Small Business and Industry Assistance
2024 Regulatory Education for Industry

Hybrid
May 29-30

Version 6 – Updated May 12, 2024

For files and resources, please visit
The Event Page on SBIAevents.com

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AGENDA

All times are Eastern (EDT UTC-4)

Jump to CDER Track | Jump to CDRH Track | Jump to CBER Track

DAY ONE: ALL THREE TRACKS: Wednesday, May 29, 2024

8:30 - 8:45

SBIA Welcome and Administrative Overview

Brenda Stodart, PharmD, BCGP, RAC-US
Captain | United States Public Health Service
Director | Small Business, and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM) | CDER

8:45 - 9:00

FDA Welcome and Keynote Speaker (Invited)

Robert M. Califf, MD
Commissioner of Food and Drugs
Food and Drug Administration

9:00 - 10:00

Plenary

Moderated by:
Elias Mallis
Director, Division of Industry and Consumer Education (DICE)
Office of Communication and Education (OCE)
Center for Devices and Radiological Health (CDRH)

Patrizia Cavazzoni, MD
Director
Center for Drug Evaluation and Research (CDER)

Jeff Shuren, MD, JD
Director
Center for Devices and Radiological Health (CDRH)

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research (CBER)

10:00 - 10:20 AM: BREAK

DAY ONE: CDER TRACK: Wednesday, May 29, 2024

Your CDER Hosts

Brenda Stodart, PharmD, BCGP, RAC-US
Captain | USPHS | *Director* | SBIA
DDI | OCOMM | CDER

Nora Lim, PharmD, BCPS
LCDR | USPHS | *Pharmacist*
SBIA | DDI | OCOMM | CDER

10:20 - 10:30

Day One Introductions

Brenda Stodart
Captain | USPHS | *Director* | SBIA
DDI | OCOMM | CDER

10:30 - 11:10

Selective Safety Data Collection in Clinical Trials

Throughout drug development and the lifespan of a drug, sponsors are collecting and assessing the safety profile of a drug. As information accumulates, the risk profile of a drug may be well established such that continued comprehensive collection of safety data in clinical trials will yield little additional knowledge on its risk profile. This presentation discusses the recent ICH E19 guideline and its adoption by several regulatory authorities, including FDA, in an effort to facilitate the conduct of important clinical trials designed to answer questions about the long-term efficacy and safety of drugs.

Mary T. Thanh Hai, MD
Deputy Director for Clinical
Office of New Drugs (OND) | CDER | FDA

11:10 - 11:50

Enhancing Clinical Trial Innovation

Center for Drug Evaluation and Research (CDER) proactively fosters drug development by providing scientific and regulatory advice and direction. Changes in the drug development landscape require novel clinical trial designs and innovative strategies for trial execution, an expanding range of drug development tools, and wider application in regulatory drug development of real-world data sources. CDER is exploring new efforts to accelerate the pace of clinical trial innovation through the promotion and adoption of emerging innovation. This presentation will cover these new efforts and share opportunities for stakeholders to engage with CDER on clinical trial innovation.

Kevin Bugin, PhD, MS, RAC
Deputy Director | OND | CDER | FDA

11:50 AM - 1:05 PM: LUNCH BREAK

All times shown are Eastern (EDT UTC-4)

DAY ONE: CDER TRACK: Wednesday, May 29, 2024

1:05 - 1:45

AI in Drug Development

The growth in data volume and complexity combined with cutting-edge computing power and methodological advancements in artificial intelligence (AI) have the potential to transform how drugs are developed, manufactured and utilized. Concurrent with these technological advancements, CDER has seen a 2 to 3-fold yearly increase in the number of drug and biologic application submissions using AI with over 100 submissions reported in 2021.These submissions traverse the landscape of drug development from drug discovery to post market safety monitoring and cut across a range of therapeutic areas. Importantly, the diverse uses of AI in these submissions highlight the need for a emphasizes the importance of adopting a risk-based approach with measures commensurate with the level of risk posed by the specific context of use for AI. This presentation will highlight FDA's experience with submissions that have AI components.

