AGENDA
All times are Eastern (EDT UTC-4)

DAY ONE: Keynote & Plenary: Monday, June 5, 2023

8:40–9:00
SBIA Welcome

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

9:00–9:15
FDA Welcome

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

9:15–10:45
Plenary: User Fee Impact on FDA Programs

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)

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

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

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

10:45 - 11:00 AM: BREAK
DAY ONE: CDER Sessions: Monday, June 5, 2023

Your CDER Hosts

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<tr>
<th>Name</th>
<th>Title/Position</th>
<th>Office</th>
<th>CDER</th>
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<tr>
<td>Renu Lal, PharmD</td>
<td>Lieutenant Commander, USPHS</td>
<td>DDI</td>
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<td>Nora Lim, PharmD, BCPS</td>
<td>Lieutenant, USPHS, Pharmacist</td>
<td>SBIA</td>
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<td>Forest &quot;Ray&quot; Ford, PharmD, BCPS</td>
<td>Captain, USPHS</td>
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11:00 - 11:30

**Biosimilar Program Updates and What's New Under BsUFA III**

This presentation will review the new BsUFA III commitments, focusing on supplement categories and associated timelines, guidance commitments and regulatory science.

The presentation will provide an overview of the new BsUFA regulatory science program commitments, research priorities, goals, and objectives. In addition, the speakers will describe and explain research that can improve the efficiency of biosimilar development and advance the development of interchangeable products and the regulatory impact.

Legislative updates will also be reviewed that impact biosimilar development and 351(a) and 351 (K) BLA license holders. This presentation will also describe and explain the resources available for health care providers and other stakeholders to learn more about biosimilar and interchangeable biosimilars through the Purple Book and other FDA educational resources.

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11:30 – 12:00

**FDA Formal Meetings: What's New Under PDUFA, BsUFA, and OMUFA**

This session will provide an overview of FDA formal meetings under reauthorizations of PDUFA and BsUFA as well as the first authorization of OMUFA. In addition, updates to FDA's transition to in-person face-to-face meetings will be provided.

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12:00 – 12:15

**Question and Answer Panel**

Stacey Ricci, Kimberly Maxfield, Elizabeth Thompson

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12:15 - 12:45 PM: LUNCH BREAK

12:45 – 12:50

**Welcome Back**
### DAY ONE: CDER Sessions: Monday, June 5, 2023

**12:50 – 1:20**

**ESG (Electronic Submissions Gateway)...The Road to Modernization**

| Jessica Bernhardt, MS | AdminApps Program Manager, ESG Program Manager  
Office of Information Management & Technology (OIMT)  
Office of Digital Transformation (ODT)  
Office of the Commissioner (OC) |

This presentation will outline the evolution and modernization of ESG along with plans for the next generation.

**1:20 – 1:40**

**eCTD v4.0 and Latest on eCTD**

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

This session will provide an FDA eCTD v4.0 Implementation Update.

**1:40 – 2:00**

**Electronic Submission Practicalities and Application Tips**

| Heather Crandall | Operations Research Analyst  
DDMSS | OBI | OSP | CDER |

Metrics, best practices, and most common validation errors.

**2:00 – 2:15**

**Question and Answer Panel**

| Jessica Bernhardt, Jonathan Resnick, Heather Crandall |

**2:15 – 2:30 PM: BREAK**
DAY ONE: CDER Sessions: Monday, June 5, 2023

2:30 – 3:00

Data Standards
This presentation will be an overview of the CDER-CBER Data Standards Program (DSP). It will also highlight a number of the OSP's key Initiatives along with updates on current project progress.

Hao (Ray) Wang
Director
Data Standards Staff (DSS)
Office of Strategic Program (OSP) | CDER

3:00 – 3:30

PDUFA VII Goals for Digital Health Technologies - A Regulatory Review Perspective
Section IV.C of the PDUFA VII commitment letter describes FDA’s goals to enhance the use of DHT-generated data in drug development and review. This presentation takes a look at this data and its use from a regulatory review perspective.

