Activity Outline
FDA Science Forum
May 31 - June 1, 2017
FDA White Oak, Great Room

Description
The FDA Science Forum is held every few years to inform the public about the cutting-edge science conducted at the Agency, and to show how scientific research is used in FDA's regulatory decisions to protect and promote public health. The Forum, which is open to FDA staff, FDA collaborators, and the public, offers an opportunity to hear FDA's scientific experts and renowned scientific thought leaders from across the country speak on a range of topics associated with regulatory science. The goals of this year's forum are to: 1) highlight the science conducted at FDA and show how scientific research informs regulatory decisions, focusing specifically on agency wide research topic areas of interest 2) expose FDA staff to cutting-edge research and technology currently being conducted/used in Centers and research being conducted by external scientists/organizations 3) enhance the scientific knowledge base needed to support Agency responsibilities for the approval of biologics, medical products, tobacco, food safety, and veterinary medicines.

References
FDA's Strategic Plan for Regulatory Science

Learning Objectives After completion of this activity, the participant will be able to:

1. Discuss the identification and evaluation of new biomarkers
2. Discuss FDA's response to urgent public health needs
3. Explore the relation between microbiome and human health
4. Explain the current developments in additive manufacturing and 3D printing technologies and their use in FDA-regulated products.
5. Identify Omics Technologies at the FDA
6. Explain issues related to patient and consumer engagement and communication
7. Describe opportunities and challenges of the use of modeling and simulation in the different phases of the life cycle of FDA-regulated products
8. Describe nanotechnology research at FDA

Target Audience
This activity is intended for physicians, pharmacists, nurses and reviewers who are involved in the clinical review and medical product approval areas.

Schedule
Pre-Forum Session
May 31, 2017
Non-CE

8:30 – 8:40 AM	Introduction **Bernadette Johnson-Williams, M. Ed, Senior Advisor for STEM, Office of the Chief Scientist**
8:40 – 8:50 AM	Welcome **FDA Acting Chief Scientist, Luciana Borio, M.D.**
8:50 – 9:05 AM	Remarks and Introduction of keynote speaker **FDA Commissioner, Scott Gottlieb, M.D.**
9:05 – 9:45 AM	Frontiers in Biomedical and Regulatory Science **Keynote Speaker: Eric Lander, PhD, President and Founding Director of the Broad Institute**

FDA Science Forum
Day 1
May 31, 2017

9:45 – 10:55 AM Poster Session 1 and Break *
Topics

1. Identification and Evaluation of New Biomarkers
2. FDA Response to Urgent Public Health Needs

10:55 – 12:40 PM **Concurrent Sessions 1 & 2**

Concurrent Session 1: Identification and Evaluation of New Biomarkers
Great Room Section B

Session Chair : **Lisa Meier McShane, PhD, Chief, Biostatistics Branch, Biometric Research Program, National Institutes of Health /National Cancer Institute**

10:55 – 11:25 AM FDA/National Institutes of Health Interactions and BEST
Lisa Meier McShane, PhD, Chief, Biostatistics Branch, Biometric Research Program, National Institutes of Health/NCI

11:25 – 11:35 AM Biomarker Qualification Program with Update, Case Studies and Challenges
Christopher Leptak, MD, PhD, Associate Director Of Biomarker Development Regulatory Science Team, **Center for Drug Evaluation and Research**

11:35 – 11:45 AM Biomarker Data in the Population Assessment of Tobacco and Health (PATH) Study
Cindy M. Chang, PhD, MPH, Epidemiologist, Center for Tobacco Products

11:45 – 11:55 AM Transcript, Proteo, and Metabol-omics as Tools for Translational Biomarker Discovery and Evaluation
William B. Mattes, PhD, DABT, Director, **Division of Systems Biology, National Center for Toxicological Research**

11:55 – 12:05 PM CDRH Perspectives on Imaging Biomarkers-Analytical Validation Expectations
Daniel M. Krainak, PhD, Biomedical Engineer, Center for Devices and Radiological Health

