Activity Outline
Regulatory Education for Industry (REdI) Annual Conference
May 29 - 30, 2019
The Revere, Boston, MA

Activity Coordinator
Lisa Misevicz
lisa.misevicz@fda.hhs.gov

Description

This activity is designed to provide participants with a strong, basic foundation in understanding the FDA's drug and medical device regulatory requirements. Attendees will leave with a set of tools to assist in preparing regulatory filings and interacting with the FDA. The drugs track will focus on the essentials of New Drug Applications (NDA) and Biologics License Applications (BLA). The devices track will address globalization, harmonization, and standardization of medical device regulation. FDA speakers will be available to answer questions one-on-one at the end of each day. CDER and CDRH invite you to interact with and learn directly from FDA's regulatory experts.

References

- Medical Device Regulation: CFR Title 21 - Food and Drugs: Parts 800 to 1299
- Pharmaceutical Regulation: CFR Title 21 - Food and Drugs: Parts 200 to 300

Learning Objectives

- Attendees are able problem solve and address drug/device regulatory issues as they arise based on activity content.
- Attendees are able to successfully determine the appropriate FDA office to contact relevant to their medical product submission.
- Attendees will be able to identify and apply several essential components of New Drug Applications (NDAs) and Biologics License Applications (BLAs) submission.
- Attendees will be able to discuss regulatory content related to medical devices globalization, harmonization, and standardization.

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

Agenda
Day 1 May 29, 2019

Time	Topic	Speaker
8:20 - 8:30 AM	REdI Annual Conference Overview	Brenda Stodart, PharmD, BCGP
8:30 - 9:00 AM	Keynote – Office of Regulatory Affairs (ORA) Update	Joseph Matrisciano, JD, PE
9:00 - 10:00 AM	Plenary Session: Combination Products	James Bertram, PhD Kristina Lauritsen, PhD
10:00 - 10:20 AM	AM Break	*Not offered for CE*
10:20 - 10:30 AM	Device Track - Day 1 Overview	Elias Mallis
10:20 - 10:30 AM	Drug Track - Day 1 Overview	Forest Ford
10:30 - 11:10 AM	Basic Components of NDA/BLA Submission Drug Track - Keynote – Center for Drug Evaluation and Research (CDER) Initiatives	Douglas Throckmorton, MD *Not offered for CE*
10:30 - 11:10 AM	Device Track - Incorporating a Total Product Life Cycle Approach	William Maisel *Not offered for CE*
11:10 - 11:50 AM	Device Track - A Case Study on Medical Device Determination and Product Classification	Kimberly Piermatteo, MHA
11:10 - 11:50 AM	Drug Track - Meetings: Pre-submission and Special Programs	Callie Cappel-Lynch

11:50 - 1:05 PM	Lunch	*Not offered for CE*
1:05 - 1:45 PM	Device Track - 510(k) Program Updates	Angela DeMarco, MS
1:05 - 1:45 PM	Drug Track - Basic Components of New Drug Application/ Biologics License Application (NDA/BLA) Submission	Lois Almoza, MS
1:45 - 2:25 PM	Device Track - Appropriate Use of Voluntary Consensus Standards and the Conformity Assessment Program	Scott Colburn, RN, BSN
1:45 - 2:25 PM	Drug Track - NDA and BLA Application Process: A Brief Overview	Swati Patwardhan, MS, RAC
2:25 - 2:45 PM	*Break*	
2:45 - 3:25 PM	Device Track - Facilitating Patient Access to Medical Devices: the Expanded Access, Early Feasibility Study, and Breakthrough Devices Programs	Maureen Dreher, PhD
2:45 - 3:25 PM	Drug Track - A Medical Officer's Approach to NDA/BLA Review	Virginia Sheikh, MD, MHS
3:25 - 4:25 PM	Device Track - Building Quality Clinical Data into Premarket Approval Applications (PMAs)	DONNA HEADLEE, RN
3:25 - 4:25 PM	Drug Track - Electronic Common Technical Document (eCTD) Submission of Study Data	Jonathan Resnick Chao (Ethan) Chen, MBA
4:25 - 5:00 PM	1:1 Q&A sessions with CDER and CDRH	Callie Cappel-Lynch Lois Almoza, MS Swati Patwardhan, MS, RAC Jonathan Resnick Chao (Ethan) Chen, MBA Angela DeMarco, MS Maureen Dreher, PhD Scott Colburn, RN, BSN William Maisel Elias Mallis Kimberly Piermatteo, MHA DONNA HEADLEE, RN James Bertram, PhD Kristina Lauritsen, PhD Virginia Sheikh, MD, MHS *Not offered for CE*

