

CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE (SBIA)

# REGULATORY EDUCATION FOR INDUSTRY (REI) ANNUAL CONFERENCE 2022



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JUNE 6-10

Version 6 – Updated May 29, 2022

For files and resources, please visit  
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## AGENDA

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### DAY ONE: Keynote & Plenary: Monday, June 6, 2022

8:40– 9:00

#### 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

#### Keynote

**Robert M. Califf, MD**

*Commissioner of Food and Drugs*

*Food and Drug Administration*

9:15 – 10:45

#### Plenary: COVID19: What's Next for FDA?

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)*

*Panelist: Douglas C. Throckmorton, MD*

*Deputy Director Regulatory Programs*

*Center for Drug Evaluation and Research (CDER)*

**10:45 - 11:00 AM: BREAK**

# CDER: Advances in Regulatory Programs

## DAY ONE: CDER Sessions: Monday, June 6, 2022

### Your CDER Hosts

**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

11:00 - 11:20

### PDUFA Program Overview and Reauthorization Process Update

This presentation is intended to provide a background and overview of the prescription drug user fee act (PDUFA), its importance in supporting new drug product review and regulation, and performance. The presentation will also discuss themes of the upcoming PDUFA VII proposed enhancements and the process for reauthorization.

**Kevin Bugin, PhD, MS, RAC**  
*Deputy Director for Operations*  
 Office of New Drugs (OND) | CDER

11:20 - 11:50

### Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products

Meetings between a Sponsor or Applicant and the FDA often represent critical points in the regulatory process; therefore it is important that there are efficient, consistent procedures for the timely and effective conduct of such meetings. The presentation will focus on types of meetings, why, when and how to request a meeting and share best practices for meeting interactions with OND.

**Jeannie Roule**  
*Chief, Project Management Staff*  
 Urology, Obstetrics, and Gynecology  
 Division of Regulatory Operations for Rare Diseases,  
 Pediatrics, Urologic and Reproductive (DRORDPURM)  
 Office of Regulatory Operations (ORO)  
 OND | CDER

11:50 – 12:05

### Question and Answer Panel

**Kevin Bugin, Jeannie Roule**

**12:05 - 12:35 PM: LUNCH BREAK**

## CDER: Advances in Regulatory Programs

### DAY ONE: CDER Sessions: Monday, June 6, 2022

12:35 - 1:20

#### Advances in Drug Supply Chain Security – Focus on Distribution

This presentation will review advances in drug supply chain security, focusing on the distribution of drugs in the U.S. Requirements under the Drug Supply Chain Security Act (DSCSA) have enabled FDA and industry to better detect counterfeits and other illegitimate product in the supply chain, prevent them from entering the supply chain, and respond to protect patients from receiving them. Enhanced drug distribution security requirements will go into effect in November 2023 providing electronic product tracing and verification down to the package-level for most prescription drugs

**Connie Jung, RPh, PhD**  
*Captain*, United States Public Health Service  
*Senior Advisor for Policy*  
 Office of Drug Security, Integrity, and Response (ODSIR)  
 Office of Compliance (OC) | CDER

1:20 – 1:40

#### IT and Informatics Goals – CDER’s Perspective

This presentation explores FDA’s and CDER’s modernization goals and key initiatives, including an expansion on the IT/Informatics goals in PDUFA VII.

**Mary Ann Slack**  
*Director*  
 Office of Strategic Programs (OSP) | CDER

1:40 – 2:00

#### Electronic Submissions Gateway (ESG) Transparency and Modernization

The FDA will present the phased approach of how ESG is modernizing its technology and enhancing the user experience.

**J. Lowell Marshall, PMP, FAC-COR III**  
 Office of Information Management Technology (OIMT)  
 Office of Digital Transformation (ODT)  
 Office of the Commissioner (OC)

2:00 – 2:20

#### Standardizing Quality Submissions and Assessments: PQ/CMC and KASA

This presentation will describe FDA's efforts to create data standards for Electronic CTD-Q submissions for quality submissions to CDER, CBER, and CVM, and how these standards will be used in assessments and knowledge management.

