EVENT DETAILS

Version 4 – April 25, 2019
Click above to check for latest version

Regulatory Education for Industry (REdI) Annual Conference

May 29-30, 2019 | Revere Hotel - Boston, MA

AGENDA

Wednesday, May 29

7:30 a.m. Registration Opens

Online Participants: The Adobe Connect Rooms will open at 7:45 a.m. at SBIAevents.com

8:05 – 8:20 Administrative Announcements

8:20 – 8:30

Welcome and REdI Overview

Brenda Stodart
Captain, United States Public Health Service
Program Director, CDER Small Business and Industry Assistance
Division of Drug Information (DDI) | Office of Communications (OCOMM) | Center for Drug Evaluation and Research (CDER) | FDA

8:30 – 9:00

Keynote: Office of Regulatory Affairs (ORA) Update

Joseph Matrisciano Jr.
Program Division Director and District Director
Division 1 | Office of Medical Devices and Radiological Health Operations and New England District Office | ORA | FDA

9:00 – 10:00

Plenary: Navigating the World of Combination Products

Combination products are comprised of two or more different regulated articles (i.e., combination of drug, device, or biologic). While manufacturers of such products are often focused on developing new and innovative technologies, one should also keep in mind the regulatory considerations associated with each component in the context of the combination product as a whole. This session will provide stakeholders with an overview of FDA's regulation of combination products, discuss changes due to legislative updates over the past couple of years, and also present unique perspectives from both CDER and CDRH.

James Bertram
CDRH Product Jurisdiction Officer
Office of Device Evaluation Center for Devices and Radiological Health

Kristina Lauritsen
Combination Product Policy Advisor
Office of Executive Programs (OEP) | CDER

10:00 – 10:20 N E T W O R K I N G B R E A K

Please note that during this break, we will divide the main room into the CDER track and the CDRH track rooms.

Please select a seat in the appropriate track room as early as possible.

Wednesday, May 29

DRUG TRACK

10:20 – 10:30

Day One Moderator Overview

The moderator will provide a brief overview of day one.

Forest "Ray" Ford, Jr.
Commander, USPHS
Consumer Safety Officer
DDI | OCOMM | CDER

10:30 – 11:10

Keynote: Center for Drug Evaluation and Research (CDER) Initiatives

Doug Throckmorton
Deputy Director for Regulatory Affairs
CDER

11:10 – 11:50

Meetings: Pre-submission and Special Programs

This session will provide participants with better understanding of processes, requirements, and best practices for PDUFA meetings. The session will also aid participants to develop an understanding of special programs that may affect the review process or timelines for their application. Best practices for communications with FDA will also be reinforced.

Callie Cappel-Lynch
Senior Regulatory Project Manager
Division of Metabolism and Endocrinology Products (DMEP)
Office of Drug Evaluation (ODE) II
Office of New Drugs (OND) | CDER

DEVICE TRACK

10:20 – 10:30

Day One Introductions

A brief overview of day one.

Elias Mallis
Director
Division of Industry and Consumer Education (DICE)
Office of Communication and Education
CDRH

10:30 – 11:10

Keynote: Incorporating a Total Product Life Cycle Approach

CDRH has historically relied upon distinct programs for premarket and postmarket regulation of medical devices. To maximize resources and enhance collective decision-making, the Center is building a new approach to how it conducts business and the way it is structured. This session will discuss the exciting, important advances CDRH is taking toward a total product life cycle approach, incorporating steps that lead to the design, production, use and impact of safe, effective and high-quality medical devices.

William Maisel
Chief Medical Officer
Director, Office of Device Evaluation
Acting Director, Office of Compliance
CDRH

11:10 – 11:50

A Case Study on Medical Device Determination and Product Classification

Stakeholders often ask if their product is regulated by FDA as a medical device and if yes, how is it classified by FDA? Through an illustrative case study, this session will provide stakeholders with a better understanding of various approaches and methods available to assist them in determining if their product meets the definition of a medical device and how it may be classified by FDA, including identification of applicable regulatory requirements.

Kim Piermatteo
Commander, USPHS
Consumer Safety Officer
Premarket Programs Branch
DICE | CDRH

Wednesday, May 29

11:50 – 1:05 p.m. NETWORKING LUNCH

Lunch is self-pay at the location of your choice and allows an opportunity for you to network with fellow participants.

DRUG TRACK

1:05 – 1:45

Basic Components of New Drug Application/ Biologics License Application (NDA/BLA) Submission

This session will describe the content and format of NDA/BLA application. It will also discuss briefly the documentation required for these applications.

Lois Almoza
Regulatory Health Project Manager
Division of Transplant and Ophthalmology Products (DTOP)
Office of Antimicrobial Products (OAP)
OND | CDER

1:45 – 2:25

NDA and BLA Application Process: A Brief Overview

This session will discuss the application review process and industry communication associated with the application review.

