



# FDA Facts: Centers of Excellence in Regulatory Science and Innovation (CERSI)

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In recent years, as major scientific and technological breakthroughs have created unprecedented opportunities for medical progress, the FDA has worked hard to support innovative approaches to the development and evaluation of its regulated products, helping to speed safe and effective new treatments to people in need. FDA initiatives, like Critical Path<sup>1</sup> and Advancing Regulatory Science<sup>2</sup>, reflect the importance of collaboration in driving innovation.

In October 2011, the FDA awarded \$2 million to launch local Centers of Excellence in Regulatory Science and Innovation (CERSI)<sup>3</sup> at the University of Maryland and Georgetown University. The FDA chose the nation's capital area to facilitate the greatest possible face-to-face interaction, including hands-on research, training, and the potential for clinical activities.

The centers are part of the FDA's effort to strengthen the science needed to transform product development and evaluation by creating opportunities for cutting-edge collaborative research, scientific exchange, and training for FDA and academic scientists. Research at these centers focuses on the priority areas that the FDA identified in its regulatory science strategic plan as essential for protecting and promoting public health. The centers are managed by the FDA's Office of the Chief Scientist and teams of scientists from across the agency, who are working closely with their university partners and, when appropriate, other collaborators.

## Overview

Working with FDA scientists, researchers at these centers support the agency's innovation efforts in product development by advancing the laboratory, population, behavioral, and

manufacturing sciences that underpin it. Leveraging this knowledge makes it possible for the FDA to base its regulatory decisions on the best, most current scientific evidence. And the experience the FDA brings to these collaborations helps ensure that new scientific approaches being developed in academia are applied in a manner that increases their usefulness for evaluating products and making sound regulatory decisions.

### The Center of Excellence in Regulatory Science at University of Maryland<sup>4</sup>

Launched in 2011 at the College Park and Baltimore campuses, this center focuses on projects that target three priority areas in the FDA's strategic plan: Transforming Toxicology to Enhance Product Safety; Ensuring FDA Readiness to Evaluate Innovative Emerging Technologies; and Harnessing Diverse Data to Improve Health Outcomes. Research projects address membrane transporters in drug development; innovative and emerging technologies like laser-based therapeutic devices and advanced tissue engineering; and prescription drug use. The center also offers variety of educational opportunities to promote regulatory science to the public, such as lectures and degree programs.

### The Center of Excellence in Regulatory Science at Georgetown University

Established in August 2011, the Georgetown center, located in Washington, D.C., focuses on two FDA strategic priority areas: Stimulating Innovation in Clinical Trials and Personalized Medicine and Harnessing Diverse Data to Improve Health Outcomes. The center is conducting collaborative research on pharmacogenomics, modeling autoimmune disorders like multiple sclerosis and vaccine-related negative side effects, and studying the benefits and barriers to voluntary data-sharing among all types of medical product researchers and developers. These efforts will help industry and the FDA get



more out of the data we have, speeding and improving the review process. In addition, FDA staff can access a broad variety of continuing professional educational opportunities in Georgetown's clinical settings.

## Additional FDA Academic Collaborating Centers

The two new centers described above build on a history of productive academic/FDA collaboration, both through memoranda of understanding<sup>5</sup> and through established Centers of Excellence that are advancing research in food safety and nutrition.

Established in April 1996 by the FDA and the University of Maryland in College Park, the Joint Institute for Food Safety and Applied Nutrition (JIFSAN)<sup>6</sup> advances the use of the principles of food safety risk analysis to enhance public health, food protection, applied nutrition, and animal health. JIFSAN's resources and initiatives include the International Food Safety Training Laboratory and a portfolio of international food safety training programs such as Good Agricultural Practices; Good Aquacultural Practices; Commercially Sterile Packaged Foods; and Food Safety Risk Analysis.

Established in 1988 by the FDA and the Illinois Institute of Technology (IIT) in Chicago, the Institute for Food Safety and Health (IFSH)<sup>7</sup> is a one-of-a-kind applied food research institute that provides stakeholders with the opportunity to develop and exchange knowledge, experience, and expertise to address key issues in food safety, food defense, and nutrition. It is operated as a consortium of the FDA's Center for Food Safety and Applied Nutrition, IIT, and the food industry.

Supported by the FDA through congressional funding since 2002 and located at the University of Mississippi, Oxford, Mississippi, the National Center for Natural Product Research<sup>8</sup> houses the FDA's program for Botanical Dietary Supplement Research. The center facilitates the identification and analysis of ingredients in botanical dietary supplements, and helps ensure that they are safe and their labeling is truthful and not misleading. The center uses an extensive international network for access to authentic plant materials; botanicals scientific information; and extensive in-vitro toxicological testing protocols.

Western Center for Food Safety<sup>9</sup> at University of California, Davis, in partnership with the Western Institute for Food Safety

and Security (WIFSS), conducts multidisciplinary applied research on pre- and post-harvest food safety issues to enhance protection for FDA-regulated food products. WCFSS initiatives include field tracking of microbial contamination of fresh produce and the Produce Safety Research Network, a partnership for targeted research to protect food safety.

In addition, a virtual Center of Excellence at the University of Arkansas for Medical Sciences<sup>10</sup> was established in August 2011 by the FDA and the State of Arkansas. It conducts joint research, educational training, collaborations and outreach in support of the FDA's mission to protect and promote public health, with a particular focus on nanotechnology and regulatory science training.

These centers provide important sources of expertise, collaboration, and training for the FDA, helping to resolve challenges associated with complex scientific, public health, and regulatory issues, and assist academia and innovators in successfully applying new science to advancing public health. Both patients and public health benefit.

For more information, see the Centers of Excellence for Regulatory Science and Innovation Web page<sup>3</sup>.

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1. Critical Path  
<http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/default.htm>
2. Advancing Regulatory Science  
<http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/default.htm>
3. Centers of Excellence in Regulatory Science and Innovation (CERSI)  
<http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm301667.htm>
4. Center of Excellence in Regulatory Science at University of Maryland  
<http://www.cersi.umd.edu>
5. memoranda of understanding  
<http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/AcademiaMOUs/default.htm>
6. Joint Institute for Food Safety and Applied Nutrition (JIFSAN)  
<http://jifsan.umd.edu/>
7. Institute for Food Safety and Health (IFSH)  
<http://www.iit.edu/ifsh/>
8. National Center for Natural Product Research  
<http://www.pharmacy.olemiss.edu/ncnpr/fdapartnership.html>
9. Western Center for Food Safety  
<http://wcf.s.ucdavis.edu/>
10. Center of Excellence at the University of Arkansas for Medical Sciences  
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm267818.htm>