Regulatory Education for Industry (REdI) 2026

May 19 & 20

Version 5 – Updated May 11, 2026

For files and resources, please visit
The Event Page on FDA.gov

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: May 19th, 2026

9:00 - 9:15

SBIA Welcome and Administrative Overview

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

9:15 - 10:15

Plenary

Moderated by:
Brenda Stodart

Michael Davis, MD, PhD
Deputy Director
Center for Drug Evaluation and Research (CDER)

Owen Faris, PhD
Deputy Director
Center for Devices and Radiological Health (CDRH)

Katherine Szarama, PhD
Acting Director
Center for Biologics Evaluation and Research (CBER)

10:15 - 11:00 AM: BREAK

DAY ONE: CDER TRACK: May 19th, 2026

Your CDER Hosts

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

Kori Adair, PharmD
Pharmacist
SBIA | DDI | OCOMM | CDER

11:00 - 11:10

Day One Introductions

Brenda Stodart

11:10 - 11:50

Clinical Trial Innovation: From Policy to Practice

This presentation will highlight recent activities and emerging priorities of CDER's Center for Clinical Trial Innovation (C3TI). Participants will gain insight into ongoing initiatives, including C3TI's Demonstration Program, and learn about opportunities to engage with CDER to advance innovative approaches to clinical trial design and conduct.

Meghana Chalasani, MHA
Associate Director for Clinical Trial Innovation
Office of New Drugs (OND) | CDER

11:50 - 12:30

From Framework to Approval: Operationalizing FDA's Real-World Evidence Program in Regulatory Decision-Making

This session will highlight the evolution of FDA's RWE Program from its statutory foundation to full integration within CDER review practices. The presentation will cover the increasing volume and complexity of RWD/RWE submissions, lessons from cases where RWE supported regulatory decisions on effectiveness, and the growing role of external control studies—particularly in rare disease and oncology. Attendees will gain practical insight into how RWE is operationalized in regulatory review and what constituted regulatory-grade evidence.

Motiur Rahman, PhD, MS, MPharm
Senior Epidemiologist Policy Advisor
Real-World Evidence Analytics
Office of Medical Policy | CDER

12:30 PM - 1:30 PM: LUNCH BREAK & QUESTIONS (IN-PERSON ONLY)

All times shown are Eastern (EDT UTC-4)

DAY ONE: CDER TRACK: May 19th, 2026

1:30 - 2:10

Quality Assurance Through CGMP: Understanding FDA Drug Manufacturing Inspections

This presentation will aid in understanding the FDA's risk-based approach to inspections. It will discuss the difference between a minor observation and a critical deficiency. It will review some common deficiencies and approaches to screening for these deficiencies at a facility as part of the routine internal audit/inspection. A review of what an FDA 483 is, the expected timeline for a response and things to consider when developing corrective actions including the significance of repeat 483 observations will be covered. Attendees will be provided with information regarding present resources available to industry such as FDA Guidance Documents which can be used to aid in filling in any knowledge gaps and help to further understand GMP expectations.

Anastasia M. Shields, Pharm.D, MS, BCPS
Commander, United States Public Health Service
Office of Human & Animal Drug Inspectorate II, Branch 3
Office of Inspections and Investigations

2:10 - 2:50

ICH E6(R3): Achieving Quality Through Purpose-Driven Clinical Trials

This presentation offers FDA perspective on implementing ICH E6(R3), highlighting its paradigm shift from process-driven to purpose-driven clinical trials. The presentation will show how E6(R3)'s core principles of Quality by Design, risk proportionality, and fit-for-purpose clinical trial quality can be applied in practice by identifying and managing Critical-to-Quality factors throughout the lifecycle of the clinical trial. The presentation emphasizes that quality improvements arise not from doing more work, but from doing the right work, focused where it matters most for participant protection and the reliability of trial results.