Swati Patwardhan
Senior Regulatory Project Manager
Division of Anesthesia, Analgesia, and Addiction Products (DAAAP)
ODE II | OND | CDER

DEVICE TRACK

1:05 – 1:45

510(k) Program Updates

The most common pathway for a new medical device to become legally marketed in the United States is through the premarket notification process, also known as a 510(k) submission. This session will discuss updates made to the 510(k) Program in the past year, including new policies and current pilots.

Suggested pre-requisite:
510(k) Basics (CDRH Learn)

Angela Demarco
Policy Analyst
510(k) Program
Office of Device Evaluation
CDRH

1:45 – 2:25

Appropriate Use of Voluntary Consensus Standards and the Conformity Assessment Program

Standards play an important role in regulatory submissions. This session will provide an overview of the recently published guidance on the Appropriate Use of Voluntary Consensus Standards in Premarket Submissions, issued September 2018. This session will also touch briefly on the changes to the Recognized Consensus Standards Database and updates to the program related to the enactment of the 21st Century Cures Act. The session will provide an update on the Accreditation Scheme for Conformity Assessment (ASCA) Program and conclude with how to locate FDA guidance documents, recognized standards, and web resources.

Suggested pre-requisite:
Standards Overview (CDRH Learn)

Scott Colburn
Captain, USPHS
Director, CDRH Standards and Conformity Assessment Program
Office of the Center Director
CDRH

2:25 – 2:45 NETWORKING BREAK

Wednesday, May 29

DRUG TRACK

2:45 – 3:45

Electronic Common Technical Document (eCTD) and Submission of Study Data

This presentation covers points to consider when preparing your eCTD submission and sending to FDA.

Jonathan Resnick
Electronic Submissions Capability Team
Office of Business Informatics (OBI)
Office of Strategic Programs (OSP) | CDER

Chao (Ethan) Chen
Director
DDMSS | OBI | OSP | CDER

3:45 – 4:25

A Medical Officer's Approach to NDA/BLA Review

The FDA medical officer is responsible, in collaboration with other members of the review team, for evaluating the safety and efficacy of a proposed product, as presented in a submitted NDA/BLA package. During this talk, Dr. Sheikh will provide a high-level overview of a medical officer's approach to evaluating the components of an NDA/BLA submission. She will discuss the NDA/BLA filing review, the analysis of safety, internal meetings, communications with the sponsor, sponsor meetings, the clinical review, and product labeling.

Virginia M.W. Sheikh
Medical Officer
Division of Antiviral Products (DAVP)
OAP | OND | CDER

4:25 – 5:00

Q&A Sessions with the Day One Speakers

The speakers from throughout the day will be available in locations around the room to answer questions from participants.

DEVICE TRACK

2:45 – 3:25

Facilitating Patient Access to Medical Devices: The Expanded Access, Early Feasibility Study, and Breakthrough Devices Programs

CDRH's vision is that patients in the United States have access to high quality, safe and effective medical devices of public health importance first in the world. Ten years ago, the medical device regulatory landscape was perceived to have limited options for bringing new therapies and devices to patients in a timely manner. FDA, however, has initiated several novel regulatory programs to advance medical device innovation and safety by focusing on our vision of bringing safe and effective medical devices to US patients in a timely manner. This presentation will provide an overview of multiple programs at CDRH that enable patient access to important devices which address unmet medical needs. Specifically, this presentation will introduce the Expanded Access Program, the Early Feasibility Study Program, and the Breakthrough Devices Program.

Suggested pre-requisite:
IDE Basics (CDRH Learn)
Early Feasibility Study Program (CDRH Learn)

Maureen Dreher
Director, Investigational Device Exemption Program (Acting)
Office of Device Evaluation
CDRH

3:25 – 4:05

Building Quality Clinical Data into Premarket Approval Applications (PMAs)

Devices that present the highest risk to patients and have a significant impact on public health are generally regulated under the Premarket Approval (PMA) Program. The PMA review process is a scientific and regulatory review to evaluate the reasonable safety and effectiveness of a new Class III medical device. This evaluation is based on valid scientific evidence. It is critical that valid scientific evidence is supported with high quality data. This session will provide an introduction to the Premarket Program, Valid Scientific Evidence and elements and strategies that lead to quality data.

Donna Headlee
Chief, Premarket Programs Branch
DICE | CDRH

4:05 – 4:30

Q&A Sessions with the Day One Speakers

The speakers from throughout the day will be available in locations around the room to answer questions from participants.

Wednesday, May 29

5:00 – 7:00 p.m. NETWORKING OPPORTUNITY

On Wednesday evening, a networking opportunity is available for attendees at the Rooftop@Revere lounge in the hotel.

This is an optional, self-pay event.

