89th ADVISORY FORUM
VIRTUAL, 4-5 OCTOBER

13TH GLOBAL SUMMIT ON REGULATORY SCIENCE (GSRS23)

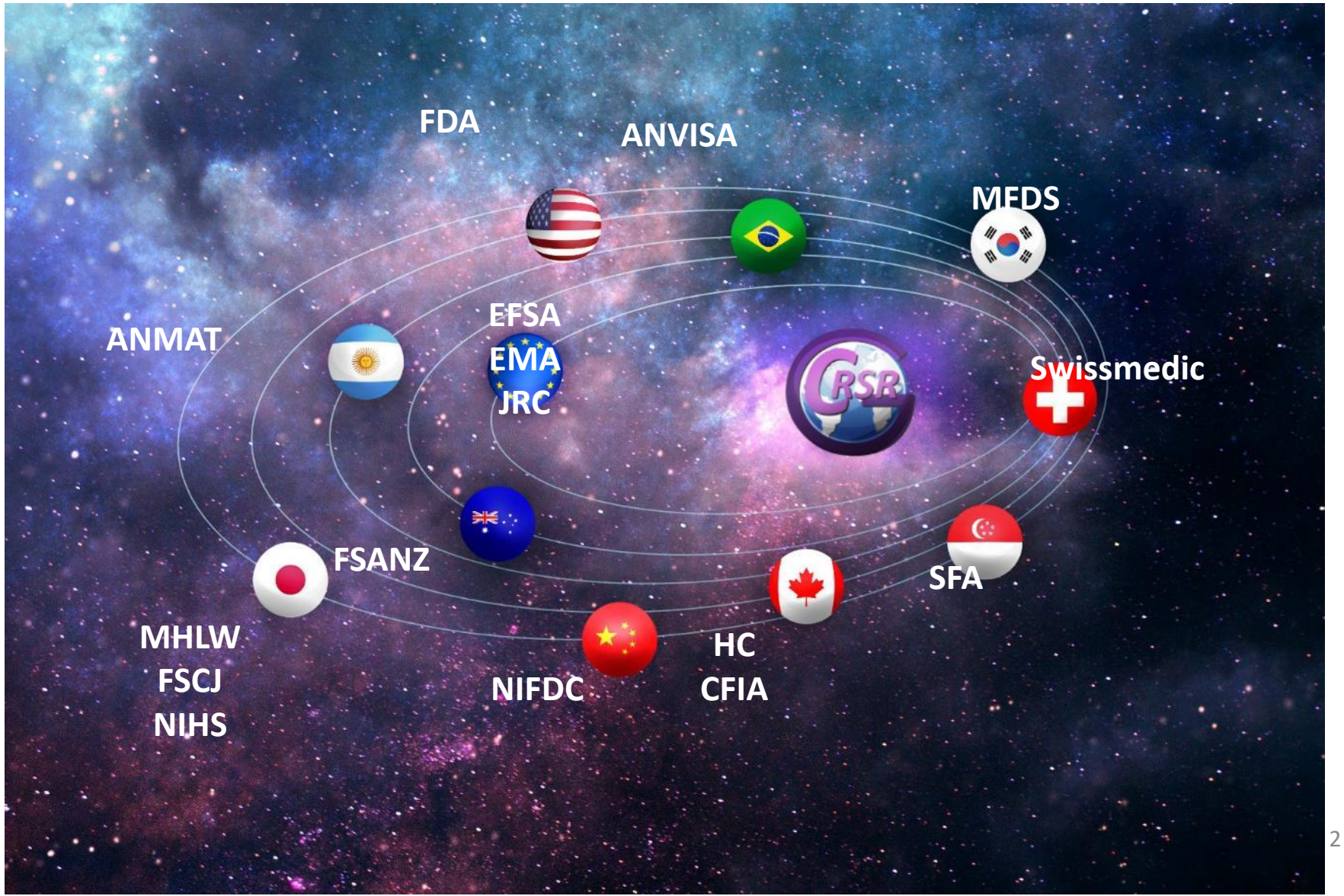
Georges Kass
NIF Unit

EUROPEAN FOOD SAFETY AUTHORITY

GCRSR: THE GLOBAL COALITION FOR REGULATORY SCIENCE RESEARCH

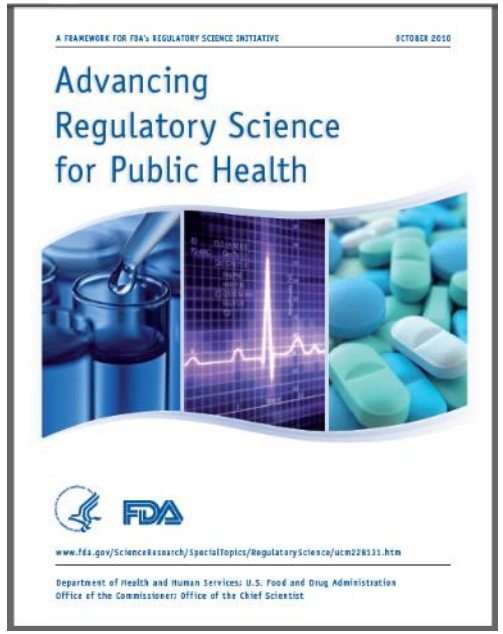
- **Members: 17**
- **Countries: 11**
- **WGs: 5**

Global Coalition for Regulatory Science Research



A BRIEF HISTORY

2010: FDA released a white paper on “Advancing Regulatory Science”




EDITORIAL

Advancing Regulatory Science

Margaret A. Hamburg is Commissioner of the U.S. Food and Drug Administration.

ENSURING THE SAFETY AND QUALITY OF FOOD AND MEDICAL PRODUCTS HAS NEVER BEEN MORE complicated. Societies around the world face increasingly complex challenges that require harnessing the best available science and technology on behalf of patients and consumers. This effort requires a strong field of regulatory science to develop new tools, standards, and approaches that efficiently and consistently assess the safety, efficacy, quality, and performance of products. Yet, despite being a critical component of the scientific enterprise, regulatory science has long been underappreciated and underfunded.

Today, we are neither effectively translating scientific discoveries into therapies nor fully applying knowledge to ensure the safety of food and medical products. We must bring 21st-century approaches to 21st-century products and problems. Toxicology is a prime example. Most of the toxicology tools used for regulatory assessment rely on high-dose animal studies and default extrapolation procedures and have remained relatively unchanged for decades, despite the scientific revolutions of the past half-century. We need better predictive models to identify concerns earlier in the product development process to reduce time and costs. We also need to modernize the tools used to assess emerging concerns about potential risks from food and other product exposures.

The U.S. Food and Drug Administration (FDA) is prepared to lead the way in strengthening regulatory science and transforming toxicology. But this will require collaborations and partnerships with academia, industry, and other government agencies. Fortunately, this work has already begun. For example, the FDA and the European Medicines Agency have recently worked to characterize novel biomarkers that identify drug-induced kidney toxicity in preclinical animal models, and several of these biomarkers have now been qualified for regulatory use. And last year, the FDA and the U.S. National Institutes of Health (NIH) launched a new NIH-FDA Regulatory Science Initiative to encourage new research in the field; we recently awarded our first set of grants—$9.4 million over 3 years to support four research projects. The FDA will continue to make targeted investments in such collaborations, including, if resources are available, Centers of Excellence in Regulatory Science housed in academic settings and focused on collaborative, multidisciplinary, multisectoral regulatory science research.

