



Science that speeds health innovation

CENTER FOR EXCELLENCE IN REGULATORY SCIENCE AND INNOVATION



Funded by a grant from the U.S. Food and Drug Administration (FDA), the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI) is a collaborative initiative between the University of Maryland, College Park, the University of Maryland in Baltimore, and the FDA that focuses on the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products in an effort to help modernize and improve the way drugs and medical devices are developed and evaluated.

Through the M-CERSI, researchers, regulators, and industry professionals can learn from one another in the effort to develop regulatory science practices that promote innovation in medical devices and pharmaceuticals, while also addressing critical safety concerns.



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Quick Facts About the M-CERSI

WHY DID THE FDA FUND A CENTER FOR REGULATORY SCIENCE AND INNOVATION?

According to the FDA, “regulatory science will be a driving force in the 21st century as the FDA works with diverse partners to protect and promote the health of our nation and the global community.” M-CERSI efforts focus on promoting innovation in support of the development and evaluation of safe and effective products through training, applied collaborative science, professional development and scientific exchanges.

WHAT IS REGULATORY SCIENCE?

Regulatory science is the application of basic science to the development and utilization of new tools, standards, and approaches for the assessment of medical product efficacy, safety, and quality. It provides a critical bridge between basic scientific research discoveries and new marketed, medical products.

WHAT DOES THE M-CERSI DO?

The four collaborative research projects of the M-CERSI are:

- *Improving pre-clinical assessments of the safety and efficacy of new drugs and devices.* This project focuses on transporters that can impact drug safety or cause drug-to-drug interactions, as well as allow for more efficient drug discovery and development.
- *Ensuring readiness to evaluate innovative and emerging technologies.* This project focuses on hyperspectral imaging and tissue engineering.
- *Harnessing diverse data through information sciences to improve health outcomes.* This project focuses on the impact of Patient-Prescriber Agreements (PPAs) as well as drug usage in nursing home patients.
- *Addressing minority health and health disparities.* These projects focus on race and ethnicity in clinical trial enrollment.

These initiatives follow the August 2011 FDA Strategic Plan for Regulatory Science (<http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm267719.htm>). FDA scientists from the Center for Drug Evaluation and Research (CDER) and from the Center for Devices and Radiological Health (CDRH) are involved in the M-CERSI.

WHO IS INVOLVED IN THE M-CERSI AND WHY THE UNIVERSITY OF MARYLAND?

Participating University of Maryland schools include pharmacy, engineering, and medicine. Co-principal investigators on the grant are Dr. William Bentley, PhD, Chair of the Fischell Department of Engineering at UM College Park, and Dr. James Polli, PhD, the Shangraw/Noxell Chair in Pharmaceutical Sciences at the UM School of Pharmacy in Baltimore. Maryland faculty work with scientists at the FDA, which is headquartered in Silver Spring, MD. The FDA team is led by Dr. York Tomita of the Office of the Chief Scientist. A steering committee of Maryland faculty and FDA scientists oversees M-CERSI activities. There are three research project teams, as well as an education team. M-CERSI also consults its Advisory Panel and engages with members of its Industrial Consortia.



M-CERSI Educational Programs

M-CERSI provides monthly lectures on current topics in regulatory science at the FDA, which are presented by academics and scientists from the University of Maryland and industry. An annual M-CERSI Day is held to showcase M-CERSI activities and provide a forum for the FDA and the public to listen to scientific issues that impact drug and device development and evaluation. UM College Park is developing an M.S. degree in Regulatory Science and Engineering. The UM School of Pharmacy in Baltimore offers an online M.S. degree in Regulatory Science, which features drug regulatory science in chemistry, manufacturing, and, controls; clinical research; and post-marketing safety. Visit <http://ter.ps/2bg> for more information.

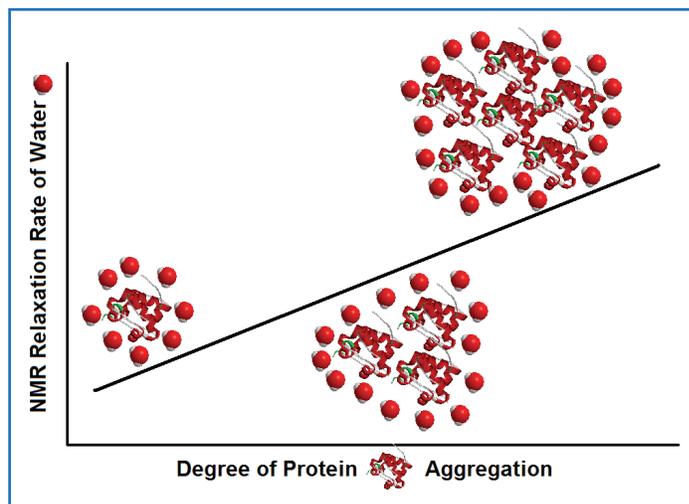
M-CERSI has initiated a Personalized Education Program where FDA scientists take classes and gain laboratory experience. Also, the M-CERSI Exchange Program promotes scientific exchange between FDA scientists and academic and industrial scientists by hosting public conferences at Maryland and nearby institutions, such as the NIH (www.aimbe.org/aimbenih-workshop/). Maryland students gain insight into solving product development issues and evaluating problems through an "America's Got Regulatory Science Talent" Competition. More information can be found here: <http://ter.ps/2bh>.