**Norman Schmuff**  
*Associate Director*  
 Office of Pharmaceutical Manufacturing  
 Assessment (OPMA)  
 Office of Pharmaceutical Quality (OPQ) | CDER

2:20 – 2:35

#### Question and Answer Panel

**Mary Ann Slack, J. Lowell Marshall,**  
 and **Norman Schmuff**

**2:35 - 2:50 PM: BREAK**

## CDER: Advances in Regulatory Programs

### DAY ONE: CDER Sessions: Monday, June 6, 2022

2:50 – 3:20

#### CDER NextGen Portal - An Update

This presentation will visit recent updates and their applications in the CDER NextGen Portal.

**Seyoum Senay**

Supervisory Operations Research Division of Data Management Services and Solutions (DDMSS)  
Office of Business Informatics (OBI)  
Office of Strategic Programs (OSP) | CDER

3:20 – 3:40

#### eCTD Updates

This presentation will cover published updates during the past year, submission metrics, and plans to implement the next version of eCTD, 4.0.

**Jonathan Resnick**

*Project Management Officer*  
DDMSS | OBI | OSP | CDER

3:40 – 4:00

#### Study Data Technical Rejection Criteria Update

The eCTD validations that validate standardized study data were made effective in September 2021. This presentation will give an update about those validations, including the top errors that have been causing rejection since September 2021 and how to avoid those errors.

**Heather Crandall**

Cloud Collaboration Capability Team  
DDMSS | OBI | OSP | CDER

4:00 – 4:20

#### Question and Answer Panel

**Seyoum Senay, Jonathan Resnick, and  
Heather Crandall**

4:20 – 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**

# CDER: Advances in Regulatory Programs

## DAY TWO: CDER Sessions: Tuesday, June 7, 2022

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 – 9:05

### FDA Oncology Center of Excellence (OCE) Innovative Programs: Real Time Oncology Review (RTOR), Assessment Aid, and Project Orbis

This presentation will describe OCE’s Innovative programs, how FDA Oncology uses these programs and how they may impact the oncology community.

**Tamy Kim, PharmD**  
*Director for Regulatory Affairs and Policy*  
 Oncology Center of Excellence (OCE) and  
 Supervisory Associate Director for Regulatory  
 Affairs Office of Oncologic Diseases (OOD)  
 OND | CDER

9:05 - 9:35

### Integrated Assessment of Marketing Applications (IAMA)

The Integrated Assessment of Marketing Applications (IAMA) is one of the FDA’s Center for Drug Evaluation and Research (CDER) New Drug Regulatory Program Modernization initiatives. This session will provide a review of the IAMA and the changes being made to support a collaborative and issue-focused marketing application review process.

**Rhonda M. Hearn-Stewart, MD**  
*Associate Director for Implementation*  
 Integrated Assessment of Marketing  
 Applications  
 OND Special Programs  
 OND | CDER

9:35 – 10:05

### BsUFA III: Overview of Commitments

This presentation will provide an overview for the Biosimilar User Fee Act (BsUFA) reauthorization for fiscal years (FYs) 2023-2027, known as BsUFA III. It will also provide an overview for new commitments in the BsUFA III reauthorization.

**Keith Olin, PharmD**  
*Captain, United States Public Health Service*  
 Director of Process and Knowledge Management  
 Office of Therapeutic Biologics and Biosimilars  
 (OTBB)  
 OND | CDER

10:05 – 10:20

### Question and Answer Panel

**Tamy Kim, Rhonda M. Hearn-Stewart, and Keith Olin**

**10:20 – 10:35: BREAK**

## CDER: Advances in Regulatory Programs

### DAY TWO: CDER Sessions: Tuesday, June 7, 2022

10:35 – 11:50

#### Partnering Across FDA to Advance Therapies for Rare Diseases

FDA's Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), and the Office of the Commissioner's Office of Orphan Products Development (OOPD) are committed to facilitating and advancing the development and timely approval of safe and effective therapies to improve the lives of children and adults with rare diseases. This presentation will provide an overview of the FDA's advancements to regulate therapies for rare diseases, describe our rare disease programs and activities, and discuss how FDA collaborates with partners across FDA and with external stakeholders.

