

CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE (SBIA)

REGULATORY EDUCATION FOR INDUSTRY (REdI)

Annual Conference 2023



JUNE 5-9

VIA WEBCAST | www.fda.gov/CDERSBIA

Version 5 – Updated May 26, 2023

For files and resources, please visit

[The Event Page on SBIAevents.com](https://www.fda.gov/sbiaevents)

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AGENDA

All times are Eastern (EDT UTC-4)

[Jump to CDER Sessions](#)

June 5-6

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June 8-9

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**

<b>Your CDER Hosts</b>		
<b>Renu Lal, PharmD</b> <i>Lieutenant Commander, USPHS</i> DDI   OCOMM   CDER	<b>Nora Lim, PharmD, BCPS</b> <i>Lieutenant, USPHS, Pharmacist</i> SBIA   DDI   OCOMM   CDER	<b>Forest "Ray" Ford, PharmD, BCPS</b> <i>Captain, USPHS</i> DDI   OCOMM   CDER

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.

**Stacey Ricci, M.Eng, ScD,**  
*Director of Scientific Review Staff (SRS)*  
Office of Therapeutic Biologics and Biosimilars (OTBB)  
Office of New Drugs (OND) | CDER

**Kimberly Maxfield, PhD**  
*BsUFA Regulatory Science Program Coordinator*  
OTBB | OND | CDER

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.

**Elizabeth Thompson, MS**  
*Chief Project Management Staff*  
Division of Regulatory Operations for Nonprescription Drugs (DRO-NPD)  
Office of Regulatory Operations (ORO)  
OND | CDER

12:00 – 12:15

**Question and Answer Panel**

**Stacey Ricci, Kimberly Maxfield, Elizabeth Thompson**

**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

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

**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)

1:20 – 1:40

### eCTD v4.0 and Latest on eCTD

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

**Jonathan Resnick**

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

1:40 – 2:00

### Electronic Submission Practicalities and Application Tips

Metrics, best practices, and most common validation errors.

**Heather Crandall**

*Operations Research Analyst*  
DDMSS | OBI | OSP | CDER

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 VI 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**

1:50 – 2:20

**PDUFA VII Chemistry, Manufacturing, and Controls (CMC) Assessment Updates**

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).

**Paresma Patel, PhD,**  
*Director, Division of New Drug API (DNDAPI)*  
 Office of New Drug Products (ONDP)  
 Office of Pharmaceutical Quality (OPQ) | CDER

2:20 – 2:35

**Question and Answer Panel**

**Kathleen (Kathy) Weil, Kerry Jo Lee**  
 and **Paresma Patel**

**2:35 – 2:50: BREAK**

2:50 – 3:20

**Best Practices for Human Drug Product Recalls**

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.

**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

3:20 – 3:50

**A Rough Guide to Biologics Manufacturing**

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.

**Joel Welch, PhD**  
*Associate Director for Science & Biosimilar Strategy*  
 Chair for Emerging Technology Team  
 Office of Biotechnology Products (OBP)  
 OPQ | CDER

**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)

[Jump to CDER Sessions](#)  
June 5-6

[Jump to CDRH Sessions](#)  
June 7-8

[Jump to CBER Sessions](#)  
June 8-9

8:30 – 8:45

### Welcome to REdI 2022 Device Track, Part 1

**Elias Mallis**

*Director*

Division of Industry and Consumer Education (DICE)  
Office of Communication and Education (OCE)  
FDA Center for Devices and Radiological Health (CDRH)

8:45 – 9:25

### Medical Device Regulatory Framework: Where to Start?

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.

**Kendra Holter, MSN, RN**

*Consumer Safety Officer*

Premarket Programs Branch  
DICE | OCE | CDRH

#### Suggested pre-requisites:

- [How to Study and Market Your Device](#)
- [Is My Product a Medical Device?](#)
- [How is My Medical Device Classified?](#)

9:25 – 10:05

### Biocompatibility Basics

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.

**Jennifer Goode**

*Biocompatibility Program Advisor*

Office of Product Evaluation and Quality (OPEQ)  
CDRH

#### 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**

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.

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

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.

