning (10:00-13:00) and in the afternoon (14:00-17:00).

For more information visit our website:

<https://ec.europa.eu/jrc/en/event/conference/gsr519-global-summit-regulatory-science-2019-nano-technology-and-nanoplastics>