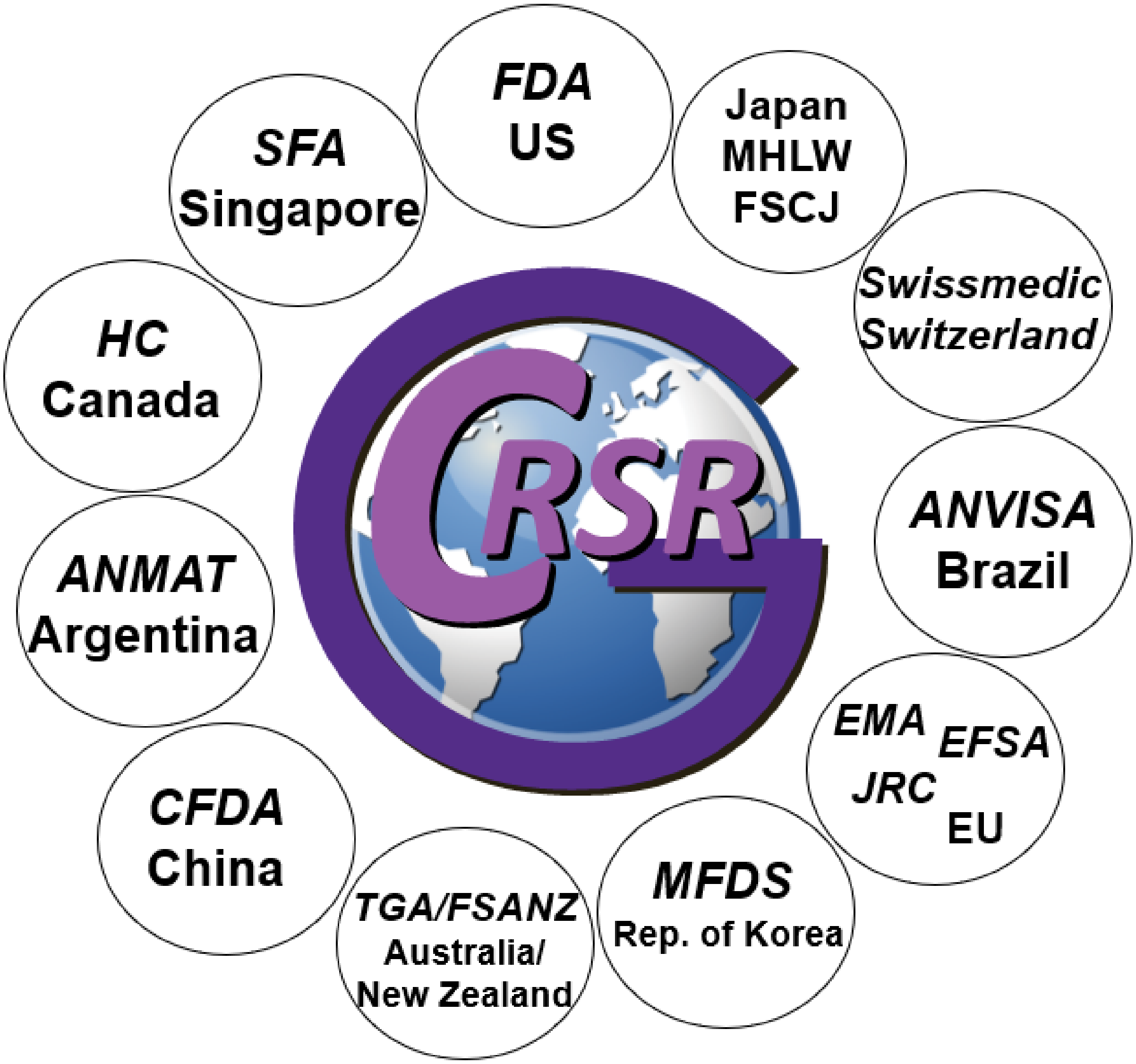

Global Coalition for Regulatory Science Research (GCRSR)

GCRSR Executive Committee Meeting

WebEx

Wednesday, September 23, 2020

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Global Coalition for Regulatory Science Research (GCRSR)

The GCRSR was established in 2013 under the leadership of the US-FDA. This is an international coalition with the objectives of facilitating education, scientific training and scientific exchanges in the field of regulatory science. It focuses on research to support regulatory decision making by identifying and promoting best practices to understand and interpret data from innovative technologies such as genomics. To date, GCRSR discussions have been focused on (1) defining the role of global research collaborations in advancing regulatory science and its impact on public health, (2) exploring the future of regulatory science research as a tool for advancing regulatory science in the areas of food safety and medical products, and (3) developing strategies for training of regulatory scientists in a global setting.

Date: September 23, 2020 (Tuesday)
Time: 7:00 am – 9:00 am U.S. Central Standard Time

Venue: WebEx

GCRSR Co-Chairs:

- William Slikker Jr., Ph.D., NCTR/US FDA, USA
- Marta Hugas, Ph.D., EFSA/EU, Italy

GCRSR Program Administrator:

- Justin Wiencek, NCTR/US FDA, USA

GCRSR Executive Committee Meeting
WebEx

Wednesday, September 23, 2020
7:00 am – 9:00 am U.S. Central Standard Time

Agenda

- Introductions and Welcome of Members
- Introductions of Guests
- GSRS20 Scientific Program Overview (Bill Slikker and Marta Hugas)
- GCRSR Working Groups:
    - Emerging technologies (William Slikker)
    - Bioinformatics (Weida Tong)
    - Nanotechnology (Anil Patri)
    - Scientific Exchange Program – Cross-Training (Primal Silva)
    - Shared Regulatory Research Priorities Working Group (SRRP WG) (Primal Silva and Marta Hugas)
- Theme and Location (local host) for the GSRS21
- GCRSR Leadership Discussion
- Virtual photo of GCRSR members/attendees
- Adjournment

Proposal to host GSRS21 in….

GCRSR Executive Committee Meeting Participants (2019)

Asia

Toru Kawanishi, Food Safety Commission of Japan (FSCJ), Japan
Ryo Iwase, Ministry of Health, Labour and Welfare (MHLW), Japan
Okuda Haruhiro, National Institute of Health Sciences (NIHS), Japan
Kumiko Ogawa, National Institute of Health Sciences (NIHS), Japan
Kazuo Koyama, Food Safety Commission of Japan (FSCJ), Japan
Jun Young Yang, National Institute of Food and Drug Safety Evaluation, Republic of Korea
Xingchao Geng, China Food and Drug Administration (CFDA), China
Tay Geng Yu, Singapore Food Agency (SFA), Singapore
Joanne Chan, Singapore Food Agency (SFA), Singapore

Europe

Marta Hugas, European Food Safety Authority (EFSA), EU
Elke Anklam, European Commission, Joint Research Center (JRC), EU
Birgit Sokull-Kluettgen, European Commission, Joint Research Center (JRC), EU
Dolores Ossa, European Medicines Agency (EMA)
Lada Leyens, Swissmedic, Switzerland

North America

Primal Silva, Canadian Food Inspection Agency (CFIA), Canada
Supriya Sharma, Health Canada (HC), Canada
Shan Zou, National Research Council Canada, Canada
William Slikker, Jr., US Food and Drug Administration (FDA), USA
Ritu Nalubola, US Food and Drug Administration (FDA), USA
Weida Tong, US Food and Drug Administration (FDA), USA
Anil Patri, US Food and Drug Administration (FDA), USA
Shraddha Thakkar, US Food and Drug Administration (FDA), USA
Justin Wiencek, US Food and Drug Administration (FDA), USA

South America

Mariano Saborido, National Administration of Drugs, Food and Medical Devices (ANMAT), Argentina
Yesica Anastasio, National Administration of Drugs, Food and Medical Devices (ANMAT), Argentina

India

Amit Kumar Dinda, All India Institute of Medical Sciences, India

Global Coalition for Regulatory Science (GCRSR)
Executive Committee Members and Representatives - 2020

ARGENTINA:

National Administration of Drugs, Food and Medical Devices (ANMAT)
Carlos Chile (Member)
Yesica Anastasio
Mg Sebastian Duarte

AUSTRALIA:

Food Standards Australia New Zealand (FSANZ)
Scott Crerar (Member)
Trevor Webb

Therapeutic Goods Administration (TGA)
John Skerritt (Member)

BRAZIL:

National Health Surveillance Agency (ANVISA)
Jarbas Barbosa da Silva Júnior (Member)
Monica Soares
Lúcia de Fátima Teixeira Masson
Laila Sofia Mouawad

CANADA:

Health Canada
Supriya Sharma (Member)

Canadian Food Inspection Agency (CFIA)
Primal Silva (Member)
Elie Chamoun
Neil Vary

CHINA:

National Institutes of Food and Drug Control (NIFDC)
Bo Li (Member)
Xingchao Geng

National Medical Products Administration (NMPA)
Naiyuan Zhou
Zhenbin Mao

EU:

European Commission, Joint Research Center (JRC)
Elke Anklam (Member)

European Food Safety Authority (EFSA)
Marta Hugas (Member, Co-Chair)

European Medicines Agency (EMA)
Anthony Humphreys (Member)

JAPAN:

