Activity Outline
FDA Regulatory Education for Industry (REdI) Annual Conference 2022
June 6 - 10, 2022

Activity Coordinators:
Forest Ford (forest.ford@fda.hhs.gov), Brenda Stodart (brenda.stodart@fda.hhs.gov)

Description
The drugs Track will focus on several key components of the PDUFA VII goals. It will identify new processes and enhancements to existing practices of the human drug review program, including new approaches to increase efficiencies and expand communication and feedback. Subject matter experts will provide cutting edge insights and perspectives on how these goals will be implemented at the practical level. The devices track will provide an introduction to the device regulatory framework, and useful insights into the development of a high quality marketing submission. It will also discuss key program updates across the device total product lifecycle to allow audiences to be current on important device regulatory policies. The biologics track will focus on the development of advanced therapies, including cellular and tissue-based products, gene therapies, and xenotransplantation products. Speakers will present updates on various regulatory aspects of cellular and gene therapy product development along with new topics related to the regulation of xenotransplantation products and post-marketing safety signal evaluation and risk mitigation for approved advanced therapies.

This activity may reference off-label use of FDA-approved products.

References
- Drug Development & Approval Process https://www.fda.gov/drugs/development-approval-process-drugs
- CDRH Learn https://www.fda.gov/training-and-continuing-education/cdrh-learn
- CBER OTAT Learn: https://www.fda.gov/vaccines-blood-biologics/news-events-biologics/otat-lea rn

Learning Objectives
- Problem solve and address drug/device regulatory issues as they arise based on activity content.
- Identify the appropriate FDA office to contact relevant to their medical product submission.
- Identify and apply several essential components of New Drug Applications (NDAs), Biologics License Applications (BLAs), Medical Device submissions.

Target Audience
This activity is intended for physicians, pharmacists, and nurses.

Agenda
Day 1 June 6, 2022

Time	Topic	Speaker
8:40 - 9:00 AM EDT	Welcome - Opening Remarks	Brenda Stodart, PharmD, BCGP, RAC
9:00 - 9:15 AM EDT	Keynote	Robert M. Califf, MD
9:15 - 10:45 AM EDT	Plenary COVID19: What's Next for FDA?	Jeff Shuren, MD, JD Peter Marks, MD, PhD Douglas Throckmorton, MD Patrizia Cavazzoni, MD
10:45 - 11:00 AM EDT	*BREAK*	
11:00 - 11:20 AM EDT	PDUFA Program Overview and Reauthorization Process Update	Kevin Bugin, PhD, RAC
11:20 - 11:50 AM EDT	Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products	Jeannie Roule
11:50 - 12:05 PM EDT	Question and Answer Panel	Kevin Bugin, PhD, RAC Jeannie Roule
12:05 - 12:35 PM EDT	*LUNCH*	
12:35 - 1:20 PM EDT	Advances in Drug Supply Chain Security – Focus on Distribution	Connie Jung
1:20 - 1:40 PM EDT	IT and Informatics Goals – CDER's Perspective	Mary Ann Slack, BS
1:40 - 2:00 PM EDT	Electronic Submissions Gateway (ESG) Transparency and Modernization	Lowell Marshall, BS
2:00 - 2:20 PM EDT	Standardizing Quality Submissions and Assessments: PQ/CMC and KASA	Norman Schmuff, PhD
2:20 - 2:35 PM EDT	Question and Answer Panel	Mary Ann Slack, BS Lowell Marshall, BS Norman Schmuff, PhD
2:35 - 2:50 PM EDT	*BREAK*	
2:50 - 3:20 PM EDT	CDER NextGen Portal - An Update	Seyoum Senay, MS
3:20 - 3:40 PM EDT	eCTD Updates	Jonathan Resnick
3:40 - 4:00 PM EDT	Study Data Technical Rejection Criteria Update	Heather Crandall

4:00 - 4:20 PM EDT	Question and Answer Panel	Seyoum Senay, MS Jonathan Resnick Heather Crandall
4:20 - 4:25 PM EDT	CDER Day One Closing	Forest Ford