With an advanced field of regulatory science, new tools, including functional genomics, proteomics, metabolomics, high-throughput screening, and systems biology, can replace current toxicology assays with tests that incorporate the mechanistic underpinnings of disease and of underlying toxic side effects. This should allow the development, validation, and qualification of preclinical and clinical models that accelerate the evaluation of toxicities during drug development. The goals include developing biomarkers to predict toxicity and screen

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TOXICOLOGICAL SCIENCES 131(1), 9–12 (2013)
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2012 Global Summit on Regulatory Science (GSRS-2012)—Modernizing Toxicology

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2013: ESTABLISHMENT OF GCRSR

Scope:

- It is an **international coalition** of global regulatory bodies.
- It facilitates and promotes the development of **regulatory science research** in the global settings.
- It is focused on applying new tools and new approaches for **safe food and therapeutic products**.

www.GCRSR.net

9 organizations from 9 countries (Argentina, Australia, Brazil, Canada, EU, Japan, Korea, Singapore, USA)

LONG-STANDING EFSA INVOLVEMENT

Chairs

- 2013 – 2021: William Slikker Jr, FDA/NCTR, USA
- 2021 – present: Weida Tong, FDA/NCTR, USA

Vice-Chairs

- 2014 – 2015: Marion Healy, FSANZ, Australia
- 2016 – 2017: Carlos Chile, ANMAT, Argentina
- 2018 – 2021: Marta Hugas, EFSA, EU
- 2021 – present: Georges Kass, EFSA, EU

ACTIVITIES OF THE GCRSR

1. Organize an annual **Global Summit on Regulatory Science (GSRS)** conference to provide a platform for discussion, communication, and collaboration.

2. Establish **Working Groups (WGs)** to address issues important for the uptake of new tools in regulatory decision-making and to advance regulatory science.

GSRS CONFERENCES

- **GSRS13:** Nanotechnology (Little Rock, AR, USA)
- **GSRS14**: Regulatory Genomics (Montreal, Canada)
- **GSRS15**: Regulatory Bioinformatics (Parma, Italy)
- **GSRS16**: Nanotechnology Standards and Applications (Washington DC, USA)
- **GSRS17**: Emerging Technologies for Food and Drug Safety (Brasilia, Brazil)
- **GSRS18:** Risk/Benefit of Dietary Supplements and Herbal Medicine in the Era of Data Science (Beijing, China)
- **GSRS19:** Nanotechnologies and Nanoplastics (Stresa, Italy)
- **GSRS20:** Emerging Technologies and Their Application to Regulatory Science—A Global Perspective (Virtual)
- **GSRS21:** Regulatory Sciences for Food/Drug Safety with Real World Data and Artificial Intelligence (Virtual)
- **GSRS22:** Advances in Nanotechnology for Food and Medical Products: Standards, Innovations and Safety (Singapore)
- **GSRS23:** Emerging Technologies for Food and Drug Safety (Parma, Italy)

GSRS23 Program At A Glance

Theme: Emerging Technologies for Food and Drug Safety

Venue: EFSA, Parma, Italy

Sept 26, 2023 (Tuesday)

2:00 – 5:30: Workshop I
NAMs for Nanotechnology

2:00 – 5:00: Workshop II
Present and future of AI, open science and transparency in regulatory science

5:30 – 7:00: Poster over drink

Sept 27, 2023 (Wednesday)

8:30 – 9:00: Registration

9:00 – 9:30: Opening Ceremony

- FDA Senior Leadership
- EFSA Senior Leadership

10:40 – 11:10: Break

9:30 – 12:40: Session 1
Theme: NAMs Global Landscape

- 30min/talk; 5 talks

12:40 – 2:00: Lunch

2:00 – 3:50: Session 2
Theme: NAMs: Regulatory implementations

- 20min/talk; 5 talks

3:50 – 4:10: Break

4:10 – 6:15: Session 3
Theme: Regulatory Apps

- 20min/talk; 5 talks

6:15 – 8:15: Poster over drink

Sept 28, 2023 (Thursday)

8:00 – 8:30: Registration

8:30 – 10:20: Session 4
Theme: Emerging Technologies

- 20min/talk; 5 talks

10:20 – 10:40: Break

10:40 – 12:20: Session 5
Theme: AI/ML

- 20min/talk; 5 talks

12:20 – 1:30: Lunch

1:30 – 3:00: Session 6
Theme: Horizon scanning I

- 20min/talk; 4 talks

3:00 – 3:15: Break

3:15 – 4:15: Session 7
Theme: Horizon scanning II

- 20min/talk; 3 talks

4:15 – 4:35: Closing Remarks

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