U of Maryland Center for Excellence in Regulatory Science and Innovation

- Promote innovation in support of the development and evaluation of safe and effective products
- Main components:
    - Regulatory science collaborative research
        - Priority areas; Innovation Awards
    - Training and scientific exchange (bi-directional)
        - Monthly lectures at FDA
        - Science Exchange and Conference Grants
        - "America's Got Regulatory Science Talent" Competition
        - MS programs
- James Polli and William Bentley
- York Tomita, Frank Weichold, Sufian AlKhald, Shaila Shaheed, Leslie Wheelock, Jill Zung

UNIVERSITY of MARYLAND

M-CERSI

www.cersi.umd.edu

Priority Areas

- Improving pre-clinical assessments of the safety and efficacy of new drugs and devices
- Ensuring readiness to evaluate innovative and emerging technologies
- Harnessing diverse data through information sciences to improve health outcomes
- Addressing minority health and health disparities

FDA Staff Training

- Monthly lectures at White Oak since Spring 2012
  - David Greenblatt (Tufts University) - Drug Interactions with Fruit Beverages and Natural Products: Mechanisms and Consequences
  - John Fisher (University of Maryland) - Bone Tissue Engineering with Biomaterials and Bioreactors
  - Curtis Klaassen (University of Kansas) – New and Future Mechanisms of Hepatotoxicity
  - Peter Sorger (Harvard) - Measuring and Modeling Oncogenic Networks and Drugs that Target Them
  - Diane Jorkasky (Complexa Therapeutics) – Clinical Pharmacology Consideration in Oncology
  - Richard Kim (Western University, Canada) - Clinical and Pharmacogenomic Predictors of Statin Disposition and Response
- M-CERSI Day in Sept

2013-14 Science Exchange and Conference Grants

- Leveraging Big Data II-What does it Mean for Improving Product Development and Healthcare? (Feb 11)
- The Annual Mid Atlantic Micro/Nano Alliance Spring Symposium (Mar 3)
- AIMBE/NIH Workshop on Validation and Qualification of New In Vitro Tools and Models for the Pre-clinical Drug Discovery Process (Mar 6-7)
- Innovative Approaches to Pediatric Drug Development and Pediatric Medical Counter Measures: A Role for Physiologically-Based PK? (May 5)
- Questioning the Bioequivalence Standards for Antiepileptic Drugs: Implications for Regulation of Narrow Therapeutic Index Drugs (May 12)
- International Workshop on Tissue Phantoms and Standardization in Biophotonics (May 21)
- Top-Down Analysis of Antibodies (Jun 20)
- MALDI Mass Spectrometry Imaging of Drug Metabolism (TBD)

MS Programs

- MEng in Regulatory Science and Engineering (College Park)
  - A non-thesis program, the MEng (Master of Engineering) program will require 30 credits of coursework (10 courses)
  - Certificate in Regulatory of Science and Engineering is also planned (12 credits; 4 courses)
- MS in Regulatory Science (Baltimore)
  - non-thesis program; 30 credit; online exclusively; started 1/2014
  - REGS 603 Drug, Biologic, and Device Regulation
  - REGS 614 Drug Discovery
  - REGS 621 Drug Development
  - REGS 631 Clinical Research
  - REGS 641 Regulated Products in the Marketplace