Cheryl Grandinetti, PharmD
Associate Director for Clinical Policy
Division of Clinical Compliance Evaluation
OSI | OC | CDER

2:50 - 3:05 PM: BREAK

All times shown are Eastern (EDT UTC-4)

DAY ONE: CDER TRACK: May 19th, 2026

3:05 - 3:45

The Use of AI to Advance Drug Development

AI has the potential to transform drug development by reducing the time and cost of drug development. This could lead to faster patient access to new medicines. FDA is seeing the use of AI across drug development life cycle. FDA is working collaboratively to support innovation and the use AI in drug development.

Anindita (Annie) Saha, BSE
Associate Director for Data Science and AI Policy (Acting)
Office of Medical Policy | CDER

3:45 - 4:25

FDA CDER Emerging Drug Safety Technology Program

This presentation shares insights and lessons learned from Emerging Drug Safety Technology Meetings (EDSTM), which facilitate dialogue between FDA and industry on the use of AI and emerging technologies in pharmacovigilance. Attendees will learn how the program serves as a central point of contact for discussing innovative safety surveillance tools and their application to pharmacovigilance.

Oanh Dang, PharmD, BCPS
Senior Pharmacist
Regulatory Science and Applied Research Lead
CDER Emerging Drug Safety Technology Co-Lead
Regulatory Science Staff
Office of Surveillance and Epidemiology | CDER

4:25 - 4:35

Day One Closing

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

Brenda Stodart

4:35 - 4:50

1:1 Speaker Discussion - ONSITE ATTENDEES ONLY

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

Day One Afternoon Speakers

4:50 PM: DAY ONE CDER TRACK ADJOURN

All times shown are Eastern (EDT UTC-4)

DAY TWO: CDER TRACK: May 20th, 2026

9:00 - 9:15

CDER Track Day 2 Welcome, Administrative Overview

Kori Adair, PharmD
Pharmacist
CDER Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Center for Drug Evaluation & Research (CDER)

9:15 - 9:55

Advanced Drug Manufacturing in CDER

Advanced technologies are revolutionizing drug manufacturing to enable faster production, higher quality processes, and more resilient supply chains that directly benefit U.S. patients. This overview of CDER's approach to supporting advancing manufacturing will explain how coordinated efforts across policy, assessment, inspection, and research facilitate the adoption of transformative manufacturing technologies. CDER's support for advanced manufacturing has already enabled medicines for U.S. patients with conditions ranging from diabetes to cystic fibrosis.

Adam Fisher, PhD
Staff Director
Office of Quality Assurance
Office of Pharmaceutical Quality (OPQ) | CDER)

9:55 - 10:35

FDA PreCheck (A CDER perspective)

Discover how the FDA's PreCheck program is enabling voluntary early engagement to facilitate the development of new pharmaceutical manufacturing facilities. This presentation will provide a CDER perspective on how the program can allow manufacturers accepted into the pilot program to proactively engage with the FDA to enable earlier facility evaluation before submitting marketing applications, potentially reducing lead times and minimizing the potential for facility challenges for new plants during drug application reviews. Attendees will gain practical insights into this innovative program to support the establishment of new pharmaceutical manufacturing facilities and improve manufacturing readiness for commercial production.

Cyrus Agarabi, PharmD, PhD, MBA, RPh
Captain | United States Public Health Service (USPHS)
Associate Director for Scientific Program Coordination
Immediate Office | OPQ | CDER

10:35 - 10:50 AM: BREAK

DAY TWO: CDER TRACK: May 20th, 2026

10:50 - 11:30

FDA Electronic Submission Update 1) Updates to eCTD for v3.2.2 and v4.0; 2) FDA Information Request (IR) Modernization Proof of Concept; 3) FDA CDER NextGen Portal

Topic areas will address eCTD, CDER Nextgen Portal, and a proof of concept around modernizing the Information Request process. 1) A look at eCTD for the past year at FDA. The presentation will cover updates made to specifications, common errors in submissions, and the current status of eCTD v4.0 Implementation; 2) Through a PDUFA VII demonstration project, FDA conducted outreach sessions in the Spring of 2025 to review current IR processes and identify challenges. A proof of concept was developed, leveraging FDA's cloud infrastructure to help address identified challenges. This presentation provides an overview of the project and outcomes; 3) One stop shop for the purpose of non-eCTD Submissions, Collaboration and Reporting. The Portal continues to reduce regulatory overhead for sponsors, research institutes, and small businesses.

