Global Summit on Regulatory Science[1] (GSRS16)
Nanotechnology Standards and Applications

September 7-9, 2016

Natcher Auditorium
National Institutes of Health (NIH)
45 Center Drive
Bethesda, Maryland, USA

Background

The Global Summit on Regulatory Science (GSRS) was established in 2011 as an annual forum for regulatory agencies to discuss how research could be used more effectively as a tool for advancing regulatory science, food safety, medical technologies, and public health. (*Slikker et al, 2012*[2]). Each GSRS meeting focuses on an area of regulatory science that would benefit from discussions aimed at identifying future research directions. GSRS13 focused on nanotechnology (*Howard et al, 2014*[3]). A one-day workshop on nanomaterial measurement science and standards was held on October 11, 2015 in Parma, Italy, the day before GSRS15, and was hosted by the European Food Safety Authority. This workshop concerned nanomaterials *in the "pristine state"* (*i.e*., as-produced or as-sold for utilization in medical and food applications) as a dry powder or an aqueous suspension, and nanomaterials *in complex matrices*, including biological (*e.g*., blood, tissues, and fluids) and food (*e.g*., actual food, food packaging, and feed) matrices. The workshop focused solely on translating the science of *nanomaterial physico-chemical measurements* to the development of standards that are critical for regulations on medical and food products. The workshop participants generated a summary of priority standards needs which is provided in Appendix A. GSRS16 builds on the scope of the GSRS15 workshop as described below.

GSRS16: Scope, Goals, and Outcomes

With the rapid global advances in nanotechnology research and the proliferation of new nanomaterial-containing medical and food products, it is challenging to keep pace with the science necessary to enact appropriate regulations. Emerging products contain nanomaterials of varying

---

[1] http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofScientificandMedicalPrograms/NCTR/WhatWeDo/ucm289679.htmThe Global Summit on Regulatory Science (GSRS) is an international conference for discussion of innovative technologies and partnerships to enhance translation of basic science into regulatory applications within the global context.

[2] Slikker, W. Jr., Miller, M.A., Valdez, M.L., and Hamburg, M.A. 2012. Advancing global health through regulatory science research: Summary of the Global Summit on Regulatory Science Research and Innovation. Regul. Toxicol. Pharmacol. 62, 471-473.

[3] Howard, P.C., Tong, W., Weichold, F., Healey, M., Slikker, W. 2014. Global Summit on Regulatory Science 2013. Regul. Toxicol. Pharmacol. 70, 728-732.

attributes and properties, *e.g.*, type, composition, and functionality, and hence require consideration of new or modified methods for nanomaterial measurements. Even though regulatory agencies have already been engaged in the review and approval of such new products, significant challenges remain in utilizing advances in nanomaterial measurement science to develop practical standards that lend confidence to results. For example, equivalency of different sources of the same nominal material is a technical challenge for standardization and regulatory oversight. For the purposes of GSRS16, standards are defined to include three items: (1) reference materials developed by governmental organizations (particularly national metrology institutes), legally recognized bodies such as Pharmacopeias, and the private sector (in compliance with ISO Guide 34); (2) consensus-based documentary standards produced by international standards development organizations; and (3) consensus-based testing guidance documents produced by international organizations and regulatory agencies.

As stated previously, the GSRS15 Workshop focused on physico-chemical measurements and standards relevant to nanomaterials in the "pristine state" and in complex matrices as defined previously. GSRS16 expands on the GSRS15 focus to include both physico-chemical and biological measurements and standards for specific applications, namely nanomaterial-containing drugs, medical devices, food and food contact materials, and personal care products. Robust and validated measurement methods are an essential first step in determining the safety and efficacy of nanomaterials for these applications. Standards are needed to perform accurate and reproducible measurements of physico-chemical and biological properties for informed and expedient regulatory decisions on product safety.

Participation in GSRS16 extends beyond government regulatory, research, and standards agencies to include academic institutions and industry. There will be ample opportunities to learn about cutting-edge science and measurement methods that are being developed by each of these stakeholder groups, and to discuss how such knowledge may be used to develop standards relevant for the regulation of nanomaterial-containing products. Presentations will encompass aspects of nanomaterials ranging from novel science and measurement methods to consensus-based documentary and reference material standards. The meeting will not include any discussions on policy.