12:05 – 12:15 PM Next Generation Sequencing (NGS): FDA Approval of the 1st NGS Companion Diagnostic
Hisani Madison, PhD, MPH, Scientific Reviewer, Center for Devices And Radiological Health

12:15 – 12:40 PM Panel Discussion
Lisa Meier McShane, PhD; Christopher Leptak, MD, PhD; Cindy M. Chang, PhD, MPH; William B. Mattes, PhD, DABT; Daniel M. Krainak, PhD; and Hisani Madison, PhD, MPH

Concurrent Session 2: FDA Response to Urgent Public Health Needs

Great Room Section C

Session Chair: **RADM Palmer Orlandi, Jr, PhD, Chief Science Officer and Director of Research**, **Office**

of Foods and Veterinary Medicine

10:55 – 11:10 AM	FDA's Coordinated Response to Recent Foodborne Outbreaks **CDR Kari Irvin, MS**, **CORE Response Manager, Center for Food Safety and Applied Nutrition**
11:10 – 11:25 AM	Characterization and Analysis of Multidrug Resistant Foodborne Pathogens **Heather Tate, PhD, MS, Epidemiologist, Center for Veterinary Medicine**
11:25 – 11:40 AM	Forensic Analysis of a Mass Poisoning in Mozambique Associated with a Homebrewed Beverage **Travis Falconer, PhD, Chemist, Office of Regulatory Affairs**
11:40 - 11:55 AM	Use of a FDA Real Time Mobile Communication Platform System during Medical Countermeasure Events: RAPID **Henry "Skip" Francis, MD, Director for Data Mining and Informatics Evaluation and Research, Center for Drug Evaluation and Research**
11:55 – 12:10 PM	Development of Total and Neutralizing Anti-Ebolavirus Antibody Assays for Deployment in West Africa to Evaluate Clinical Trials of MCM including Vaccines and Immunotherapies **Gerardo Kaplan, PhD, Principal Investigator, Office of Blood Research and Review, Center for Biologics Evaluation and Research**
12:10 – 12:25 PM	Development of Mouse Models to Assess Efficacy and Potency of ZIKA Virus Therapeutics **Daniela Verthelyi, MD, PhD, Lab Chief, Office of Biotechnology Products, Center for Drug Evaluation and Research**
12:25 – 12:40 PM	Q&A Session **RADM Palmer Orlandi, Jr, PhD, Chief Science Officer and Director of Research, Office of Foods and Veterinary Medicine**
12:40 – 1:30 PM	Lunch*
1:30 – 3:30 PM	**Concurrent Sessions 3 & 4**

Concurrent Session 3: Microbiome and Human Health

Great Room Section B

Session Chair: **Ryan Ranallo, PhD, Program Officer, National Institutes of Health/ National Institute of Allergy and Infectious Diseases**

1:30 – 1:45 PM	The Human Microbiota in Health and Disease **Ryan Ranallo, PhD, Program Officer, National Institutes of Health, National Institute of Allergy and Infectious Diseases**
1:45 – 2:00 PM	MetaGenomeTrakr and Food Safety Microbiome Research at Center for Food Safety and Applied Nutrition **Andrea Ottesen, Ph.D., Research Microbiologist, Center for Food Safety and Applied Nutrition**

2:00 – 2:15 PM	MAIT Cells Alter the Murine Microbiome Reducing Colonization Resistance against *Clostridium difficile*. **Paul Carlson, PhD, Senior Staff Fellow, Center for Biologics Evaluation and Research**
2:15 - 2:30 PM	The Effect of Chlortetracycline on Swine Fecal Microbiome and Resistome **Daniel A. Tadesse, PhD, Research Microbiologist, Center for Veterinary Medicine**
2:30 - 2:45 PM	Interaction of Silver Nanoparticles Beyond Intestinal Bacterial Microbiota: Effects of Intestinal Virome and phages **Sangeeta Khare, PhD, Research Microbiologist, National Center for Toxicological Research**
2:45 – 3:00 PM	Impact of TNF Antagonist Treatment on the Gut Microbiome: an in Vivo Pilot Study **Odile Engel, PhD, Researcher, Center for Drug Evaluation and Research**
3:00 – 3:30 PM	Q&A Session **Ryan Ranallo, PhD, Program Officer, National Institutes of Health, National Institute of Allergy and Infectious Diseases**