Food Safety Commission of Japan (FSCJ)
Ryosuke Ogawa (Member)
Toshiro Kawashima Kaoruko
Tachibana
Atsutaka Kubosaki

Pharmaceuticals Medical Devices Agency (PMDA)
Daisuke Koga (Member)
Junko Sato
Tomohiro Hatta

Ministry of Health, Labour and Welfare (MHLW)
Hirooki Tanabe (Member)
Naoyuki Yasuda

Deputy Director General, National Institute of Health Sciences
Yukihiro Goda

Korea:

Ministry of Food and Drug Safety (MFDS), Rep. Of Korea
Jong Kwon Lee (Member)
Jun Young Yang

SINGAPORE:

Singapore Food Agency (SFA)
Tan Lee Kim (Member)
Joanne Chan

SWITZERLAND:

Swissmedic
Joerg Schlaepfer
Philippe Girard (Member)

UNITED STATES OF AMERICA:

US Food and Drug Administration (FDA)
Anna Abram (Member)
William Slikker Jr. (Co-Chair**)
Weida Tong
Anil Patri
Justin Wiencek (Program Administrator)

Note: * 2nd Co-Chair (2-Year term)
**Co-Chair (5-year term)

Global Coalition for Regulatory Science Research (GCRSR)
September 24, 2019
Ispra, Italy

GCRSR Executive Committee Participants:
William Slikker, Co-Chair (FDA), USA
Marta Hugas, Co-Chair (EFSA), EU
Elke Anklam (JRC), EU
Joanne Chan, Singapore Food Agency (SFA), Singapore
Jun Young Yang (MFDS), Rep. Of Korea
Kazuo Koyama (FSCJ), Japan
Kumiko Ogawa (NIHS), Japan
Mariano Saborido (ANMAT), Argentina
Okuda Haruhiro (NIHS), Japan
Primal Silva (CFIA), Canada
Ryo Iwase (MHLW), Japan
Supriya Sharma (HC), Canada
Tay Geng Yu (SFA), Singapore
Toru Kawanishi (FSCJ), Japan
Xingchao Geng (NIFDC), China
Yesica Anastasio (ANMAT), Argentina

Representatives:
Anil Patri (FDA), USA
Arnd Hoeveler (JRC), EU
Birgit Sokull-Kluettgen (JRC), EU
Dolores Ossa, European Medicines Agency (EMA)
Elie Chamoun (CFIA), Canada
Reinhilde Schoonjans (EFSA), EU
Ritu Nalubola (FDA), USA
Weida Tong (FDA), USA

Observer:
Amit Kumar Dinda, All India Institute of Medical Sciences, India
Lada Leyens, Swissmedic, Switzerland
Shraddha Thakkar (FDA), USA

Executive Secretariat: Justin Wiencek (FDA), USA

Meeting Minutes

The GCRSR executive meeting was held on September 24, 2019 at the Joint Research Centre (JRC) campus in Ispra, Italy; the meeting commenced at 1:40pm. William Slikker and Marta Hugas, Co-Chairs of the GCRSR, opened the meeting with a welcome and thank you to JRC for hosting and assisting FDA/NCTR with the logistical coordination for the GCRSR/GSRS19 meetings. William Slikker also expressed thanks for JRC's support in helping the GSRS19 Scientific Program Committee recruit speakers for the GSRS19.

A roll call of the attendees was conducted (listed above). The attendees thanked JRC and the FDA for their collaborative work in coordinating the GCRSR and GSRS19 meetings.

Agenda topics presented and discussed:

- **Introductions of Guests**
    - Bill and Elke Anklam welcomed GCRSR observers from Switzerland, Lada Leyens, and India, Amit Kumar Dinda.
    - Bill also thanked all the countries' GCRSR members for attending the GCRSR Executive meeting.
    - The co-chairs also thanked Birgit Sokull-Kluettgen and Anil Patri and the scientific program committee for putting together an exciting and informational meeting.
    - This is the 9th Global Summit on Regulatory Science that the GCRSR has co-hosted and both Marta and Bill expressed their excitement for the GSRS as it continues to move forward.
- **Summary of Accepted Minutes from the 2018 Annual GCRSR Executive Committee Meeting Held on September 17, 2018**
    - Bill thanked Xingchao Geng for an excellent meeting on Dietary Supplements and Herbal Medicine in Beijing, China last September.
- **Vote on Acceptance of GCRSR Executive Committee Meeting Teleconference Minutes dated February 13, 2019**
    - Bill presented the official minutes and asked for a vote to accept the minutes and asked if there were any additional comments/changes.
        - No additional comments/changes were provided.
    - A motion was made by Primal Silva to accept the GCRSR Executive

Committee Meeting Teleconference Minutes dated February 13, 2019.
- **The minutes were approved by a voice vote of all voting members.**

- **GSRS19 Scientific Program Overview (Anil Patri and Birgit Sokull-Kluettgen)**
  - Birgit gave an overview of the scientific program of the upcoming GSRS19 meeting.
  - Birgit reported that there is a total of 196 registered participants from 34 different countries that were registered for the GSRS19 Conference.
  - The GSRS19 Nanotechnology and Nanoplastics will take place at hotel la Palma located in Stresa, Italy.
  - Both Birgit and Anil thanked all the world agencies that contributed to the success of the 2019 GSRS meeting.
  - The theme and topics that are being covered at this year's meeting include Nanotechnology and Nanoplastics.
  - The scientific program committee is trying to bridge the challenges and priority research areas that our agencies face.
  - Anil thanked all of those by name that were part of the scientific program committee.
  - Anil hopes this will unlock future collaboration and looks forward to future collaboration with the many agencies.
  - Bill stated that this is an exciting topic and feels by having this conference now that the GCRSR and all agencies involved are trying to get out in front of Nanoplastics as this is a global challenge.

GCRSR Working Groups:

- **Emerging technologies (William Slikker)**
  - Bill brought to the attention of the members the 2017 manuscript that was completed in 2018 and published in the Summer of 2018 before the 2018 GSRS in Beijing.
  - Weida Tong, Shraddha Thakkar and others are still working to complete the 2018 summary manuscript. The manuscript is very close to completion and is just waiting on final clearances from a few authors.

- **Working Group Reports**
    - Bill is looking for membership on the emerging technology working group.
    - Currently there are only 3 countries that are involved in the emerging technologies working group.
    - Please e-mail Bill (William.Slikker@fda.hhs.gov) or Justin Wiencek (Justin.wiencek@fda.hhs.gov) if you are interested in joining the Emerging Technologies working group.
    - The GSRS 2020 meeting will focus on Emerging Technologies. This will be the theme for the 2020 meeting.
    - Lyda Lyens proposed that one topic area that would be of interest would be AI.
    - Weida discussed that a future meeting may include an AI meeting.
    - Elke mentioned that the EU just published a flagship publication on AI.
    - Reinhilde Schoonjans stated there is still a strong need for the inclusion of research on the microbiome.
- **Bioinformatics (Weida Tong)**
    - Weida gave a brief summary on the Bioinformatics Working group, which is also looking for additional members.
    - The focus of the work group is technical, reliability, and utility of the Bioinformatics working group.
    - Weida provided background information and functions of the Bioinformatics working group.
    - The 2nd working group is working on finalizing the 2018 GSRS summary manuscript.
    - Shraddha Thakkar gave an update and a brief summary of the GSRS18 manuscript.
    - Its contents are what was presented and gleaned from the 2018 GSRS presentations and meetings.
    - A major outcome was discovered that there are many “grey” areas during the presentations on herbal medicines.
    - The working group concluded that there is a need to move toward a more harmonization of government agencies.

    - This was a great review of where we are and where we need to go.
    - Weida expressed the type of expertise needed for the working group on Bioinformatics science. Particularly those dealing with statistical data analysis.
        - Toru Kawanishi expressed interest and will work in providing help for the Bioinformatics working group.

- **Nanotechnology (Anil Patri)**
    - Anil presented the current activities for Nanotechnology working group.
        - Investment in Nanotechnology is still moving forward.
        - The need to continue to develop standards.
        - Anil discussed the standards across all of Nano and the challenges of the Nanotechnology.
        - Anil discussed features of the Nanoplastics and how it is a global problem.
        - A Nanomedicine subgroup has been established.
    - The working group has also been very involved with organizing the GSRS19 meeting.
    - A lot of progress has been made through the Nano Task Force and the NTF will soon release a report.
    - EFSA is in the process of organizing a Scientific Colloquium on Nanoplastics in June 2020.
    - Primal thanked Anil and the Nano working group program committee as well as their scientific work.
    - Primal offered those that are interested in collaborations to please let him know specifically if interested in Nanoplastics.
    - Elke also suggested the facilities of JRC are well equipped to research Nano.
    - Elke talked about the standardization of Micro plastics. She also discussed the current research that is being conducted at JRC and the challenges of micro plastics research.
  - It was identified that communication, visibility and awareness need to expand and continue to develop.
  - Amit Kumar Dinda gave a summary of the Nano work that is being conducted in India and a few of the challenges of Nanotechnology.