Andrew Potter
Mathematical Statistician
Division of Biometrics I (DBI)
Office of Biostatistics (OB)
Office of Translational Sciences (OTS) | CDER

3:30 – 4:00

PDUFA VII Goals For Digital Health Technologies (DHT) - An IT Perspective
Section IV.C of the PDUFA VII commitment letter describes FDA’s goals to enhance the use of DHT-generated data in drug development and review. This presentation expands on the previous presentation to discuss activities underway and planned to support submission and review of DHT-generated data.

Mary Ann Slack
Director
OSP | CDER

4:00 – 4:15

Question and Answer Panel
Hao (Ray) Wang, Andrew Potter, and Mary Ann Slack

4:15 – 4:25

Day One Closing
Forest "Ray" Ford, PharmD, BCPS
Captain, United States Public Health Service
DDI | OCOMM | CDER

4:25 PM: DAY ONE ADJOURN
DAY TWO: CDER Sessions: Tuesday, June 6, 2023

8:30 – 8:45
Day Two Welcome and Overview
Renu Lal, PharmD  
Lieutenant Commander, USPHS  
DDI | OCOMM | CDER  
Nora Lim, PharmD, BCPS  
Lieutenant, USPHS, Pharmacist  
SBIA | DDI | OCOMM | CDER  
Forest "Ray" Ford, PharmD, BCPS  
Captain, USPHS  
DDI | OCOMM | CDER

8:45 – 9:15
Leveraging SBIA’s Resources
Includes Question and Answer Session
Renu Lal, PharmD, BCACP  
Lieutenant Commander  
United States Public Health Service (USPHS)  
Team Lead, Division of Drug Information (DDI)  
Deputy Director, SBIA  
OCOMM | CDER

9:15 - 9:45
Overview of FDA Split Real Time Application Review (STAR) Pilot Program
The FDA will present an overview of the CDER STAR Pilot Program and discuss considerations and criteria for applications that may qualify for the program.

LaShawn Schnupp, PharmD  
Senior Regulatory Health Project Manager  
STAR Program Manager  
Program Development, Implementation, and Management Staff (PDIMS)  
Office of Program Operations (OPO) | OND | CDER
J. Paul Phillips, MS  
Director  
OPO | OND | CDER

9:45 – 10:30
Use-Related Risk Analysis (URRA) and Human Factor (HF) Protocol Reviews: What to Submit for an Efficient Review
The FDA will discuss:
- The HF commitments under PDUFA VII and BSUFA III
- Tips for efficient review of HF Protocol
- Tips for efficient review of URRA

Lolita Sterrett, PharmD  
Associate Director for Human Factors  
Division of Medication Error Prevention and Analysis 2 (DMEPA 2)  
Office of Medication Error Prevention and Risk Management (OMEPRM)  
Office of Surveillance and Epidemiology (OSE)  
CDER

10:30 – 10:45
Question and Answer Panel
LaShawn Schnupp, J. Paul Phillips, and Lolita Sterrett

10:45 – 11:00: BREAK
DAY TWO: CDER Sessions: Tuesday, June 6, 2023

11:00 – 11:30
The Modernization of Clinical Trials through Digital Health Technologies (DHT), Decentralized Clinical Trials (DCT) and Point of Care Trials
The FDA will discuss how clinical trials are advancing through the use of DHTs, DCTs and point of care trials. FDA will provide an overview of DHT PDUFA VII commitments.
Beth Kunkoski
Health Science Policy Analyst
Clinical Methodologies
Office of Medical Policy (OMP) | CDER

11:30 – 12:00
PDUFA VII Real-World Evidence
The FDA will discuss the new provisions under PDUFA VII: Advancing Real-World Evidence (RWE) for Use in Regulatory Decision Making
Kimberly Smith
CAPT, USPHS
Real-World Evidence (RWE) Analytics
OMP | CDER

12:00 - 12:15
Question and Answer Panel
Beth Kunkoski and Kimberly Smith

12:15 – 12:45: LUNCH BREAK

12:45 – 12:50
Welcome Back

12:50 – 1:20
PDUFA VII PMR (Postmarketing Requirements) Commitments: Preapproval & Postapproval
The FDA will discuss the new PMR commitments under PDUFA VII:
- The timing for communicating “anticipated” PMRs during the preapproval process
- The postapproval process for responding to PMR release requests
Kathleen (Kathy) Weil
Senior Science Policy Analyst
PMR/PMC Program Manager
Safety Policy Research and Initiatives Team (SPIRIT)
Immediate Office | OND | CDER