*Includes 15-minute Question and Answer Panel*

**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

**Sandra Retzky, DO, JD, MPH**

*Director, Office of Clinical Policy and Programs (OCPD)*

Office of Orphan Product Development (OOPD)

Office of the Commissioner (OC) | FDA

**Julienne Vaillancourt, RPh, MPH**

*Captain, United States Public Health Service*

*Policy Advisor and Rare Disease Liaison*

Office of the Director

Center for Biologics Evaluation and Research (CBER)

#### 11:50 – 12:20: LUNCH BREAK

12:20 – 1:05

#### FDA Adverse Event Reporting System (FAERS) Reporting and Review

Understanding the reporting of Individual Case Safety Reports to FDA and learn how to access and view the publicly available data in FAERS.

*Includes Question and Answer Panel*

**Suranjan De, MS, MBA**

*Deputy Director*

Regulatory Science Staff (RSS)

Office of Surveillance & Epidemiology (OSE)

CDER

1:05 – 1:35

#### Enhancement and Modernization of the FDA Drug Safety System: Review of Postmarket Safety Commitments under PDUFA VII

Reviewing FDA's commitments to enhance and modernize drug safety under PDUFA VII.

*Includes Question and Answer Panel*

**Amy Ramanadham, PharmD., MS**

*Lieutenant Commander, USHPS*

*Acting Associate Director for Drug Safety Operations*

Office of the Center Director (OCD) | CDER

*Including panelists:*

**Claudia Manzo, PharmD**

*Director*

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

**Patricia Bright, PhD**

*Acting Sentinel Program Lead*

Sentinel Core Team | OSE

## CDER: Advances in Regulatory Programs

### DAY TWO: CDER Sessions: Tuesday, June 7, 2022

1:35 – 2:05

#### Risk Evaluation and Mitigation Strategies (REMS) Integration and Innovation

FDA is championing and actively exploring innovative technologies to facilitate the completion of REMS requirements, including mandatory education, within prescribers' and pharmacists' workflows. Under the auspices of the public HL7 CodeX FHIR Accelerator Community and through the REMS Integration Use Case, FDA is supporting the use of standardized application programming interfaces (APIs), like the open source and freely available HL7® FHIR® APIs, with pharmacy data standards, i.e., National Council for Prescription Drug Programs (NCPDP), to reduce undue burden on prescribers, pharmacists, and other stakeholders.

The use case ultimately aims to advance the provision of timely safety information to patients and health professionals, improve the quality of REMS data for feedback and evaluation, and optimize safe medication use and REMS outcomes. This presentation will discuss the REMS Integration Use Case, provide updates on the progress in developing an open source prototype to demonstrate the art of the possible, and discuss the potential future REMS ecosystem.

*Includes Question and Answer Panel*

**George Neyarapally, PharmD, JD, MPH, RPh**  
*Regulatory Science Research Policy Lead*  
 Regulatory Science & Applied Research Team  
 OSE | CDER

**Edward D. Millikan, PharmD, RPh**  
*Senior Clinical Informatics Pharmacist*  
 Division of Mitigation Assessment and Medication Error  
 Surveillance (DMAMES)  
 Office of Medication Error Prevention and Risk Management  
 (OMEPRM)  
 Office of Surveillance and Epidemiology (OSE)  
 CDER

2:05 – 2:20: BREAK

2:20 – 2:50

#### Leveraging SBIA's Resources

Navigating the various SBIA platforms, identifying individual resources, and customizing searches for most useful results.

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

2:50 – 3:50

#### Prescription Drug Labeling Updates

This session will discuss (1) required and voluntary Physician Labeling Rule (PLR) labeling, (2) new prescription drug labeling resources including recently published human prescription drug labeling guidances, and (3) the similarities and differences between labeling databases (i.e., Drugs@FDA, DailyMed, and FDALabel).