- **Scientific Exchange Program – Cross-Training (Primal Silva)**
    - Primal thanked Shraddha and others who have participated in the working group.
    - New member Jung Kwon Yong from South Korea joined the working group.
    - The working group updated the catalog with information from FDA and EFSA.
    - The working group will continue to update the catalog as new information becomes avalible.
    - Contributions to the catalog are compiled from several countries and agencies.
    - Primal asked that you spread and promote the information amongst your agencies and organizations about the catalog.
    - Once the catalog is hosted on the website, Shraddha will share the link with Justin and he will send out to the members of the GCRSR for test and evaluation.
    - Please send any feedback you may have to Primal and Shraddha.
- **Shared Regulatory Research Priorities Working Group (SRRP WG) (Primal Silva and Marta Hugas)**
    - How can we share the regulatory research with all the agencies?
        - November 2018 was the first meeting.
        - Terms of reference were established.
        - As research priorities evolve they will be updated as they are given to the work group.
        - The working group is scheduled to meet again in the spring of 2020.
            - Canada, USA, EU and Japan are the current stakeholders.
        - Please send any contributions or suggestions to Primal.
        - Primal presented the many areas of the research priorities.
        - Weida asked who will maintain this and the catalog.
            - Primal stated that it is up to all of us to ensure the currency of the document.
        - A question was asked if once a research priority has been “solved” then will a repository be developed.
            - Primal stated that if dropped from the list it will be stated as such in the document on the website with an asterisk or another way to identify the research priority that is no longer needed.

        - Anil will give a summary of the Nano achievements tomorrow at the GSRS meeting. This will be documented in the research catalog.
- Theme and Location (local host) for the GSRS20
    - The GSRS 2020 meeting will focus on Emerging Technologies particularly the ones that promise to be used in regulatory decision making.
    - This will be the 10th anniversary of the Global Summit on Regulatory Science.
    - Bill proposed the GSRS20 meeting to be at the campus of NIH in Bethesda MD.
        - The National Center for the Advancement of Translational Science (NCATS) will be the co-hosting this along with the GCRSR.
        - Possibly have a training course.
        - Two and half days of presentations which will cover September 28-30, 2019.
        - Anil gave a brief presentation and overview of the venue.
    - Focus will be fit for purpose Emerging Technologies.
            - Possible topics include for the 2020 meeting are AI, precision medicine, imaging, and the microbiome.
        - Please send e-mail if you would like to be on the scientific, committee to Bill or Justin (Willam.Slikker@fda.hhs.gov or Justin.wiencek@fda.hhs.gov).
        - Primal suggested to have interdisciplinary topics and try not to get siloed into one area.
        - A suggestion was made to have a specific Emerging Technology and expand it from there.
        - Also focus on what is regulated in our agencies, foods and drugs in particular.
- GCRSR Leadership Discussion
    - Bill gave an overview of the GCRSR for the benefit of the country representatives from India and Switzerland. If they would like to become part of the GCRSR they will need to speak with the head of their agencies to determine the level of interest to become a member.
    - Supriya inquired if we want to expand the research topic areas or keep the same rotation of the working groups and having the theme tied to those

working groups.

    - This will be discussed further in a latter teleconference.

- Adjournment
  - Meeting adjourned at 5:04pm.
- Photo of GCRSR Participants
  - Photo was taken of all of those in attendance at the 2019 GCRSR meeting.

GSRS20 – Conference at a Glance

Plenary Session 1

Update on emerging technologies for regulatory application – A global perspective

Track A: Artificial Intelligence (AI)	Track B: OMICS, Biomarkers, Precision Medicine	Track C: Microphysiological Systems (MPS) and Stem Cells

Plenary Session 2

Update on emerging technologies for regulatory application – A global perspective

Track D: Bioimaging	Track E: Microbiome
Workshop 1: Artificial Intelligence (AI)	Workshop 2: Nanotechnology/ Nanoplastics

Working Group Reports

FOOD BIOLOGICAL CONTAMINANTS

Baseline Practices for the Application of Genomic Data Supporting Regulatory Food Safety

Dominic Lambert
Canadian Food Inspection Agency, Ottawa Laboratory (Carling), Ottawa, ON, Canada
Arthur Pightling
U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, College Park, MD
Emma Griffiths
Simon Fraser University, Department of Molecular Biology and Biochemistry, Burnaby, BC, Canada
Gary Van Domselaar
Public Health Agency of Canada, National Microbiology Laboratory, Winnipeg, MB, Canada
Peter Evans
U.S. Department of Agriculture, Food Safety and Inspection Service, Washington, DC
Sharon Berthelet
Canadian Food Inspection Agency, Ottawa Laboratory (Carling), Ottawa, ON, Canada
Duncan Craig
Food Standards Australia New Zealand, Canberra, Australia
P. Scott Chandry
Commonwealth Scientific and Industrial Research Organisation, Melbourne, Australia
Robert Stones
Food and Environment Research Agency, Sand Hutton, York, United Kingdom
Fiona Brinkman
Simon Fraser University, Department of Molecular Biology and Biochemistry, Burnaby, BC, Canada
ALexandre Angers-Loustau and Joachim Kreysa
European Commission, Joint Research Center, Ispra, Italy
Weida Tong
U.S. Food and Drug Administration, National Center for Toxicological Research, Little Rock, AR
Burton BLais [1]
Canadian Food Inspection Agency, Ottawa Laboratory (Carling), Bldg 22, 960 Carling Ave, Central Experimental Farm, Ottawa, ON, Canada K1A 0Y9

The application of new data streams generated from next-generation sequencing (NGS) has been demonstrated for food microbiology, pathogen identification, and illness outbreak detection. The establishment of best practices for data integrity, reproducibility, and traceability will ensure reliable, auditable, and transparent processes underlying food microbiology risk management decisions. We outline general principles to guide the use of NGS data in support of microbiological food safety. Regulatory authorities across intra- and international jurisdictions can leverage this effort to promote the reliability, consistency, and transparency of processes used in the derivation of genomic information for regulatory food safety purposes, and to facilitate interactions and the transfer of information in the interest of public health.

Received August 17, 2016. Accepted by AH November 22, 2016.

The opinions expressed by the authors do not necessarily reflect the opinions or policies of their respective institutions. Any statements in this article should not be considered present or future policy of any regulatory agency.

The authors declare no conflicts of interest.

[1] Corresponding author's e-mail: burton.blais@inspection.gc.ca; burton.blais@canada.ca

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Report on the
2016 Global Summit on Regulatory Science (GSRS16)
Nanotechnology Standards and Applications

7-9 September 2016

**U.S. National Institutes of Health Campus, Natcher Auditorium,
Bethesda, Maryland, USA**

1.0 Introduction

The global increase in applications of nanotechnology has produced medical and consumer products with new or enhanced functionality. Nanotechnology-enabled devices are faster, smaller, lighter, and smarter. In the medical field, there are new developments in precision and targeted medicines for improved therapeutic outcomes, while minimizing toxicity and patient side-effects. New *in vitro* diagnostics and *in vivo* imaging agents are under development for early disease detection, and there is continued improvement of advanced medical devices. These exciting advances in science, technology, and medicine provide an opportunity for additional regulatory science research to ascertain how different nanomaterial characteristics influence biological attributes, biocompatibility, biodistribution, safety, and efficacy. The 2016 Global Summit on Regulatory Science (GSRS16) was a collaborative effort among global regulatory, standards, and research agencies, and stakeholders from industry and academia. GSRS16 was aimed at highlighting recent advances in nanotechnology, educating the community on current research and regulatory perspectives, and developing consensus on the needs for nanotechnology standards. A major goal of this summit was to establish an inventory of research and standards critical to supporting the responsible development and safety evaluation of nanotechnology-based products. In this report, the general term “standard” encompasses consensus-based documentary standards, reference materials (RMs), and guidance documents.

OUTLINE

Global Coalition for Regulatory Science Research (GCRSR)

Cross-Training Working Group

The Global Coalition for Regulatory Science Research (GCRSR)

The GCRSR was officially established in 2013 and consists of representative governmental agencies that regulate food and medical products in many countries. Its mission is to communicate, among the global researchers/regulators, current advances in science and their potential to impact the global regulatory process.

Scope of Cross-Training Working Group

At the GCRSR Executive Committee meeting on September 6, 2016, a consensus was reached that the Coalition would benefit from *strengthening* GCRSR capabilities in areas of training and collaborative research opportunities and called for establishment of the Cross-Training Working Group (CTWG). Dr. Primal Silva, Canadian Food Inspection Agency will act as Chair of the CTWG to establish the group. Nominations for co-chair are welcome. Ongoing implementation of the group will be maintained by the GCRSR Secretariat.

Objectives

The two objectives of Cross-Training Working Group are to:

1. Strengthen personnel training through the establishment of a network for the sharing of relevant training opportunities,
2. Build capacity and promote scientific collaboration within the Coalition by enabling discussions on strategic personnel exchanges.