The goals of GSRS16 are three-fold:

(1) Educate a broad group of stakeholders on the state of the art in nanotechnology science, measurement methods, and standards for regulatory applications.

    Knowledge concerning regulatory applications has largely been limited to regulatory and standards agencies. The plenary sessions are designed to educate a broader group of stakeholders on the current state of science and relevant standards for regulatory applications, and on the current state of all nanotechnology standards.

(2) Identify the most immediate needs in nanotechnology science, measurement methods, and standards relevant to regulatory applications

    There has been significant progress over the last 15 years in nanomaterial measurement methods, the effects and utility of nanomaterials in biological systems, and the

development of reference materials, consensus-based documentary standards, and testing guidance documents for nanotechnology. This workshop provides an opportunity to build on this existing knowledge in order to prioritize needs for science, measurement methods, and standards relevant to regulatory applications, and to enable much needed technologies in the pre-clinical, clinical and food testing realms for societal benefit.

(3) Facilitate greater coordination between stakeholders in the development of standards

It is recognized that standards for nanomaterial measurements intended for medical or food products under regulatory consideration are severely limited. A goal of this workshop is to bring together stakeholders from government regulatory, research, and standards agencies, academic institutions and industry to initiate a dialogue on enhancing coordination in the development of standards for regulatory purposes.

There are two desired outcomes of this meeting:

(1) Publication of a GSRS16 meeting report

Information generated by the brainstorming panel sessions will be summarized to capture and prioritize needs for new consensus-based documentary standards, guidance documents, and reference materials specifically targeted for regulatory applications of nanotechnology products. Similarly, state-of-the-art and existing gaps in nanotechnology regulatory science will be addressed across a broad spectrum of applications. This information will be incorporated in a publicly available report.

(2) Global consensus for a centralized website

There are a number of websites that contain information on standards, for example, the Nanotechnology Standards Database hosted by the American National Standards Institute[4]. A new, centralized website containing links to existing lists of international standards is needed to consolidate the information in a single location. It could be examined whether this website can be part of the European Union's Nanomaterials Observatory to be established and hosted by the European Chemicals Agency (ECHA).

GSRS16: Meeting Structure

The first day of GSRS16 begins with a welcome from the Commissioner of the US Food and Drug Administration (FDA) that is followed by two plenary sessions, one with presentations by international regulatory agencies and the other with presentations on standards as defined above. Day one concludes with a poster session. Days two and three of GSRS16 have two parallel sessions on different nanomaterial-containing applications, including drugs, medical devices, food and food contact materials, and personal care. At the end of each parallel session, there is a brainstorming exercise on research and standards with a panel composed of the speakers from the session. Day three concludes with a plenary session summarizing the discussions in each of the parallel sessions. Recommendations from the participants concerning measurement and standards needs for the various application areas will form the basis for the report.

[4] http://nanostandards.ansi.org/tiki-index.php

The agenda below for each session includes the names of the speakers, their affiliations, and the general topic of their presentations followed by an abstract number, which can be cross-referenced with the Abstract Book. Acronyms are defined in a glossary; see Appendix B.

Preparatory Brief for Meeting Participants

Read-ahead material will be provided to meeting participants prior to the workshop. Sources of information include lists of:

- Guidance documents
- Consensus-based documentary standards
- Protocols and assays
- Reference materials

Participants are encouraged to send *needs for new standards* to Debra Kaiser at debra.kaiser@nist.gov by September 6, 2016. Submitted needs will be used to facilitate discussions.

Organizing Committee

Global Coalition for Regulatory Science Research (GCRSR)

Co-Chair, William Slikker, Jr., Ph.D. (Food and Drug Administration (FDA), US

Co-Chairs

Anil Patri, Food and Drug Administration (FDA), US
Paul Howard, Food and Drug Administration (FDA), US

Members

Wim De Jong, National Institute for Public Health and the Environment (RIVM), The Netherlands

Fergal Donnelly, European Commission (EC), European Union (EU)

Piotr Grodzinski, National Institutes of Health/National Cancer Institute (NIH/NCI), US

Vincent Hackley, National Institute of Standards and Technology (NIST), US

Reinhilde Schoonjans, European Food Safety Authority (EFSA), EU

Wenlei Jiang, Food and Drug Administration (FDA), US

Debra Kaiser, National Institute of Standards and Technology, US

Georgios Katalagarianakis, European Commission, EU

Ruben Pita, European Medicines Agency (EMA), EU

Kumiko Sakai-Kato, National Institute of Health Sciences (NIHS), Ministry of Health, Labour and Welfare (MHLW), Japan

