

**Quarterly Research Highlights, Activities, and Publications****Globalization of Regulatory Science**

Global Summit on Regulatory Science—The NCTR, Zhejiang University (China), and Division of Medicine and Health Sciences, Chinese Academy of Engineering (China) hosted the 2nd Global Summit on Regulatory Science Conference (GSRS-



2012, that was held in Hangzhou, China, on May 9-11, 2012. 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 FDA's initiative on advancing regulatory science.

Regulatory Sciences Program—Twenty scientists, including thirteen NCTR postdoctoral fellows and staff from six different countries, enrolled in the inaugural class to obtain a Graduate Certificate in Regulatory Sciences developed at the Fay W. Boozman College of Public Health, University of Arkansas for Medical Sciences, in Little Rock, Arkansas. This program was developed under the Memorandum of Understanding between FDA and the State of Arkansas promoting development of regulatory science. Two courses began in August 2012: *FDA Regulations* and *Methods of Risk Assessment*. *Design and Management of Clinical Trials* and *Good Laboratory Practices* will be offered in the spring semester. The certificate program fills a critical need for knowledge in regulatory sciences and demonstrates FDA's global influence. Hyperlink:

<http://publichealth.uams.edu/academics/certificates/certificate-in-regulatory-science/>

Metabolomics—Dr. Richard Beger, Director, Biomarkers and Alternative Models Branch in the Division of Systems Biology at NCTR, attended the Metabomeeting 2012 meeting held September 25-27 in Manchester, UK. Dr. Beger presented a talk titled: *Metabolic Profiles of Urine and Serum from Children with Acetaminophen Overdose*. Overdose of acetaminophen (APAP), a widely used over-the-counter analgesic and antipyretic drug, can cause liver injury or liver failure. The results of NCTR and other preclinical APAP studies indicate that acylcarnitines (a special class of fatty acids that can be converted into energy by mitochondria in the cells) detected in blood are increased and therefore are potential early and noninvasive biomarkers of APAP-induced liver injury. Overall, the current metabolomic data suggest that APAP toxicity involves a cells

reduced ability to convert these special fatty acids into energy. This research will continue, and Metabolomics will analyze more samples from children with APAP overdoses over the next year.

Nanotechnology—NCTR scientists presented keynote addresses at the 6th International Conference on Nanotoxicology that was held September 4-7 in Beijing, China. The first address focused on the activities of the FDA Nanotechnology Task Force and model studies for dermal penetration of nanoscale materials. The second presentation discussed the ongoing interdisciplinary activities for the safety assessment of gold and carbon nanoparticles. The conference, organized by the National Center for Nanoscience and Technology of China, provided an international forum for the discussion of the current understanding of the toxicity of nanomaterials.

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