Potential Projects

1. Compile currently available training opportunities and resources
2. Enhance understanding of how Coalition partners conduct personnel training
    - Share standard training practices to enhance understanding the common practices
    - Examine opportunities for interoperability of training modules
3. Conduct gap analysis of current training opportunities for regulatory food and safety personnel
    - Identify gaps in the currently available training opportunities based on the training catalogue and input from working group participants
    - The training designed to address this gap could then be provided as a session during GSRS
4. Promote personnel exchanges and collaboration within the Coalition partners to facilitate personnel competency development and capacity building

Possible deliverables

1. Catalogue of training opportunities
2. Shared training resources to address gaps in currently available training opportunities (designed for Coalition participants)
3. Personnel exchanges and scientific collaborations between Coalition members
4. Compilation of best practices on personnel training

Outcomes

Cross-Training Working Group will encourage interactions among Coalition members through targeted personnel exchanges, scientific collaborations, sharing best practices and collaboratively producing training catalogue.

Contact:
Dr. Margaret Neuspiel
Margaret.Neuspiel@inspection.gc.caDr. Masha Cemma

Global Coalition for Regulatory Science Research (GCRSR)

Shared Regulatory Research Priorities Working Group Terms of Reference

The Global Coalition for Regulatory Science Research (GCRSR)

The GCRSR was officially established in 2013 and consists of representative governmental agencies that regulate food and medical products in many countries. Its mission is to communicate, among the global researchers/regulators, current advances in science and their potential to impact the global regulatory process.

Scope of Shared Regulatory Research Priorities Working Group

At the 2018 Global Summit on Regulatory Science (GSRS), consensus was reached that the Coalition would benefit from combining shared research priorities of the GCRSR members and called for establishment of the Shard Regulatory Research Priorities Working Group (SRRP WG). Primal Silva (Canadian Food Inspection Agency) and Marta Hugas (European Food Safety Authority) will act as co-Chairs of the SRPWG. Ongoing implementation will be maintained by the GCRSR Secretariat.

Objectives

The objectives of SRRP WG are to:

1. Collect future research priorities in regulatory science and inform funding organizations by leveraging shared priorities among GCRSR members.
2. Positively impact innovation of technology in the pre-market approval stage to support advancements in regulatory science.

Potential Projects

1. Create an inventory of SRRPs of GCRSR members and shortlist the top shared priorities.
    - Include in a dynamic table within an evergreen document.
2. Outreach to countries not involved in WG to incorporate their priorities as well.
3. Develop a work plan to position the GCRSR top SRRPs for a position paper.

Possible deliverables

1. Position paper about SRRPs on behalf of the GCRSR.
    - Two to three pages, to be published

Outcomes

The SRRP WG will leverage shared priorities among Coalition members to influence funding organizations and inform future research priorities in regulatory science. The SRRP WG will positively impact technological innovation in the pre-market approval stage to support advancements in regulatory science.

Contact:

Dr. Primal Silva *primal.silva@canada.ca*
Dr. Marta Hugas *marta.hugas@efsa.europa.eu*

GCRSR Executive Committee Meeting 2020 Participants' Biographical Sketches

Li Bo, PhD

Director
National Institutes for Food and Drug Control (NIFDC)
China Food and Drug Administration (CFDA)
CHINA

Email: libo@nifdc.org.cn

Dr. Li Bo is Director General of National Institutes for Food and Drug Control (NIFDC), China Food and Drug Administration (CFDA), as well as Chairman of Council for Bioassay, China Pharmacopoeia Committee, and Chairman of Council for Drug Safety Research and Evaluation, Chinese Pharmaceutical Association. His main research area is safety evaluation drugs. He firstly established a safety evaluation system in accordance with the international GLP standards in China, presided over 11 national and provincial projects, and developed new technologies and new methods on immune toxicity, biological distribution, tissue cross reactivity, and new biological markers. Leading the academic field of the safety evaluation of biotech drugs, he established the academic committee in this field to promote the standardization development of GLP in China. He also developed a series of technical standards for the national standard of bacterial endotoxin, which had independent intellectual property rights in China, and improved the quality control level of products and ensured the drug safety. He is the recipient of several public health awards such as the second prize of China National Science Progress Award and the second prize of the Beijing Science Progress Award. Dr. Li published widely in journals and books in the field of drug safety and quality. He is the author of *Safety Evaluation of Biotechnology Pharmaceuticals* and *Methodology of New Drug Research in Toxicology et al*.

Xingchao Geng, PhD

Professor
National Center for Safety Evaluation of Drugs (NCSED)
National institutes for Food and Drug Control (NIFDC)
China Food and Drug Administration (CFDA), CHINA
CHINA

Dr. Xingchao Geng received his bachelor and master's degree from Peking University Health Science Center (Beijing, China) and PhD in pharmacology at The Fourth Military Medical University in China. He joined the National Center for Safety Evaluation of Drugs (NCSED), National Institutes for Food and Drug Control (NIFDC) for Toxicological Research to develop toxicological methods for safety evaluation of novel drugs in 2004. Currently, Xingchao Geng is deputy director of NCSED/NIFDC. He is excellent in pharmacology and new compound researching and discovery. He has more than 20 years of experience in drugs screening and studying, especially in safety evaluation of drugs, and has performed about 100 non-clinical drug safety assessment studies according to GLP regulations including 20 international studies from USA and France. He specializes in the research of new biomarkers, immunotoxicity and hepatotoxicity research. He has published more than 50 papers and book chapters and has been invited to present in national and international conferences. As a visiting scholar, he worked and was trained in Huntingdon Life Sciences Company in United Kingdom, National Toxicology Research Center (NCTR) of US FDA, the United States Environmental Protection Agency (EPA), and National Institute of Environmental Health Sciences (NIEHS), *et al*.

Toru Kawanishi, PhD

Commissioner
Food Safety Commission of Japan
Cabinet Office, Government of Japan
JAPAN

Email: Toru.kawanishi.y3b@cao.go.jp

Dr. Toru Kawanishi is a Commissioner of Food Safety Commission, Cabinet Office, Japan, since July 2018.

He graduated from the University of Tokyo, Faculty of Pharmaceutical Sciences, and joined the National Institute of Health Sciences (NIHS) of Japan in April 1978. He had engaged in the study on test and evaluation methods of quality, safety and efficacy of chemical and/or biological/ biotechnological products in Division of Pharmacology, Division of Pathology, Division of Biological Chemistry and Biologicals, and Division of Drugs of the NIHS. He was then promoted to the Deputy Director-General of the NIHS in April 2011 and to the Director-General from April 2013 to March 2018. He holds a PhD (1986) in pharmaceutical sciences from the University of Tokyo.

He is the author of more than 270 scientific papers about Regulatory Science of medical products; he has also authored books and international and national scientific journals on the topic of chemical and food safety.

A list of his activities is below:

- Member, Health Sciences Council
- Member, Pharmaceutical Affairs and Food Sanitation Council
- Advisor, Pharmaceuticals and Medical Device Agency (PMDA)
  - Reviewing quality and safety aspects of new drugs submitted for registration
- Program Supervisor, Agency for Medical Research and Development (AMED)
  - field of Regulatory Science in Japan
- Committee Chair, Food Safety Commission of Japan
  - Expert Committee on Planning

Kumiko Ogawa, M.D., PhD

Head of Division of Pathology
National Institute of Health Sciences (NIHS)
JAPAN

Dr. Kumiko Ogawa graduated (1988) and received PhD (1993) from Nagoya City University Medical School, then continued research as a postdoctoral research associate in Pathology and Microbiology, University of Nebraska Medical Center (1993-1996). After serving in Experimental Pathology and Tumor Biology, Nagoya City University and Nagoya Higashi Municipal Hospital, she joined Division of Pathology, National Institute of Health Sciences (2009). She is a board-certified specialist of Japanese Society of Pathology and Japanese Society of Toxicologic Pathology. Her research interest includes toxicological pathology and carcinogenesis. She has been an expert committee member of the Food Safety committee in Japan and several evaluation committees for chemical safety in Japanese government.

Yukihiro Goda, PhD

Director-General
National Institute of Health Sciences (NIHS)
Ministry of Health, Labor, and Welfare (MHLW)
JAPAN

Dr. Yukihiro Goda is Director-General of National Institute of Health Sciences (NIHS) from 2020. He received his PhD degree from the faculty of Pharmaceutical Sciences, the University of Tokyo in 1985. Then, he started his carrier as a researcher of the division of Food Additives in NIHS, and was moved to a section chief of the division of Foods. In 2001, he was promoted to the head of the division of Pharmacognosy, Phytochemistry and Narcotics, and in 2013 he was moved to the head of the division of Drugs, and in 2018, Deputy Director Genral of NIHS. His expertise includes regulatory science of pharmaceuticals, natural medicines, illegal drugs, borderline products between foods and drugs, and natural product chemistry. He had been the chair of the expert committee of natural medicines from 2002 to 2013 in the Japanese Pharmacopoeia (JP) committee. Since 2013 he has been the chair of the expert committee of synthetic drugs in JP comittee. Also, since 2018 he has been the chair of the expert committee of planning in the Food Safety committee in Japan.

Kazuo Koyama, PhD

Senior Staff
Food Safety Commission of Japan (FSCJ)
JAPAN

Dr. Kazuo Koyama is Senior staff at the Food Safety Commission Secretariat, Cabinet Office, Government of Japan (FSCJ), since July 2018. He has been involved in analysis of scientific information regarding food safety. From 1997 to 2018, he worked for the House Foods Corporation where he focused on the development of reduction and analysis methods for hazardous chemical substances. He graduated from the University of Tsukuba, Faculty of Science & Engineering (1997). He holds a PhD (2013) in pharmaceutical sciences from the University of Kanazawa, Faculty of Natural Science & Technology.