Birgit Sokull-Klüttgen, Joint Research Centre (JRC), EU

Katherine Tyner, Food and Drug Administration (FDA), US

Agenda

Wednesday, September 7, 2016

All events in the Natcher Auditorium

8:00 am – 8:30 am **Registration and Poster Set Up**

Welcome and Plenary Address

Chair: *William Slikker, US FDA*

8:30 am – 9:00 am	Robert M. Califf, M.D. Commissioner, Food and Drugs US FDA	Global Summit on Regulatory Science

Plenary Session 1: International Regulatory Science and Standards Perspectives on Nanotechnology

*This session focuses on agency perspectives on the current state of nanomaterial use, progress and challenges. Speakers are from key government agencies that oversee regulatory research***.**

Co-Chairs: *Anil Patri, US FDA and Paul Howard, US FDA*

Presentation Time	Speaker*	Topic	Abstract
9:00 am – 9:20 am	Anil Patri, US FDA	Nanotechnology at the US FDA	1A
9:20 am – 9:40 am	Fergal Donnelly, EC, EU	Regulatory science for medical technologies	1B
9:40 am – 10:00 am	Ruben Pita, EMA, EU	Regulatory overview of nanomedicines in the EU	1C
10:00 am – 10:20 am	Break		
10:20 am – 10:40 am	Reinhilde Schoonjans, EFSA, EU	Nano-risk assessments at EFSA	1D
10:40 am – 11:00 am	Kumiko Sakai-Kato, NIHS, Japan	Japanese regulatory science and standards perspective	1E
11:00 am – 11:20 am	Xing-Jie Liang, NCNST, China	Standardization of nano-medicinal designs	1F

*see Appendix B for definitions of acronyms

11:20 am – 12:20 pm Lunch, NIH

Plenary Session 2: International Standards Perspectives on Nanotechnology

This session focuses on existing standards and pathways for the development of new standards. Speakers are from various stakeholder groups involved with standards.

Co-Chairs: Debra Kaiser, NIST and Birgit Sokull-Klüttgen, JRC

Presentation Time	Speaker	Topic	Abstract
12:20 pm – 12:30 pm		Co-Chair remarks	
12:30 pm – 12:50 pm	Vincent Hackley, NIST, US	Nanoscale reference materials	2A
12:50 pm – 1:10 pm	Birgit Sokull-Klüttgen, JRC, EU	Representative test materials	2B
1:10 pm – 1:30 pm	Gerrit Borchard, Univ. Geneva, Switzerland	Sizing of nanoscale iron sucrose in solutions	2C
1:30 pm – 1:50 pm	Alan Rawle, Malvern Instruments, US	Standards from ASTM Technical Committee E56	2D
1:50 pm – 2:10 pm	Break		
2:10 pm – 2:30 pm	Charles Clifford, National Physical Laboratory, UK	Standards from ISO Technical Committee 229	2E
2:30 pm – 2:50 pm	Kahkashan Zaidi, United States Pharmacopeia (USP)	USP standards-setting structure and processes	2F
2:50 pm – 3:10 pm	Julia Maier, European Pharmacopoeia (Ph. Eur.)	Ph. Eur. standards perspectives	2G
3:10 pm – 3:30 pm	Hany Demian, US FDA	Use of standards by the US FDA	2H

*see Appendix B for definitions of acronyms

3:30 pm – 6:00 pm **Poster Session in the Atrium of Natcher Building**

Thursday, September 8, 2016

There are two parallel sessions in the Natcher Auditorium and Balcony B. The last hour of each session will be an open brainstorming discussion on the following topics:

- Needs for advances in regulatory science, instrumentation, and methods
- Relevance and applicability of existing standards and adoption by industry
- Needs for new standards to facilitate regulatory review

Session 3: *Advances in Nanotechnology-Derived Drug Products, Natcher Auditorium*

There are a many nanotechnology-derived drug products on the market and many more under pre-clinical development or in clinical trials. Speakers from regulatory agencies, other government agencies, and industry will describe advances in such products.