1:20 – 1:50
How CDER is Accelerating Rare Disease Cures and the PDUFA VII Rare Disease Endpoint Advancement Pilot Program
This session will provide an overview on how CDER is working to advance rare disease cures with the Accelerating Rare disease Cures (ARC) Program, as well as updates on the PDUFA VII: Rare Disease Endpoint Advancement Pilot Program.
Kerry Jo Lee, MD
Associate Director for Rare Diseases
Rare Diseases Team
Division of Rare Diseases and Medical Genetics (DRDMG)
Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORDPURM)
OND | CDER
### DAY TWO: CDER Sessions: Tuesday, June 6, 2023

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<th>Time</th>
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| 1:50  | **PDUFA VII Chemistry, Manufacturing, and Controls (CMC) Assessment Updates** | Paresma Patel, PhD,  
Director, Division of New Drug API (DNDAPI)  
Office of New Drug Products (ONDP)  
Office of Pharmaceutical Quality (OPQ) | CDER                                                                                           |
|       | FDA will discuss quality assessment for products in expedited programs including an update on the Chemistry, Manufacturing, and Controls (CMC) Development and Readiness Pilot Program. FDA will also provide an update on new assessment tools and platforms including Knowledge-aided assessment & structured application (KASA). |                                                                                                           |
| 2:20  | **Question and Answer Panel**                                          | Kathleen (Kathy) Weil, Kerry Jo Lee  
Paresma Patel                                                                                     |
| 2:50  | **Best Practices for Human Drug Product Recalls**                       | Doris Chin,  
Consumer Safety Officer  
Incidents, Recalls and Shortages Branch  
Division of Supply Chain Integrity  
Office of Drug Security, Integrity, and Response (OSDIR)  
Office of Compliance (OC) | CDER                                                                                           |
|       | FDA will discuss considerations and best practices throughout a human drug recall life cycle including when to conduct a recall, reporting to FDA, implementing a recall, and evaluating recall effectiveness. |                                                                                                           |
| 3:20  | **A Rough Guide to Biologics Manufacturing**                           | Joel Welch, PhD,  
Associate Director for Science & Biosimilar Strategy  
Chair for Emerging Technology Team  
Office of Biotechnology Products (OBP)  
OPQ / CDER                                                                                       |
|       | This presentation will include a basic background on how biological products such as monoclonal antibodies and other therapeutic proteins are regulated by FDA/CDER. It will discuss the unique factors for chemistry, manufacturing, and controls for biological products, including both scientific and regulatory nuances. The presentation will also address how CDER approaches inspectional activities for these biological products. Finally, it will identify common themes for that lead to complete responses for marketing applications for these products. |                                                                                                           |
|       | Chris Downey, PhD,  
Director, Division of Biotech Manufacturing  
Office of Pharmaceutical Manufacturing Assessment (OPMA)  
OPQ | CDER                                                                                           |
DAY TWO: CDER Sessions: Tuesday, June 6, 2023

3:50 – 4:05
**Question and Answer Panel**
Doris Chin, Joel Welch, Chris Downey

4:05 – 4:15
**Day Two Closing**
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

4:15 PM: DAY TWO ADJOURN
## DAY THREE: CDRH Sessions: Wednesday, June 7, 2023

### AGENDA

All times are Eastern (EDT UTC-4)

<table>
<thead>
<tr>
<th>8:30 – 8:45</th>
<th>Welcome to REdI 2023 Device Track, Part 1</th>
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<td>Elias Mallis</td>
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<tr>
<th>8:45 – 9:25</th>
<th>Medical Device Regulatory Framework: Where to Start?</th>
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<tr>
<td></td>
<td>Kendra Holter, MSN, RN</td>
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<td><strong>Consumer Safety Officer</strong></td>
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<td>Premarket Programs Branch</td>
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The Center for Devices and Radiological Health (CDRH) provides resources to help the medical device industry understand the regulatory requirements and process for marketing medical devices in the United States. This presentation will introduce the basics of medical device regulation, highlighting these helpful resources and empowering the medical device industry to find and use these resources. The topics we will discuss include: the definition of a medical device, general and special controls defined in regulation, the use of databases to seek information to support the regulatory processes, and a brief introduction of the different types of premarket pathways as they relate to regulatory requirements.