Joanne Chan, PhD

Centre Director of the National Centre for Food Science
Singapore Food Agency
SINGAPORE

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A/P Joanne Chan is the Centre Director of the National Centre for Food Science at the Singapore Food Agency (SFA) in Singapore since 1 April 2019. She also heads the WHO Collaborating Centre on Food Contamination Monitoring and OIE Collaborating Centre on Food Safety in Singapore.

She is a chemist and she has spent over 28 years contributing to building laboratory capacity for Singapore's food safety system. She has contributed to the ASEAN region's capacity building programme as member of the ASEAN Food Testing Laboratory Committee since its formation in 2004. She has a co-appointment as Adjunct Assistant Professor with the National University of Singapore. She co-chairs the Council Committee testing of Laboratory under the national accreditation council (Singapore Accreditation Council) and serves in the advisory panel of the national chemical metrology's programme in chemical testing.

Jun Young Yang, PhD

Scientific officer, Toxicological Research Division
National Institute of Food and Drug Safety Evaluation (NIFDS)
Ministry of Food and Drug Safety (MFDS)
REPUBLIC OF KOREA

Email: yangjy@korea.kr

Dr. Jun Young Yang is the scientific officer of Toxicological Research Division at National Institute of Food and Drug Safety Evaluation (NIFDS), Ministry of Food and Drug Safety (MFDS). He received his PhD in the college of Life Science and Biotechnology, Yonsei University. He started his career as a scientific officer in NIFDS, where he has been since 2006. He worked as toxicologist at reproductive & developmental toxicology division from 2006 to 2009. Also he worked at Korean Center for Validation Alternative Method(KoCVAM) from 2009 to 2014. He serves as Korea GLP(Good Laboratory Practice) inspector. Currently he is working for Korea National Toxicology Program(KNTP) of NIFDS.

Scott Crerar, PhD

General Manager, Science and Risk Assessment
Food Standards Australia New Zealand
AUSTRALIA

Dr. Scott Crerar is General Manager of the Science and Risk Assessment Branch at Food Standards Australia New Zealand (FSANZ). This role is responsible for overseeing the scientific and risk assessment functions of the agency that includes biological sciences and genetically modified foods, chemical safety (toxicology) and nutrition, food data and analysis (food composition and dietary modelling), international and strategic science activities, and chemical residue related activities. Dr. Crerar has worked in food safety and regulation for 20 years across a range of risk assessment roles including the public health assessment of agricultural and veterinary chemicals and risk assessment of chemical and microbiological hazards across numerous primary production sectors. Dr. Crerar previously managed the FSANZ Science Strategy and the international activities including aspects relating to the APEC Food Safety Corporation Forum. Dr. Crerar is a veterinary science graduate and has post-graduate degrees in microbiology and epidemiology.

Marta Hugas, PhD

Chief Scientist
European Food Safety Authority (EFSA)
EU

Email: Marta.Hugas@efsa.europa.eu

Dr. Marta Hugas is serving as Chief Scientist at the European Food Safety Authority. This position addresses the development of EFSA's scientific strategic direction; acting as focal point on scientific matters and facilitating the understanding of science; fostering scientific cooperation as well as leveraging connections and networks for promoting EFSA's research priorities. She joined EFSA in 2003 and has since held several positions: Head of Biological Hazards Unit (BIOHAZ), Head of the Risk Assessment and Scientific Assistance Department (RASA), and Head of the Biological Hazards and Contaminants Unit (BIOCONTAM). Recently she has been appointed by the UN secretary general to the scientific group for the preparation of the 2021 UN summit on Food Systems.

Marta holds a BSc in biological sciences, an MSc in genetics and microbial biotechnology and a PhD in food microbiology. Prior to joining EFSA, she worked for the Institute for Food and Agricultural Research and Technology (IRTA) in Spain, where she was Head of the Food Microbiology and Biotechnology Unit and led a research group on applied research on meat and food safety. From 1992 to 2004 she was an Associate Professor at the University of Barcelona. Marta's areas of expertise focus on food hygiene, development of starter and bio protective cultures, probiotics for the safety of poultry meat, emerging preservation technologies as well as risk assessment of biological hazards. Dr. Hugas has extensively published papers and book chapters.

Elke Anklam, PhD

Director
Institute for Reference Materials and Measurements European Commission
Joint Research Center
BELGIUM

Email: Elke.ANKLAM@ec.europa.eu

Elke Anklam is a chemist with specialization in food, organic and radiation chemistry. After obtaining her PhD from the University Hamburg, Germany, she worked in various European Research Institutions and was a teaching professor at the Applied University of Fulda, Germany.

Since 1991, she has been working at the European Commission's Joint Research Centre (EC- JRC). From 2006 to2012, she was Director of the JRC-Institute for Health and Consumer Protection (IHCP) in Ispra, Italy and from 2012 to July 2016, Director of the JRC-Institute for Reference Materials and Measurements in Geel, Belgium.

Since July 2016, she is the Director of the JRC-Geel site and the new JRC Directorate F: Health, Consumers & Reference Material (a merger of the former IHCP and IRMM), located at the JRC-Geel and JRC-Ispra site.

Deputy Executive Director

Deputy Executive Director
Swissmedic, Swiss Agency for Therapeutic Products
SWITZERLAND

Email: Philippe.Girard@swissmedic.ch

Dr. Girard is Swissmedic's Deputy Executive Director. Philippe still heading the licensing sector and has special assignments within the Agency to drive the digital transformation forward and to reorganize the institution's information technology. He is responsible for major IT-projects and is driving several legislation projects in the fields of ATMP, devitalized cell preparations and patient's access to cannabis.

Philippe worked as a consultant, was the founder of a start-up and worked for the pharmaceutical industry prior to joining the Swissmedic. In 2007 Dr. Girard started as Head of Division for the Swissmedic OMCL (Laboratories) responsible for the analytical support for all operative sectors within the Agency. 2013 he became the Deputy Head of Sector and in 2015 Head of Sector Licensing and Board Member. Philippe was an Expert for the European Pharmacopeia and a member of the Advisory Group of the General OMCL Network. He also acted as a guest-lecturer at technical university HES-SO Valais Wallis. Philippe was responsible for the Quality Management System of the Agency and was key in the elaboration of the legislation following ratification of the Medicrime Convention in Switzerland.

Dr. Girard holds a PhD in bioprocess development from the Swiss Federal Institute of Technology Lausanne and a diploma in chemical engineering after studies at the Swiss Federal Institute of Technology Lausanne and the Iowa State University College of Engineering in Ames (USA).

North America

Primal Silva, BVSc, PhD

Chief Science Operating Officer
Canadian Food Inspection Agency (CFIA)
CANADA

Email: primal.silva@inspection.gc.ca

Dr. Primal Silva is a veterinarian and a scientist who has a PhD from the University of Sydney, Australia, and several years of postdoctoral studies at McMaster University and the Ontario Veterinary College, University of Guelph. He worked as an assistant professor at the University of Guelph before joining the federal public service in 1993 where he has held several positions with increasing responsibilities. Dr. Silva is currently the Chief Science Operating Officer in the Science Branch of the Canadian Food Inspection Agency. He is responsible for providing strategic leadership and ensuring sound management of CFIA's 13 laboratories to deliver the Agency's high priority needs in mandated science functions in Food Safety, Animal Health, and Plant Health. He provides strategic leadership and manages the Agency's research program, the CFIA's science engagements with national and international organizations. In 2016, Dr. Silva led the formation of the Biosafety Level 4 Zoonotic Laboratory Network (BSL4ZNet), a global alliance of government mandated organizations from five countries, which aims to strengthen international coordination to meet current and future high containment needs. He is also a contributing member to numerous committees and working groups at domestic and international levels including the Scientific Advisory Body of OECD.

Supriya Sharma, MD, MPH, FRCPC

Chief Medical Advisor
Health Canada
CANADA

Email: Supriya.Sharma@Canada.ca

Dr. Supriya Sharma became Health Canada's Chief Medical Advisor in August 2015. She added these responsibilities to those in the role of Senior Medical Advisor in the Health Products and Food Branch, a role she has had since March 2013. The Health Products and Food Branch has the responsibility to regulate pharmaceuticals, medical devices, biologics, vaccines, natural health products, veterinary medicines, and food. Prior to that, Dr. Sharma has held a number of positions in Health Canada over the past decade in both the pre-market and post-market health product regulatory areas including most recently Director General of the Therapeutic Products Directorate, which had the regulatory responsibility for pharmaceuticals (prescription and non-prescription) and medical devices. She has also worked as a Senior Policy Advisor as part of the National Pharmaceuticals Strategy in Health Canada. Recently, she has returned to Health Canada following a leave of absence to work in an academic research group focusing on health innovation adoption in the Canadian Health system.

Trained as a pediatrician in both Canada and Australia, Dr. Sharma was a research fellow in hematology focused on clinical research relating to thalassemia and sickle cell disease and has worked on a number of large multi-center clinical studies, including research in collaboration with Oxford University on a project in Sri Lanka. She then went on to complete a Master of Public Health at the Harvard School of Public Health with a concentration in International Health and an interest in Health Policy.