Concurrent Session 4: Advanced Manufacturing and 3D Printing

Great Room Section C

Session Chair: **Andy Christensen, President, Somaden LLC**

1:30 - 1:45 PM	A Historical Perspective of 3D Printing in Clinical Medicine **Andy Christensen**, **President, Somaden LLC**
1:45 – 2:00 PM	Techniques for Performance and Process Evaluation of Advanced Manufacturing **LCDR James Coburn, MS, Sr. Research Engineer, Center for Devices and Radiological Health**
2:00 – 2:15 PM	Continuous Manufacturing Technologies **Celia Cruz, PhD, Division Director, Center for Drug Evaluation and Research**
2:15 – 2:30 PM	Manufacturing the Seasonal Flu Vaccine **Zhiping Ye, MD, PhD, Senior Investigator, Center for Biologics Evaluation and Research**
2:30 – 2:45 PM	Practical Microscale Technologies in the Assessment of Advanced Therapeutic Products in Center for Biologics Evaluation and Research **Kyung Sung, PhD, Principal Investigator, Center for Biologics Evaluation and Research**
2:45 – 3:00 PM	Continuous Bio-manufacturing Technologies **LCDR Cyrus Agarabi, PharmD, RPh, MBA, PhD, Regulatory Research Officer, Center for Drug Evaluation And Research**
3:00 – 3:15 PM	Advancing Characterization of 3D Printed Tissue Engineered Scaffolds **Maureen Dreher, PhD, MS, Research Biomedical Engineer, Center for Devices and Radiological Health**
3:15 - 3:30 PM	Q & A Session **Andy Christensen, President, Somaden LLC**

3:30 – 4:30 PM **Poster Session 2 and Break***

Topics:

1. Microbiome and Human Health
2. Additive Manufacturing and 3D Printing
3. FDA Response to Urgent Public Health Needs

4:30 PM **End of Day 1**

FDA Science Forum
Day 2
June 1, 2017

9:15 – 10:15 AM **Poster Session 3***

Topics:

1. Omics Technologies at the FDA
2. Patient and Consumer Engagement and Communication
3. FDA Response to Urgent Public Health Needs

10:15 – 12:00 PM **Concurrent Sessions 5 & 6**

Concurrent Session 5: Omics Technologies at the FDA

Great Room Section B

Session Chair**: Minnie Sarwal**, **MD, FRCP, DCH, PhD, Professor of Surgery, Director Division Precision Transplant Medicine, University of California, San Francisco, FDA Science Board member**

10:15 – 10:30 AM Omics Technologies at the FDA
Minnie Sarwal, **MD, FRCP, DCH, PhD, Professor of Surgery, Director Precision Transplant Medicine, University of California, San Francisco, FDA Science Board member**

10:30 - 10:45 AM FDA led community-wide Sequencing Quality Control Consortium 2- (SEQC2)
Weida Tong, **PhD, Division Director, Bioinformatics and Biostatistics - National Center for Toxicological Research**

10:45 – 11:00 AM FDA's GenomeTrakr Program: Advancing Food Safety Through Whole-Genome Sequencing of Foodborne Bacteria
Errol Strain, **PhD, Director, Biostatistics and Bioinformatics Staff, Center for Food Safety and Applied Nutrition**

11:00 – 11:15 AM MicroRNA Biomarkers of Acute Pancreatic Injury Use
Rodney Rouse, **DVM, MBA, PhD, Acting Associate Director, Division of Applied Regulatory Science, Office of Translational Science, Center for Drug Evaluation and Research**