Day 2 June 7, 2022

Time	Topic	Speaker
8:30 - 8:45 AM EDT	Day Two Welcome and Overview	Forest Ford Renu Lal, Pharm.D.
8:45 - 9:05 AM EDT	FDA Oncology Center of Excellence (OCE) Innovative Programs: Real Time Oncology Review (RTOR), Assessment Aid, and Project Orbis	Tamy Kim, PharmD
9:05 - 9:35 AM EDT	Integrated Assessment of Marketing Applications (IAMA)	Rhonda Hearns-Stewart, MD
9:35 - 10:05 AM EDT	BsUFA III: Overview of Commitments	Keith Olin
10:05 - 10:20 AM EDT	Question and Answer Panel	Rhonda Hearns-Stewart, MD Keith Olin Tamy Kim, PharmD
10:20 - 10:35 AM EDT	*BREAK*	
10:35 - 11:50 AM EDT	Partnering Across FDA to Advance Therapies for Rare Diseases	Kerry Jo Lee, M.D. SANDRA RETZKY, MD, JD Julienne Vaillancourt, MPH, R. Ph
11:50 - 12:20 PM EDT	*LUNCH*	
12:20 - 1:05 PM EDT	FDA Adverse Event Reporting System (FAERS) reporting and review	Suranjan De
1:05 - 1:35 PM EDT	Enhancement and Modernization of the FDA Drug Safety System: Review of postmarket safety commitments under PDUFA VII	Amy Ramanadham Patricia Bright, PhD Claudia Manzo, PharmD
1:35 - 2:05 PM EDT	Risk Evaluation and Mitigation Strategies (REMS) Integration and Innovation	Ed Millikan, PharmD, R. Ph George Neyarapally, PharmD, JD, MPH, R. Ph
2:05 - 2:20 PM EDT	*BREAK*	
2:20 - 2:50 PM EDT	Leveraging SBIA's Resources	Renu Lal, Pharm.D.
2:50 - 3:50 PM EDT	Prescription Drug Labeling Updates	Eric Brodsky, MD
3:50 - 4:20 PM EDT	Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs – An Overview of FDA's Guidance for Industry	Jamie Gamerman, JD
4:20 - 4:30 PM EDT	CDER Day Two Closing	Brenda Stodart, PharmD, BCGP, RAC

Day 3 June 8, 2022

Time	Topic	Speaker
8:30 - 8:45 AM EDT	Welcome to REdI 2022 Device Track, Part 1	Elias Mallis
8:45 - 9:25 AM EDT	Navigating the Medical Device Regulatory Framework Utilizing CDRH Resources	Kimberly Piermatteo, MHA
9:25 - 10:05 AM EDT	Chemical Characterization of Non-targeted Analysis of Medical Device Extracts	Berk Oktem, PhD, DABT
10:05 - 10:25 AM EDT	BREAK	*Not offered for CE*
10:25 - 11:05 AM EDT	Introduction to the Breakthrough Devices and Safer Technologies Programs	Ouided Rouabhi, MS
11:05 - 11:45 AM EDT	CDRH Health of Women Program: The Science of Sex and Gender	Terri Cornelison, MD, PhD
11:45 - 12:45 PM EDT	*LUNCH*	
12:45 - 1:25 PM EDT	510(k) Submission Types and Reasons for Conversion	Melissa Hall
1:25 - 2:05 PM EDT	eSTAR: CDRH's PDF Template for Premarket Submissions	LILI DUAN, PhD

2:05 - 2:25 PM EDT	*BREAK*	
2:25 - 2:35 PM EDT	Welcome to REdI 2022 Device Track, Part 2	Joseph Tartal
2:35 - 3:15 PM EDT	FDA Registration and Listing Process Overview	Edward Nyack
3:15 - 3:55 PM EDT	EPRC Requirements of Radiation Emitting Medical Devices	Lowell Howard, PhD
3:55 - 4:00 PM EDT	CDRH Day One Closing Remarks	Joseph Tartal