Day 2 May 30, 2019

Time	Topic	Speaker
8:50 - 9:00 AM	Device Track - Day 2 Overview	Joseph Tartal
8:50 - 9:00 AM	Drug Track - Day 2 Overview	Renu Lal, Pharm.D.
9:00 - 9:40 AM	Devices Track - Quality System Regulation and ISO 13485 Comparison: Corrective and Preventive Action (CAPA) Requirements	Joseph Tartal
9:00 - 9:40 AM	Drug Track - Regulatory Highlights for Biosimilars and Interchangeables	Eva Temkin, JD
9:40 - 10:20 AM	Device Track Corrective and Preventive Action (CAPA) Case Study	Tonya Wilbon
9:40 - 10:20 AM	Drug Track - CDER's Process for Reviewing Nonproprietary Name Suffix for Biological Products and Safety Considerations for Product Design, Container Labels, and Carton Labeling	Lubna Merchant, PharmD, M.S.

10:20 - 10:40 AM	AM Break	*Not offered for CE*
10:40 - 11:20 AM	Device Track - Quality System: FDARA, 21st Century Cures Act, and Recent Postmarket Policy Updates	Vidya Gopal
10:40 - 11:20 AM	Drug Track - CDER's Review of Prescription Drug Labeling	ANN TRENTACOSTI, MD
11:20 - 12:00 PM	Device Track - Medical Device Single Audit Program (MDSAP) Overview	Kenneth Chen, MS
11:20 - 12:00 PM	Drug Track - Ready to Launch: Essentials of Submitting Initial Materials to the Office of Prescription Drug Promotion	Rachael Conklin, RN, MS
12:00 - 1:15 PM	*Lunch*	
1:15 - 2:35 PM	Device Track - FDA's Import Requirements for Medical Devices Overview of the FDA Exports Program for Medical Devices	Ethny Obas, MT Terri Garvin, JD
1:15 - 2:35 PM	Drug Track - SBIA – Program Overview And Chemistry Manufacturing and Controls (CMC)– NDA requirements and Common Pitfalls of Biologics License Applications (BLAs)	Balajee Shanmugam, PhD Renu Lal, Pharm.D. Steven Bowen, PhD
2:35 - 2:55 PM	PM Break	*Not offered for CE*
2:55 - 3:35 PM	Device Track - FDA Medical Device Inspections	Maura Rooney, MS
2:55 - 3:35 PM	Drug Track - The Dos and Don'ts of Pre-Approval Inspections: What to Expect When Being Inspected	Sean Marcsisin, PhD, RAC
3:35 - 3:40 PM	Closing and Event Review	Brenda Stodart, PharmD, BCGP
3:40 - 4:20 PM	1:1 Q&A sessions with CDER and CDRH	Eva Temkin, JD Lubna Merchant, PharmD, M.S. Balajee Shanmugam, PhD ANN TRENTACOSTI, MD Ethny Obas, MT Terri Garvin, JD Kenneth Chen, MS Joseph Tartal Vidya Gopal Maura Rooney, MS James Bertram, PhD Steven Bowen, PhD Sean Marcsisin, PhD, RAC

Continuing Education Accreditation

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INTERPROFESSIONAL CONTINUING EDUCATION

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 11.00 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 11.00 *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 JA0002895-0000-19-049-L04-P for 11.00 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 11.00 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.