William Slikker, Jr., PhD

Director
National Center for Toxicological Research (NCTR), FDA
USA

Email: William.Slikker@fda.hhs.gov

Dr. William Slikker, Jr. received his PhD in pharmacology and toxicology from the University of California at Davis. Dr. Slikker holds adjunct professorships in the Department of Pediatrics, as well as the Department of Pharmacology and Toxicology at the University of Arkansas for Medical Sciences. He has held committee chairmanships or elected offices in several scientific societies including the Teratology Society (serving as president) and the American Society for Pharmacology and Experimental Therapeutics (chair, Developmental Pharmacology Section and member, Program Committee). Dr. Slikker is also the co-founder and past president of the MidSouth Computational Biology and Bioinformatics Society. He is currently associate editor for *NeuroToxicology* and associate editor for the "Environmental Health" section of *Experimental Biology and Medicine*. He is the past president of The Academy of Toxicological Sciences and the Society of Toxicology. He is a recipient of the 2014 George H. Scott Memorial Award from The Toxicology Forum and was invited to present the Warkany Lecture at the 2015 annual meeting of the Teratology Society. In early 2019, the Academy of Toxicological Sciences selected Dr. Slikker to receive the prestigious Mildred S. Christian Career Achievement Award. Currently Dr. Slikker is the director of FDA's National Center for Toxicological Research (NCTR).

Weida Tong, PhD

Director, Division of Bioinformatics and Biostatistics
NCTR/FDA
USA

Email: weida.tong@fda.hhs.gov

Dr. Tong is Director of Division of Bioinformatics and Biostatistics at FDA's National Center for Toxicological Research (NCTR/FDA). He has served as a science advisory board member for several large projects involving multiple institutes in Europe and USA. He also holds several adjunct positions at universities in US and China. His division at FDA is to develop bioinformatic methodologies and standards to support FDA research and regulation and to advance regulatory science and personalized medicine. The most visible projects from his group are (1) leading the Microarray Quality Control (MAQC) consortium to develop standard analysis protocols and quality control metrics for emerging technologies to support regulatory science and precision medicine; (2) development of liver toxicity knowledge base (LTKB) for drug safety; (3) *in silico* drug repositioning for the enhanced treatment of rare diseases; and (4) development of the FDA bioinformatics system, ArrayTrack™ suite, to support FDA review and research on pharmacogenomics. In addition, his group also specializes in molecular modeling and QSARs with specific interest in estrogen, androgen, and endocrine disruptor. Dr. Tong has published more than 230 papers and book chapters.

Terms of Reference

Executive Committee Global Coalition for Regulatory Science Research

Purpose

The primary purpose of the Executive Committee (the Committee) is to guide the formation and development of a global coalition that forges international partnerships and collaborations. The activities of the Committee will facilitate and promote the development of regulatory science research as a tool for advancing regulatory science applicable to the public health impacts of safe food and therapeutic products.

Role

The Committee will guide the activities of the Global Coalition on Regulatory Science Research (the Coalition) through promotion and development of research needed to support regulatory decision making, establishment of best practices to understand and interpret data from innovative technologies, and facilitation of translation of basic science innovations into regulatory applications applicable to public health impacts of safe food and medical products. The Committee's activities will include:

- Establishing a sustainable and annual Global Summit on Regulatory Science (GSRS)
- Facilitating global collaborations in advancing regulatory science
- Identifying specific topics of regulatory science to be considered by the Coalition and the critical research, scientific questions and consensus building needs
- Developing and implementing strategies to facilitate development of new technologies from basic research to regulatory decision making tools
- Developing strategies for training of regulatory scientists in a global setting, including exchanging students and scientists
- Evaluating the impact of the Coalition activities
- Other activities as agreed by the Committee.

Boundaries

The Committee (and Global Coalition) will focus on scientific issues related to advancing the regulatory science applicable to safe food and therapeutic products. Scientific issues relevant to other regulated products, such as tobacco and cosmetics, are outside the scope and mandate of the Committee (and Coalition).

Membership

Membership of the Committee comprises representatives of agencies responsible for the safety of food and therapeutic products are listed and updated in Annex 1. Additional members may be invited to join at the discretion of the Committee and membership will be reviewed every two years by the Committee.

The Committee is chaired by the Chair and Vice-Chair. The Chair serves a five-year term and the Vice-Chair serves a three-year term. Both positions may be renewed for one term each upon approval by the Committee.

Review

The terms of the reference for the Committee will be reviewed two years following its establishment on 10 September 2013.

Modus Operandi

Secretariat: The elected Chair provides the Secretariat for the Committee for a five-year period and subsequently will be renewable for an additional five year period if agreeable to the Chair and Steering Committee. The Secretariat will arrange meetings, circulate meeting agendas and papers, prepare outcome notes and document the Committee's activities including these associated with GCRSR working groups. The Secretary will also assist the scientific program committee of GSRS to develop Summit materials.

The Secretariat will coordinate the development of the website to communicate the Coalition activities including theses related to the Summit and Working Groups with the public. In addition, the Secretariat will communicate with the Committee members and other interested parties in a timely manner and will post materials on the website.

Meetings: the Committee will meet at least biannually with one meeting being held in conjunction with the Global Summit on Regulatory Science. The Committee will utilize both face to face and electronic opportunities for meeting.

The Chair and Vice Chair will be engaged on development of the agendas and co-chairing of the Executive Committee meetings, as well providing leadership and chairing sessions for the annual Summit.

Working Groups: as appropriate, the Committee may establish working groups to assist in its activities, which will be chaired by members of the Committee. Each Working group will establish its own mandate and elect its Chair. The mandate, expected outputs, and defined life span of each Working Group should be agreed by the Executive Committee. Working groups should report regularly to the Committee and present proposed strategies and activities for endorsement by the Committee. Each Working group should be reviewed periodically by the Committee.

Decision Making

Decisions of the Committee will be by consensus unless otherwise decided by the Committee. If consensus cannot be reached on a matter, the Committee will vote on the matter with the majority view prevailing, where each member organization has one vote.

Confidentiality

Each Committee member will maintain the confidentiality of information in accordance with their respective laws.

Statement of Intent to Participate in the

Executive Committee for the

Global Coalition for Regulatory Science Research

Noting that in 2011, attendees at the Global Summit on Regulatory Science and Innovation explored how research could be used more effectively as a tool for advancing regulatory science, food safety, medical technologies, and global public health, and that the attendees recognized that the formation of a Global Coalition of Regulatory Research Scientists (Coalition) to work collaboratively to build knowledge, promote the development of regulatory science, and discover novel ways to clearly define research needs would strengthen the product safety net around the world; and

Further noting that the first step in building a Coalition involves formation of an Executive Committee, the United States Food and Drug Administration (USFDA) invited leaders from National Regulatory Authorities (NRAs) from across the globe to participate in an Executive Committee for the Coalition;

The undersigned (Participants) express their intent to participate in the Executive Committee of the Coalition as follows:

Purpose

This document is intended to establish and guide the work of the Executive Committee toward the formation and development of an international coalition, which forges international partnerships and collaborations that facilitate and promote the development of regulatory science. Specifically, the Executive Committee is intended to guide the Coalition to promote and develop the research needed to support regulatory decision making, establish best practices to understand and interpret data from innovative technologies, and facilitate the translation of basic-science innovation into regulatory applications. These goals may be accomplished by: (1) holding workshops, conferences and scientific meetings that build a common understanding of regulatory science research needs, approaches and interpretation, (2) exchanging scientists and students for the purpose of promoting the development of regulatory science research, (3) encouraging innovation in the development and use of Regulatory Science Principles, (4) overseeing, nurturing and promoting the sustainability of the Coalition, and (5) other appropriate activities as decided by the Participants.

Organization Leadership

The Executive Committee is intended to initiate, coordinate and evaluate all Coalition activities. At the first meeting, the Executive Committee is intended to decide on a chairperson to serve a two-year term in conjunction with the Director of the FDA's National Center for Toxicological Research (NCTR) who should serve as a co-chair for the first five years and, in subsequent years, the Committee is expected to decide on successor chairpersons.

Establishment of Meetings, Membership, and Agenda

At the first meeting, the Executive Committee is intended to: (1) develop a meeting schedule and operating procedures, (2) determine the membership of the Coalition, and (3) outline a strategic agenda for the development and sustainability of the Coalition. The Co-chairs should lead the discussion around the development and implementation of a strategic agenda for the Coalition including a decision on the Coalition's general membership; a meeting schedule including frequency of meetings and locale; the process for creation of committees needed to execute specific workshops, conferences, and scientific exchanges; and identification of potential options for identifying a sustainable funding stream. The Executive Committee should meet biannually with one meeting being held annually in conjunction with a global summit on regulatory science and Executive Committee meetings should be co-chaired by the elected co-chair and the NCTR co-chair.

For the first five-year period (September 2013 – September 2018), and renewable for five-year periods thereafter, the Executive Committee is intended to function as follows:

- NCTR should serve as the Secretariat for the Executive Committee.
- NCTR should document Executive Committee activities, including recommendations, decisions, issues, action items, meeting summaries, and other pertinent materials and should communicate the same to the Executive Committee members and other interested parties in a timely manner by posting the materials on a website hosted by FDA's NCTR.
- All decisions of the Executive Committee are to be by consensus unless otherwise decided by the Executive Committee.