Tala Fakhouri, PhD, MPH
Associate Director for Policy Analysis
Office of Medical Policy (OMP) | CDER | FDA

1:45 - 2:25

ClinicalTrials.gov: Meeting Transparency and Reporting Requirements

ClinicalTrials.gov is a web-based resource that provides the public with easy access to information on clinical studies. The public availability of clinical trial information is intended to facilitate research by identifying open clinical trials for patients and health care providers and to help researchers stay current on developments in specific fields of interest, find collaborators, and identify unmet research needs. This presentation will describe the ClinicalTrials.gov registration and reporting requirements for applicable clinical trials and the actions that may be taken by FDA in response to noncompliance with these requirements.

Laurie Muldowney, MD
Deputy Director
Office of Scientific Investigations (OSI)
Office of Compliance (OC) | CDER | FDA

2:25 - 2:45 PM: BREAK

DAY ONE: CDER TRACK: Wednesday, May 29, 2024

2:45 - 3:25

Diversity in Clinical Trials: Drug Trials Snapshot Perspective

This presentation will highlight the importance of FDA's effort to make demographic data available and transparent with the Drug Trials Snapshot.

Aden S. Asefa, MPH
Drug Trials Snapshot Lead
Office of Drug Evaluation Sciences (ODES)
OND | CDER | FDA

3:25 - 4:05

Combination Products - Updates and Best Practices

Combination products offer opportunities for development of innovative diagnostic and therapeutic products. This session will include a brief overview of combination product regulation, provide updates on recent guidance, and share best practices for submissions to FDA and engaging with CDER.

Kristina Lauritsen, PhD
Combination Product Regulatory Advisor
Product Jurisdiction and Combo Product Team
Office of Executive Programs (OEP) | CDER | FDA

4:05 - 4:10

Day One ONLINE Closing

This will be the close of the CDER Track online broadcast for Day One.

Brenda Stodart
Captain | USPHS | Director | SBIA
DDI | OCOMM | CDER

4:10 - 4:35

1:1 Question and Answer Discussion - ONSITE ATTENDEES ONLY

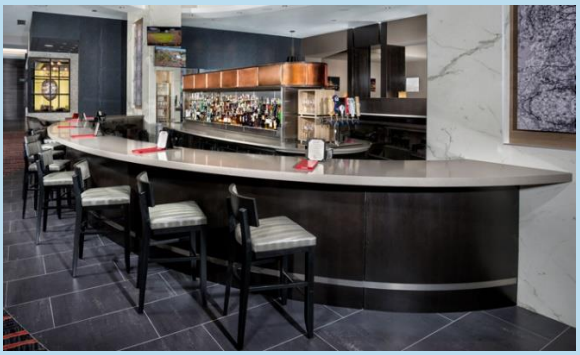
This is an opportunity for onsite attendees to have 1:1 time with today's presenters.

Day One Speakers

4:35 PM: DAY ONE CDER TRACK ADJOURN

4:45 – 5:45 PM: NETWORKING OPPORTUNITY

Onsite attendees are invited to gather at THE HOTEL's Lobby Bar to continue the conversation with fellow attendees.



All times shown are Eastern (EDT UTC-4)

DAY TWO: CDER TRACK: Thursday, May 30, 2024

8:30 - 9:05

Welcome and Introduction to SBIA

CDER Small Business and Industry Assistance (SBIA) offers many services to industry stakeholders, including free conferences and webinars, recordings of these events, a podcast, webpages with a wealth of information, opportunities to stay connected and up to date with the latest regulatory information, and more. This presentation will provide an overview of CDER SBIA and will discuss different ways to leverage the resources this program provides.

Renu Lal, PharmD, BCACP
Lieutenant Commander | USPHS
Team Lead | Division of Drug Information (DDI)
Deputy Director | SBIA | DDI | OCOMM | CDER) | FDA

9:05 - 9:45

Key Information in Informed Consent (Clinical Trials)

The presenters will provide a brief background on FDA's informed consent requirements, and discuss proposed provisions to make informed consent more understandable for potential participants with reference to the new draft guidance on "***Key Information and Facilitating Understanding in Informed Consent***."

Alyson Karesh, MD
Senior Clinical Advisor
Office of Medical Policy (OMP) | CDER | FDA

Suzanne R. Pattee, JD
Regulatory Counsel | Office of Clinical Policy (OCP)
Office of Clinical Policy and Programs (OCPP)
Office of the Commissioner (OC) | FDA

9:45 - 10:25

FDA eCTD v4 Implementation Update and CDER NextGen Portal Update

The **ICH eCTD v4** standard is ready and FDA CDER/CBER plan to begin support this year. The presenter will provide an update on FDA's implementation and how industry can learn more about it.

