2019 FDA Science Forum: Transforming Health: Innovation in FDA Science
Wednesday, September 11, 2019 – Thursday, September 12, 2019
FDA White Oak Campus, Great Room

Activity Coordinator
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Description

The FDA Science Forum is held biannually to share with the public the unique scientific research and collaborative efforts of our 11,000 scientists. These researchers use novel science and technologies to inform FDA's regulatory decision-making—*and* drive innovation. FDA scientific experts and nationally renowned scientists will speak on eight varied regulatory topics during the 2019 FDA Science Forum, *Transforming Health: Innovation in FDA Science*. Sessions in the two-day event will highlight such areas of FDA research as new predictive tools for developing and evaluating therapeutics, advancing artificial intelligence, and evaluating digital health devices, and novel methods of tackling critical public health challenges like addiction. FDA's Science Forum welcomes the public, industry, academia, patient advocates, sister agencies, and current and potential collaborators to learn about the Agency's regulatory science. This type of science is rarely undertaken by industry or academia but makes critical contributions to product quality and safety.

References

FDA's Strategic Plan for Regulatory Science. Available: https://www.fda.gov/science-research/advancing-regulatory-science/strategic-plan-regulatory-science

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

1. Describe the breadth and diversity of approaches in the field of precision medicine and health in the regulatory space.
2. Discuss the potential utility and challenges of using Advanced Technology such as Advanced Manufacturing, Genomics, Computational Modeling to support the FDA's mission.
3. Explain product accessibility, bioterrorism and cybersecurity on food safety and medical devices and perverting preventing and mitigating product shortage.
4. Describe the principles and progress of example predictive tools used to evaluate the safety and effectiveness of FDA-regulated products.
5. Identify required information to assess if artificial intelligence (AI) applications can be used to evaluate real world evidence or devices and to analyze large data sets that are related to FDA's mission
6. Distinguish the varied levels of activities conducted by CDC and FDA in protecting public health from emerging outbreak threats by hearing the perspectives of subject matter experts and engaging in a panel discussion
7. Discuss the role of FDA in responding to the US public health crisis with opioids in the areas of the regulatory assessment of drug abuse potential, and how preclinical (biochemical and animal behavioral) evaluations of novel opioids are conducted.
8. Identify strategies used to communicate science and/or research findings to different stakeholder populations

Target Audience

This activity is intended for physicians, pharmacists, nurses, general public, patient advocates, academia, industry stakeholders, and FDA scientific community who are involved in FDA regulatory science to support FDA's mission.

AGENDA
Day 1
September 11, 2019

8:30 a.m.–8:35 a.m.	**Introduction** Rokhsareh Shahidzadeh, MSN Not offered for CE
8:35 a.m.-8:45 a.m.	**Welcome** FDA Chief Scientist, RADM Denise Hinton Not offered for CE
8:45 a.m.-8:55 a.m.	**Opening Remarks** Amy Abernethy, M.D., PhD, FDA Principal Deputy Commissioner, Chief Information Officer Not offered for CE
8:55 a.m.–9:10 a.m.	**Remarks and Introduction of Keynote Speaker** FDA Acting Commissioner Ned Sharpless, MD Not offered for CE
9:10 a.m.–9:40 a.m.	**Keynote Speaker:** Francis Collins MD, PhD, Director, National Institutes of Health FDA and NIH: Partners in Transformation

9:40 a.m.-9:50 a.m. **Break**

Poster Session 1
Great Room Section C and Room 1504

Time	Topics
9:50 a.m.–10:50 a.m.	Precision Health Advanced Technology **Not offered for CE**

10:50 a.m.– 12:50 p.m. Concurrent Sessions 1 & 2

Concurrent Session 1: Precision Health
Great Room Section A
Session Chairs/Moderator: Rhonda Moore, PhD