M-CERSI Research

M-CERSI supports mechanisms for scientific exchange, education and training, as well as regulatory science research. The center brings together diverse thoughts and ideas around emerging technologies and methodologies for regulatory science. The sum of these interwoven activities is a vibrant, cutting edge center that stimulates innovative thought, advances understanding of regulatory science and practices, and generates new knowledge in support of the FDA's mission to promote and protect the public health.

The M-CERSI supports Innovation Awards and Exchange Awards to advance UM-FDA collaborative research projects that foster the development of regulatory science in the areas of medications and/or medical devices. M-CERSI Innovations in Minority Health Awards aim to address racial and ethnic health disparities.

The 2012/2013 Innovation Awards and Innovation Awards in Minority Health supported four research projects, including the following initiatives: Analyzing Medical Device Recalls and Regulatory Decision Making to Advance Regulatory Science, Novel High-Throughput Quality Control of Pharmaceutical Preparations, Improving Health Literacy and Cultural Competency of FDA Consumer Materials, Racial/Ethnic Differences in Pediatric Antipsychotic Use by FDA Labeled Status.



With the growing prevalence of protein-based pharmaceuticals, the task to control their quality becomes most challenging. An M-CERSI Innovation Award project led by Prof. Y. Bruce Yu (UM School of Pharmacy) paves the way to noninvasively detecting the unwanted protein aggregation. This aggregation becomes evident from the growth in the NMR relaxation rate of water in the protein drug solution (see figure above) without even opening the vial.

To learn more about the M-CERSI Innovation and Exchange Awards, visit www.cersi.umd.edu.

Industrial Consortia Program

The CERSI Industrial Consortia program provides a vehicle for facilitating communication with industry, working toward a new level of public transparency for regulatory processes and procedures. Researchers, regulators and industry professionals can benefit from interaction and joint efforts to develop regulatory science practices that promote innovation in medical devices and pharmaceuticals. Consortia activities address broad issues, such as risk benefit, as well as more technical projects on specific topics. Industry/University collaborative spinout projects are developed with Consortia members.

M-CERSI CONSORTIA MEMBERS:



LOCKHEED MARTIN



Waters



SIEMENS

MDMA

MEDICAL DEVICE MANUFACTURERS ASSOCIATION
Innovation Today for Better Health Care Tomorrow™



MedStar Health



M-CERSI Leadership



Dr. William E. Bentley, Co-PI

Dr. Bentley is the Robert E. Fischell Distinguished Professor of Engineering and founding Chair of the Fischell Department of Bioengineering. Dr. Bentley received his undergraduate (BS, '82) and

Master of Engineering degrees ('83) from Cornell University and his Ph.D. ('89) from the University of Colorado, Boulder, all in chemical engineering. At Maryland since 1989, Dr. Bentley has focused his research on the development of molecular tools that facilitate the expression of biologically active proteins. He has authored over 200 related archival publications. Recent interests are on deciphering and manipulating signal transduction pathways, including those of bacterial communication networks, for altering cell phenotype. He has served on advisory committees for the NIH, NSF, DOD, DOE, USDA, and several state agencies. Dr. Bentley is a Fellow of the AAAS and AIMBE and is an elected member of the American Academy of Microbiology.



Dr. James E. Polli, Co-PI

Dr. Polli is Professor of Pharmaceutical Sciences and Ralph F. Shangraw/Noxell Endowed Chair in Industrial Pharmacy and Pharmaceutics at the University of Maryland School of Pharmacy. Dr. Polli's

research interest revolves around oral drug absorption and pharmaceutical quality of orally administered medicines. He has served as advisor to 15 Ph.D. graduates. He received a B.S. in Pharmacy from the Philadelphia College of Pharmacy and Science and a Ph.D. (pharmaceutics) from the University of Michigan. He is a fellow and Member-at-Large of American Association of Pharmaceutical Scientists (AAPS), an Editorial Board member of several journals, an Associate Editor of Pharmaceutical Research, former Vice-Chair of the United States Pharmacopeia (USP) Expert Committee on Biopharmaceutics, and a member of the FDA Advisory Committee on Pharmaceutical Sciences and Clinical Pharmacology.

FOR MORE INFORMATION, PLEASE VISIT US AT WWW.CERSI.UMD.EDU

