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Workshop Report

Global Summit on Regulatory Science 2013

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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.

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1. Introduction

Regulatory science is comprised of fundamental and applied science that is used to make regulatory decisions by governing bodies and agencies. Regulatory science can span the breadth of many fields where scientific data are used to develop policies or laws to protect the population. It is not defined as a specific discipline as much as by regulatory needs. For instance, a regulatory agency that is concerned about environmental interactions might emphasize atmospheric science, oceanography, ecology and environmental science. The examples most relevant to this Global Summit on Regulatory Science are the scientific disciplines of medicine, pharmacology, bioinformatics and toxicology that generate the necessary data that is used by a regulatory agency to develop regulations regarding the safety of a medical product, or, food ingredient or contact material.

At the US Food and Drug Administration (FDA), Regulatory Science is "*... the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products*." In order to attain this goal of developing new tools, standards and approaches, the FDA developed a strategic plan that outlines eight different science priority areas to further the development and application of regulatory science (see text box below).

Eight Science Priority Areas in the FDA's Advancing Regulatory Science (FDA, 2010, 2011)

1. Modernize Toxicology to Enhance Product Safety;
2. Stimulate Innovation in Clinical Evaluations and Personalized Medicine to Improve Product Development and Patient Outcomes;
3. Support New Approaches to Improve Product Manufacturing and Quality;
4. Ensure FDA Readiness to Evaluate Innovative Emerging Technologies;
5. Harness Diverse Data through Information Sciences to Improve Health Outcomes;
6. Implement a New Prevention-Focused Food Safety System to Protect Public Health;
7. Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Security; and
8. Strengthen Social and Behavioral Science to Help Consumers and Professionals Make Informed Decisions about Regulated Products.

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Focused research and development and analysis of scientific data in any of the eight science priority areas can have a significant impact on the evaluation of regulated product safety, providing the appropriate communication of efficacy and safety to the consumer, with the eventual outcome of advancing public health decisions and promoting public safety.

2. Global Summit on Regulatory Science (GSRS)

The Global Summit on Regulatory Science is "*an international conference for discussion of innovative technologies and partnerships to enhance translation of basic science into regulatory applications within the global context*." (http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofScientificandMedicalPrograms/NCTR/WhatWeDo/ucm289679.htm). The conference provides a focused meeting and opportunity for scientists from government, industry, and academic research to objectively assess the utility of emerging technologies for addressing regulatory-research questions and to discuss the best way to translate these technologies into real-world applications. The conference provides a platform where regulatory scientists from around the world including laboratory scientists, risk assessment/management experts, and policy makers can exchange views on key gaps in the available data, provide information on specific emerging methodologies and technologies, and recommend how these new approaches can be used to conduct research to decrease these uncertainties. Structuring the summit to optimize the participation of these international experts in this way increases the confidence of regulatory assessments and decisions in their respective countries. This conference also provides a venue for discussion of global collaboration and regulatory-science research and training needs.

Previous meetings of the Global Summit on Regulatory Science focused on areas of high impact to regulatory science. The First Global Summit on Regulatory Science was held in Little Rock, Arkansas, on 11–12 August 2011. The conference focused on the theme of mechanisms for the inclusion of regulatory research as a tool for advancing regulatory science, food safety, medical technologies, and public health (Slikker et al., 2012). The Second Global Summit on Regulatory Science was held in Hangzhou, China, on 9–11 May 2012. The theme of the conference was to objectively assess the utility and promises of modernizing toxicology as an effective means to facilitate the maturation of emerging technologies such as toxicogenomics, next-generation sequencing, and bioinformatics, into products that benefit consumers (Miller et al., 2013). The current article will describe the 2013 Global Summit on Regulatory Science that focused on nanotechnology with lectures from esteemed individuals from the US and other countries with an emphasis on standards and standard approaches to evaluate the safety of nanomaterials. This third annual summit was convened 12–13 September 2013 on the campus of the U.S. Food & Drug Administration's National Center for Toxicological Research (NCTR) in Jefferson, Arkansas and in Little Rock, Arkansas. Approximately 100 attendees from 10 countries (Argentina, Australia, Brazil, Canada, China, Japan, Republic of Korea, Singapore, USA and European Food Safety Authority representing the European Union) attended and participated in the two-day meeting which was thematically focused on nanotechnology as an emerging focus of regulatory science.

3. Global Summit on Regulatory Science 2013

Nanotechnology is defined as the manipulation of matter at the atomic scale, to form material with at least one dimension of approximately 1–100 nm, where the material that is formed has unique properties as a result of the size that differs from bulk product (that is, larger particle size) (NNI). The intent of the 2013 Global Summit on Regulatory Sciences was to introduce the area of nanotechnology, and have presentations on standards development, promises and applications of nanotechnology, and summarize the regulatory approach of the U.S. Food and Drug Administration. The Keynote Speaker for the 2013 conference was the Commissioner of the FDA. The Commissioner emphasized that the role of regulatory agencies is to promote public health by ensuring the regulated products that are available to the public are effective, as affordable as possible, and safe.

One of the primary roles of toxicology is to provide the scientific data necessary for risk assessment and for making risk management decisions. The development of new areas of science in the 20th and 21st centuries has not changed the key role of our understanding of the mechanisms of action and quantitative measures of toxicology; what has changed though are the tools that are used to quantify the toxicity. The ever increasing development and improvement in available technologies points out the need for trained scientists to understand these new emerging technologies and properly evaluate the data produced by them in order to improve our understanding of risk in regulated products.

The NCTR has had a long standing tradition of training undergraduate students that matriculate from local and regional universities, and has had a post-graduate training program with students from every region of the world. The FDA and the State of Arkansas have entered into a Memorandum of Understanding (MOU) as a result of the signatures of the Agency Commissioner and State Governor. This MOU presently serves as an agreement to foster and encourage continued and enhanced cooperation and collaboration between the Arkansas State Universities, the State of Arkansas and the FDA in order to generate and evaluate scientific data, and produce, develop and train new scientists with expertise in the subdisciplines of regulatory science. This has led to the development of a Certificate Program in Regulatory Science at the University of Arkansas for Medical Sciences, with didactic courses that enable the students to better understand the role the fundamental sciences of toxicology, pharmacology, risk assessment and clinical sciences play in regulatory decision making. Recent graduates of this program received their certificates from Dr. Hamburg, the FDA Commissioner.

Section 1 of the 2013 Global Summit on Regulatory Sciences focused on "Introduction to Nanotechnology". Two key presentations were instrumental in bringing the attendees to a working knowledge of nanotechnology. The lectures focused on the physics and chemistry of nanomaterials. The ability by man to make nanoscale materials from bulk materials is not new to science. This technology has been used for centuries in the formation of some color glass and more recently in the development of liposomes. What is new is the ability to manipulate matter at the near atomic level, and by taking advantage of the unique properties of matter at this scale, to either create combinations of materials that heretofore have not existed or create new surface features on materials that change their interaction with biological systems.

In the U.S., the coordination of nanotechnology development by U.S. Government agencies has been the responsibility of the National Nanotechnology Coordination Office (NNCO) through the National Nanotechnology Initiative (NNI). The NNI was envisioned and chartered during the President Clinton Administration, and now involves the cooperation of twenty-five U.S. federal agencies. The NNI has released a Strategic Plan (NNI, 2011a) for the NNI cooperative program and the release of key documents such as the Environmental Health and Safety Research Strategy (NNI, 2011b). An outcome of 21st Century approaches to the development of nano- and other technologies is the concept of Risk Governance, which has at its core, the necessity to assess and answer key questions emerging from the exchanges between science, policy,