Time	Presentation	Speaker
10:50 a.m.–10:55 a.m.	Introduction	Rhonda Moore, PhD CDER-FDA
10:55 a.m.–11:10 a.m.	Regulatory Perspective on Digital Health for Precision Medicine	Bakul Patel, MSEE, MBA CDRH-FDA
11:10 a.m.–11:25 a.m.	Sex and Gender Differences in Health and Disease	Beverly Lyn-Cook, PhD NCTR-FDA
Time	**Presentation**	**Speaker**
11:25 a.m.–11:40 a.m.	Clinical Trials In 200 Microliters – Extending Approval in Rare Diseases Using *In Vitro* Data.	Jim Weaver, PhD CDER-FDA
11:40 a.m.–11:55 a.m.	Genomic Biomarker Use in Cardiovascular Disease Clinical Trials	Oluseyi Adeniyi, PhD, PharmD CDER-FDA
11:55 a.m.–12:25 p.m.	Learning Healthcare Systems and Big Data: Advancing the Goal of Precision Pain Medicine	Sean Mackey, MD, PhD Stanford University
12:25 p.m.–12:50 p.m.	Panel Discussion /Q&A	Bakul Patel, MSEE, MBA Beverly Lyn-Cook, PhD Jim Weaver, PhD Oluseyi Adeniyi, PhD., PharmD Sean Mackey, MD, PhD

Concurrent Session 2: Advanced Technology
Great Room Section B
Session Chairs/Moderator: Darón Freedberg, PhD. CBER-FDA

Time	Presentation	Speaker
10:50 a.m.–11:15 a.m.	Accelerating Innovation in Manufacturing Technology for Biomanufactured Products: Manufacturing U.S. and NIST	Kelley Rogers, PhD National Institute of Standards and Technology
11:15 a.m.–11:30 a.m.	MetagenomeTrakr Pilot Program for Rapid Foodborne Pathogen Detection	Paul Morin, PhD ORA-FDA
11:30 a.m.–11:45 a.m.	The Promise of Microbial Genomics: How Microbiology is Standing Up to the Many Challenges of a 21st Century Food Supply	Marc Allard, PhD CFSAN-FDA
11:45 a.m.–12:00 p.m.	Editing the Genome without DNA Breaks	Jakob Reiser, PhD CBER-FDA
12:00 p.m.–12:15 p.m.	Computational Modeling for Medical Devices	Pras Pathmanathan, PhD, CDRH-FDA
12:15 a.m.–12:30 p.m.	Avian Influenza A Susceptibilities to Pulmonary Surfactant Protein D: Confirmation of N-glycan sub-type as a Pathogenic Factor in Influenza	John Cipollo, PhD CBER-FDA
Time	**Presentation**	**Speaker**
12:30 p.m.–12:50 p.m.	Panel Q & A, Advanced technology at FDA: Potential Utility and Regulatory Challenges Moderator: Glenn Black, PhD CBER-FDA	Kelley Rogers, PhD Paul Morin, PhD Marc Allard, PhD Jakob Reiser, PhD Pras Pathmanathan, PhD John Cipollo, PhD Anil Patri, PhD, OC-FDA

12:50 – 1:40 p.m. **Lunch** **Not offered for CE**

Concurrent Session 3 & 4

1:40 p.m.– 3:40 p.m.

Concurrent Session 3: Product Accessibility, Integrity, and Security
Great Room Section A
Session Chairs/Moderator: Stephen Perrine, M. S, .and Leslie Rivera Rosado, PhD

Time	Presentation	Speaker
1:40 p.m.–1:45 p.m.	Introduction Product Accessibility, Integrity, and Security	Leslie Rivera Rosado, PhD, CDER-FDA Stephen Perrine, M.S. CFSAN-FDA
1:45 p.m.–2:00 p.m.	Violent Non-State Actor Use of Food as a Delivery System: Comparing ideological and Non-Ideological Perpetrators	Markus Binder, M.A. University of Maryland
2:00 p.m.–2:15 p.m.	Product Availability: A Drug Shortage Perspective	Hyun J. Son Pharm.D CDER-FDA
2:15 p.m.–2:30 p.m.	Bio-Terrorism Regulations and Food Security	Desmond Brown, D.Sc. ORA-FDA
2:30 p.m.–2:45 p.m.	FDA Food Defense Efforts – A Preventive Approach to Food Terrorism	Ryan Newkirk, PhD, MPH CFSAN-FDA
2:45 p.m.–3:00 p.m.	CBER-Regulated Products: Preventing and Mitigating Shortages	Anita Richardson, MAS CDER-FDA
3:00 p.m.–3:15 p.m.	On the 'Cyber-Securability' of Medical Devices	Eugene Vasserman, PhD Kansas State University
Time	**Presentation Title**	**Speaker**
3:15 p.m.–3:40 p.m.	Panel Discussion	Moderators: Leslie Rivera Rosado, PhD Stephen Perrine, M.S. Panel members: Markus Binder, M.S. Hyun J. Son Pharm.D. Desmond Brown, M.S. Ryan Newkirk, PhD, CFSAN-FDA Anita Richardson, MAS Eugene Vasserman, PhD