Co-Chairs: *Katherine Tyner, US FDA and Ruben Pita, EMA*

Presentation Time	Speaker*	Topic	Abstract
8:30 am – 8:40 am		Co-Chair remarks	
8:40 am – 9:00 am	Katherine Tyner, US FDA	Quality considerations and regulatory perspectives	3A
9:00 am – 9:20 am	Ruben Pita, EMA, EU	Standards for nanomedicines - EU perspective	3B
9:20 am – 9:40 am	Piotr Grodzinski, NCI/NIH, US	Cancer nanomedicines - NCI Alliance for Nano in Cancer	3C
9:40 am – 10:00 am	Neil Desai, Celgene/AADi, US	Nanoparticle albumin-bound drugs	3D
10:00 am – 10:20 am	Break		
10:20 am – 10:40 am	Lawrence Tamarkin, Cytimmune, US	Cancer medicines: challenges and opportunities	3E
10:40 am – 11:00 am	Xiaoming Xu, US FDA	Quality considerations for drug products	3F

*see Appendix B for definitions of acronyms

11:00 am – 12:00 pm Brainstorming discussion on prioritized research and standards needs

Moderator: *Kenneth Dawson, Univ. College Dublin*
Panel: *Session 3 speakers*
Rapporteur: *Vincent Hackley, NIST*

12:00 pm – 1:00 pm Lunch, NIH

Session 4: *Advances in Nanotechnology-Derived Medical Devices, Balcony B*

Nanomaterials are already being applied in medical devices, yet there are many more nanotechnology applications for medical devices under development or in clinical trials. Speakers from government regulatory agencies and research centers and public health and academic institutions will describe advances in such devices.

Co-Chairs: ***Peter Goering, CDRH/FDA and Wim De Jong, RIVM***

Presentation Time	Speaker	Topic	Abstract
8:30 am – 8:40 am		Co-Chair remarks	
8:40 am – 9:00 am	Peter Goering, CDRH/FDA, US	Device materials with immobilized nanostructures	4A
9:00 am – 9:20 am	Indira Hewlett, CBER/FDA, US	Nanotechnology assays for pathogen detection	4B
9:20 am – 9:40 am	Wim De Jong, RIVM, The Netherlands	Risk assessment: nanomaterials in devices	4C
9:40 am – 10:00 am	Hari Shanker Sharma, Uppsala University, Sweden	Neurotoxicity of gold and iron oxide nanoparticles	4D
10:00 am – 10:40 am	Break		
10:40 am – 11:00 am	Liming Xie, NCNST, China	Nanosilver standards and toxicity evaluation	4E

*see Appendix B for definition of acronyms

11:00 am – 12:00 pm Brainstorming discussion on prioritized research and standards needs

Moderator: *Brendan Casey, US FDA*
Panel: *Session 4 speakers*
Rapporteur: *Rosalie Elespuru, US FDA*

12:00 pm – 1:00 pm Lunch, NIH

Session 5: *Liposomal Drug Products, Natcher Auditorium*

There exist medical products in which the drug substance is contained in liposomes, or microvesicles, and some regulatory agencies have prepared guidance for industry in manufacturing and testing such liposomal drug products. Speakers from academic institutions and government research agencies and centers will describe the state of science in such drug products.

Co-Chairs: ***Wenlei Jiang, US FDA and Kumiko Sakai-Kato, NIHS***

Presentation Time	Speaker*	Topic	Abstract
1:00 pm – 1:10 pm		Co-Chair remarks	
1:10 pm – 1:30 pm	Frank Szoka, Univ. California San Francisco, US	Use of chemical and physical stresses on liposomal drugs	5A
1:30 pm – 1:50 pm	Kumiko Sakai-Kato, NIHS, Japan	Japanese liposome guidelines and regulatory science	5B
1:50 pm – 2:10 pm	Esther Chang, Georgetown University, US	Targeting and eliminating cancer stem cells	5C
2:10 pm – 2:30 pm	Stephan Stern, NCL/NCI, US	Nanomedicine pharma-cokinetics and drug release	5D
2:30 pm – 2:50 pm	Break		
2:50 pm – 3:10 pm	Diane Burgess, Univ. Connecticut, US	Continuous manufacturing for liposomal formulation	5E
3:10 pm – 3:30 pm	Duanyun Si, NCNST, China	*In vivo* PK/PD assessments for nano-drugs	5F

*see Appendix B for definitions of acronyms

3:30 pm – 4:30 pm Brainstorming discussion on prioritized research and standards needs

Moderator: *Wenlei Jiang, US FDA*
Panel: *Session 5 speakers*
Rapporteur: *Ruben Pita, EMA*

Session 6: *Nanomaterials in Food and Food Contact Materials, Balcony B*

This session focuses on nanomaterials in food/feed products and food contact materials, and potential safety issues, including effects on the microbiome. Speakers from regulatory agencies and public health institutions will discuss issues concerning the use of nanomaterials in food- and feed-related products and materials.