11:15 – 11:30 AM FDA-ARGOS Microbial Reference Genomes for Regulatory Use: Zika and Ebola
Heike Sichtig, PhD, Subject Matter Expert, Principal Investigator, Center for Devices and Radiological Health

11:30 – 11:45 AM Glycomics Work-Flows for the Characterization of Vaccine Glycoprotein Antigens,
John Cipollo, **PhD, Principal Investigator, Lab of Bacterial Polysaccharides, Center**

for Biologics Evaluation and Research

11:45 – 12:00 PM Q&A Session
Minnie Sarwal, **MD, FRCP, DCH, PhD, Professor of Surgery, Director Division Precision Transplant Medicine, University of California, San Francisco, FDA Science Board member**

Concurrent Session 6: Patient and Consumer Engagement and Communication

Great Room Section C

Session Chair: **Brian J. Zikmund-Fisher, PhD, Associate Professor of Health Behavior and Health Education, University of Michigan**

10:15 – 10:20 AM Patient and Consumer Engagement and Communication
Brian J. Zikmund-Fisher, PhD, Associate Professor of Health Behavior and Health Education, University of Michigan

10:20 - 10:35AM Use of Flavored Tobacco Products: Findings from the Population Assessment of Tobacco and Health (PATH) Study
Bridget Ambrose, PhD, MPH, Supervisory Epidemiologist, Center for Tobacco Products

10:35 – 10:50 AM Understanding Mothers' Attitudes and Motivations Regarding Menu Labeling: Testing Messaging Concepts and Treatments,
Kathleen Yu, MPH, Social Scientist, Center For Food Safety and Applied Nutrition

10:50 – 11:05 AM Development of Tools to Capture the Patient Perspective with Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices
Michelle Tarver, MD, PhD, Medical Officer, Center for Devices and Radiological Health

11:05 - 11:20 AM Upper Limb Prostheses Patient Preference Study to Inform Clinical Trial Design and Regulatory Decisions
Heather Benz, PhD, Medical Device Fellow, Center for Devices and Radiological Health

11:20 - 11:35 AM Advancing the Science of Patient Input in a Regulatory Setting through Internal Capacity Building and Research
Million Tegenge, PhD, RPh, Visiting Scientist, Center for Biologics Evaluation and Research

11:35 - 11:50 AM Communicating Risk Information about Drugs: the Effect of Quantitative Information Type on Risk Perceptions and Understanding
Paula Rausch, PhD, RN, Associate Director, Research and Risk Communications, Center for Drug Evaluation and Research

11:50 - 12:00 PM Moderator's Comments and Closing Remarks
Brian J. Zikmund-Fisher, PhD, Associate Professor of Health Behavior and Health Education, University of Michigan

12:00 – 1:00 PM Lunch*

1:00 – 2:00 PM **Poster Session 4 and Break***

Topics:

1. Computational Modeling and Simulation at FDA
2. Current Progress in Nanotechnology Research at FDA

2:00 – 3:40 PM **Concurrent Sessions 7 & 8**

Concurrent Session 7: Computational Modeling and Simulation at FDA

Great Room Section B
Session Chairs: **Grace Peng, PhD, Director of Computational Modeling and Simulation, National Institutes of Health/ National Institute of Biomedical Imaging and Bioengineering**

2:00 – 2:10 PM Overview
Grace Peng, PhD, Director of Computational Modeling and Simulation, National Institutes Of Health/ National Institute of Biomedical Imaging and Bioengineering

2:10 – 2:20 PM Advancing Regulatory Science at FDA with Modeling and Simulation
Tina Morrison, PhD, Chair, Modeling and Simulation Working Group, Center for Devices and Radiological Health

2:20 – 2:30 PM Computational Electromagnetic Modeling and Medical Devices
Leonardo Angelone, Research Biomedical Engineer, Ph.D, Center for Devices and Radiological Health

2:30 – 2:40 PM Using (Q)SAR Modeling to Inform Drug Safety Assessment
Naomi Kruhlak, PhD, Chemist, Center for Drug Evaluation and Research