Concurrent Session 4: Predictive Tools

Great Room Section B
Session Chairs/Moderator: Donna Mendrick, PhD

Time	Presentation	Speaker
1:40 p.m.–2:10 p.m.	Digital Biomarkers Discovery from Patient-Generated Health Data	Luca Foschini, PhD Evidation Health
2:10 p.m.– 2:25 p.m.	MRI In Nonclinical Safety Assessment	Serguei Liachenko MD, PhD NCTR-FDA
2:25 p.m.–2:40 p.m.	The VICTRE Project: The First All-*In-Silico* Imaging Clinical Trial	Aldo Badano, PhD CDRH-FDA
2:40 p.m.– 2:55 p.m.	Use of The MHC Associated Peptide Proteomic Assay to Understand the Immunogenicity Risk of Therapeutic Proteins	Zuben Sauna, PhD CBER-FDA
2:55 p.m.– 3:10 p.m.	Cardiac and Hepatic Cellular Systems to Model Human Drug Effects	Alexandre Ribeiro, PhD CDER-FDA
3:10 p.m.– 3:25 p.m.	C. elegans for Rapid Developmental Neurotoxicity Assessment of Mixtures	Piper Hunt, PhD CFSAN-FDA
3:25 p.m.– 3:40 p.m.	Determination of Seafood Decomposition by Mass Spectrometry with Sensory-Driven Modeling	Randy L. Self, PhD ORA-FDA

Poster Session 2
Great Room Section C and Room 1504

Time	Topics
3:40 p.m.– 4:40 p.m.	Advanced Technology Product Accessibility, Integrity, and Security Predictive Tools **Not offered for CE**

End of Day One

Day 2
September 12, 2019

Poster Session 3
Great Room Section C and Room 1504

Time	Topics
9:00 a.m.–10:00 a.m.	Predictive Tools Advancing Digital Health and Artificial Intelligence **Not offered for CE**

Concurrent Session 5: Advancing Digital Health and Artificial Intelligence

Great Room Section A
Session Chair / Moderator: Qi Liu, PhD / Richard Forshee, PhD

Time	Presentation	Speaker
10:00 a.m. – 10:05 a.m.	Welcome to Advancing Digital Health and Artificial Intelligence	Qi Liu, PhD CDER-FDA
10:05 a.m. – 10:45 a.m.	Deep Learning for Polypharmacy and Drug Repurposing	Marinka Zitnik, PhD Stanford University
10:45 a.m. – 11:05 a.m.	FDA's Real-World Evidence Program – Technology and Innovation as a Cornerstone	Jacqueline Corrigan-Curay, J.D., MD CDER-FDA
11:05 a.m. – 11:25 a.m.	Assessment of Devices that Rely on Artificial Intelligence / Machine Learning	Berkman Sahiner, PhD CDRH-FDA
11:25 a.m. – 12:00 p.m.	AI at FDA: Potential Utility and Regulatory Challenges	Richard Forshee, PhD, CBER-FDA Yaning Wang, PhD, CDER-FDA Berkman Sahiner, PhD, CDRH-FDA Errol Strain, PhD, CVM-FDA Rhonda Moore, PhD, CDER-FDA Joshua Xu, PhD, NCTR-FDA Marinka Zitnik, PhD, CDER-FDA

Concurrent Session 6: Outbreak!