The **CDER NextGen Portal** is CDER's one stop shop for the purpose of non-eCTD submission, collaboration and reporting. The presenter will discuss types of submissions currently supported and recent updates.

Jonathan Resnick
Project Management Officer
Division of Data Management Services and Solutions (DDMSS) | Office of Business Informatics (OBI)
Office of Strategic Programs (OSP) | CDER | FDA

Seyoum Senay
Supervisory Operations Research
DDMSS | OBI | OSP | CDER | FDA

10:25 - 10:40 AM: BREAK

All times shown are Eastern (EDT UTC-4)

DAY TWO: CDER TRACK: Thursday, May 30, 2024

10:40 - 11:20

Electronic Submission Gateway (ESG) Modernization: ESG NextGen

The presenter will provide an overview of the background and vision for the modernization of the Electronic Submission Gateway (ESG), which is known as ESG NextGen. The presentation will provide an overview of the modernization effort, impact to industry, timeline and scope for Release I & II as well as the overall product roadmap.

Jessica Bernhardt, MS
ESG Program Manager
Division of Application Services (DAS)
Enterprise Application Branch (EAB)
Office of Digital Transformation (ODT)
Office of Information Management and Technology (OIMT) | FDA

Joining for Q&A:
Bin Duan
ESG NextGen Lead Architect
CTO | Precise Software Solutions Inc.

11:20 - 12:00 PM

Artificial Intelligence (AI) | Machine Learning (ML): The New Frontier of Drug Development and Regulation

The presenter will first give a brief background about AI/ML, followed by a landscape analysis of the AI/ML related regulatory submissions at the CDER | FDA. Some reviews and research examples will be shared. Challenges related to the applications of AI/ML and regulatory considerations for their application in drug development will be discussed.

Qi Liu, PhD, MStat, FCP
Associate Director for Innovation & Partnership
Office of Clinical Pharmacology (OCP)
Office of Translational Sciences (OTS) | CDER | FDA

12:00 - 1:15 PM: LUNCH BREAK

All times shown are Eastern (EDT UTC-4)

DAY TWO: CDER TRACK: Thursday, May 30, 2024

1:15 - 1:55

Reimagining Clinical Research: The Transformation of Trial Design & Conduct

CDER's Office of Compliance must balance the critical interests involved in supporting innovation in clinical research along with FDA's role as a global regulatory and enforcement agency focused on protecting public health. The presenter will share perspectives on regulatory and enforcement considerations associated with various clinical trial innovation activities, including evolving study designs (e.g., master protocols), and operational approaches (e.g., decentralized clinical trial [DCT]), and data sources (e.g., real-world data (RWD)).

Dave Burrow, PharmD, JD
Director
Office of Scientific Investigations (OSI) CDER | FDA

1:55 - 2:35

Advanced Manufacturing Technologies (AMT) Designation Program

An introduction to FDA draft guidance for industry, ***Advanced Manufacturing Technologies Designation Program*** (December 2023), which contains recommendations to persons and organizations interested in participating in the Program and details about key concepts important for program utilization.

Ranjani Prabhakara, PhD
Policy Lead
Office of Policy for Pharmaceutical Quality (OPPQ)
Office of Pharmaceutical Quality (OPQ)
CDER | FDA

2:35 - 2:55 PM: BREAK

DAY TWO: CDER TRACK: Thursday, May 30, 2024

2:55 - 3:35

Innovative Approaches to Emerging Threats

New public health challenges continually emerge, requiring the Office of Compliance's careful attention and swift action to protect consumers. We must apply innovative strategies to address long-standing risks as well as quickly pivot when urgent problems arise. Learn how the CDER Office of Compliance is utilizing past lessons learned to implement adaptations designed to surmount regulatory and enforcement challenges while ensuring the safety our drug supply.

Jill P. Furman, JD
Director
Office of Compliance (OC)
CDER | FDA

3:35 - 3:45

CDER Track Closing Remarks

This will be the close of the CDER Track online broadcast for Day One.