**Eric Brodsky, MD**  
*Associate Director*  
 Labeling Policy Team  
 Office of New Drug Policy (ONDP)  
 Office of New Drugs (OND) | CDER

*Includes Question and Answer Session*

## CDER: Advances in Regulatory Programs

### DAY TWO: CDER Sessions: Tuesday, June 7, 2022

3:50 – 4:20

#### Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs – An Overview of FDA’s Guidance for Industry

Over the past few decades, FDA has promoted enrollment practices that would lead to clinical trials that better reflect the population most likely to use the drug if the drug is approved, primarily through broadening eligibility criteria. Despite these efforts, challenges to participation in clinical trials remain, and certain groups continue to be underrepresented in many clinical trials. This guidance recommends approaches that sponsors of clinical trials intended to support a new drug application or a biologics license application can take to increase enrollment of underrepresented populations in their clinical trials.

**Jamie Gamerman, JD**  
*Regulatory Counsel*  
Office of Medical Policy (OMP)  
Office of Medical Policy Initiatives (OMPI)  
CDER | FDA

*Includes Question and Answer Session*

4:20 – 4:30

#### 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

**4:30 PM: DAY TWO ADJOURN**



# DAY THREE: CDRH Sessions: Wednesday, June 8, 2022

## AGENDA

All times are Eastern (EDT UTC-4)

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June 9-10

8:30 – 8:45

### Welcome to REI 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

### Navigating the Medical Device Regulatory Framework Utilizing CDRH Resources

This presentation will walk you through the regulatory framework for marketing medical devices and provide an overview of the CDRH resources available to assist you. The presentation will also include helpful tips and strategies for navigating the regulatory process.

**Kim Piermatteo, MHA**

*Commander, United States Public Health Service  
Education Program Administrator  
DICE | OCE | CDRH*

**Suggested pre-requisites:**

- [Overview of Device Regulation](#)
- [How to Study and Market Your Device](#)

9:25 – 10:05

### Chemical Characterization of Non-targeted Analysis of Medical Device Extracts

Chemical Characterization and Non-targeted Analysis information is used to determine the extractable or leachable substances (E/L) including additives, degradants and impurities, present in patient contacting components of medical devices. Non-targeted Analysis of Medical Device Extracts generally involves one or more extractions followed by use of multiple analytical methods with sufficient sensitivity to identify and quantify E/L substances that could present a toxicological concern to the patient. This presentation will provide an overview of the use of ISO 10993-18:2020, and key scientific aspects of an extractables study: information gathering, selection of extraction conditions, sample extraction, extract sample processing, system selection and qualification, quantification, and identification.

**Berk Oktem, PhD, DABT**

*Chemist*

Division of Biology, Chemistry, and Materials Science  
(DBCMS)  
Office of Science and Engineering Laboratories (OSEL)  
CDRH

**10:05 - 10:25: BREAK**

**DAY THREE: CDRH Sessions: Wednesday, June 8, 2022**

10:25 - 11:05

**Introduction to the Breakthrough Devices and Safer Technologies Programs**

This presentation will provide an introduction to the Breakthrough Devices Program and Safer Technologies Program. The Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The Safer Technologies Program (STeP) is a voluntary program for certain medical devices and device-led combination products that are reasonably expected to significantly improve the safety of currently available treatments or diagnostics that target an underlying disease or condition associated with morbidities and mortalities less serious than those eligible for the Breakthrough Devices Program. The goal of both programs is to provide patients and health care providers with timely access to these medical devices by expediting their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization, consistent with the Agency's mission to protect and promote the public health. This presentation will include an explanation of the principles and benefits of each program, eligibility considerations, and program features available to Breakthrough and STeP devices. The presentation will also cover how to request entrance into each program and provide an overview of the review process.