Day 4 June 9, 2022

Time	Topic	Speaker
8:30 - 8:45 AM EDT	CDRH Day Two Welcome & Overview	Joseph Tartal
8:45 - 9:25 AM EDT	Quality Management System Regulation (QMSR) Proposed Rule Overview and Status Update	Melissa Torres
9:25 - 10:05 AM EDT	Purchasing Controls At a Glance	Joseph Hillring
10:05 - 10:25 AM EDT	*BREAK*	
10:25 - 11:05 AM EDT	Process Validation At a Glance	Tonya Wilbon
11:05 - 11:45 AM EDT	Remote Regulatory Assessments (RRAs) for Medical Device Facilities	Brittani Franklin, BS, Chemistry
11:45 - 11:55 AM EDT	Closing for CDRH Sessions	Joseph Tartal
11:55 - 1:00 PM EDT	*LUNCH*	
1:00 - 1:10 PM EDT	Welcome to CBER Track	Larissa Lapteva, MD
1:10 - 1:35 PM EDT	Introduction and Update for the Office of Tissues and Advanced Therapies (OTAT)	Wilson Bryan
1:35 - 2:00 PM EDT	Common Product Quality Issues for Gene and Cellular Therapy Products	Carolyn Laurencot, PhD
2:00 - 2:25 PM EDT	Common Preclinical Challenges in the Regulatory Pathway for Cellular and Gene Therapy Products	Melek Sunay, PhD
2:25 - 2:40 PM EDT	Questions & Answers Session	Carolyn Laurencot, PhD Melek Sunay, PhD
2:40 - 3:05 PM EDT	Cellular And Gene Therapy in Oncology: Common Issues Encountered In Regulatory Submissions	Asha Das, MD
3:05 - 3:30 PM EDT	Design Considerations for Clinical Trials in Rare Diseases	ROSA SHERAFAT-KAZEMZADEH, MD
3:30 - 3:45 PM EDT	Questions & Answers Session	Asha Das, MD ROSA SHERAFAT-KAZEMZADEH, MD
3:45 - 4:00 PM EDT	*BREAK*	
4:00 - 4:40 PM EDT	Communication Best Practices – Interacting with Regulatory Project Managers in CBER/OTAT	Eden Chane, MS
4:40 - 4:45 PM EDT	Day Four Closing	Larissa Lapteva, MD

Day 5 June 10, 2022

Time	Topic	Speaker
8:30 - 8:40 AM EDT	CBER Day Two Welcome & Overview	Larissa Lapteva, MD
8:40 - 9:20 AM EDT	Post-marketing Surveillance and REMS for CBER Products	Meghna Alimchandani, MD
9:20 - 9:45 AM EDT	CBER Surveillance Program: BEST Initiative	Joyce Obidi, PhD
9:45 - 10:05 AM EDT	Questions & Answers Session	Meghna Alimchandani, MD Joyce Obidi, PhD
10:05 - 10:20 AM EDT	*BREAK*	
10:20 - 10:45 AM EDT	FDA Regulatory Oversight for Xenotransplantation Products	Judith Arcidiacono, M.S.
10:45 - 11:15 AM EDT	Chemistry, Manufacturing and Controls (CMC) Considerations for Xenotransplantation Products	Archana Siddam, PhD
11:15 - 11:35 AM EDT	Xenotransplantation Products: Approach to Clinical Development	Patricia Beaston, MD, PhD

11:35 - 11:55 AM EDT	Questions & Answers Session	Judith Arcidiacono, M.S. Archana Siddam, PhD Patricia Beaston, MD, PhD
11:55 - 1:00 PM EDT	*LUNCH*	
1:00 - 1:30 PM EDT	OTAT's Stakeholder Outreach and Patient Engagement Program	Anne Rowzee, PhD
1:30 - 2:00 PM EDT	The CBER Advanced Technologies Team	Manuel Osorio, PhD
2:00 - 2:20 PM EDT	Overview of FDA-EMA Parallel Scientific Advice Program for The Center for Biologics Evaluation and Research (CBER)	Crystal Melendez, RN, BSN, MT, DCPM
2:20 - 2:40 PM EDT	Questions & Answers Session	Anne Rowzee, PhD Manuel Osorio, PhD Crystal Melendez, RN, BSN, MT, DCPM
2:40 - 3:00 PM EDT	*BREAK*	
3:00 - 3:30 PM EDT	Medical Devices in CBER	Alyssa Kitchel, PhD
3:30 - 4:00 PM EDT	Safety-Related Impurities in Plasma-Derived Products	Mikhail Ovanesov, PhD
4:00 - 4:25 PM EDT	Common Mistakes in Demonstrating Analytical Method Suitability	Emnet Yitbarek, PhD
4:25 - 4:45 PM EDT	Questions & Answers Session	Alyssa Kitchel, PhD Mikhail Ovanesov, PhD Emnet Yitbarek, PhD
4:45 - 4:50 PM EDT	CBER & Conference Closing Remarks	Larissa Lapteva, MD

Continuing Education Accreditation

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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.