Brenda Stodart
Captain | USPHS | *Director* | SBIA
DDI | OCOMM | CDER

3:45 - 4:20

1:1 Question and Answer Discussion - ONSITE ATTENDEES ONLY

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Day Two Speakers

4:20 PM: CDER TRACK ADJOURN

All times shown are Eastern (EDT UTC-4)

DAY ONE: CDRH TRACK: Wednesday, May 29, 2024

Jump to CDER Track | Jump to CDRH Track | Jump to CBER Track

10:20 - 10:30

Welcome to REdI 2024 Device Track, Part 1

Kim Piermatteo, MHA
CDR | USPHS
Education Program Administrator
Division of Industry and Consumer Education (DICE)
Office of Communication and Education (OCE) | CDRH

10:30 – 11:10

Foundations of Medical Device Regulation in a World of Change

This presentation will introduce the basics of medical device regulation, highlighting helpful resources and empowering the industry to use them as a path for marketing their new ideas in the everchanging world of medical devices. The topics we will discuss include: the definition of a medical device, classification and regulatory controls of medical devices, and the use of various CDRH resources to support bringing a device to market.

Kendra Holter, MSN, RN
Consumer Safety Officer
Premarket Programs Branch
DICE | OCE | CDRH

Suggested pre-requisites:

- How to Determine if Your Product is a Medical Device
- How to Study and Market Your Device
- Is My Product a Medical Device?
- How is My Medical Device Classified?

11:10 – 11:50

Accelerating Medical Device Innovation with Regulatory Science Tools

The Center for Devices and Radiological Health (CDRH) provides resources to facilitate medical device innovation and accelerate upstream pre-competitive innovation within the medical device industry. These resources include providing innovators with regulatory science tools to help develop and assess medical technologies that can spin out multiple products. The tools reduce the need for device developers to design ad-hoc test methods and allow them to focus their limited resources on how well their new product works, not how well it may be tested. This presentation will provide an update on the FDA's Catalog of Regulatory Science Tools that help assess new medical devices and provide helpful resources and tips for finding and using these tools that can assist with development and assessment of emerging medical technologies.

Edward Margerrison, PhD
Director
Office of Science and Engineering Laboratories (OSEL)
CDRH

11:50 AM – 1:05 PM: LUNCH BREAK

All times shown are Eastern (EDT UTC-4)

DAY ONE: CDRH TRACK: Wednesday, May 29, 2024

1:05 – 1:45

Recognized Consensus Standards: The Ultimate Weapon to Streamline Conformity Assessment and Advance Innovation

Demonstrating that a medical device is safe and effective is what conformity assessment is all about. The testing performed in support of product claims requires thoughtful planning and a rigorous approach, ideally through a reliance upon standards. Citing consensus standards, particularly FDA-recognized consensus standards, has a double benefit: it both reduces regulatory burden and promotes innovation and competition, important benefits for the patients we serve. These benefits are amplified when using standards included in the Accreditation Scheme for Conformity Assessment, or ASCA. This session will explain why and how manufacturers should rely upon consensus standards, emphasizing the practical aspects of citing standards in device submissions.

Suggested pre-requisites:

- Division of Standards and Conformity
- Appropriate Use of Voluntary Consensus Standards

Simon Choi, MPH, PhD
Senior Policy Advisor
Division of Standards and Conformity Assessment
Office of Readiness and Response (ORR)
Office of Strategic Partnerships and Technology Innovation (OST) | CDRH

1:45 – 2:25

Regulation of Medical Device Clinical Trials and Innovation in Clinical Evidence Generation

CDRH is uniquely positioned to advance the development of high-quality, safe, and effective technologies to meet the needs of all patients. Clinical investigations often play a critical role in understanding the safety and effectiveness of new medical technologies in the populations that are intended to use them. This presentation will discuss FDA oversight of device investigations under the investigational device exemption (IDE) regulations. In addition, it will provide a brief overview of innovative regulatory programs that may be utilized to help support clinical evidence generation and promote the advancement of transformative technologies in healthcare, including the Early Feasibility Studies Program, Breakthrough Devices Program, and Safer Technologies Program and using real-world evidence.

Christina Savisaar, PhD
Policy Analyst
Policy and Operations Team 1
Division of Clinical Policy and Quality (DCEA1)
Office of Clinical Evidence and Analysis (OCEA)
Office of Product Evaluation and Quality (OPEQ)
CDRH

2:25 – 2:45: BREAK

All times shown are Eastern (EDT UTC-4)

DAY ONE: CDRH TRACK: Wednesday, May 29, 2024

2:45 – 3:25

The 510(k) Program: Overview and Updates

The 510(k) Program is the most common pathway for new medical devices to become legally marketed in the United States. This session will include a high-level overview of the program and associated resources. The presentation will also highlight updates, including new policies, for the premarket program.