For SBIA updates and additional information, please visit:

CDER SBIA Homepage

Thursday, May 30

DRUG TRACK

8:35 – 8:50: **Administrative Announcements**

8:50 – 9:00

Day Two Moderator Overview

Moderator will provide a brief overview of day two.

Renu Lal
Lieutenant, USPHS
Pharmacist
SBIA | DDI | OCOMM | CDER

9:00 – 9:40

Regulatory Highlights for Biosimilars and Interchangeables

An overview of FDA's perspective on the regulatory considerations applicable to development of biosimilar and interchangeable products under section 351(k) of the Public Health Service Act. Highlights will be discussion of FDA's biosimilars action plan, biological regulatory modernization, and recently-issued guidance including the updated draft guidance on nonproprietary naming of biological products.

Eva Temkin, JD
Acting Director, Policy Staff
Office of Therapeutic Biologics and Biosimilars (OTBB)
OND | CDER

9:40 – 10:20

CDER's Review of Prescription Drug Labeling

An overview of key aspect of CDER's review of the prescribing information; with a focus on ensuring that FDA-approved labeling is consistent with regulations and guidances and is also a useful communication tool for healthcare providers. The presentation will also discuss what's new in the world of labeling (i.e., recently approved guidances).

Ann Marie Trentacosti
Medical Lead
Labeling Development Team
OND | CDER

DEVICE TRACK

8:35 – 8:50: **Administrative Announcements**

8:50 – 9:00

Day Two Introductions

A brief overview of day two.

Joseph Tartal
Deputy Director
DICE | CDRH

9:00 – 9:40

Quality System Regulation and ISO 13485 Comparison: Corrective and Preventive Action (CAPA) Requirements

Corrective and Preventive Action (CAPA) is the life blood of any quality management system, be that it complies with 21 CFR 820 or conforms to ISO 13485:2016. After an introduction to both the regulation and standard, this session will highlight and compare their aspects as they relate to CAPA.

Suggested pre-requisite:
Overview of the Quality System Regulation (CDRH Learn)
Corrective and Preventive Action Basics (CDRH Learn)

Joseph Tartal
Deputy Director
DICE | CDRH

9:40 – 10:20

Corrective and Preventive Action (CAPA) Case Study

Many manufacturers overuse or underuse the CAPA subsystem and struggle with deciding when and when not to open a CAPA. This session will provide tips to help your company decide when to open a CAPA and will walk through addressing a complaint/nonconformance using the CAPA subsystem.

Tonya Wilbon
Chief, Postmarket and Consumer Branch
DICE | CDRH

10:20 – 10:40 NETWORKING BREAK

Thursday, May 30

DRUG TRACK

10:40 – 11:20

CDER's Process for Reviewing Nonproprietary Name Suffix for Biological Products and

Safety Considerations for Product Design, Container Labels, and Carton Labeling

Outlines how CDER reviews distinguishing suffixes identified by FDA or requested by a sponsor that is designated in the nonproprietary names of originator biological products, related biological products, and biosimilar products newly licensed under section 351(a) or 351(k) of the Public Health Service Act (PHS Act). It also discusses the guidance on safety considerations for product design, container labels and carton labeling design to minimize medication errors. This provides sponsors with a set of principles and recommendations for ensuring that critical elements of product labels and labeling are designed to promote safe use. Also provides sponsors with a set of principles for developing drug products using a systems approach to minimize medication errors relating to product design.

Lubna Merchant
Acting Director
Division of Medication Error Prevention and Analysis (DMEPA)
Deputy Director, Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE) | CDER

11:20 – 12:00

Ready to Launch: Essentials of Submitting Initial Materials to the Office of Prescription Drug Promotion

Proper submission of promotional materials to the Office of Prescription Drug Promotion (OPDP) contributes to timely receipt and review of the materials. This presentation will cover the fundamentals of submitting promotional materials to OPDP, with a particular focus on submissions occurring during the launch phase. We will cover topics such as Accelerated Approval submissions, press releases, annotations, electronic submissions, and resubmissions and/or amendments. The goal of this presentation is to improve understanding of the submission requirements for OPDP and to address challenges that may occur during this process.

Rachael Conklin
Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)
Office of Medical Policy (OMP)
CDER

DEVICE TRACK

10:40 – 11:20

Quality System: FDARA, 21st Century Cures Act, and Recent Postmarket Policy Updates

Enactment of the 2017 Food and Drug Administration Reauthorization Act (FDARA) and the 2016 21st Century Cures Act (Cures Act) resulted in several changes to the Federal Food, Drug and Cosmetic Act. These changes impact both premarket and postmarket activities. This session will explain the changes to postmarket activities as required by FDARA and the Cures Act. It will address recent post market policy changes. This session will also explain how FDA plans to or has addressed these laws.