Co-Chairs: ***Reinhilde Schoonjans, EFSA and Dragan Momcilovic, US FDA***

Presentation Time	Speaker*	Topic	Abstract
1:00 pm – 1:10 pm		Co-Chair remarks	
1:10 pm – 1:30 pm	Wim DeJong, RIVM, The Netherlands	Risk assessment: nanomaterials in food	6A
1:30 pm – 1:50 pm	Chia-Ding Liao, Taiwan FDA	Characterization of nanoparticles in food	6B
1:50 pm – 2:10 pm	David Lefebvre, Health Canada	Safety assessment considerations in food	6C
2:10 pm – 2:30 pm	Timothy Duncan, US FDA	Models for exposure to food contact materials	6D
2:30 pm – 2:50 pm	Break		
2:50 pm – 3:10 pm	Treye Thomas, CPSC, US	Nanoparticle migration from food contact matls	6E
3:10 pm – 3:30 pm	Albert Braeuning, German Federal Inst. for Risk Assessment	Effects of orally ingested silver nanoparticles	6F
3:30 pm – 3:50 pm	Sangeeta Khare, US FDA	Intestinal microbiome and immunotoxicity	6G

*see Appendix B for definitions of acronyms

3:50 pm – 4:50 pm Brainstorming discussion on prioritized research and standards needs

Moderator: *Reinhilde Schoonjans, EFSA*
Panel: *Session 6 speakers*
Rapporteur: *Dragan Momcilovic, US FDA*

Friday, September 9, 2016

There are two parallel sessions in the Natcher Auditorium and Balcony B. The last hour of each session will be an open brainstorming discussion on the following topics:

- Needs for advances in science, instrumentation, and methods
- Relevance and applicability of existing standards and adoption by industry
- Needs for new standards to facilitate regulatory review

Session 7: *Targeted Nanomaterials for Biomedical Applications, Natcher Auditorium*

This session focuses on complex, multifunctional nanomaterials for biomedical applications; for example, nanomaterials that contain a targeting agent and a drug designed to deliver the nanomaterial to the intended site of action more efficiently. Speakers from academic institutions, government agencies, and industry will describe promising research on such targeted nanomaterials and potential effects on the immune system due to nanomaterial surface properties.

Co-Chairs: ***Piotr Grodzinski, NCI/NIH and Xing-Jie Liang, NCNST***

Presentation Time	Speaker*	Topic	Abstract
8:30 am – 8:40 am		Co-Chair remarks	
8:40 am – 9:00 am	Kenneth Dawson, Univ. College Dublin, Ireland	'Statistically defined drugs' for better categorization	7A
9:00 am – 9:20 am	Rangaramanujan Kannan, Johns Hopkins Univ., US	Targeted dendrimer nano-therapies for CNS disorders	7B
9:20 am – 9:40 am	Lily Yang, Emory Univ., US	Targeted drug delivery for cancer therapy	7C
9:40 am – 10:00 am	Marina Dobrovolskaia, NCL/NCI, US	*In vitro–in vivo* correlations in immunotoxicity tests	7D
10:00 am – 10:20 am	Break		
10:20 am – 10:40 am	Clarice Hutchens, Pfizer, US	Information on Nanomedicine Alliance	7E
10:40 am – 11:00 am	Jan Simak, US FDA	Effects of nanomaterials on thrombosis and hemostasis	7F

*see Appendix B for definitions of acronyms

11:00 am – 12:00 pm Brainstorming discussion on prioritized research and standards needs

Moderator: *Piotr Grodzinski, NCI/NIH*
Panel: *Session 7 speakers*
Rapporteur: *Wimolnut Manheng, US FDA*

12:00 pm – 1:00 pm Lunch, NIH

Session 8: *Nanomaterials in Personal Care Products, Balcony B*

There are hundreds of personal care products containing nanomaterials, such as sunscreens and cosmetics, yet issues concerning the safety of such products and new products still need to be fully resolved. Speakers from government regulatory and research agencies and non-governmental organizations will describe research and regulatory landscapes.