**Suggested pre-requisites:**
- How to Study and Market Your Device
- Is My Product a Medical Device?
- How is My Medical Device Classified?

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<tr>
<th>9:25 – 10:05</th>
<th>Biocompatibility Basics</th>
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<tr>
<td></td>
<td>Jennifer Goode</td>
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<td><strong>Biocompatibility Program Advisor</strong></td>
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<td>Office of Product Evaluation and Quality (OPEQ)</td>
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This session will provide an overview of the FDA Biocompatibility, including some key definitions. Participants will learn when and how biocompatibility is considered, and how to apply a risk-based approach for biocompatibility.

**Suggested pre-requisites:**
- Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1
- Color Additives for Medical Devices
- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1"

| 10:05 - 10:25: BREAK |
DAY THREE: CDRH Sessions: Wednesday, June 7, 2023

10:25 - 11:05

**Appropriate Use of Voluntary Consensus Standards and the Conformity Assessment Program**

Scott A. Colburn  
Director  
Standards and Conformity Assessment Program  
Office of Strategic Partnerships and Technology Innovation (OST) | CDRH

A reliance upon consensus standards reduces regulatory burden, streamlines conformity assessment, enhances device quality and promotes global harmonization. When manufacturers cite FDA-recognized standards, uncertainty about conformity assessment documentation is reduced and less paperwork is required. This session introduces the audience to the practical aspects of citing standards in device submissions and offers tips on why and how to participate in the Accreditation Scheme for Conformity Assessment (ASCA), CDRH’s new initiative to streamline conformity assessment in device review.

**Suggested pre-requisites:**
- Standards and Conformity Assessment Program
- Module 1: Standards Overview
- Module 2: Standards: Resources and Use in Premarket Submissions
- Module 3: CDRH Standards Recognition Process
- Module 4: How to Use Consensus Standards in Premarket Submissions
- Module 5: The ASCA Pilot: Streamlining Conformity Assessment in Device Submission

11:05 - 11:45

**Detangling the 510(k) Process**

Andrew Sprau  
Consumer Safety Officer  
Premarket Programs Branch  
DICE | OCE | CDRH

The 510(k) process can be complicated and confusing. It can feel like you are tangled up in unknown requirements when all you want to do is help patients with your medical device. You may be asking yourself: What is substantial equivalence? Why do I need a predicate device and how do I find one? When will the review process be completed and what are the steps involved? The answers to these questions as well as helpful hints and tips will be explored in Detangling the 510(k) Process.

**Suggested pre-requisites:**
- Premarket Notification 510(k)
- The 510(k) Program

11:45 - 12:45: LUNCH BREAK

12:45 – 12:50

**Welcome Back**
DAY THREE: CDRH Sessions: Wednesday, June 7, 2023

12:50 – 1:30

CDRH Portal: Overview and Feature Walkthrough

The CDRH portal is a new platform that provides industry with secure submission progress tracking and online upload for CDRH premarket submissions. This presentation will provide an overview of the CDRH Portal and its current features.

Nelson Anderson, B.S.
Platform Owner, CDRH Portal
Division of Regulatory Systems, Tools, and Data Management
Office of Regulatory Programs (ORP)
Office of Product Evaluation and Quality (OPEQ) | CDRH

1:30 - 2:10

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

Do you want to save money on your CDRH marketing application fee? Are you a Small Business with gross receipts and sales of less than $100 million for the most recent tax year? If so, you could be eligible for a Small Business Determination (SBD) and reduced or waived User Fee for your submission. This session discusses the SBD qualification requirements, essential definitions, and submission process. It will conclude with helpful tips and strategies to avoid common mistakes in SBD Certification Requests that might delay your approval.