**Ouided Rouabhi, MS**  
*Acting Assistant Director*  
 Policy and Operations Team  
 Division of Clinical Science and Quality  
 Office of Clinical Evidence and Analysis (OCEA)  
 Office of Product Evaluation and Quality (OPEQ)  
 CDRH

11:05 - 11:45

**CDRH Health of Women Program: The Science of Sex and Gender**

Understanding the unique issues related to the health of women is critical to understanding the performance of medical devices in women. As the device ecosystem continues to emerge, the scientific community is learning how to integrate biological sex and gender identity into understanding the presentation of disease, risk assessment, proper testing, effective treatment, and how to incorporate this knowledge to help move the science forward. This presentation will address the Health of Women Program mission, vision and strategic priorities and discuss how scientific knowledge about the health of women has evolved alongside advancements in medical technology. This presentation will also discuss CDRH's commitment to identify and act on opportunities to improve the lives of those relying on FDA expertise and to address the complex and rapidly changing regulatory challenges related to the health of women.

**Terri L. Cornelison, MD, PhD, FACOG**  
*Director, Health of Women Program*  
*Chief Medical Officer*  
 Health of Women  
 Office of Strategic Partnerships and  
 Technology Innovation (OST)  
 CDRH

**11:45 - 12:45: LUNCH BREAK**

## DAY THREE: CDRH Sessions: Wednesday, June 8, 2022

12:45 – 1:25

### 510(k) Submission Types and Reasons for Conversion

This session will provide an overview of the 510(k) process, describe the different 510(k) submission types, then will discuss some common reasons for conversion utilizing real examples.

**Melissa Hall, MS**  
*510(k), 513(g), Device Determination Program Expert*; Division of Regulatory Programs 1 (DRP1)  
 Office of Regulatory Programs (ORP)  
 OPEQ | CDRH

**Suggested pre-requisites:**

- [The 510\(k\) Program](#)
- [The Special 510\(k\) Program: Final Guidance](#)
- [Safety and Performance Based Pathway Performance Criteria](#)
- [The 510\(k\) Program: Evaluating Substantial Equivalence in Premarket Notification \[510\(k\)\]](#)
- [The Special 510\(k\) Program](#)
- [The Abbreviated 510\(k\) Program](#)
- [Safety and Performance Based Pathway](#)

1:25 - 2:05

### eSTAR: CDRH's PDF Template for Premarket Submissions

Did you know that CDRH offers a free interactive PDF form that guides submitters through the process of preparing a comprehensive medical device submission? The free eSTAR program is available for voluntary use for all medical device submitters for 510(k)s and De Novos. This presentation will provide you an overview of the eSTAR program, including where to find the eSTAR template, how to enter data into an eSTAR template, and how to submit a complete eSTAR file to CDRH. We will also discuss frequently asked questions, common errors and best practices for use of the eSTAR program.

**Lili Duan, PhD**  
*Policy Analyst*  
 Division of Regulatory Programs IV  
 ORP | OPEQ | CDRH

**Suggested pre-requisite:**

- [Voluntary eSTAR Program](#)

**2:05 - 2:25 PM: BREAK**

**DAY THREE: CDRH Sessions: Wednesday, June 8, 2022**

2:25 – 2:35

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

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

2:35 – 3:15

**FDA Registration and Listing Process Overview**

The Center for Devices and Radiological Health (CDRH) requires establishments to register and list electronically, using FURLS/DRLM, if the establishment is involved with specified regulated activities for regulated medical devices. This presentation will provide an overview of the regulatory authority, which establishments are required to register and list, and will review the process for medical device establishment registration and device listing. This presentation will also discuss establishment registration after deactivation and other registration and listing policies and processes.

**Edward Nyack, BS, MPP**  
Product Owner, FURLS/DRLM  
ORP | OPEQ | CDRH

**Suggested pre-requisites:**

- [How to Register and List](#)
- [Who Must Register, List and Pay the Fee](#)
- [Frequently Asked Questions about the New Device Registration and Listing Requirements](#)

3:15 – 3:55

**EPRC Requirements of Radiation Emitting Medical Devices**

Many radiation-emitting medical devices are also considered by FDA regulations to be Electronic Products, regulated by FDA under 21 Code of Federal Regulations (CFR) Subchapter J. This presentation will review the basics of FDA's Electronic Product regulations for medical devices as part of FDA's Electronic Product Radiation Control Program (EPRC). It will include examples of electronic products, a review of the EPRC program, relevant performance standards and their guidance documents, as well as a review of FDA's reporting requirements for electronic products.