Kathryn J De Laurentis, PhD
Policy Analyst
510(k), De Novo, 513(g), Device Determinations & Custom Devices Lifecycle Team
Division of Regulatory Programs 1 (DRP1)
Office of Regulatory Programs (ORP)
OPEQ | CDRH

3:25 – 4:05

Advancing Innovation in Healthcare with Combination Products

Combination products are composed of at least two different types of medical products (that is, 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, share some best practices, and review some recent program updates.

Hina Pinto
Associate Director
Regulatory Policy and Combination Products Team
OPEQ | CDRH

4:05 – 4:10

Day One ONLINE Closing

This will be the close of the CDRH Track online broadcast for Day One.

Kim Piermatteo
CDR | USPHS
Education Program Administrator
DICE | OCE | CDRH

4:10 – 4:35

1:1 Question and Answer Discussion – ONSITE ATTENDEES ONLY

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Day One Speakers

4:35 PM: DAY ONE CDRH TRACK ADJOURN

4:45 – 5:45 PM: NETWORKING OPPORTUNITY

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DAY TWO: CDRH TRACK: Thursday, May 30, 2024

8:50 – 9:00

Welcome to REdI 2023 Device Track, Part 2

Joseph Tartal
Deputy Director
DICE | OCE | CDRH

9:00 – 9:40

Overview of the Final Rule and the Quality Management System Regulation

The new regulation is here, and DICE is here to help! This introductory presentation will provide an overview of the Final Rule and the new regulation, Quality Management System Regulation. This overview will include the major provisions of the final rule, highlight a few key definitions, and describe the incorporation by reference and the basic structure of the new regulation. This will help you to start this important quality transition.

Joseph Tartal
Deputy Director
DICE | OCE | CDRH

9:40 – 10:20

An Innovative Approach to Navigating the Quality Management System Regulation

FDA revised the Quality System regulation to harmonize the quality management system requirements for medical devices with requirements used by other regulatory authorities. The regulation is now named the Quality Management System Regulation (QMSR). This presentation introduces an innovative approach to navigating the QMSR, the “new” 820, offering insights into how to proactively adapt to these regulatory changes. It will provide an understanding of the differences of the “prior” and the “new” 820 regulation and will reference the ISO 13485:2016 standard. Join us to explore this forward-thinking approach and unlock the potential for transformative change into continuous quality management system improvements and compliance.

Tonya A. Wilbon
Branch Chief
Postmarket and Consumer Branch
DICE | OCE | CDRH

10:20 - 10:40 AM: BREAK

All times shown are Eastern (EDT UTC-4)

DAY TWO: CDRH TRACK: Thursday, May 30, 2024

10:40 - 11:20

UDI for Patient Safety and Transformation

The FDA established the unique device identification system to adequately identify medical devices sold in the United States from manufacturing through distribution to patient use. It has been 10 years since the FDA published the Unique Device Identification System; Final Rule in September 2013. This session will present an overview of the final rule requirements and current program status. It will also present how Unique Device Identifier (UDI) is being leveraged for innovation and transformation of FDA patient safety goals.

Indira Rao Konduri, MS
Deputy Director
FDA UDI Implementation Lead
Division of Regulatory Programs 3 (DRP3)
Office of Regulatory Programs (ORP)
OPEQ | CDRH

11:20 - 12:00

Global Market Innovation with Medical Device Export Certificates

Establishments exporting medical devices from the United States (U.S.) are often asked by foreign customers or foreign governments to supply proof of the devices' regulatory or marketing status as regulated by the U.S. Food and Drug Administration (FDA). This presentation provides a comprehensive overview of medical device export certificates and their critical role in facilitating international trade and market access. It will focus on Certificate to Foreign Government (CFG) and the newly added Certificate to Foreign Government – for Devices Not Exported from the U.S. (CFG-NE). It will also discuss the issuance of electronic certificates and how to validate them.

Ruth Bediakoh
Consumer Safety Officer
Postmarket and Consumer Branch
DICE | OCE | CDRH

12:00 - 1:15 PM: LUNCH BREAK

DAY TWO: CDRH TRACK: Thursday, May 30, 2024

1:15 - 1:55

Medical Device Reporting: Viewing Adverse Events as Opportunities for Transformation

Medical Device Reporting is a postmarket surveillance tool that the FDA uses to monitor device performance and detect potential device-related safety concerns. The review and analysis of medical device reports may help identify opportunities for improvement to the quality management system. This presentation will discuss the regulatory requirements for medical device reporting, including the responsibilities of manufacturers, importers, and device user facilities. It will also suggest innovative best practices to implement an effective medical device reporting process.