Suggested pre-requisite:
- Reduced Medical Device User Fees: Small Business Determination (SBD) Program
- How to Complete Form FDA 3602: MDUFA Small Business Qualification and Certification for a Business Headquartered in the United States
- How to Complete Form FDA 3602A: MDUFA Foreign Small Business Qualification and Certification Request for a Business Headquartered Outside the United States

Jason Brookbank
Assistant Division Director
Division of Financial Management
Office of Management (OM) | CDRH

2:10 - 2:30 PM: BREAK
## Welcome to REdI 2023 Device Track, Part 2

### 2:30 – 2:40

#### Welcome to REdI 2023 Device Track, Part 2

**Joseph Tartal**  
*Deputy Director*  
*DICE | OCE | CDRH*

## Managing Medical Device Nonconforming Product with Quality

### 2:40 – 3:20

#### Managing Medical Device Nonconforming Product with Quality

Manufacturers are required to establish and maintain procedures to control product that does not conform to specified requirements. But what do you do when you have nonconformances? Do you continue to market nonconforming products, rework nonconforming products before marketing or do you dispose of the nonconforming products? This presentation will answer these questions and compare the requirements of the Quality System Regulation, 21 CFR 820.90, and ISO 13485:2016.

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

## Handling Medical Device Complaint Files with Quality

### 3:20 – 4:00

#### Handling Medical Device Complaint Files with Quality

Manufacturers are required to maintain complaint files and procedures for handling medical device complaints. These procedures can vary a great deal depending on factors including risk, size of the company and complexity of the device. This presentation will provide the regulatory requirements for medical device complaint files. It will also provide key components of complaint files, common pitfalls and challenges associated with managing complaint files, and review strategies for addressing them.

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

## CDRH Day One Closing Remarks

### 4:00 – 4:05

#### CDRH Day One Closing Remarks

**Joseph Tartal**  
*Deputy Director*  
*DICE | OCE | CDRH*

## 4:05 PM: DAY THREE ADJOURN
### DAY FOUR: CDRH Sessions: Thursday, June 8, 2023

#### 8:30 – 8:45

**CDRH Day Two Welcome & Overview**

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#### 8:45 – 9:25

**Addressing Regulatory Science Gaps in Artificial Intelligence (AI) and Machine Learning (ML)**

Artificial intelligence (AI)/machine learning (ML)-based technologies have the potential to transform healthcare. However, due to the rapid application of the technology into many different areas and types of medical data, there are many challenges in developing robust evaluation methods, and in better understanding the effects of these devices in the real world. The AI/ML research program at CDRH's Office of Science and Engineering Laboratories (OSEL) focuses on test methodologies for assessing AI/ML performance both in the pre-market and real-world settings to reasonably ensure the safety and effectiveness of novel AI/ML algorithms. This presentation will cover the regulatory science gaps pertaining to the medical AI/ML space, and efforts by OSEL researchers to address these gaps.

**Alexej Gossman, PhD**

Staff Fellow

Division of Imaging, Diagnostics, and Software Reliability (DIDSR)

Office of Science and Engineering Laboratories (OSEL) | CDRH

#### 9:25 – 10:05

**Radiation-Emitting Medical Devices Update**

The FDA issued a final rule in February 2023, to amend and appeal certain radiological health regulations that will clarify and update these regulations to reduce the burden of regulatory requirements for radiation emitting products and medical devices without compromising patient safety. This presentation provides an overview of key amendments to the electronic product radiation control (EPRC) regulations. It will focus on those changes to the EPRC regulatory requirements for some electronic radiation emitting products which are also medical devices (such as diagnostic x-ray medical equipment), and medical devices which incorporate radiation emitting products into their final assembly (such as medical devices which incorporate a laser component).

**Laurel Burk, PhD**

Director

Division of Radiological Imaging Devices and Electronic Products

Office of Radiological Health (Office of Health Technology 8)

Office of Product Evaluation and Quality (OPEQ) | CDRH

**Suggested pre-requisite:**

- [How To Get Your Electronic Product on the US Market](#)
- [Electronic Product Certification and Quality Testing Programs](#)

#### 10:05 - 10:25: BREAK
## CDRH Medical Device Import Overview

The Food and Drug Administration (FDA) is responsible for ensuring that medical devices (including in vitro diagnostics and radiation-emitting products) comply with applicable United States (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 U.S. or territory. This presentation will provide a brief overview of the import process of medical devices. It will highlight many aspects of the import cycle, answer frequently asked questions, and provide the audience with links to resources regarding the importation process.