2:40 – 2:50 PM Modeling the U.S. Blood Supply for Emergency Preparedness
Mark Walderhaug, PhD, Microbiologist, Center for Biologics Evaluation and Research

2:50 - 3:00 PM Potential Uses for Modeling and Simulation in Veterinary Medicine
Marilyn Martinez, PhD, Senior Scientist, Center for Veterinary Medicine

3:00 - 3:10 PM Contamination of Food by Radionuclides after a Nuclear Accident
Danielle Larese, PhD, ORISE Fellow, Office of Regulatory Affairs

3:10 – 3:20 PM Modeling and Simulation in Tobacco Regulatory Science
Antonio Paredes, MA, MS, Lead Mathematical Statistician, Center for Tobacco Products

3:20 – 3:40 PM Q&A Session
Grace Peng, PhD, Director of Computational Modeling and Simulation, National Institutes of Health/ National Institute of Biomedical Imaging and Bioengineering

Concurrent Session 8: Current Progress in Nanotechnology Research at FDA

Great Room Section C

Session Chair: **Anil Patri, PhD, Director, Nanotechnology CORE, National Center for Toxicological Research**

2:00 – 2:20 PM Current Progress in Nanotechnology Research at FDA (NTF, CORES, Research Infrastructure Facilities)
Anil Patri, PhD, Director, Nanotechnology CORE, National Center for Toxicological Research

2:20 – 2:30 PM	The Safety of Nanomaterials Using Silver Nanoparticles as an Example **Mary Boudreau, PhD, Research Toxicologist, National Center for Toxicological Research**
2:30 - 2:40 PM	Drug Products Containing Nanomaterials **Katherine Tyner, PhD, Acting Associate Director of Science, Center for Drug Evaluation and Research**
2:40 - 2:50 PM	Nanotechnology and Medical Devices **Peter Goering, PhD, Research Toxicologist, Center for Devices and Radiological Health**
2:50 - 3:00 PM	Nanomaterial Based in Vitro Diagnostics for Pathogens **Indira Hewlett, PhD, Laboratory Chief, Center for Biologics Evaluation and Research**
3:00 - 3:10 PM	Potential Exposure to Nanoparticles from Nanotechnology-Enabled Food Contact Materials **Timothy Duncan, PhD, Research Chemist, Center for Food Safety and Applied Nutrition**
3:10 - 3:40 PM	Panel discussion **Anil Patri, PhD; Mary Boudreau, PhD; Katherine Tyner, PhD; Peter Goering, PhD; and Indira Hewlett, PhD**
3:40 – 3:50 PM	Closing Remarks and Adjourn **Carol Linden, PhD, Director, Office of Regulatory Science and Innovation**

***non-CE**

Continuing Education

The Food and Drug Administration, Center for Drug Evaluation and Research is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The Food and Drug Administration – Center for Drug Evaluation and Research designates this live activity for a maximum of 7 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

The FDA-Center for Drug Evaluation and Research is accredited by the Accreditation Council for Pharmacy Education as a Provider of continuing pharmacy education. (ACPE Universal Activity No. 0601-0000-17-099-L04-P). This program meets the criteria for 7 contact hour(s) of pharmacy education.

This activity is a knowledge-based activity**.** These CE activities are primarily constructed to transmit knowledge (i.e., facts). The facts must be based on evidence as accepted in the literature by the health care professions.

FDA, Center for Drug Evaluation and Research is an approved provider of continuing nursing education by the Maryland Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.
This 7 contact hour Education Activity is provided by FDA, Center for Drug Evaluation and Research. Each nurse should claim only the time that he/she actually spent in the educational activity.

Requirements for receiving CE credit
Physicians, pharmacists, nurses and those claiming non-physician CME: attendance is verified by a sign-in sheet and completion of the final activity evaluation. For multi-day activities, participants must sign in every day. Final activity evaluations must be completed within two weeks after the activity.