**Lowell Howard, PhD**  
Electrical Engineering, Electronic Products  
Division of Radiological Health  
OPEQ | CDRH

**Suggested pre-requisites:**

- [How to Get Your Electronic Product on the U.S. Market](#)
- [Electronic Product Certification and Quality Testing Programs](#)

3:55 – 4:00

**CDRH Day One Closing Remarks**

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

**4:00 PM: DAY THREE ADJOURN**

**DAY FOUR: CDRH Sessions: Thursday, June 9, 2022**

8:30 – 8:45

**CDRH Day Two Welcome & Overview**

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

8:45 – 9:25

**Quality Management System Regulation (QMSR) Proposed Rule Overview and Status Update**

Manufacturers are required to establish and maintain a quality system to ensure product consistently meet applicable requirements and specification. Title 21 Code of Federal Regulations (CFR) Part 820, Quality System regulation, provides current good manufacturing practice requirements for establishing a quality system and has a direct impact on the safety and effectiveness of medical devices. This presentation will provide a high-level overview and update on the status of the proposed rule published to amend the Quality System regulation and harmonize with other requirements.

**Melissa Torres**  
Associate Director for International Affairs  
Office of Center Director (OCD)  
CDRH

**Suggested pre-requisite:**

- [Federal Register: Proposed Rule, Quality Management System Regulation](#)

9:25 – 10:05

**Purchasing Controls At a Glance**

Purchasing Controls are critical elements of a firm's Production and Process Controls Subsystem and overall quality system. They ensure that device manufacturers select only those suppliers, contractors, and consultants who have the capability to provide quality product and services. This presentation will explain the requirements identified in the Quality System Regulation and the International Organization for Standardization (ISO) 13485: 2016 for Purchasing Controls. The attendees will learn about the similarities and differences of these requirements.

**Joseph Hillring**  
Consumer Safety Officer  
Postmarket and Consumer Branch  
DICE | OCE | CDRH

**Suggested pre-requisite:**

- [Purchasing Controls](#)

**10:05 - 10:25: BREAK**

**DAY FOUR: CDRH Sessions: Thursday, June 9, 2022**

10:25 – 11:05

**Process Validation At a Glance**

Process validation is a major key element of the Production and Process Controls subsystem and supports the main goal of a quality system to consistently produce products suitable for their intended use. It establishes by objective evidence that a process consistently produces a result or product meeting its predetermined specifications. This presentation will discuss the process validation requirements of the Quality System regulation (Title 21 Code of Federal Regulation Part 820) and the requirements of the International Organization for Standardization (ISO) 13485: 2016. It will review the similarities and differences of these requirements. Participants will also review examples of implementing these process validation requirements.

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

**Suggested pre-requisite:**

- [Process Validation](#)

11:05 – 11:45

**Remote Regulatory Assessments (RRAs) for Medical Device Facilities**

Remote Regulatory Assessments (RRAs) is a voluntary program for medical device facilities being implemented by FDA’s Office of Medical Device and Radiological Health Operations (OMDRHO). This presentation will discuss this new inspectional tool FDA will be utilizing moving forward. Attendees will obtain insight geared towards the agency’s jurisdiction to conduct a RRA, the process of completing a RRA, and they will be able to identify any additional RRA resources.