**Yvette Montes**  
Consumer Safety Officer  
Imports and Registration and Listing Team (IRLT)  
Division of Regulatory Programs 2 (DRP2)  
Office of Regulatory Programs (ORP)  
Office of Product Evaluation and Quality (OPEQ)  
CDRH

## All About the Form FDA 483 and ORA Electronic Reading Room

After an inspection, your firm might be issued a Form FDA 483 (483). This presentation will provide an overview of what it means to get a 483, your firm’s responsibility, and how to respond to the FDA. This presentation will also include an overview of the ORA Freedom of Information Act (FOIA) Electronic Reading Room, which is a public site that displays copies of ORA domestic inspection and related records.

**William Chang, MBA, PE**  
Lieutenant Commander, US Public Health Service  
Office of Medical Device and Radiological Health Operations (OMDRHO)  
Division 1 - East  
Office of Regulatory Affairs (ORA)

### Suggested pre-requisites:
- [Office of Regulatory Affairs](#)
### 1:05 – 1:15

**CBER Sessions Welcome**

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<th>Larissa Lapteva, MD, MHS, MBA</th>
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<td>Associate Director</td>
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<td>Division of Clinical Evaluation General Medicine (DCEGM)</td>
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<td>Office of Clinical Evaluation (OCE)</td>
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<td>Office of Therapeutic Products (OTP)</td>
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<td>Center for Biologics Evaluation and Research (CBER)</td>
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### 1:15 – 2:05

**PDUFA VII Enhancements- Interactions with Office of Therapeutic Products (OTP)**

This presentation will provide an overview of new and enhanced programs for interactions with OTP as part of the Prescription Drug User Fee Act (PDUFA) VII.

**Mara Miller, MA**  
Division Director

| Division of Review Management and Regulatory Review 2 |
| Office of Review Management and Regulatory Review |
| OTP | CBER |

*Includes Question and Answer Session*

### 2:05 – 3:00

**Overview of Pediatric Research Equity Act (PREA) and Rare Pediatric Disease PRVs**

This presentation will discuss the Pediatric Research Equity Act (PREA), Pediatric Study Plans (PSPs) and the Rare Pediatric Disease Priority Review Voucher (RPD PRV) program with a focus on CBER-regulated products.

**Adrienne Hornatko-Munoz, RAC-US**  
Senior Project Manager

| Office of the Regulatory Operations (ORO) |
| CBER |

*Includes Question and Answer Session*

### 3:00 – 3:05: BREAK
DAY FOUR: CBER Sessions: Thursday, June 8, 2023

3:05 – 4:35 Early Stages of Product Development: What You Need to Know

<table>
<thead>
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<th>Time</th>
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<tr>
<td>3:05 – 3:25</td>
<td><strong>Preclinical Development for Cellular and Gene Therapy Products</strong>&lt;br&gt;Ernesto Moreira, MD&lt;br&gt;Biologist&lt;br&gt;Pharmacology/Toxicology Branch I&lt;br&gt;OTP</td>
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<tr>
<td>3:25 – 3:45</td>
<td><strong>Preclinical Considerations for the Development of Cellular and Gene Therapy Products for IND Submissions</strong>&lt;br&gt;Gregory Conway, PhD, MA&lt;br&gt;Biological Reviewer&lt;br&gt;Office of Pharmacology and Toxicology (OPT)&lt;br&gt;OTP</td>
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<td>3:45 – 4:15</td>
<td><strong>Clinical Readiness for IND Submissions</strong>&lt;br&gt;Shelby Elenburg, MD&lt;br&gt;Medical Officer&lt;br&gt;Division of Clinical Evaluation General Medicine (DCEGM)&lt;br&gt;OCE</td>
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<td>4:15 – 4:35</td>
<td><strong>Questions &amp; Answers</strong>&lt;br&gt;Ernesto Moreira, Gregory Conway, Shelby Elenburg</td>
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<td>4:35 – 4:40</td>
<td><strong>CBER Day One Closing Remarks</strong>&lt;br&gt;Larissa Lapteva, MD, MHS, MBA&lt;br&gt;Associate Director&lt;br&gt;DCEGM</td>
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**4:40 PM: DAY FOUR ADJOURN**
### 8:30 – 8:35
**CBER Day Two Welcome & Overview**

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

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### 8:35 – 9:30
**CMC Developmental Readiness Pilot (CDRP) Program**

This presentation will discuss Accelerating Product Development and the FDA’s PDUFA VII initiative to help Cell and Gene and other Advanced Therapy Sponsors meet Chemistry Manufacturing and Controls (CMC) Regulatory Expectations in BLAs through a CMC Developmental Readiness Pilot (CDRP) Program.