Co-Chairs: ***Nakissa Sadrieh, US FDA and Nigel Walker, NTP/NIEHS***

Presentation Time	Speaker	Topic	Abstract
8:30 am – 8:40 am		Co-Chair remarks	
8:40 am – 9:00 am	Nakissa Sadrieh, US FDA	Personal care products: US regulatory landscape	8A
9:00 am – 9:20 am	Birgit Sokull-Klüttgen, JRC, EU	Cosmetic products: EU regulatory landscape	8B
9:20 am – 9:40 am	David Andrews, Environmental Working Group (EWG), US	EWG and nanomaterials in personal care products	8C
9:40 am – 10:00 am	Monita Sharma, PETA Int'l Sci. Consortium Ltd., England	Nanomaterials and *in vitro* tests	8D
10:00 am – 10:20 am	Break		
10:20 am – 10:40 am	Shou-Chieh Huang, Taiwan FDA	Nanoparticles in sunscreens	8E
10:40 am – 11:00 am	Sri Nadadur, NIEHS/NIH, US	Nano Health Implications Research Consortium	8F

*see Appendix B for definition of acronyms

11:00 am – 12:00 pm Brainstorming discussion on prioritized research and standards needs

Moderator: *Nigel Walker, NTP/NIEHS*
Panel: *Session 8 speakers*
Rapporteur: *Paul Howard, US FDA*

12:00 pm – 1:00 pm Lunch, NIH

Session 9: *Wrap-up and Conclusions, Natcher Auditorium*

Co-chairs: ***Vince Hackley, NIST and Anil Patri, US FDA***

1:00 pm – 3:00 pm Summaries from brainstorming discussion moderators

3:00 pm – 3:10 pm Closing remarks

Appendix A: Summary of Standards Needs Identified at the GSRS15 Workshop

The one-day GSRS15 Workshop on *Nanomaterial Physico-chemical Measurement Standards for Regulatory Consideration* focused on nanomaterials for applications in drugs, medical devices, foods and feed. The first session concerned measurements of nanomaterials in the "pristine state" (*i.e.*, as-produced or as-sold for utilization in medical and food applications) either as a dry powder or an aqueous suspension, and the second session concerned measurements of nanomaterials in complex matrices, including biological (*e.g.*, blood, tissues, and fluids) and food (*e.g.*, actual food, food packaging, and feed) matrices. The following priority standards needs were identified in the brainstorming sessions.

I. Pristine Nanomaterials

A. ***Reference Materials***

1. Liposomes
2. Quantitative surface coatings (species, coverage)
3. Number concentration in aqueous solution (may include these data with renewal of NIST Gold Nanoparticle RMs 8012 and 8013)
4. Multi-modal by size (same nanomaterial)
5. Shape (needs to be specified)

B. ***Documentary Standards***

1. Dynamic light scattering standard test method with specifications for regulatory use
2. Surface coating: composition and stability measurement methods
3. Surface coating: zeta potential measurement method
4. Guidance document with a tiered approach of methods to measure size and size distribution
5. Asymmetric Flow/Sedimentation Field Flow Fractionation (ISO/PWI, Japan)
6. Electron microscopy: SEM (ISO/PWI 19749 USA); TEM (ISO/PWI USA/Japan); cryogenic TEM (ASTM WK 54615 USA); and low-voltage TEM

II. Nanomaterials in Complex Matrices

A. ***Reference Materials***

1. Simulated body fluids (no nanomaterials)
2. Simulated body fluids (containing nanomaterials)
3. Nanomaterials in representative food and food packaging materials

B. ***Documentary Standards***

1. Drug substance release rate from a liposome
2. Quantitation of nanomaterials in blood
3. Quantitation of nanomaterials in tissue
4. Guides for sample preparation for variety of methods, *e.g.*, SEM, TEM, ICP-MS
5. Speciation: relative and total concentrations (*e.g.*, ions, complex nanomaterials)
6. Migration of nanomaterials in food packaging materials

III. Overarching Needs for Standardization

A. A comprehensive public database of reference materials hosted by an organization such NIST or BAM (Federal Inst. for Materials Research and Testing), Germany
B. Clarification/specification regarding appropriateness for use and range of applicability of standards with respect to regulatory needs
C. Increased proficiency testing (inter-laboratory testing) to validate reference materials and test methods
D. Guidelines for harmonization performance criteria