Heather Crandall
IT Advisor
Office of Digital Transformation (ODT) | CDER

and

Jonathan Resnick, PMP
IT Advisor
ODT | CDER

and

Seyoum Senay, MS
Supervisory Operations Research
ODT | CDER

11:30 - 12:10 PM

Verifying Data Reliability: Observations on Bioavailability/Bioequivalence and Good Laboratory Practice Studies supporting the Development of New and Generic Drugs and Therapeutic Biologics

The Office of Study Integrity and Surveillance in the Center for Drugs evaluates BA/BE and GLP study sites to ensure ethical, scientific, and regulatory standards are met. We verify that data generated for new and generic drug and therapeutic biologics reviews are sufficiently reliable for regulatory decisions. Effective sponsor/applicant oversight of study data generation is essential for successful product development. We'll review recent challenges and highlight ways to improve future studies.

Sean Y. Kassim, PhD
Director
Office of Study Integrity and Surveillance
Office of Translational Sciences | CDER

12:10 - 1:10 PM: LUNCH BREAK & QUESTIONS (IN-PERSON ONLY)

DAY TWO: CDER TRACK: May 20th, 2026

1:10 - 1:50

Clinical Trial Innovation: Reducing Regulatory Uncertainty

Clinical research is undergoing a dynamic transformation propelled by evolving study designs, operational approaches, and technologies. In this fast-moving landscape, adaptability and strategic planning are no longer optional – they are essential for navigating what is ahead. In this session, Emily Gebbia will offer strategic insights on elevating trial quality and minimizing regulatory uncertainty – including practical tools to help research professionals thrive in today's complex and rapidly changing environment.

Emily Gebbia, JD
Associate Director of Regulatory Development
Office of Scientific Investigations (OSI)
Office of Compliance (OC) | CDER

1:50 - 2:30

Approaches for Streamlining the Nonclinical Safety Assessment for CDER-Regulated Products

This presentation will give brief overviews of possible strategies to reduce, refine, and replace animal testing in the context of the nonclinical safety assessment for drug products intended to treat non-oncology indications regulated within the Office of New Drugs (OND). Brief overviews and case examples will be presented that include discussion of the new draft guidances relating to new approach methodologies (NAMs) and monoclonal antibodies as well as weight of evidence assessments such as the ICH S1B(R1) addendum to the testing of carcinogenicity for small molecules.

Jessica Bonzo, PhD
Lead Pharmacologist
Division of Pharmacology and Toxicology II (DPTII)
Office of Immunology and Inflammation (OII) |
Office of New Drugs (OND) | CDER

2:30 - 2:45 PM: BREAK

All times shown are Eastern (EDT UTC-4)

DAY TWO: CDER TRACK: May 20th, 2026

2:45 - 3:25

Update on Rare Diseases at FDA Center for Drug Evaluation and Research

This presentation will highlight recent developments in rare diseases, including resources for rare disease drug developers, notable approvals, relevant guidances, and pilot programs.