Pharmacy participants: partial credit cannot be awarded therefore you must attend the entire activity to receive CPE credit. No exceptions. Pharmacists will need their NABP e-profile ID number as well as their DOB in MMDD format in order to claim CE credit.

Statements of Credit
Physicians and Nurses Statements of Credit for CE will be issued 10 weeks after the last session of this activity. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty Disclosure:
Internal Faculty

- LCDR Cyrus Agarabi, Pharm.D., M.B.A, Ph.D. Regulatory Research Officer, Center for Drug Evaluation and Research /OPQ/OBP/DBRRII, nothing to disclose
- Bridget Ambrose, PhD, MPH, Epidemiologist, Center for Tobacco Products/OS/DPHS, discloses the following "spouse receives a salary from GenePeeks as an employee"
- Leonardo Angelone, Research Biomedical Engineer, Ph.D., Center for Devices and Radiological Health/OSEL/DBP, nothing to disclose
- Heather Benz, PhD, Staff Fellow, Center for Devices and Radiological Health/OCD, nothing to disclose
- Luciana Borio, M.D., FDA Acting Chief Scientist, Office of the Commissioners/OCS/OCET, nothing to disclose
- Mary Boudreau, PhD, Research Toxicologist, OCS/ National Center for Toxicological Research/OR/DBT, nothing to disclose
- Paul Carlson, PhD, Principal Investigator, Center for Biologics Evaluation and Research/OVRR/DBPAP/LMPCI, nothing to disclose
- Cindy M. Chang, PhD, MPH, Epidemiologist, Center for Tobacco Products/OS/DPHS, nothing to disclose
- John Cipollo, PhD, Research Chemist, Center for Biologics Evaluation and Research/OVRR/DBPAP/LBP, nothing to disclose
- LCDR James Coburn, MS, Sr. Research Engineer, Center for Devices and Radiological Health/OSEL/DBP, nothing to disclose
- Celia Cruz, PhD, Supervisory Chemist/Director, Center for Drug Evaluation and Research/OPQ/OTR/DPQR, nothing to disclose
- Maureen Dreher, PhD, MS, Research Biomedical Engineer, Center for Devices and Radiological Health/OSEL/DAM, nothing to disclose
- Timothy Duncan, PhD, Research Chemist, Center for Food Safety and Applied Nutrition/OFS/DFPST/PEB, nothing to disclose
- Odile Engel, PhD, Senior Staff Fellow, Center for Drug Evaluation and Research/OPQ/OBP/DBRRI, nothing to disclose
- Travis Falconer, Ph.D., Chemist, ORA, nothing to disclose
- Henry "Skip" Francis, M.D, Director, Datamining and Informatics Research and Evaluation Team, Center for Drug Evaluation and Research/OTS, nothing to disclose
- Peter Goering, PhD, Research Toxicologist, Center for Devices and Radiological Health/OSEL/DBCMS, nothing to disclose
- Scott Gottlieb, M.D., Commissioner, Food and Drug Administration
- Indira Hewlett, PhD, Laboratory Chief, Center for Biologics Evaluation and Research/OBRR/DETTD/LMV, nothing to disclose
- CDR Kari Irvin, MS, CORE Response Manager, Center for Food Safety and Applied Nutrition, nothing to disclose