Dianna Kenner-Staves, PharmD
Consumer Safety Officer
Postmarket and Consumer Branch
DICE | OCE | CDRH

1:55 - 2:35

Innovations in Medical Device Remanufacturing and Servicing

Many devices are reusable and need preventive maintenance and repair during their useful life. For these devices, proper servicing is critical to their continued safe and effective use. However, there is a lack of clarity regarding the distinction between “servicing” and “remanufacturing” activities. FDA has been working to promote clarity on the distinction between “servicing” and “remanufacturing.” This presentation will highlight best practices for entities involved in remanufacturing and servicing of devices and will equip attendees with useful strategies for distinguishing between these activities. To navigate the complex regulatory requirements landscape, we will provide entities engaged in remanufacturing with insights for success.

Katelyn Bittleman, PhD
Policy Analyst
Compliance and Quality Staff
OPEQ | CDRH

2:35 - 2:55 PM: BREAK

DAY TWO: CDRH TRACK: Thursday, May 30, 2024

2:55 - 3:35

Step into the Closing Meeting: Navigating an FDA Closeout and Beyond

Form FDA 483, Inspectional Observations, is issued to the firm's top management at the closing meeting when the investigator has observed deviations from the regulations. The presenter will review the most common 483 citations issued to the medical device industry in 2023 with comparisons made to prior years. The presentation will cover closeout meeting activities, including issuance of the 483, the annotation process, discussion items, responding in writing to 483 observations, and what firms can expect following the closeout meeting.

Sara Onyango, DHSc, MPH, MSN
LCDR | USPHS
Medical Device Specialist
Investigator
Medical Device and Radiological Health
Operations/Division I
Office of Regulatory Affairs

3:35 - 3:40

CDRH Track Closing Remarks

This will be the close of the CDRH Track online broadcast for Day One.

Joseph Tartal
Deputy Director
DICE | OCE | CDRH

3:40 - 4:20

1:1 Question and Answer Discussion - ONSITE ATTENDEES ONLY

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Day Two Speakers

4:20 PM: CDRH TRACK ADJOURN

All times shown are Eastern (EDT UTC-4)

DAY ONE: CBER TRACK: Wednesday, May 29, 2024

Jump to CDER Track | Jump to CDRH Track | Jump to CBER Track

10:20 - 10:30

CBER Track Welcome

Larissa Lapteva, MD, MHS, MBA
Associate Director
Division of Clinical Evaluation General Medicine (DCEGM)
Office of Clinical Evaluation (OCE)
Office of Therapeutic Products (OTP)
Center for Biologics Evaluation and Research (CBER)

Session 1: Innovation in Development of Advanced Therapies

10:30 - 11:10

Regulatory Approach for Gene Therapies: Incorporating Human Somatic Genome Editing

Over the past decade, development of gene therapies has been gaining momentum with increasing number of novel gene therapy products becoming available to treat serious and life-threatening diseases. This presentation will provide an overview of genome editing technologies and the regulatory approach for gene therapies that incorporate genome editing.

Brian Stultz, MS
Chief | Gene Therapy Branch 2 (GTB2)
Division of Gene Therapy 1 (DGT1)
Office of Gene Therapy CMC (OGT)
OTP | CBER

11:10 - 11:50

Facilitating Development of Gene Therapies for Rare Diseases

Center for Biologics Evaluation and Research actively collaborates with external stakeholders and other regulatory agencies to advance the development of new treatments for rare and ultrarare diseases. This presentation will discuss CBER's work in advancing gene therapies for rare diseases including engagement in the Bespoke Gene Therapy Consortium and collaborations with the WHO and other international partners.

Gopa Raychaudhuri, PhD
Associate Director for Special Programs
Office of the Director (OD) | CBER

11:50 - 12:00

Q&A with Session 1 Speakers

Brian Stultz, Gopa Raychaudhuri

12:00 - 1:00 PM: LUNCH BREAK

All times shown are Eastern (EDT UTC-4)

DAY ONE: CBER TRACK: Wednesday, May 29, 2024

Session 2: Regulatory Communications – I

1:00 - 1:30

Overview of CBER's Office of Communication, Outreach and Development

This presentation will provide an overview of the Office of Communication, Outreach and Development including activities related to external communications such as manufacturers assistance, CBER's web and social media presence, inquiries from the public and healthcare professionals, CBER's training and professional development programs, and disclosure work.