Scott K. Winiecki, MD
Associate Director for Rare Disease (Acting)
Rare Disease Team
Division of Rare Diseases and Medical Genetics
Office of Rare Diseases, Pediatrics, Urological, and Reproductive Medicine
OND | CDER

3:25 - 3:35

CDER Track Closing Remarks

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

Kori Adair

3:35 - 3:50

1:1 Speaker Discussion - ONSITE ATTENDEES ONLY

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

Day Two Afternoon Speakers

3:50 PM: CDER TRACK ADJOURN

All times shown are Eastern (EDT UTC-4)

DAY ONE: CDRH TRACK: May 19th, 2026

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

11:00 - 11:10

Welcome to Device Track

Michelle Gabriele Sandrian, PhD
Premarket Industry Education Team Assistant Director
Division of Industry and Consumer Education (DICE) | CDRH

11:10 – 11:50

Classifying Your Device: A Database Walkthrough

This presentation will provide a practical guide to using the FDA's Product Classification Database, a critical starting point for device regulation. Attendees will learn how to determine if a product meets the definition of a medical device and how to effectively search the database to find the appropriate product classification. The session will cover multiple search strategies, how to analyze the components of a classification page to find key regulatory information (such as submission type and device class), and an overview of related resources like guidance documents and standards.

Morgan Lee, PE, CSP
Lieutenant Commander, United States Public Health Service (USPHS)
Premarket Industry Education Team
DICE | CDRH

11:50 – 12:30

Medical Device User Fees: Small Business Determination (SBD) Program

This presentation provides an overview of the Medical Device User Fee Amendments (MDUFA) Small Business Determination (SBD) program, including eligibility criteria for small business designation and the fee benefits and waivers available to qualifying small businesses. Topics covered include business revenue thresholds, documentation requirements for domestic and foreign businesses, the Small Business Request (SBR) process, and common application mistakes that delay determinations. Attendees will leave with practical tips to ensure a smooth and successful application process.

Robert Fink
Advisor (On Detail)
Office of Operations (OO)
Office of Finance, Budget, and Acquisitions (OFBA)

12:30 – 1:30 PM: LUNCH BREAK & QUESTIONS (IN-PERSON ONLY)

All times shown are Eastern (EDT UTC-4)

DAY ONE: CDRH TRACK: May 19th, 2026

1:30 – 2:10

eSTAR: Tips and Tricks to Maximize this Innovative Tool

This presentation will introduce tips and tricks on navigating CDRH's interactive, electronic Submission Template and Resource (eSTAR). Serving as a comprehensive, standardized resource, the template consolidates the necessary information and links needed for preparation of a high-quality submission. The topics we will cover include review of features of an interactive template, discussion on how to access and save eSTAR, differentiation between major and minor versions, and explanation of various documentation features of the template, such as how to respond to an additional information request and how to document compliance with recognized consensus standards.

Kendra Holter, MSN, RN
Premarket Industry Education Team
DICE | CDRH

2:10 – 2:50

AI in Medical Devices

This presentation will provide an overview of premarket submissions for Artificial Intelligence (AI)-enabled device software functions (AI-DSFs). Topics will include common challenges in premarket review of AI-DSFs and resources available on the FDA website. Attendees will learn how to prepare complete submissions that support efficient discussion with FDA review teams.

Aneesh Deoras
Acting Division Director
Digital Health Technology Assessment
Digital Health Center of Excellence (DHCoE)
Office of Strategic Partnerships and Technology Innovation (OST) | CDRH

2:50 – 3:05: BREAK

DAY ONE: CDRH TRACK: May 19th, 2026

3:05 – 3:45

Building Security into Medical Device Design: A Premarket Perspective

Cybersecurity threats to the healthcare sector have become more frequent and severe, increasing the potential for clinical impact on medical devices and patients. In response, Congress added Section 524B, "Ensuring Cybersecurity of Devices," to the FD&C Act, establishing requirements for cyber devices. This presentation will provide an overview of Section 524B of the FD&C Act. The session will also explore the FDA's guidance, "Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions," and how its recommendations on security risk management, architecture, testing, labeling and management of cybersecurity throughout the total product lifecycle can help manufacturers comply with their obligations under Section 524B.

