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

Session 4: Broad Agency Announcement (BAA) Research Contract Program Presentations – 1:45-3:00 PM

Speaker name and title	**Gary A. Hill, Ph.D.** **Vice President** **MANILA Consulting Group, Inc.**
Contractor	**MANILA Consulting Group, Inc.**
Biography	**Over his 40-year career, Dr. Hill has managed multiple concurrent projects with large teams of technical staff involving complex behavioral health and health policy issues. His expertise combines substantive knowledge of research methods, evaluation design, applied statistics, automated data collection, and performance monitoring and reporting systems. For the past 2 decades, Dr. Hill has successfully managed large, complex projects for several Health and Human Services agencies. His recent experience includes directing evidence-based reviews for the National Cancer Institute, the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Administration for Community Living. He currently serves as the project director for a Food and Drug Administration project supporting the agency's initiative related to advancing research and development of regulatory science and innovation. He also recently served as project director for the multiagency, national cross-site evaluation of the Safe Schools/Healthy Students (SS/HS) Initiative and SAMHSA's comparative effectiveness research project investigating the adoption of evidence-based behavioral health programs and practices by primary behavioral healthcare providers.**
Title of the project	**The National Medical Device Curriculum: Supporting Innovation by Enhancing Academic Regulatory Knowledge**
Presentation Abstract	**This presentation will describe the development of a case study-based curriculum that offers instructors the flexibility to tailor lessons to undergraduate and graduate students in diverse fields of study based on local needs and academic requirements and goals. The case study format is similar to that used by the Harvard Business Review. It is a first of a kind initiative to help FDA reach the goal of advancing regulatory science and innovation. The case studies and accompanying instructor guides are being made available to university professors on the FDA Web site who can use hands-on interactive exercises to teach students about regulatory issues, including basic concepts. The curriculum can be used for undergraduate and graduate students enrolled in a certificate or degree programs in engineering, medicine, pharmacology, regulatory science, or public health. Topics include medical device classification, intended use and indications for use, regulatory paths, 510(k), premarket approval, human factors, pre-submission meetings, IDE and clinical trials, quality management system, design controls, combination products, bench testing, animal testing, biocompatibility testing, and adverse events.**