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

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

**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](#)

**2:10 - 2:30 PM: BREAK**

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

2:30 – 2:40

**Welcome to REdI 2022 Device Track, Part 2**

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

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

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

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**

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

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 Products and 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 Burke, 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**

**DAY FOUR: CDRH Sessions: Thursday, June 8, 2023**

10:25 – 11:05

**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

11:05 – 11:45

**All About the Form FDA Form-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](#)

11:45 – 11:55

**Closing for CDRH Sessions**

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

**11:55 – 1:00: LUNCH BREAK**

1:00 – 1:05

**Welcome Back**

# DAY FOUR: CBER Sessions: Thursday, June 8, 2023

## AGENDA

All times are Eastern (EDT UTC-4)

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June 5-6

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June 7-8

[Jump to CBER Sessions](#)

June 8-9

1:05 – 1:15

### CBER Sessions 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)

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.

*Includes Question and Answer Session*

**Mara Miller, MA**

*Division Director*

Division of Review Management and Regulatory Review 2

Office of Review Management and Regulatory Review

OTP | CBER

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.

*Includes Question and Answer Session*

**Adrienne Hornatko-Munoz, RAC-US**

*Senior Project Manager*

Office of the Regulatory Affairs (ORO)

CBER

**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**

3:05 – 3:25

**Preclinical Development for Cellular and Gene Therapy Products**

In this presentation early interaction opportunities with CBER, including INTERACTs and pre-INDs meetings, will be explained and discussed from the perspective of preclinical product development.

**Ernesto Moreira, MD**  
*Biologist*  
Pharmacology/Toxicology Branch I  
OTP | CBER

3:25 – 3:45

**Preclinical Considerations for the Development of Cellular and Gene Therapy Products for IND Submissions**

This presentation will provide information regarding the pharmacology and toxicology part of IND applications, common deficiencies observed in INDs, and the concept of prospect of direct benefit as it applies to preclinical development of OTP-regulated products.

**Gregory Conway, PhD, MA**  
*Biological Reviewer*  
Office of Pharmacology and Toxicology (OPT)  
OTP | CBER

3:45 – 4:15

**Clinical Readiness for IND Submissions**

This presentation will focus on clinical considerations for first-in-human (FIH) study design in cell, gene, and tissue-based products, including considerations for rare diseases.

**Shelby Elenburg, MD**  
*Medical Officer*  
Division of Clinical Evaluation General Medicine (DCEGM)  
OCE | OTP | CBER

4:15 – 4:35

**Questions & Answers**

**Ernesto Moreira, Gregory Conway,  
Shelby Elenburg**

4:35 – 4:40

**CBER Day One Closing Remarks**

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

**4:40 PM: DAY FOUR ADJOURN**



**DAY FIVE: CBER Sessions: Friday, June 9, 2023**

8:30 – 8:35

**CBER Day Two Welcome & Overview**

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

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*

**9:30 – 9:35: BREAK**

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 2  
 Office of Cellular Therapy & Human Tissue CMC  
 (OCTHT) | OTP | CBER

*Includes Question and Answer Session*

**10:30 – 10:35: BREAK**

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*

**11:30 – 12:30: LUNCH BREAK**

12:30 – 12:35

**Welcome Back**

**DAY FIVE: CBER Sessions: Friday, June 9, 2023**

12:35 – 1:30

**Overview and Updates on FDA’s Implementation of the Estimand Framework and Complex Innovative Trial Design Review Program**

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.

*Includes Question and Answer Session*

**John Scott, PhD, AM**  
*Director*  
 Division of Biostatistics (DB)  
 Office of Biostatistics and Pharmacovigilance (OBPV)  
 | CBER

**1:30 – 1:35: BREAK**

1:35 – 2:30

**Postmarketing Safety and Pharmacovigilance for Vaccines**

This presentation will provide an overview of postmarketing safety monitoring for vaccines, including examples of pharmacovigilance activities, such as safety-related postmarketing studies.

*Includes Question and Answer Session*

**Meghna Alimchandani, MD**  
*Deputy Director*  
 Division of Pharmacovigilance (DPV)  
 OBPV | CBER

**2:30 – 2:40: BREAK**

2:40 – 3:35

**Expanded Access to Investigational Biologics for Treatment Use**

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.

*Includes Question and Answer Session*

**Lei Xu, MD, PhD**  
*Branch Chief*  
 General Medicine Branch 2 (GMB2)  
 DCEGM | OCE | OTP | CBER

**3:35 – 3:40: BREAK**

## 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*

**Wei Wang, PhD**

*Microbiologist*

Division of Manufacturing and Product Quality (DMPQ)

Office of Compliance and Biologics Quality (OCBQ)

CBER

4:30 – 4:35

### CBER & Conference Closing Remarks

**Larissa Lapteva, MD, MHS, MBA**

*Associate Director*

DCEGM | OCE | OTP | CBER

**4:35 PM: CONFERENCE ADJOURN**