Justin Post
Cybersecurity Specialist
Division of Medical Device Cybersecurity (DMDC)
Office of Readiness and Response (ORR)
Office of Strategic Partnerships and Technology Innovation (OST) | CDRH

3:45 – 4:25

Regulatory Science Challenges in AI Medical Devices

The rapid growth of artificial intelligence (AI) in healthcare has created unprecedented challenges for regulatory evaluation. We explore regulatory science tools (RSTs) that support the assessment of AI-enabled medical devices throughout their lifecycle, with emphasis on high-quality synthetic data and open-source computational pipelines. Attendees will discover practical resources from FDA's RST Catalog that support innovation in healthcare technology.

Aldo Badano
Director
Division of Imaging, Diagnostics, and Software Reliability (DIDSR)
Office of Science and Engineering Labs (OSEL)
CDRH

4:25 – 4:35

Day One Closing

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

Michelle Gabriele Sandrian

4:35 – 4:50

1:1 Speaker Discussion – ONSITE ATTENDEES ONLY

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

Day One Afternoon Speakers

4:50 PM: DAY ONE CDRH TRACK ADJOURN

All times shown are Eastern (EDT UTC-4)

DAY TWO: CDRH TRACK: May 20th, 2026

9:10 – 9:15

Day 2 Welcome and Introduction

Tonya Wilbon
Assistant Director
Postmarket Industry Education and Consumer Education Teams
Division of Industry and Consumer Education (DICE)
CDRH

9:15 – 9:55

Quality Management System Regulation (QMSR): Incorporation By Reference (IBR) Demystified

Tonya Wilbon

The U.S. Food and Drug Administration's transition to the Quality Management System Regulation (QMSR), introduces a pivotal shift in how medical device manufacturers interpret and apply regulatory requirements—particularly through incorporation by reference. This presentation, "QMSR: Incorporation by Reference Requirements Demystified," provides a clear and practical exploration of what incorporation by reference means within the 2026 QMSR framework and how it impacts compliance obligations. Attendees will gain an understanding of the external standards that are incorporated by reference into the QMSR, how to interpret their regulatory significance, and what this integration means for existing quality management systems. The session will break down common areas of confusion, outline expectations for demonstrating compliance during inspections, and provide practical strategies to navigate QMSR incorporation by reference with clarity and confidence.

9:55 – 10:35

Strategic Review of the QMSR Supplemental Provisions Requirements

Ruth Bediakoh
Consumer Safety Officer
Postmarket Industry Education Team
DICE | CDRH

This presentation provides a strategic analysis of the Supplemental Provisions within the Quality Management System Regulation (QMSR), focusing on the additional requirements to the ISO 13485:2016 standard. We will examine the specific requirements of 21 CFR 820.35 (Control of records) and 820.45 (Device labeling and packaging controls). We will highlight the FDA's expectations and help attendees learn how to refine their quality management system to satisfy U.S. statutory requirements and ensure seamless compliance and inspection readiness.

10:35 - 10:50 AM: BREAK

All times shown are Eastern (EDT UTC-4)

DAY TWO: CDRH TRACK: May 20th, 2026

10:50 - 11:30

FDA Medical Device Importation: Regulatory Compliance, Common Challenges, and Available Resources

The Food and Drug Administration (FDA) is responsible for ensuring that medical devices (including in vitro diagnostics) comply with applicable U.S. regulations at every point of the device cycle, to include those of foreign origin. Foreign establishments must comply with these applicable regulations before, during, and after the medical device is imported into the United States or territory. FDA does not recognize regulatory authorizations from other countries. This presentation will cover a brief overview of the import process of medical devices, FDA ImportShield Program (FISP) (nationalized entry review), common FDA Automated Commercial Environment (ACE) errors, recent and current updates to published import alerts and import alert removals. It will further review common definitions, regulatory requirements and will provide the audience with links to resources to enhance the importation process.

Yvette Montes
Consumer Safety Officer
Office of Regulatory Programs (ORP)
Office of Product Evaluation and Quality (OPEQ)
CDRH

11:30 - 12:10

Overview of Early Alert Recalls

The CDRH “Early Alert” communication pilot was established in 2024 to minimize the time between the FDA’s initial awareness of a potentially high-risk medical device removal or correction and the agency’s public communication of a potentially high-risk recall. Early Alert communications include information regarding when a company removed products from the market, corrected products, or updated instructions for using products due to potentially high safety risks. This session will provide information on “Early Alert” communications and provide the latest updates and insights into how these communications enhance transparency and protect public health.