Appendix B: Glossary of Acronyms

CBER	Center for Biologics Evaluation and Research, FDA (US)
CDER	Center for Drug Evaluation and Research, FDA (US)
CDRH	Center for Devices and Radiological Health, FDA (US)
CEN	European Committee for Standardization (EU)
CPSC	Consumer Products Safety Commission (US)
EC	European Commission (EU)
EFSA	European Food Safety Authority (EU)
EMA	European Medicines Agency (EU)
EU	European Union
EWG	Environmental Working Group
FDA	Food and Drug Administration (US and Taiwan)
GSRS	Global Summit for Regulatory Science
ISO	International Organisation for Standardization
JRC	Joint Research Centre (EU)
NCL	Nanotechnology Characterization Laboratory (US)
NCI	National Cancer Institute (US)
NCNST	National Center for Nanoscience and Technology (China)
NIEHS	National Institute of Environmental Health Sciences (US)
NIH	National Institutes of Health (US)
NIHS	National Institute of Health Sciences (Japan)
NIST	National Institute of Standards and Technology (US)
NTP	National Toxicology Program (US)
OECD	Organisation for Economic Co-operation and Development
PETA	People for the Ethical Treatment of Animals (England)
Ph. Eu.	European Pharmacopoeia (EU)
RIKILT	RIKILT-Institute of Food Safety (The Netherlands)
RIVM	National Institute for Public Health and the Environment (The Netherlands)
RM	Reference Material
USP	United States Pharmacopeial (US)

GLOBAL COALITION FOR REGULATORY SCIENCE RESEARCH (GCRSR)

Attendees at the Global Summit on Regulatory Science and Innovation held August 11, 2011, in Little Rock, Arkansas, explored how research could be used more effectively as a tool for advancing regulatory science, food safety, medical technologies, and global public health. The participants recognized that the formation of a Global Coalition for Regulatory Science Research (GCRSR) would allow regulatory authorities world-wide to work collaboratively to assimilate knowledge, promote the development of regulatory science, and discover novel ways to clearly define research needs that would strengthen the product safety net around the world.

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 Executive Committee agreed to forge 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.

The GCRSR held its first meeting on September 10, 2013, at the Jefferson Laboratories of the FDA in Jefferson, Arkansas. Subsequent meetings have been held in Canada, co-hosted by the Canadian Food Inspection Agency (CFIA); and in Italy, co-hosted by the European Food Safety Authority (EFSA). Organizational leaders from nine countries/regions made a firm commitment to participate on the Executive Committee for the Global Coalition for Regulatory Science Research. In 2014, the Coalition membership expanded to include executive leadership from the European Union's European Medicines Agency (EMA) and the European Food Safety Authority (EFSA). This year, 2016, the GCRSR membership expanded to include the European Commission's Joint Research Centre (JRC).

The standing goals of the GCRSR include: (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.

For the first five-year period (September 2013-September 2018), and renewable five-year periods thereafter, the Executive Committee will function with staff from the FDA's National Center for Toxicological (NCTR) serving as the Secretariat and Co-Chair for the Executive Committee. The Executive Committee members are charged with participating in regularly scheduled meetings and will meet in person at the annual meeting in conjunction with the Global Summit on Regulatory Science (GSRS). The Executive Committee of the GCRSR is co-chaired by an elected co-chair and the NCTR co-chair. All activities of the Executive Committee are undertaken in compliance with applicable laws and regulations of the Executive Committee Participants' countries and are to be subject to the availability of appropriated funds, personnel, and other resources.

ACKNOWLEDGEMENTS

The Global Coalition for Regulatory Science (GCRSR) would like to thank the following for their support to the GSRS16:

Food and Drug Administration (FDA)

Burroughs-Wellcome Fund

Arkansas Research Alliance (ARA)

In addition, the GCRSR would like to thank the **Session Chairs, Speakers, Conference Liaison and Support Team.** Their valuable time and energy contributed greatly to the success of the GSRS16. We look forward to your participation in the GSRS17!

GSRS16 CONFERENCE LIAISON

Roben Brooks, US FDA

GSRS16 SUPPORT TEAM

Amy Babb, US FDA

Ashley Groves, US FDA

Nathan Koonce, US FDA

Daniel Wakefield, US FDA