Great Room Section B
Session Chairs/Moderator: Surender Khurana, PhD

Time	Presentation	Speaker
10:00 a.m.–10:30 a.m.	Innovation in Science: Protecting People from Emerging Infectious Disease Threats	Christopher R. Braden, MD Centers for Disease Control and Prevention (CDC)
10:30 a.m. –10:45 a.m.	Foodborne Outbreak Investigations in the Whole Genome Sequencing Era	Jennifer Beal, MPH CFSAN-FDA
10:45 a.m. –11:00 a.m.	Immune Responses to Zika Infections	Steven Wood, PhD, CDRH-FDA
11:00 a.m.–11:15 a.m.	Tracking antibiotic resistance in Salmonella: The role of the National Antimicrobial Resistance Monitoring System.	Patrick McDermott, PhD, CVM-FDA
11:15 a.m.–11:30 a.m.	Emerging & Pandemic Threat Preparedness	Jerry Weir, PhD, CBER-FDA
11:30 a.m.–11:40 a.m.	Strengthening Regulatory Science to Support the Development of Medical Countermeasures for Emerging Infectious Diseases	Tracy MacGill, PhD, OC-FDA
11:40 a.m.–12:00 p.m.	Panel Discussion	Panel Discussion Moderator: Chad Nelson, PhD, OC-FDA Christopher R. Braden, MD Steven Wood, PhD Patrick McDermott, PhD Jennifer Beal, MPH

12:00 – 1:00 p.m. **Lunch** **Not offered for CE**

Poster Session 4
Great Room Section C and Room 1504

Time	Topics
1:00 p.m.– 2:00 p.m.	Advancing Digital Health and Artificial Intelligence Outbreak!

	Addiction Impacting Public Health Through Electronic Media: Empowering Consumers, Patients, and Other Stakeholders **Not offered for CE**

Concurrent Sessions 7 & 8
2:00 – 4:00 p.m.
Concurrent Session 7: Addiction

Great Room Section A
Session Chairs/Moderators: Katherine Bonson, PhD, Chad Reissig, PhD

Time	Presentation	Speaker
2:00 p.m.–2:05 p.m.	Introduction	Katherine Bonson, PhD, CDER-FDA
2:05 p.m.–2:20 p.m.	Drug abuse in the U.S.	Chad Reissig, PhD, CDER-FDA
2:20 p.m.–2:35 p.m.	FDA response to the opioid crisis	Marta Sokolowska, PhD, CDER-FDA
2:35 p.m.–2:50 p.m.	Assessing the structural and pharmacological similarity of newly identified drugs of abuse to controlled substances using PHASE	Christopher Ellis, PhD, CDER-FDA
2:50 p.m.–3:10 p.m.	Preclinical pharmacology of novel synthetic opioids appearing in clandestine drug markets	Michael Baumann, PhD National Institute on Drug Abuse (NIDA)
3:10 p.m.–3:25 p.m.	FDA assessment of the abuse potential of drugs, including opioids	Katherine Bonson, PhD, CDER-FDA
3:25 – 4:00 p.m.	Panel Discussion	Chad Reissig, PhD Marta Sokolowska, PhD Christopher Ellis, PhD Michael Baumann, PhD Katherine Bonson, PhD

Concurrent Session 8: Impacting Public Health Through Electronic Media: Empowering Consumers, Patients, and Other Stakeholders

Great Room Section B
Session Chair/Moderator: Ryan Kennedy, PhD

Time	Presentation	Speaker

2:00 p.m.– 2:20 p.m.	Tobacco Regulatory Science – Understanding the Role of Flavor in E-Cigarette Marketing	Ryan Kennedy, PhD Johns Hopkins Bloomberg School of Public Health
2:20 p.m.– 2:35 p.m.	Using Content Analysis to Understand Tobacco Industry Use of Technology to Engage Consumers	Mario Navarro, PhD, CTP-FDA
2:35 p.m.– 2:50 p.m.	Consumers' Use of Personal Electronic Devices in the Kitchen	Amy Lando, MPP, CFSAN-FDA Michael Bazaco, PhD, CFSAN-FDA
2:50 p.m.– 3:05 p.m.	Assessment of Patient Perspective on Risks and Benefits Associated with High Intensity Focused Ultrasound (Hifu) for The Ablation of Prostate Tissue in Men With Localized Prostate Cancer	Charles Viviano, M.D., PhD CDRH-FDA
3:05 p.m.- 3:20 p.m.	Clinical Outcome Assessments in Medical Product Development	Elektra Papadopoulos, MD, CDER-FDA
3:20 p.m.– 3:35 p.m.	Collect Once, Use Many Times: Challenges and Opportunities for the Use of Real-World Evidence to Improve Healthcare	Gregory Pappas, MD., PhD, CBER-FDA
3:35 p.m.– 4:00 p.m.	Panel Discussion Moderator: Ryan Kennedy	Ryan Kennedy, PhD Mario Navarro, PhD Amy Lando, MPP Michael Bazaco, PhD Charles Viviano, MD, PhD Elektra Papadopoulos, MD Gregory Pappas, M.D., PhD