Nick Walker
Supervisory Electronics Engineer
ORP | OPEQ | CDRH

12:10 - 1:10 PM: LUNCH BREAK & QUESTIONS (IN-PERSON ONLY)

DAY TWO: CDRH TRACK: May 20th, 2026

1:10 - 1:50

Voluntary Malfunction Summary Reporting (VMSR) Program

The FDA's Voluntary Malfunction Summary Reporting (VMSR) Program, launched in 2018, offers a streamlined and highly effective alternative to traditional individual malfunction reporting—yet many eligible manufacturers remain unaware of its advantages. This presentation explores how the VMSR program enables manufacturers with eligible product codes to submit quarterly summary reports in place of multiple 30-day malfunction reports, significantly reducing administrative burden while maintaining robust safety standards. The session will outline eligibility criteria, participation steps using Form FDA 3500A, and key exceptions requiring individual reports, such as deaths, serious injuries, and certain recall-related events. Attendees will gain practical insights into leveraging this voluntary program to optimize compliance and contribute to a more efficient and effective medical device reporting system.

Michelle Rios
Assistant Director
Medical Device Reporting (MDR) Team
Division of Surveillance Support
ORP | OPEQ | CDRH

1:50 - 2:30

Medical Device Single Audit Program (MDSAP): State of the Program

The Medical Device Single Audit Program (MDSAP) 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 presentation will provide a brief update on the program and an in-depth look on how the US FDA is using MDSAP.

Kenneth Chen, MS,
Lieutenant Commander
United States Public Health Service
Lead Project Manager
Medical Device Single Audit Program (MDSAP): State of the Program
FDA Regulatory and Inspection Teams | CDRH

2:30 - 2:45 PM: BREAK

All times shown are Eastern (EDT UTC-4)

DAY TWO: CDRH TRACK: May 20th, 2026

2:45 - 3:25

QMSR: Device Inspection Process

With the implementation of the Quality Management System Regulation (QMSR), the FDA retired the Quality System Inspection Technique (QSIT) and implemented a new Medical Device Risk-based inspection process, documented in the revised Compliance Program 7382.850, Inspection of Medical Device Manufacturers. The goal of the Medical Device Risk-based inspection process is to evaluate if the manufacturer's: Quality management system (QMS) meets FDA requirements and provides reasonable assurance that devices will be safe and effective, and 2) Risk management and risk-based decision making are effectively used in the QMS. Attendees will gain an understanding of the key principles of the risk-based inspection process, the inspection types and models, and the FDA's regulatory strategy when assessing firms' compliance. The presentation will also provide an overview of the FDA 483 citations issued since implementation of the new QMSR on February 2, 2026.

Janet Pulver, MS
Medical Device Senior Operations Officer
Office of Medical Device and Radiological Health Inspectorate (OMDRHI)
Office of Inspections and Investigations (OII)

3:25 - 3:35

CDRH Track Closing Remarks

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

Tonya Wilbon

3:35 - 3:50

1:1 Speaker Discussion - ONSITE ATTENDEES ONLY

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

Day Two Afternoon Speakers

3:50 PM: CDRH TRACK ADJOURN

All times shown are Eastern (EDT UTC-4)

DAY ONE: CBER TRACK: May 19th, 2026

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

11:00 - 11:10

CBER Track Welcome

Graeme Price, PhD
Branch Chief
Gene Therapy Branch 5
Division of Gene Therapy 2 (DGT2)
Office of Gene Therapy CMC (OGT)
Office of Therapeutic Products (OTP)
CBER

11:10 - 11:50

An Overview of FDA's New Draft Guidance on Bayesian Approaches in Drug and Biologic Trials

In this talk, the speaker will introduce attendees to the use of Bayesian statistics in drug development, summarize FDA's recent guidance on the topic, and provide several examples of the use of Bayesian methods in CBER applications.