_Ramjay Vatsan, PhD, CQA_  
*Associate Director for Policy*  
Office of Gene Therapy  
OTP | CBER

*Includes Question and Answer Session*

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### 9:30 – 9:35: BREAK

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### 9:35 – 10:30
**CMC Considerations for Tissue Engineered Product Development**

This presentation will discuss the CMC requirements for tissue engineered products, including considerations for early phase product development and product characterization.

_Wen (Aaron) Seeto, PhD_  
*Staff Fellow*  
Tissue Engineering Branch 2  
Division of Cell Therapy  
Office of Cellular Therapy & Human Tissue CMC (OCTHT) | OTP | CBER

*Includes Question and Answer Session*

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### 10:30 – 10:35: BREAK

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### 10:35 – 11:30
**Identifying and Controlling Attributes Related to Potency for Cell and Gene Therapy Products**

This presentation will discuss approaches to identifying product attributes related to potency for cell and gene therapy products and developing meaningful potency assays for lot release testing and comparability assessments.

_Matthew Klinker, PhD_  
*Biologist/CMC Reviewer*  
Cell Therapy Branch 2 (CTB2)  
OCTHT | OTP | CBER

*Includes Question and Answer Session*

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### 11:30 – 12:30: LUNCH BREAK

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### 12:30 – 12:35
**Welcome Back**
### DAY FIVE: CBER Sessions: Friday, June 9, 2023

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>12:35 – 1:30</td>
<td><strong>Overview and Updates on FDA’s Implementation of the Estimand Framework and Complex Innovative Trial Design Review Program</strong></td>
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<td>This presentation will provide an introduction and recent updates on two FDA initiatives related to modernizing clinical trial design: The estimand framework of ICH E9(R1) and the PDUFA VI / PDUFA VII complex innovative trial design (CID) paired meeting program.</td>
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<td></td>
<td>John Scott, PhD, AM&lt;br&gt;Director&lt;br&gt;Division of Biostatistics (DB)&lt;br&gt;Office of Biostatistics and Pharmacovigilance (OBPV)</td>
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<td><em>Includes Question and Answer Session</em></td>
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<td>1:30 – 1:35</td>
<td><strong>BREAK</strong></td>
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<tr>
<td>1:35 – 2:30</td>
<td><strong>Postmarketing Safety and Pharmacovigilance for Vaccines</strong></td>
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<td>This presentation will provide an overview of postmarketing safety monitoring for vaccines, including examples of pharmacovigilance activities, such as safety-related postmarketing studies.</td>
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<td>Meghna Alimchandani, MD&lt;br&gt;Deputy Director&lt;br&gt;Division of Pharmacovigilance (DPV)&lt;br&gt;OBPV</td>
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<td><em>Includes Question and Answer Session</em></td>
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<td>2:30 – 2:40</td>
<td><strong>BREAK</strong></td>
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<td>2:40 – 3:35</td>
<td><strong>Expanded Access to Investigational Biologics for Treatment Use</strong></td>
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<td>This presentation will outline the regulatory requirements on expanded access to investigational drugs/biologics for treatment use and will provide practical recommendations on how to submit expanded access IND requests to FDA/CBER.</td>
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<td>Lei Xu, MD, PhD&lt;br&gt;Branch Chief&lt;br&gt;General Medicine Branch 2 (GMB2)&lt;br&gt;DCEGM</td>
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<td><em>Includes Question and Answer Session</em></td>
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<tr>
<td>3:35 – 3:40</td>
<td><strong>BREAK</strong></td>
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</table>
DAY FIVE: CBER Sessions: Friday, June 9, 2023

3:40 – 4:30

Requirements and GMP Inspection of Facility for Cell and Gene Therapy Products

This presentation will summarize the systems that are covered by the FDA pre-license inspection (PLI) and pre-approval inspection (PAI) of facilities for cell and gene therapy products, including (but are not limited to) the facility design and qualifications, quality systems, and examples of objectionable observations.

Includes Question and Answer Session

4:30 – 4:35

CBER & Conference Closing Remarks

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

4:35 PM: CONFERENCE ADJOURN