IPCE CREDIT™

This activity was planned by and for the healthcare team, and learners will receive 32.5 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 32.50 *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 JA0002895-0000-22-054-L04-P for 32.50 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 32.50 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.

Attention Pharmacists and Pharmacy Techs: Failure to provide your correct NABP AND Date of Birth information, in the required format, may result in the loss of credit for this activity. NABP profile number should be the 6-7 digit profile number assigned by the CPE Monitor and your birth date should be in the MMDD format (e.g. 0721) Do not provide your pharmacy license number. Please click the "My Account" tab and then navigate to "Edit Contact Information" to verify that your information is correct.

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 8 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- Alimchandani, Meghna, MD, Physician, OBE/CBER - *nothing to disclose*
- Arcidiacono, Judith, M.S., International Regulatory Expert, FDA - *nothing to disclose*
- Beaston, Patricia, MD, PhD, Medical Officer, FDA - *nothing to disclose*
- Bright, Patricia, PhD, Acting Sentinel Lead, FDA CDER OSE RSS - *nothing to disclose*
- Brodsky, Eric, MD, Associate Director, FDA/CDER/OND/Labeling Policy Team - *nothing to disclose*
- Bryan, Wilson - *nothing to disclose*
- Bugin, Kevin, PhD, RAC, Deputy Super Office Director of Operations, US FDA - *nothing to disclose*
- Califf, Robert M., MD, Commissioner, Food and Drug Administration - *My financial disclosure report and ethics agreement are publicly available documents (posted online).*
- Cavazzoni, Patrizia, MD, Deputy Director for Operations, Center for Drug Evaluation and Research, Food and Administration, FDA - *nothing to disclose*
- Chane, Eden, MS, Regulatory Project Manger, Division Of Regulatory Project Management - *nothing to disclose*
- Cornelison, Terri, MD, PhD, Chief Medical Officer & Director, Health of Women, FDA, Center for Devices and Radiological Health - *nothing to disclose*
- Crandall, Heather, Operations Research Analyst, FDA - *nothing to disclose*
- DUAN, LILI, PhD, Policy Analyst, FDA - *nothing to disclose*
- Das, Asha, MD, Physician, OTAT - *I have the following relationship(s): Progenics Pharmaceuticals (subsidiary of Lantheus Medical Imaging) - Employee*
- De, Suranjan, SUPERVISORY HEALTH SCIENCE, FDA - *nothing to disclose*
- Ford, Forest, CSO, FDA - *nothing to disclose*
- Franklin, Brittani, BS, Chemistry, Consumer Safety Offcier, OMDRHO - *nothing to disclose*
- Gamerman, Jamie, JD, Regulatory Counsel, FDA/CDER - *nothing to disclose*
- Hall, Melissa, Consumer Safety Officer, FDA - *nothing to disclose*
- Hearns-Stewart, Rhonda, MD, Physician, FDA - *nothing to disclose*
- Hillring, Joseph, Consumer Safety Officer, FDA - *nothing to disclose*
- Howard, Lowell, PhD, Electrical Engineer, CDRH, OHT-8, Office of Radiological Health - *nothing to disclose*
- Jung, Connie, Senior Advisor for Policy, FDA/CDER/Office of Compliance - *nothing to disclose*
- Kim, Tamy, PharmD, Director for Regulatory Affairs and olicy, FDA, Oncology Center for Excellence - *nothing to disclose*
- Kitchel, Alyssa, PhD, Biomedical Engineer, FDA - *nothing to disclose*
- Lal, Renu, Pharm.D., Pharmacist, FDA - *nothing to disclose*
- Lapteva, Larissa, MD, Associate Director, CBER - *nothing to disclose*
- Laurencot, Carolyn, PhD, Associate Director for Regulatory Science and Review, DCGT, OTAT, CBER, FDA - *nothing to disclose*
- Lee, Kerry Jo, M.D., Medical Officer, FDA - *nothing to disclose*
- Mallis, Elias, Director, Division of Industry and Consumer Education, U.S. Food and Drug Administration - *nothing to disclose*
