

**The Food and Drug Administration's (FDA's)
2015 ORSI Science Symposium
April 27, 2015
SPEAKER ABSTRACTS AND BIOGRAPHIES**

Speaker	Dr. Carol Linden
Title	Director, Office of Regulatory Science & Innovation
Biography	<p>Dr. Linden currently serves as the Director, Office of Regulatory Science and Innovation in the Office of the Chief Scientist, Office of the Commissioner, U.S. Food and Drug Administration. There she oversees a broad array of both intramural and extramural programs focused on bringing understanding of the latest in scientific and technological advances to the process of regulating products that support the health of the American public. Prior to assuming this position, Dr. Linden was the Principal Deputy Director of the Office of the Biomedical Advanced Research and Development Authority (BARDA) in the Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services. Her duties included oversight of advanced development and acquisition programs for Project BioShield medical countermeasures for CBRN threats as well as pandemic influenza vaccines, drugs, diagnostics and infrastructure. From October 2006 through April 2008 she also served as the Acting Director of BARDA, responsible for a doubling in the size of the office and implementation of the legislation that established the office.</p> <p>In 2009, Dr. Linden co-chaired with the Department of Defense the Working Group on Strengthening the Biosecurity of the United States, which was mandated by an Executive Order, and produced a report with recommendations submitted to the White House. She also played an active role in the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight, which made recommendations to support improvements in eight areas. More recently, she provided expertise to the Federal Experts Security Advisory Panel under the Executive Order "Optimizing the Security of Biological Select Agents and Toxins in the United States, and co-chaired a 2014 working group under the FESAP to review opportunities for improvements to the Select Agent Program.</p> <p>Dr. Linden previously served as the Senior Scientist for the Office of Research and Development in the Science and Technology Directorate of the Department of Homeland Security, overseeing treaty and regulatory compliance as well as international collaborations. Immediately prior to this position, she served as Deputy Director of the Office of Research Programs. Prior to joining the Department of Homeland Security, Dr. Linden was the Scientific Director for the Defense Threat Reduction Agency (DTRA) Chemical and Biological Defense Directorate from mid-2003 until spring of 2004. Before her detail to DTRA, she served as the Director for the Department of Defense Medical Chemical and Biological Defense Research Programs for over 3 years, managing all aspects of the joint services medical Chemical and Biological Defense Program. Dr. Linden served a critical function in coordinating the working relationship between the technology base and advanced development, facilitating the transition of candidate vaccines, diagnostic technologies and therapies to the developer.</p> <p>Dr. Linden obtained her bachelor's degree in biology from Bryn Mawr College, and a Ph.D. from the University of California Los Angeles in molecular biology. She conducted postdoctoral research at the California Institute of Technology and University of Maryland prior to joining the research staff at the U.S. Army Medical Research Institute of Infectious Diseases, where she subsequently served as the Chief, Research Plans and Programs.</p>