- Gerardo Kaplan, PhD, Principal Investigator, Center for Biologics Evaluation and Research/OBRR/DETTD/LEP, discloses the following "I am currently the recipient of a grant from the Defense Threat Reduction Agency (DTRA)-DoD for research on an Ebola virus ultra-sensitive antigen detection test. I am also the Inventor on an US and International patent on an Ebola virus vaccine and antibody detection test"
- Sangeeta Khare, PhD, Research Microbiologist, National Center for Toxicological Research/OR/DM, nothing to disclose
- Daniel M. Krainak, Ph.D., Biomedical Engineer, Center for Devices and Radiological Health/OIR/DRH/MREP, nothing to disclose
- Naomi Kruhlak, PhD, Lead, Chemical Informatics Program, Center for Drug Evaluation and Research/OTS/OCP/DARS, nothing to disclose
- Danielle Larese, PhD, ORISE Fellow, Winchester Engineering and Analytical Center, ORA/FDA, nothing to disclose
- Christopher Leptak, MD, PhD, Associate Director of Biomarker Development Regulatory Science Team, Center for Drug Evaluation and Research/OND, nothing to disclose
- Carol Linden, PhD, Director, Office of Regulatory Science and Innovation, OCS, nothing to disclose
- Hisani Madison, PH.D., MPH, Scientific Reviewer, Center for Devices and Radiological Health/OIR/DMGP/MPCB, nothing to disclose
- Marilyn Martinez, PhD, Senior Biomedical Research Scientist, Center for Veterinary Medicine/ONADE, nothing to disclose
- William B. Mattes, PhD, DABT, Director, Division of Systems Biology, National Center for Toxicological Research/OR/FDA, discloses the following "spouse receives salary from Medimmune, a subsidiary of AstraZeneca, as an employee"
- Tina Morrison, Ph.D, Deputy Director, Division of Applied Mechanics, Center for Devices and Radiological Health/OSEL, nothing to disclose
- RADM Palmer Orlandi, Jr, PhD, Chief Science Officer and Director of Research, OFVM, nothing to disclose
- Andrea Ottesen, Ph.D, Research Microbiologist, Center for Food Safety and Applied Nutrition/ORS/DM/MMSB, nothing to disclose
- Antonio Paredes, MA, MS, Lead Mathematical Statistician, Center for Tobacco Products/OS, nothing to disclose
- Anil Patri, PhD, Director, Nanotechnology CORE, National Center for Toxicological Research/OSC, nothing to disclose
- Paula Rausch, PhD, RN, Associate Director, Research and Risk Communications, Center for Drug Evaluation and Research/OCOMM, nothing to disclose
- Rodney Rouse, D.V.M., M.B.A., Ph.D, Acting Associate Director, Division of Applied Regulatory Science, Center for Drug Evaluation and Research/OTS/OCP/DARS, nothing to disclose
- Heike Sichtig, PhD, Subject Matter Expert, Principal Investigator, Center for Devices and Radiological Health/OIR/DMD/VIR2, nothing to disclose
- Errol Strain, PhD, Director, Biostatistics and Bioinformatics Staff, Center for Food Safety and Applied Nutrition/OAO, nothing to disclose
- Kyung Sung, PhD, Principal Investigator, Center for Biologics Evaluation and Research/OTAT/DCGT/CTTB, nothing to disclose
- Daniel A. Tadesse, PhD, Research Microbiologist, Center for Veterinary Medicine/OR/DAFM, nothing to disclose
- Michelle Tarver, MD, PhD, Medical Officer, Center for Devices and Radiological Health/ODE/DOED, nothing to disclose
- Heather Tate, PhD, MS, Epidemiologist, National Antimicrobial Resistance Monitoring System (NARMS), Center for Veterinary Medicine/OR, nothing to disclose
- Million Tegenge, PhD, RPh, Visiting Scientist, Center for Biologics Evaluation and Research/OBE, nothing to disclose
- Weida Tong, Ph.D., Division Director, Division of Bioinformatics and Biostatistics, National Center for Toxicological Research/OR, nothing to disclose
- Katherine Tyner, PhD, Acting Associate Director of Science, Center for Drug Evaluation and Research/OPQ/SS, nothing to disclose
- Daniela Verthelyi, MD, PhD, Lab Chief, Lab of Immunology, Center for Drug Evaluation and Research/OPQ/OBP/DBRRIII, nothing to disclose
- Mark Walderhaug, PhD, Associate Office Director, Center for Biologics Evaluation and Research/OBE, nothing to disclose
- Bernadette Johnson-Williams, M. Ed, Senior Advisor for STEM, Office of the Chief Scientist, nothing to disclose
- Zhiping Ye, MD, PhD, Senior Investigator, Center for Biologics Evaluation and Research/OVRR/DVP/LPRVD, nothing to disclose