John Scott, PhD
Acting Deputy Director
Office of Biostatistics and Pharmacovigilance (OBPV)
and
Director
Division of Biostatistics
Office of Biostatistics and Pharmacovigilance (OBPV)
CBER

11:50 - 12:30

Benefit-Risk Assessment to Inform FDA Regulatory Decision

This presentation will discuss FDA's framework for assessment of benefit-risk of a drug/biological product and use of quantitative benefit-risk assessment to help address complexity and uncertainty of decision problems.

Hong Yang, PhD
Director
Division of Analytics and Benefit-Risk Assessment (DABRA)
OBPV | CBER

12:30 - 1:30 PM: LUNCH BREAK & QUESTIONS (IN-PERSON ONLY)

All times shown are Eastern (EDT UTC-4)

DAY ONE: CBER TRACK: May 19th, 2026

1:30 - 2:10

Using DHTs for Data Collection in Clinical Trials: Electronic Diaries as a Case Study

This talk discusses how electronic diaries (eDiaries) can improve safety data collection in vaccine clinical trials by enhancing data quality, participant compliance, and real-time monitoring compared to traditional paper diaries.

Ujwani Nukala, PhD
Visiting Associate
DABRA | OBPV | CBER

2:10 - 2:50

Modernizing Adverse Event Reporting for CBER-Regulated Products

This presentation outlines the Biologics Effectiveness and Safety (BEST) Innovative Methods (IM) program to modernize the safety surveillance of vaccines and biologics. The program leverages artificial intelligence and large language models to automate detection and reporting of adverse events. This initiative aims to accelerate the evaluation of potential health risks, improve patient safety, and enhance transparency in adverse event reporting.

Luis Santana-Quintero, PhD
Data Scientist
HIVE Lead
Analytics and Real-World Evidence Branch (ARWEB)
DABRA | OBPV | CBER

2:50 - 3:05 PM: BREAK

DAY ONE: CBER TRACK: : May 19th, 2026

3:05 - 3:45

Regulatory Perspective on Novel Blood Components and Related Products

This presentation will give an overview of the regulatory framework for blood and blood components and how FDA approaches the evaluation of novel products.

Wendy Paul, MD
Director
Division of Blood Components and Devices (DBCD)
Office of Blood Research and Review (OBRR)
CBER

3:45 – 4:25

Introducing ICH Q3E: Key Concepts in the New Guideline for Extractables and Leachables

This presentation offers a general overview of the major concepts within the new International Council for Harmonisation (ICH) Q3E guideline on Extractables and Leachables. The guideline establishes a holistic, science- and risk-based framework for assessing and controlling leachable impurities to ensure patient safety and product quality. Its scope primarily covers organic leachables in new drug products, including biologics and combination products, as well as significant lifecycle changes to existing products. This framework provides a systematic process for developing scientifically sound control strategies that are tailored to the risks associated with a specific product.

Silvia De Paoli, PhD
Biological Reviewer
Clinical Review Staff (CRS)
DBCD | OBRR | CBER

4:25 – 4:35

Day One Closing

Graeme Price, PhD

4:35 – 4:50

1:1 Speaker Discussion – ONSITE ATTENDEES ONLY

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

Day One Afternoon Speakers

4:50 PM: DAY ONE CBER TRACK ADJOURN

All times shown are Eastern (EDT UTC-4)

DAY TWO: CBER TRACK: May 20th, 2026

9:05– 9:15

CBER Track Day 2 Welcome

Peter J. Weina, PhD, MD
Associate Director for Medical Countermeasures and Scientific Affairs
Office of Vaccines Research and Review (OVRR)
CBER

9:15 - 9:55

Regulatory Considerations for Bacteriophage Products Targeting Bacterial Infections

A review of the regulatory pathways that are available to enable patient treatment, research studies, and commercial product development, including the CMC (chemistry, manufacturing, and controls) expectations for each approach.