Lorrie McNeill
Director
Office of Communication, Outreach and Development (OCOD) | CBER

1:30 - 2:10

HCT/P Donor Screening/Testing and Requests for Exemption

Every year Center for Biologics Evaluation and Research receives inquiries on donor eligibility for donors of cells and tissues used in biological products. This presentation will outline regulations and policy considerations in 21 CFR part 1271 related to making a donor eligibility determination for donors of human cells, tissues, or cellular or tissue-based products (HCT/Ps) including exemptions and alternatives under 21 CFR 1271.155.

Scott A. Brubaker
Director | Division of Human Tissues (DHT)
Office of Cellular Therapy and Human Tissue (OCTHT)
OTP | CBER

2:10 - 2:25

Q&A with Session 2 Speakers

Lorrie McNeill, Scott A. Brubaker

2:25 - 2:40 PM: BREAK

DAY ONE: CBER TRACK: Wednesday, May 29, 2024

Session 3: Regulatory Communications – II

2:40 - 3:20

Types of Regulatory Submissions

CBER's Office of Therapeutic Products has been receiving an increasing number of regulatory submissions for novel biologics, drugs, and devices. This presentation will provide an overview of regulatory submissions reviewed in CBER/OTP throughout the product life cycle for Prescription Drug User Fee Act (PDUFA) and Medical Device User Fee Act (MDUFA) submissions, including timelines, expectations, and best practices.

Cara Pardon, MS
Regulatory Project Manager
Division of Review Management and Regulatory Review 1 (DRMRR1)
Office Review Management and Regulatory Review (ORMRR) | OTP | CBER

3:20 – 4:00

Patient Engagement

This presentation will provide an overview of how CBER engages with patients and patient advocates to advance the development of CBER-regulated products, how patient input is considered in CBER's product review, and the importance of patient engagement in all stages of product development.

Karen Jackler
Program Manager | Patient Engagement
Office of the Director | CBER

4:00 – 4:20

Q&A with Session 3 Speakers

Cara Pardon, Karen Jackler

4:20 – 4:30

Day One Closing

Larissa Lapteva, MD, MHS, MBA
Associate Director
DCEGM | OCE | OTP | CBER

4:45 – 5:45 PM: NETWORKING OPPORTUNITY

Onsite attendees are invited to gather at
THE HOTEL's Lobby Bar to continue the conversation with fellow attendees.

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DAY TWO: CBER TRACK: Thursday, May 30, 2024

8:30 - 8:35

CBER Track Day 2 Welcome

Larissa Lapteva, MD, MHS, MBA
Associate Director
DCEGM | OCE | OTP | CBER

Session 4: Topics from Office of Vaccines Research and Review

8:35 - 9:05

Use of Real-World Evidence in Accelerated Approval

Office of Vaccines Research and Review has been at the forefront of the recent COVID-19 pandemic and continues to review high volumes of medical products used for disease prevention. This presentation will summarize the accelerated approval regulations and discuss situations in which real-world evidence could be used as confirmatory studies.

Hector S. Izurieta, MD, MPH, PhD
Associate Director | Novel Clinical Investigations
Office of Vaccines Research and Review (OVRR) | CBER

9:05 - 9:35

Artificial Intelligence Challenges for Regulating Vaccine Development

Artificial Intelligence is rapidly developing technology that challenges the ability of regulators world-wide to provide adequate and concise guidance to drug and vaccine developers. This presentation will outline considerations for use of AI in vaccine development.

Peter J. Weina, PhD, MD
Associate Director for Medical Countermeasures and Scientific Affairs | OVRR | CBER

9:35 - 10:05

CBER's Advanced Manufacturing Programs for Sponsors

Product manufacturers increasingly rely on advanced manufacturing technologies to improve the efficiency and speed of new product development. This presentation will provide a detailed overview of Advanced Manufacturing Technologies for CBER-regulated products.