Other Provisions:

All activities of the Executive Committee are to be undertaken in compliance with applicable laws and regulations of the Executive Committee Participants' countries.

All activities of the Executive Committee are to be subject to the availability of appropriated funds, personnel, and other resources.

Nothing in this Statement of Intent is intended to be binding under international or other law.

This Statement of Intent may be amended or terminated by decision of the Executive Committee and any Participant in the Executive Committee may withdraw his/her membership upon 30 days written notice to the Co-Chairs of the Executive Committee.

The undersigned express their intention to participate in the Executive Committee.

Patricia Aprea
Head of the Biological Products Department
National Administration of Drugs, Food and Medical Devices
Argentina

John Skerritt
National Manager,
Therapeutic Goods Administration,
Australia

Valeria Garay
Coordinator of ANMAT Federal Programs
National Administration of Drugs, Foods and Medical Devices (ANMAT)
Argentina

Dirceu Barbano
Head
National Health Surveillance Agency
Brazil

Roberta Sammartino
Foods Expert
National Administration of Drugs, Foods and Medical Devices
Argentina

Ana Paula Soares Juca´da Silveira e Silva
Head of the International Affairs Office
National Health Surveillance Agency
Brazil

Marion Healy
Executive Manager for Risk Assessment
Food Standards Australia New Zealand (FSANZ)
Australia

Supriya Sharma
Senior Medical Advisor
Health Products and Food Branch
Health Canada
Canada

Martine Dubuc
Chief Food Safety Officer and Vice-President, Science Branch
Canadian Food Inspection Agency
Canada

Jin-ho Wang
Director General of the National Food & Drug Safety Evaluation
National Institute of Food and Drug Safety Evaluation
Republic of Korea

Primal Silva
Executive Director
Animal Health Science Directorate/
Science Branch
Canadian Food Inspection Agency
Canada

Chew Siang-Thai
Deputy CEO
Regulatory Programmes & Operations
Director-General
Agri-Food and Veterinary Services
Singapore

Hubert Deluyker
Director of Science Strategy and Coordination
European Food Safety Authority (EFSA)
Europe

Paul Chiew King Tiong
Group Director, Laboratories Group
Agri-Food and Veterinary Services
Singapore

Nobumasa Nakashima
Office Director
Office of International Programs
Pharmaceuticals and Medical Devices Agency
Affiliate of Ministry of Health, Labour and Welfare
Japan

Margaret Hamburg, M.D.
Commissioner for Food and Drugs
Food and Drug Administration
United States of America

Yasuko Inokuma
Deputy Director, Evaluation and Licensing Division
Pharmaceutical and Food Safety Bureau
Ministry of Health, Labour and Welfare
Japan

GCRSR Published

Reports/Manuscripts

The global role of regulatory science research was recognized and discussed, and the Global Summit on Regulatory Science (GSRS11) conference was initiated.

2011

Regulatory Toxicology and Pharmacology 62 (2012) 471–473

Contents lists available at SciVerse ScienceDirect

Regulatory Toxicology and Pharmacology

journal homepage: www.elsevier.com/locate/yrtph

Workshop Report

Advancing global health through regulatory science research: Summary of the *Global Summit on Regulatory Science Research and Innovation*

William Slikker Jr.*, Margaret Ann Miller, Mary Lou Valdez, Margaret A. Hamburg

United States Food and Drug Administration, Silver Spring, MD 20993, United States

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ABSTRACT

As a first step in the implementation of the Food and Drug Administration's (FDA) Pathway to Global Product Safety and Quality (Anonymous, 2011), FDA's Office of International Programs (OIP) and the National Center for Toxicological Research (NCTR) sponsored a *Global Summit on Regulatory Science Research and Innovation*. Through a series of presentations and panel discussions, the Global Summit participants explored how research could be used more effectively as a tool for advancing regulatory science, food safety, medical technologies, and public health. Speakers provided an overview of each of the components in the global regulatory-science research initiative, including scientific innovation and modernizing toxicology; and discussed how the integration of these components is needed to achieve the promise of regulatory science at the global level. All participants agreed with the formation of a Global Coalition of Regulatory Research Scientists who will work collaboratively to build knowledge, promote the development of regulatory science, discover novel ways to clearly define research needs, and improve public health.

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The second Global Summit on Regulatory Science (GSRS12) was held in China with a theme focusing on modernizing toxicology.

2012

TOXICOLOGICAL SCIENCES 131(1), 9–12 (2013)
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Advance Access publication August 24, 2012

2012 Global Summit on Regulatory Science (GSRS-2012)—Modernizing Toxicology

Margaret A. Miller,* Weida Tong,* Xiaohui Fan,† and William Slikker Jr*,[1]

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Regulatory science encompasses the tools, models, techniques, and studies needed to assess and evaluate product safety, efficacy, quality, and performance. Several recent publications have emphasized the role of regulatory science in improving global health, supporting economic development and fostering innovation. As for other scientific disciplines, research in regulatory science is the critical element underpinning the development and advancement of regulatory science as a modern scientific discipline. As a regulatory agency in the 21st century, the Food and Drug Administration (FDA) has an international component that underpins its domestic mission; foods, drugs, and devices are developed and imported to the United States from across the world. The Global Summit on Regulatory Science, an international conference for discussing innovative technologies, approaches, and partnerships that enhance the translation of basic science into regulatory applications, is providing leadership for the advancement of regulatory sciences within the global context. Held annually, this international conference provides a platform where regulators, policy makers, and bench scientists from various countries can exchange views on how to develop, apply, and implement innovative methodologies into regulatory assessments in their respective countries, as well as developing a harmonized strategy to improve global public health through global collaboration.

Key Words: **regulatory science; food safety; toxicogenomics; global public health.**

WhatWeDo/ucm281823.htm) that was held in Hangzhou, China, on May 9–11, 2012. Over 80 scientists from 10 countries representing government, industry, and academic research communities participated in the conference to objectively assess the utility and promise of modernizing toxicology as a tool to facilitate the transfer of emerging technologies (such as toxicogenomics, next-generation sequencing, and bioinformatics) into products that benefit consumers, an important topic emphasized by the U.S. FDA's initiative on advancing regulatory science (http://www.fda.gov/downloads/scienceresearch/specialtopics/regulatoryscience/ucm268225.pdf).

The goals of the Global Summit were to (1) foster the development of sustainable regulatory systems that promote global public health by insuring the safety of medical products and food; (2) strengthen regulatory systems by instructing research scientists on the core capacities associated with conducting regulatory science laboratory studies; (3) promote the development of regulatory science as a modern discipline; and (4) develop a global coalition of regulatory research science. Presentations and panel discussions focused on four themes: (1) advancing toxicology through partnership, collaboration, and research training; (2) innovative technologies and toxicology; (3) toxicology in medical product development and safety; and (4) new paths toward advancing regulatory science. Each theme

Margaret A. Miller, Weida Tong, Xiaohui Fan, William Slikker, Jr. **2012 Global Summit on Regulatory Science (GSRS-2012) - Modernizing Toxicology**, *Tox Sci*, 131: 9-12 (2013).

Global Coalition for Regulatory Science Research (GCRSR) was established which oversees the GSRS conferences.

2013

Regulatory Toxicology and Pharmacology 70 (2014) 728–732

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Workshop Report

Global Summit on Regulatory Science 2013

Paul C. Howard [a,*], Weida Tong [a], Frank Weichold [b], Marion Healy [c], William Slikker [a]

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[c] Food Standards Australia New Zealand, Canberra BC, Australia

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ABSTRACT

Regulatory science has been defined as the science that is used to develop regulatory decisions by government bodies. Regulatory science encompasses many scientific disciplines that oversee many studies producing a wide array of data. These may include fundamental research into the cellular interaction or response to a particular chemical or substance, hazard-assessment and dose–response studies in animal species, neurophysiological or neurobehavioral studies, best practices for the generation and analysis of genomics data, bioinformatics approaches, and mathematical modeling of risk. The Global Summit on Regulatory Science is an international conference with a mission to explore emerging and innovative technologies, and provide a platform to enhance translation of basic science into regulatory applications. The Third Global Summit on Regulatory Science which focused on nanotechnology is discussed.

Published by Elsevier Inc.

Paul C. Howard, Weida Tong, Frank Weichold, Marion Healy, William Slikker. **Global Summit on Regulatory Science 2013**, *Regulatory Toxicology and Pharmacology*, 70:728–732 (2014).

GCRSR Working Groups were established to address specific areas of need for translation of emerging technologies for global regulatory application.