Susan Lehman, PhD
Senior Staff Fellow
Laboratory of Mucosal Pathogens and Cellular Immunology (LMPCI)
Division of Bacterial, Parasitic, and Allergenic Products (DBPAP)
OVRR | CBER

9:55 - 10:35

Regulatory Considerations in the Safety Assessment of Vaccine Adjuvants and Adjuvanted Vaccines

Description of regulatory and safety considerations of adjuvants and adjuvanted vaccines for infectious disease indications.

Meghan Maguire Thon, PhD
Lead Biologist
Regulatory Review Branch 3 (RRB3)
Division of Review Management and Regulatory Review (DRMRR)
OVRR | CBER

10:35 – 10:50 AM: BREAK

All times shown are Eastern (EDT UTC-4)

DAY TWO: CBER TRACK: May 20th, 2026

10:50 - 11:30

Office of Therapeutic Products Highlights and FAQs

The presentation will be an overview of updates from the Office of Therapeutic Products from the past year and answer some frequently asked questions.

Nadia Whitt, MS
Branch Chief
Regulatory Review Branch 1
Division of Review Management & Regulatory Review 1
Office of Review Management and Regulatory Review (ORMRR)
Office of Therapeutic Products (OTP) | CBER

11:30 - 12:10

Advanced Manufacturing Technologies (AMT) Designation Program: CBER Experience

FDA's Advanced Manufacturing Technologies Designation Program offers a framework to request designation of a method or combination of methods of manufacturing a drug as an AMT. Designated AMTs may provide greater assurance of quality, shorten drug development time, assist industry in more efficiently meeting regulatory requirements for commercial manufacturing, and strengthen regulatory predictability for products that use a designated AMT. This presentation will discuss the AMT Designation Program and lessons learned through CBER's implementation of the program.

Kimberly Schultz, PhD
Director
Division of Gene Therapy 2 (DGT2)
Office of Gene Therapy CMC (OGT)
OTP | CBER

12:10 - 1:10 PM: LUNCH BREAK & QUESTIONS (IN-PERSON ONLY)

DAY TWO: CBER TRACK: May 20th, 2026

1:10 - 1:50

Bioinformatics Expectations for Off-Target Assessment in Human Genome Editing Products

This presentation will outline bioinformatics expectations for next-generation sequencing and analysis methods used to assess off-targets in regulatory submissions of human genome editing products to the FDA.

Yongwook Choi, PhD
Bioinformatics Reviewer
Division of Cell Therapy 1 (DCT1)
Office of Cellular Therapy and Human Tissue CMC (OCTHT)
OTP | CBER

1:50 - 2:30

Mitigating Cross-Contamination in Multi-Product facilities- A Regulatory Perspective on Facility Design

Facility design considerations to mitigate cross-contamination in multi-product facilities, including lessons learned from two case studies and how these incidents were resolved.

Christine Harman, PhD
Lead Consumer Safety Officer
Division of Manufacturing and Product Quality (DMPQ)
Office of Compliance and Biologics Quality (OCBQ)
CBER

2:30 - 2:45 PM: BREAK

DAY TWO: CBER TRACK: May 20th, 2026

2:45 - 3:25

The Five W's of CBER Facility Inspections for Biological Products

An overview of the approach and process of facility inspections conducted by CBER in support of biologics licensure, including inspection timelines, readiness, and scheduling, coverage of the major systems and concluding with commonly encountered issues that are cited on 483s.

Holly Brevig, PhD
Quality Assurance Specialist
DMPQ | OCBQ | CBER

3:25 - 3:35

CBER Track Closing Remarks

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

3:35 - 3:50

1:1 Speaker Discussion - ONSITE ATTENDEES ONLY

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

Day Two Afternoon Speakers

3:50 PM: CBER TRACK ADJOURN

All times shown are Eastern (EDT UTC-4)