- Manzo, Claudia, PharmD, Director, Office of Medication Error Prevention and Risk Management - *nothing to disclose*
- Marks, Peter, MD, PhD, Center Director, FDA/CBER - *nothing to disclose*
- Marshall, Lowell, BS, ESG IT Program Manager, OIMT - *nothing to disclose*
- Melendez, Crystal, RN, BSN, MT, DCPM, Regulatory Project Manager, FDA - *nothing to disclose*
- Millikan, Ed, PharmD, R. Ph, Senior Informatics Pharmacist, Office of Medication Error Prevention and Risk Management | Office of Surveillance and Epidemiology - *nothing to disclose*
- Neyarapally, George, PharmD, JD, MPH, R. Ph, Senior Pharmacist/Regulatory Science Research Policy Lead, OSE/FDA/CDER - *nothing to disclose*
- Nyack, Edward, Senior Program Analyst, Center for Devices and Radiological Health (CDRH) - *nothing to disclose*
- Obidi, Joyce, PhD, Health Scientist, FDA - *nothing to disclose*
- Oktem, Berk, PhD, DABT, Chemist, US FDA - *nothing to disclose*
- Olin, Keith, Pharmacist, FDA/CDER - *nothing to disclose*
- Osorio, Manuel, PhD, Senior Scientist for Emerging Technologies, US Food and Drug Administration - *nothing to disclose*
- Ovanesov, Mikhail, PhD, Research Biologist, US FDA/CBER - *nothing to disclose*
- Piermatteo, Kimberly, MHA, Program Management Engineer Officer, FDA - *nothing to disclose*
- RETZKY, SANDRA, MD, JD, Medical Officer, CBER/OTAT - *nothing to disclose*
- Ramanadham, Amy, Senior Regulatory Research Officer, U.S. Food and Drug Administration - *nothing to disclose*
- Resnick, Jonathan, Project Management Officer, FDA, CDER, OBI - *nothing to disclose*
- Rouabhi, Ouided, MS, Assistant Director, FDA - *nothing to disclose*
- Roule, Jeannie, Chief, Project Management Staff, FDA/CDER/OND - *nothing to disclose*
- Rowzee, Anne, PhD, Associate Director for Policy, FDA/CBER/OTAT - *nothing to disclose*
- SHERAFAT-KAZEMZADEH, ROSA, MD, Acting Team Lead, FDA - *nothing to disclose*
- Schmuff, Norman, PhD, Laborer, FDA/CDER/OPQ/OPMA - *nothing to disclose*
- Senay, Seyoum, MS, Supervisory Operations Research, FDA - *nothing to disclose*
- Shuren, Jeff, MD, JD, Director, CDRH, FDA - *nothing to disclose*
- Siddam, Archana, PhD, Biologist, FDA - *nothing to disclose*
- Slack, Mary Ann, BS, Director, Office of Strategic Programs, CDER - *nothing to disclose*
- Stodart, Brenda, PharmD, BCGP, RAC, Program Director, FDA - *nothing to disclose*
- Sunay, Melek, PhD, Biologist, FDA/CBER/OTAT/PTB1 - *nothing to disclose*
- Tartal, Joseph, Division Deputy Director, Division of Industry and Consumer Education - *nothing to disclose*
- Throckmorton, Douglas, MD, Deputy Director for Regulatory Programs, FDA - *nothing to disclose*
- Torres, Melissa, Associate Director for International Affairs, Center for Devices and Radiological Health - *nothing to disclose*
- Vaillancourt, Julienne, MPH, R. Ph, Rare Disease Liaison/Policy Advisor, FDA/CBER/OD - *nothing to disclose*
- Wilbon, Tonya, Branch Chief, FDA/CDRH/OCE/DICE - *nothing to disclose*
- Yitbarek, Emnet, PhD, Analytical Scientist, CBER - *nothing to disclose*

Planning Committee

- Brodsky, Eric, MD, Associate Director, FDA/CDER/OND/Labeling Policy Team - *nothing to disclose*
- Paraoan, Dianne, MPH, RN, Associate Director for Regulatory Affairs, FDA/ CDER/ OMP - *nothing to disclose*
- Stodart, Brenda, PharmD, BCGP, RAC, Program Director, FDA - *nothing to disclose*

CE Consultation and Accreditation Team

- Catherine Harrison, CE Consultant, FDA/CDER/OEP/DLOD - *nothing to disclose*
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - *nothing to disclose*

All of the relevant financial relationships listed for these individuals have been mitigated.

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

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