- Kathleen Yu, MPH, Social Scientist, Center for Food Safety and Applied Nutrition/OAO/DPHIA/CSB, nothing to disclose

External Faculty

- Andy Christensen, President, Somaden LLC, discloses the following "receives consulting income from 3D Systems Inc."
- Eric Lander, PhD, President and Founding Director of the Broad Institute, discloses the following "received stocks from Third Rock Ventures as a scientific advisory board member, honorarium from FPrime as a scientific advisory board member, stocks from Infinity Pharmaceuticals as a board member, stocks from NEON Therapeutics as a board member, stocks from Codiak as a board member. Purchased stocks from AETNA INC NEW, ALLERGAN PLC, ASTRAZENECA PLC, CARDINAL HEALTH INC, CELGENE CORP, COOPER COS INC, DENTSPLY INT'L INC, JAZZ PHARMACEUTICALS PLC, OTSUKA HOLDINGS CO LTD, PFIZER INC, SHIONOGI & CO LTD, SHIRE PLC GBP .05, ST JUDE MEDICAL INC, TEVA PHARM INDS LTD ADR, THERMO FISHER SCIENTIFIC, ZIMMER BIOMET HOLDINGS INC, ACCELERON PHARMA INC COM, AGIO PHARMACEUITICALS INC, BG MEDICINE INC, BLUEBIRD BIO INC, BLUEPRINT MEDICINES CORP, SAGE THERAPEUTICS. I am the President and Director of the Broad Institute. The Broad Institute has extensive relationships and activities with commercial interests in the healthcare industry"
- Lisa Meier McShane, PhD, Chief, Biostatistics Branch, Biometric Research Program, DCTD, National Institutes of Health /NCI, nothing to disclose
- Grace Peng, PhD, IMAG Chair, Director of Computational Modeling and Simulation and Analysis, NIBIB, National Institutes of Health, nothing to disclose
- Ryan Ranallo, PhD, Program Officer, National Institutes of Health, National Institute of Allergy and Infectious Diseases, nothing to disclose
- Minnie Sarwal, MD, FRCP, DCH, PhD, Professor of Surgery, Director of Precision Transplant Medicine, University of California, San Francisco, FDA Science Board member, discloses the following "received research grant paid from Bristol Meyers Squibb, Immucor, and Natera as a Principal Investigator for Sponsored Research"
- Brian J. Zikmund-Fisher, PhD, Associate Professor of Health Behavior and Health Education, University of Michigan, nothing to disclose

Planning Committee Members/CE Consultation and Accreditation Team

- Khaled Bouri, Ph.D., MPH, Interdisciplinary Scientist, FDA, nothing to disclose
- Emmanuel 'Tayo' Fadiran, PhD, RPh, Intramural Research Program Director, OC/OWH, retired April 28, 2017, nothing to disclose
- Virginia Giroux, MSN, ARNP, CE Program Administrator, FDA/Center for Drug Evaluation and Research/OEP/DLOD, nothing to disclose
- Justin Gorinson, CHES, ORISE Fellow, FDA/Center for Drug Evaluation and Research/OEP/DLOD, nothing to disclose
- Frank Weichold, MD, Director, Critical Path and Regulatory Science Initiative, OC/OCS/ORSI, nothing to disclose
- Bernadette Johnson-Williams, M. Ed, Senior Advisor for STEM, OC/OCS/OSPD, nothing to disclose
- Leslie Wheelock, RN, Director, OC/OCS/OSPD, nothing to disclose
- Karen Zawalick, CE Team Leader, FDA/Center for Drug Evaluation and Research/OEP/DLOD, nothing to disclose

Registration Fees and Refunds
Registration is complimentary therefore refunds are not applicable.

Requirements for Certificate of Completion (Non CE)
Must attend 80% of the lectures (verified by a sign-in sheet).

Initial Release Date: May 31, 2017