- **Emerging technology WG**
- **Bioinformatics WG**
- **Nanotechnology WG**

2014

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ELSEVIER

Workshop Report

Genomics in the land of regulatory science

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Next generation sequencing

ABSTRACT

Genomics science has played a major role in the generation of new knowledge in the basic research arena, and currently question arises as to its potential to support regulatory processes. However, the integration of genomics in the regulatory decision-making process requires rigorous assessment and would benefit from consensus amongst international partners and research communities. To that end, the Global Coalition for Regulatory Science Research (GCRSR) hosted the fourth Global Summit on Regulatory Science (GSRS2014) to discuss the role of genomics in regulatory decision making, with a specific emphasis on applications in food safety and medical product development. Challenges and issues were discussed in the context of developing an international consensus for objective criteria in the analysis, interpretation and reporting of genomics data with an emphasis on transparency, traceability and "fitness for purpose" for the intended application. It was recognized that there is a need for a global path in the establishment of a regulatory bioinformatics framework for the development of transparent, reliable, reproducible and auditable processes in the management of food and medical product safety risks. It was also recognized that training is an important mechanism in achieving internationally consistent outcomes. GSRS2014 provided an effective venue for regulators and researchers to meet, discuss common issues, and develop collaborations to address the challenges posed by the application of genomics to regulatory science, with the ultimate goal of wisely integrating novel technical innovations into regulatory decision-making.

Weida Tong, Stephen Ostroff, Burton Blais, Primal Silva, Martine Dubuc, Marion Healy, William Slikker. **Genomics in the Land of Regulatory Science**, *Regulatory Toxicology and Pharmacology*, 72(1):102-106 (2015).

Bioinformatics WG established a technical team to develop a white paper of using genomics for pathogen identification and outbreak detection.

2015

Regulatory Toxicology and Pharmacology xxx (2016) 1–6

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Workshop report

Regulatory bioinformatics for food and drug safety

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A B S T R A C T

"Regulatory Bioinformatics" strives to develop and implement a standardized and transparent bioinformatic framework to support the implementation of existing and emerging technologies in regulatory decision-making. It has great potential to improve public health through the development and use of clinically important medical products and tools to manage the safety of the food supply. However, the application of regulatory bioinformatics also poses new challenges and requires new knowledge and skill sets. In the latest Global Coalition on Regulatory Science Research (GCRSR) governed conference, Global Summit on Regulatory Science (GSRS2015), regulatory bioinformatics principles were presented with respect to global trends, initiatives and case studies. The discussion revealed that datasets, analytical tools, skills and expertise are rapidly developing, in many cases via large international collaborative consortia. It also revealed that significant research is still required to realize the potential applications of regulatory bioinformatics. While there is significant excitement in the possibilities offered by precision medicine to enhance treatments of serious and/or complex diseases, there is a clear need for further development of mechanisms to securely store, curate and share data, integrate databases, and standardized quality control and data analysis procedures. A greater understanding of the biological significance of the data is also required to fully exploit vast datasets that are becoming available. The application of bioinformatics in the microbiological risk analysis paradigm is delivering clear benefits both for the investigation of food borne pathogens and for decision making on clinically important treatments. It is recognized that regulatory bioinformatics will have many beneficial applications by ensuring high quality data, validated tools and standardized processes, which will help inform the regulatory science community of the requirements necessary to ensure the safe introduction and effective use of these applications.

Marion J. Healy, Weida Tong, Stephen Ostroff , Hans-Georg Eichler, Alex Patak, Margaret Neuspiel, Hubert Deluyker, William Slikker Jr. Regulatory Bioinformatics for Food and Drug Safety, *Regulatory Toxicology and Pharmacology* (2016).

Nanotechnology WG developed the white paper on advancing Nanotechnology Standards in regulatory application.

2016

Report on the
2016 Global Summit on Regulatory Science (GSRS16)
Nanotechnology Standards and Applications
7-9 September 2016

U.S. National Institutes of Health Campus, Natcher Auditorium, Bethesda, Maryland, USA

1.0 Introduction

The global increase in applications of nanotechnology has produced medical and consumer products with new or enhanced functionality. Nanotechnology-enabled devices are faster, smaller, lighter, and smarter. In the medical field, there are new developments in precision and targeted medicines for improved therapeutic outcomes, while minimizing toxicity and patient side-effects. New *in vitro* diagnostics and *in vivo* imaging agents are under development for early disease detection, and there is continued improvement of advanced medical devices. These exciting advances in science, technology, and medicine provide an opportunity for additional regulatory science research to ascertain how different nanomaterial characteristics influence biological attributes, biocompatibility, biodistribution, safety, and efficacy. The 2016 Global Summit on Regulatory Science (GSRS16) was a collaborative effort among global regulatory, standards, and research agencies, and stakeholders from industry and academia. GSRS16 was aimed at highlighting recent

OUTLINE

The Bioinformatics WG technical team developed/published the best practices document for microbial genomics in application for regulatory food safety.

2017

FOOD BIOLOGICAL CONTAMINANTS

Baseline Practices for the Application of Genomic Data Supporting Regulatory Food Safety

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The application of new data streams generated from next-generation sequencing (NGS) has been demonstrated for food microbiology, pathogen identification, and illness outbreak detection. The establishment of best practices for data integrity, reproducibility, and traceability will ensure reliable, auditable, and transparent processes underlying food microbiology risk management decisions. We outline general principles to guide the use of NGS data in support of microbiological food safety. Regulatory authorities across intra- and international jurisdictions can leverage this effort to promote the reliability, consistency, and transparency of processes used in the derivation of genomic information for regulatory food safety purposes, and to facilitate interactions and the transfer of information in the interest of public health.

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The role of regulatory food safety agencies worldwide is to pursue a scientifically informed approach in protecting consumers from preventable illnesses. The application of leading-edge analytical technologies for the detection and characterization of foodborne pathogens is one of the underpinnings of an effective risk-based regulatory food safety system. Approaches capable of maximizing the amount of information obtained in the course of conducting laboratory testing of samples will foster the most appropriate regulatory responses, e.g., by informing the health risk assessment process undertaken to categorize the degree of risk attending a contamination incident.

In the present era of globalization and the introduction of new food manufacturing, distribution, and consumption practices, food microbiology testing programs require high-throughput analytical technologies that provide actionable results within a short time frame. The classic approach has relied on the recovery of microorganisms (particularly bacterial pathogens) from food samples by enrichment, their identification on the

Dominic Lambert, Arthur Pightling, Emma Griffiths, Gary Van Domselaar, Peter Evans, Sharon Berthelet, Duncan Craig, Scott Chandry, Robert Stones, Fiona Brinkman, Alexandre Angers- Loustau, Joachim Kreysa, Weida Tong, and Burton Blais. **Baseline Practices for the Application of Genomic Data Supporting Regulatory Food Safety**, *Journal of AOAC INTERNATIONAL*, 100(3), No. 3 (2017).

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The Global Coalition on Regulatory Science Research members developed a manuscript on emerging technologies for food and drug safety.

2018

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Emerging technologies for food and drug safety

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A R T I C L E I N F O

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Drug safety Regulatory agencies Alternative methods Best practices
Cross-training

A B S T R A C T

Emerging technologies are playing a major role in the generation of new approaches to assess the safety of both foods and drugs. However, the integration of emerging technologies in the regulatory decision-making process requires rigorous assessment and consensus amongst international partners and research communities. To that end, the Global Coalition for Regulatory Science Research (GCRSR) in partnership with the Brazilian Health Surveillance Agency (ANVISA) hosted the seventh Global Summit on Regulatory Science (GSRS17) in Brasilia, Brazil on September 18–20, 2017 to discuss the role of new approaches in regulatory science with a specific emphasis on applications in food and medical product safety. The global regulatory landscape concerning the application of new technologies was assessed in several countries worldwide. Challenges and issues were dis- cussed in the context of developing an international consensus for objective criteria in the development, ap- plication and review of emerging technologies. The need for advanced approaches to allow for faster, less ex- pensive and more predictive methodologies was elaborated. In addition, the strengths and weaknesses of each new approach was discussed. And finally, the need for standards and reproducible approaches was reviewed to enhance the application of the emerging technologies to improve food and drug safety. The overarching goal of GSRS17 was to provide a venue where regulators and researchers meet to develop collaborations addressing the most pressing scientific challenges and facilitate the adoption of novel technical innovations to advance the field of regulatory s

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The Global Coalition on Regulatory Science Research members developed a manuscript on Regulatory landscape of dietary supplements and herbal medicines from a global perspective

2019

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Regulatory landscape of dietary supplements and herbal medicines from a global perspective

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ABSTRACT

The number of Individuals that use dietary supplements and herbal medicine products are continuous to increase in many countries. The context of usage of a dietary supplement varies widely from country-to-country; in some countries supplement use is just limited to general health and well-being while others permit use for medicinal purposes. To date, there is little consensus from country to country on the scope, requirements, definition, or even the terminology in which dietary supplement and herbal medicines categories could be classified. Transparent science-based quality standards for the ingredients across these regulatory frameworks/ definitions becomes even more important given the international supply chain. Mean while, there has been a rapid advancement in emerging technologies and data science applied to the field. This review was conceived at the Global Summit on Regulatory Sciences that took place in Beijing on September 2018 (GSRS2018) which is organized by Global Coalition for Regulatory Science Research (GCRSR) that consists of the global regulatory agencies from over ten countries including the European Union. This review summarizes a significant portion of discussions relating to a longitudinal comparison of the status for dietary supplements and herbal medicines among the different national jurisdictions and to the extent of how new tools and methodologies can improve the regulatory application.

The Global Coalition on Regulatory Science Research members developed a manuscript on perspective on nanotechnology and nanoplastics

2020