Continuing Education Accreditation

In support of improving patient care, FDA Center for Drug Evaluation and Research is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.

This activity was planned by and for the healthcare team, and learners will receive 8.50 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

CME

FDA Center for Drug Evaluation and Research designates this live activity for a maximum of 8.50 *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CPE

This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-19-068-L04-P for 8.50 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 8.50 contact hour(s).

Requirements for Receiving CE Credit

Physicians, pharmacists, nurses, and those claiming non-physician CME: participants must attest to their attendance and complete the final activity evaluation via the CE Portal (ceportal.fda.gov). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - 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.

Important Note regarding completion of evaluations and receiving credit
Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit. Physicians and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

Disclosures:

Faculty

- Adeniyi, Oluseyi, PhD, PharmD, OCP, CDER - nothing to disclose
- Allard, Marc, PhD, Resesarch Microbiologist, US FDA CFSAN – nothing to disclose
- Badano, Aldo, Deputy Director, CDRH/OSEL/DIDSR - nothing to disclose
- Baumann, Michael, PhD, Unit Chief, IRP, NIDA, NIH, DHHS - nothing to disclose
- Bazaco, Michael, PhD, MS, Epidemiologist, US Food and Drug Administration - nothing to disclose
- Beal, Jennifer, MPH, Senior Epidemiologist, FDA/CFSAN/CORE - nothing to disclose
- Binder, Markus, MA, Senior Researcher, National Consortium for the Study of Terrorism and Responses to Terrorism (START)*I received Honorarium from Emergent Biotech Solutions for a role as Consultant.*
- Black, Glenn, PhD, Associate Director for Research, FDA/CFSAN/OFS/DFPST - nothing

to disclose

- Bonson, Katherine, PhD, Pharmacologist, Controlled Substance Staff, Food and Drug Administration - nothing to disclose
- Braden, Christopher, MD, Deputy Director, National Center for Emerging and Zoonotic Infectious Diseases - nothing to disclose
- Brown, Desmond, D.Sc, Supervisory Consumer Safety Officer, FDA-OEIO-DFDT - nothing to disclose
- Cipollo, John, PhD, Research Chemist, Food and Drug Administration - nothing to disclose
- Collins, Francis S, MD, PhD, Director, National Institutes of Health - nothing to disclose
- Corrigan-Curay, Jacqueline, MD, JD, Director Office of Medical Policy, CDER *May reference off-label use.*
- Ellis, Chris, PhD, Research Chemist, Food and Drug Administration - nothing to disclose
- Forshee, Richard, PhD, Associate Director of Research, FDA/CBER/OBE - nothing to disclose
- Foschini, Luca, PhD, Chief Data Scientist, Evidation Health - nothing to disclose
- Freedberg, Daron, PhD, Senior Scientist, CBER, FDA - nothing to disclose
- Hunt, Piper, PhD, Research Biologist, FDA/CFSAN/OARSA/DT - nothing to disclose
- Kennedy, Ryan, PhD, Assistant Professor, Johns Hopkins Bloomberg School of Public Health - nothing to disclose
- Khurana, Surender, Research Biologist, FDA, nothing to disclose
- LIU, QI, PhD, Team Leader, FDA - nothing to disclose
- Lando, Amy, MPP, Social Scientist, CFSAN/FDA - nothing to disclose
- Liachenko, Serguei, MD, PhD, Director of Bioimaging, NCTR - nothing to disclose
- Lyn-Cook, Beverly, PhD, Research Biologist, National Center for Toxicological Research - nothing to disclose
- MacGill, Tracy, PhD, Director, MCM Regulatory Science, OCET, OCS, OC, FDA *My spouse received Salary from PATH for a role as Employee. My spouse received Stocks from AstraZeneca for a role as Other - Stocks retained from prior employment.*
- Mackey, Sean, MD, PhD, Professor, Chief, Division of Pain Medicine, Stanford University, School of Medicine, nothing to disclose