Disclosure

Faculty

- Almoza, Lois, MS, Regulatory Health Project Manager, FDA - nothing to disclose
- Bertram, James, PhD, Assistant Director and Product Jurisdiction Officer, FDA - nothing to disclose
- Bowen, Steven, PhD, Chemist, US Food and Drug Administration - nothing to disclose
- Cappel-Lynch, Callie, project manager, FDA - nothing to disclose
- Chen, Chao (Ethan), MBA, Director, Division of Data Management Services and Solutions, Office of Business Bioinformatics, OSP, CDER - nothing to disclose
- Chen, Kenneth, MS, Senior Regulatory Officer, CDRH/ORP/MDSAP - nothing to disclose
- Colburn, Scott, RN, BSN, Director, Standards and Conformity Assessment Program (S-CAP), CDRH - nothing to disclose
- Conklin, Rachael, RN, MS, Regulatory Review Officer, FDA - nothing to disclose
- DeMarco, Angela, MS, Biomedical Engineer, FDA - nothing to disclose
- Dreher, Maureen, PhD, Policy Analyst, FDA/CDRH - nothing to disclose
- Ford, Forest, CSO, FDA - nothing to disclose
- Garvin, Terri, JD, Regulatory Counsel, CDRH *My spouse received Salary from Abbott for a role as Employee.*
- Gopal, Vidya, CSO, FDA/CDRH - nothing to disclose
- HEADLEE, DONNA, RN, Branch Chief, FDA/CDRH - nothing to disclose
- Lal, Renu, Pharm.D., Pharmacist, FDA - nothing to disclose
- Lauritsen, Kristina, PhD, Combination Product Policy Advisor, Center for Drug Evaluation and Research - nothing to disclose
- Maisel, William *Disclosure not received.*
- Mallis, Elias, Director, U.S. Food and Drug Administration - nothing to disclose
- Marcsisin, Sean, PhD, RAC, Investigator - Pharmaceutical Quality, ORA/OPQO/IB1/G3 - nothing to disclose
- Matrisciano, Joseph, JD, PE, Program Division Director/District Director, ORA - OMDRHO Div 1 - nothing to disclose
- Merchant, Lubna, PharmD, M.S., Deputy Director, OMEPRM, FDA/CDER/OSE/OMEPRM - nothing to disclose
- Obas, Ethny, MT, Lead Consumer Safety Officer, FDA/CDRH/DICO/Exports Branch - nothing to disclose
- Patwardhan, Swati, MS, RAC, Regulatory Project Manager, Food and Drug Administration - nothing to disclose

- Piermatteo, Kimberly, MHA, Program Management Engineer Officer, FDA - nothing to disclose
- Resnick, Jonathan, Project Management Officer, FDA, CDER, OBI - nothing to disclose
- Rooney, Maura, MS, Supervisory Consumer Safety Officer, ORA OMDRHO - nothing to disclose
- Shanmugam, Balajee, PhD, Branch Chief, CDER/OPQ - nothing to disclose
- Sheikh, Virginia, MD, MHS, Medical Officer, CDER/OND/OAP/DAVP - nothing to disclose
- Stodart, Brenda, PharmD, BCGP, Program Director, FDA - nothing to disclose
- TRENTACOSTI, ANN, MD, Medical Officer, CDER/OND - nothing to disclose
- Tartal, Joseph, Division Deputy Director, Division of Industry and Consumer Education *My spouse received Other - hourly wage from New Horizons Diagnostics Corporation for a role as Other - Contractor, manufacturer.*
- Temkin, Eva, JD, Acting Deputy Director for Policy, CDER/OND/TBBS - nothing to disclose
- Throckmorton, Douglas, MD, Deputy Director for Regulatory Programs, FDA - nothing to disclose
- Wilbon, Tonya, Branch Chief, FDA/CDRH/OCE/DICE - nothing to disclose

Planning Committee

- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Kleppinger, Cynthia, MD, Medical Officer, FDA - nothing to disclose
- Stodart, Brenda, PharmD, BCGP, Program Director, FDA - 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)
Must attend 85% of the activity.