Vidya Gopal
Consumer Safety Officer
Postmarket and Consumer Branch
DICE | CDRH

11:20 – 12:00

Medical Device Single Audit Program (MDSAP) Overview

The Medical Device Single Audit Program allows recognized Auditing Organizations (AOs) to conduct a single audit of a medical device manufacturer (MDM) that will satisfy the relevant requirements of participating Regulatory Authorities (RAs). The RAs currently participating in MDSAP include the Therapeutic Goods Administration of Australia (TGA), Brazil's Agência Nacional de Vigilância Sanitária (ANVISA), Health Canada, Japan's Pharmaceuticals and Medical Devices Agency (PMDA), and the U.S. Food and Drug Administration (FDA). This session will provide an overview of the MDSAP program and describe the benefits to participation.

Kenneth Chen
Medical Device Single Audit Program Team
Office of Compliance
CDRH

Thursday, May 30

12:00 – 1:15 p.m. NETWORKING LUNCH

Lunch is self-pay at the location of your choice and allows an opportunity for you to network with fellow participants.

DRUG TRACK

1:15 – 1:35

SBIA – Program Overview

Learn more about the broad array of learning products and other resources available from CDER's Small Business and Industry Assistance program.

Renu Lal
Lieutenant, USPHS
Pharmacist
SBIA | DDI | OCOMM | CDER

1:35 – 2:35

Chemistry Manufacturing and Controls (CMC)– NDA requirements and Common Pitfalls of Biologics License Applications (BLAs)

A complete and accurate Biologics License Application (BLA) is necessary for the marketing approval of new therapeutic biologics and biosimilar products. However, BLAs are frequently submitted to the FDA with unclear or missing information which can lead to Information Requests, Post-Marketing Commitments, or Complete Responses. This presentation will discuss some of the common deficiencies encountered with BLA submissions and provide guidance on how to avoid these costly pitfalls.

Balajee Shanmugam
Branch Chief
Division of New Drug Products
ONDP | OPQ | CDER

Steven Bowen PhD.
Chemist
Office of Biotechnology Products
OPQ | CDER

DEVICE TRACK

1:15 – 1:55

FDA's Import Requirements for Medical Devices

There are approximately 136,400 foreign facilities in more than 150 countries that import FDA-regulated products to the United States. Of these imported products, approximately 35% are medical devices. This session will cover FDA's import requirements for medical devices and products that emit radiation and will review the most common entry errors that lead to import processing delays.

Terri Garvin
Consumer Safety Officer
Postmarket and Consumer Branch
DICE | CDRH

1:55 – 2:35

Overview of the FDA Exports Program for Medical Devices

Navigating the regulatory landscape when exporting medical devices can be overwhelming, but obtaining an export certificate should not be. To demystify policies and regulations regarding the exportation of medical devices, this session will cover what export certificate are, the requirements for each type of export certificate or document offered, associated fees, and most importantly how to request such documents in a matter of minutes.

Suggested pre-requisite:
Exporting Medical Devices (CDRH Learn)

Ethny Obas
Lead Consumer Safety Officer
CDRH Exports Team
Office of Compliance
CDRH

2:35 – 2:55 BREAK

Thursday, May 30

DRUG TRACK

2:55 – 3:35

The Dos and Don'ts of Pre-Approval Inspections: What to Expect When Being Inspected

The presentation will explain the overall pre-approval inspectional process to include what triggers an inspection; items that are evaluated during an inspection, and common pre-approval inspectional concerns.

Sean Marcsisin
Lieutenant, USPHS
Office of Pharmaceutical Quality Operations
Pharma Division 1
Investigations Branch 1
ORA | FDA

3:35 – 3:40

Closing Remarks

Closing thoughts from the Program Director of CDER's Small Business and Industry Assistance program.

Brenda Stodart
Captain, USHPS
Program Director, SBIA
DDI | OCOMM | CDER | FDA

3:40 – 4:20

Q&A Sessions with the Day Two Speakers

The speakers from throughout the day will be available in locations around the room to answer questions from participants.

DEVICE TRACK

2:55 – 3:35

FDA Medical Device Inspections

This session will familiarize manufacturers with the procedures that FDA's Office of Medical Devices and Radiological Health Operations uses to conduct inspections of medical device manufacturing facilities in the United States and Worldwide. You will learn what to expect before, during and after your inspection.

Maura Rooney
Supervisory Consumer Safety Officer
Office of Medical Device and Radiological Health Operations
Division 1
Office of Regulatory Affairs
FDA

3:35 – 3:40

Closing Remarks

Closing thoughts from the Director of CDRH's Division of Industry and Consumer Education.

Elias Mallis
Director
DICE | CDRH

3:40 – 4:20

Q&A Sessions with the Day Two Speakers

The speakers from throughout the day will be available in locations around the room to answer questions from participants.