- McDermott, Patrick, PhD, Director, The Division of Animal and Food Microbiology, FDA Center for Veterinary Medicine - nothing to disclose
- Mendrick, Donna, Associate Director, Regulatory Activities, NCTR - nothing to disclose
- Moore, Rhonda, PhD, Social Scientist, US FDA-CDER - nothing to disclose
- Morin, Paul, D.Sc, Microbiologist, ORA/Northeast Food and Feed Laboratory - nothing to disclose
- Navarro, Mario, PhD, Social Scientist, Center for Tobacco Products - nothing to disclose
- Nelson, Chad, PhD, Toxicologist, FDA/CFSAN - nothing to disclose
- Newkirk, Ryan, PhD, MPH, Senior Advisor for Intentional Adulteration, FDA - nothing to disclose
- Papadopoulos, Elektra, MD, MPH, Associate Director Clinical Outcome Assessments Staff, FDA/CDER/OND/IO/COA Staff - nothing to disclose
- Pappas, Gregory, MD, PhD, Associate Director, FDA/CBER/OBE - nothing to disclose
- Patel, Bakul, MS, MBA, Director, Digital Health, Center for Devices and Radiological health - nothing to disclose
- Pathmanathan, Pras, Research scientist, FDA - nothing to disclose
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- Perrine, Stephen, Policy Analyst, U.S. Food and Drug Administration - nothing to disclose
- Reiser, Jakob, PhD, Principal Investigator, FDA/CBER *My spouse received Salary from My wife works as a medical biller for a dermatologist for a role as Employee.*
- Reissig, Chad, PhD, Supervisory Pharmacologist, FDA - nothing to disclose
- Ribeiro, Alexandre, PhD, Staff Fellow, Food and Drug Administration - nothing to disclose
- Richardson, Anita, MAS, Associate Director for Policy, FDA/CBER/OCBQ - nothing to disclose
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- Strain, Errol, PhD, Senior Advisor for Science Informatics, FDA - nothing to disclose
- Vasserman, Eugene, PhD, Associate Professor, Kansas State University, *May reference off-label use.*
- Viviano, Charles, MD, PhD, Supervisory Medical Officer, FDA - nothing to disclose
- Wang, Yaning, PhD, Director, Division of Pharmaceutics, OCP/OTS/CDER/FDA - nothing to disclose
- Weaver, Jim, PhD, Research Pharmacologist, DARS/OCP/OTS/CDER/FDA - nothing to disclose
- Weir, Jerry, PhD, Director, Division of Viral Products, FDA/CBER/OVRR/DVP - nothing to disclose
- Wood, Steven, PhD, Research Biologist, Division of Biology, Chemistry and Materials Science - nothing to disclose
- Xu, Joshua, PhD, Branch Chief, Research-to-Review, Division of Bioinformatics and Biostatistics, FDA/NCTR - nothing to disclose
- Zitnik, Marinka, PhD, Postdoctoral Fellow & Assistant Professor, Stanford University & Harvard University - nothing to disclose

Planning Committee

- Bertolaccini, Kara, PharmD, Project Manager, FDA - nothing to disclose
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- SHAHIDZADEH, ROKHSAREH, MSN, Senior Regulatory Health Education Specialist, FDA - nothing to disclose
- Watkins-Bryant, Theresa, MD, Medical Officer, FDA/CTP/OS/DIHS/MEDICAL - nothing to disclose

CE Consultation and Accreditation Team

- Lisa Thompson, MSHA, MBA, CE Consultant, FDA/CDER/OEP/DLOD - nothing to disclose
- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

Registration Fee and Refunds
Registration is complimentary; therefore refunds are not applicable.

Requirements for Certificate of Completion (Non-CE)
There are no imposed requirements.