Sudhakar Agnihothram, BPharm, PhD
Associate Director of Office Regulatory Initiatives
OVRR | CBER

10:05 - 10:20

Q&A with Session 4 Speakers

Hector S. Izurieta, Peter J. Weina
Sudhakar Agnihothram

10:20 - 10:30 AM: BREAK

All times shown are Eastern (EDT UTC-4)

DAY TWO: CBER TRACK: Thursday, May 30, 2024

Session 5: Post-Approval Safety of Biological Products

10:30 - 11:10

Postmarketing Surveillance for Product Safety in Pregnancy

Pharmacovigilance, postmarketing safety, and safe use of available medical products remain important after product approval, particularly when therapies are used in vulnerable populations. This presentation will provide an overview of postmarketing safety monitoring activities related to product safety in pregnancy, including pregnancy safety studies.

Meghna Alimchandani, MD
Deputy Director
Division of Pharmacovigilance (DPV)
Office of Biostatistics and Pharmacovigilance (OBPV)
CBER

11:10 - 11:50

Update on the ICH E2D(R1) Guideline: Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports (ICSRs)

This presentation will provide an overview of the newly drafted update to E2D, the International Conference for Harmonization's (ICH) guideline on the foundational concepts, terms, and management of post-market Individual Case Safety Reports. The draft revised Guideline (ICH E2D(R1)) was opened for public comment in February 2024.

Craig Zinderman, MD, MPH
Associate Director for Medical Policy
Office of Biostatistics and Pharmacovigilance (OBPV)
CBER

11:50 - 12:00

Q&A with Session 5 Speakers

Meghna Alimchandani, Craig Zinderman

12:00 - 1:00 PM: LUNCH BREAK

All times shown are Eastern (EDT UTC-4)

DAY TWO: CBER TRACK: Thursday, May 30, 2024

Session 6: Topics from Office of Blood Research and Review

1:00 - 1:40

Blood Regulation and Safety

CBER's Office of Blood Research and Review regulates blood and blood products, including plasma derivatives and their recombinant analogues. The Office is also responsible for the regulation of blood donor screening assays and retroviral diagnostic tests. This presentation will describe FDA's approach to the regulation of blood and blood components, and donor safety.

Orieji Illoh, MD
Director
Division of Blood Components and Devices (DBCD)
OBRR | CBER

1:40 - 2:20

FDA Regulation of HIV Tests

Assurance of quality and reliability of HIV testing for blood and blood products is under purview of the Office of Blood Research and Review in CBER. This presentation will review the history of HIV testing, the current regulatory status of HIV IVDs, and how FDA is helping to expand access to novel testing options.

Julia Tait Lathrop, PhD
Associate Deputy Director
Division of Emerging and Transfusion-Transmitted Diseases (DETTD)
Office of Blood Review and Regulation (OBRR)
CBER

2:20 - 2:35

Q&A with Session 6 Speakers

Julia Tait Lathrop, Orieji Illoh

2:35 - 2:45 PM: BREAK

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DAY TWO: CBER TRACK: Thursday, May 30, 2024

Session 7: Perspectives on Bioresearch Monitoring and Product Quality

2:45 - 3:25

The Center for Biologics Evaluation and Research (CBER) Bioresearch Monitoring Program

FDA's Bioresearch Monitoring (BIMO) program is a comprehensive program of on-site inspections, data audits, and remote regulatory assessments designed to monitor all aspects of the conduct and reporting of FDA regulated research. This presentation will discuss the importance of CBER's Bioresearch Monitoring (BIMO) Program in clinical trials and in bringing new biologic products to market.

Triet M. Tran, PharmD, BCSCP
Regulatory Officer
Bioresearch Monitoring Branch (BMB)
Division of Inspections and Surveillance (DIS)
Office of Compliance and Biologics Quality (OCBQ) | CBER

3:25 - 4:05

CBER's Perspective on Evaluation and Implementation of Rapid Microbial Methods

Assurance of biological product's safety, quality, and purity is one of the cornerstones of successful product development and approval. This presentation will focus on current regulations and requirements for validation of rapid microbial methods for biological products.

Seth Schulte, MS
Biologist
Division of Biological Standards and Quality Control (DBSQC) | OCBQ | CBER

4:05 - 4:15

Q&A with Session 7 Speakers

Triet M. Tran, Seth Schulte

4:15 - 4:20

CBER Track Closing Remarks

Larissa Lapteva, MD, MHS, MBA
Associate Director
DCEGM | OCE | OTP | CBER

4:20 PM: CBER TRACK ADJOURN

All times shown are Eastern (EDT UTC-4)