**Brittani Franklin**  
*Consumer Safety Officer*  
 Office of Medical Device Radiological Health  
 Operations (OMDRHO)  
 Division II  
 Office of Regulatory Affairs (ORA)

**Suggested pre-requisites:**

- [OMPTO RRA Fact Sheet](#)
- [OMDRHO Foreign Remote Regulatory Assessment Handout](#)

11:45 – 11:55

**Closing for CDRH Sessions**

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

**11:55 – 1:00: LUNCH BREAK**

# DAY FOUR: CBER Sessions: Thursday, June 9, 2022

## AGENDA

All times are Eastern (EDT UTC-4)

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June 9-10

1:00 – 1:10

### CBER Sessions Welcome

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

*Associate Director*

Division of Clinical Evaluation Pharmacology and Toxicology (DCEPT)

Office of Tissues and Advanced Therapies (OTAT)

Center for Biologics Evaluation and Research (CBER)

1:10 – 1:35

### Introduction and Update for the Office of Tissues and Advanced Therapies (OTAT)

This presentation will describe the reorganized structure of the Office of Tissues and Advanced Therapies (OTAT) and will provide an annual update on its regulatory activities for a wide range of OTAT-regulated products including cellular, gene, and tissue-based therapies, devices, and xenotransplantation products.

**Wilson Bryan, MD**

*Director*

OTAT | CBER

1:35 – 2:00

### Common Product Quality Issues for Gene and Cellular Therapy Products

This presentation will provide an overview of product quality issues for gene and cellular therapy products that are encountered throughout product development with emphasis on challenges encountered during expedited development.

**Carrie Laurencot, PhD**

*Associate Director*

Division of Cellular and Gene Therapies (DCGT)

OTAT | CBER

2:00 – 2:25

### Common Preclinical Challenges in the Regulatory Pathway for Cellular and Gene Therapy Products

In this presentation, an overview of the Pharmacology/Toxicology review process for early communications with CBER/OTAT, such as the Initial Targeted Engagement for Regulatory Advice (INTERACT) and pre-IND meetings, as well as the preclinical content of IND submissions, will be provided in this presentation. Common issues and deficiencies observed with these submissions will be discussed, thus enabling awareness of sponsors, and facilitating the efficient development of cellular and gene therapy products.

**Melek Sunay, PhD**

Pharmacology /Toxicology Reviewer

DCEPT | OTAT | CBER

2:25 – 2:40

### Question & Answer for Two Above Sessions

**Carrie Laurencot and Melek Sunay**

**DAY FOUR: CBER Sessions: Thursday, June 9, 2022**

2:40 – 3:05

**Cellular And Gene Therapy in Oncology: Common Issues Encountered in Regulatory Submissions**

This session will focus on cellular and gene therapy product development from a clinical perspective with a focus on issues commonly encountered in regulatory submissions.

**Asha Das, MD**  
*Medical Officer*  
 DCEPT | OTAT | CBER

3:05 – 3:30

**Design Considerations of Clinical Trials for Rare Diseases**

This presentation will provide regulatory considerations on the design of clinical trials to develop biological therapies, including cellular, gene, and tissue-based therapies for the treatment of rare diseases.

**Rosa Sherafat-Kazemzadeh, MD**  
*Medical Officer*  
 General Medicine Branch 2  
 DCEPT | OTAT | CBER

3:30 – 3:45

**Question & Answer Session**

**Asha Das and  
 Rosa Sherafat-Kazemzadeh**

**3:45 – 4:00: BREAK**

4:00 - 4:40

**Communication Best Practices – Interacting with Regulatory Project Managers in CBER/OTAT**

This presentation will discuss best practices for regulatory communications between sponsors, applicants, and FDA staff, including written correspondence, requests for formal meetings and informal feedback, email correspondence and general expectations for communication timelines.

**Eden Chane**  
*Regulatory Project Manager*  
 Division of Regulatory Project Management (DRPM)  
 OTAT | CBER

*Includes Question and Answer Session (15 minutes)*

4:40 – 4:45

**CBER Day One Closing Remarks**

**Larissa Lapteva, MD, MHS, MBA**  
*Associate Director*  
 DCEPT | OTAT | CBER

**4:45 PM: DAY FOUR ADJOURN**



**DAY FIVE: CBER Sessions: Friday, June 10, 2022**

8:30 – 8:40

**CBER Day Two Welcome & Overview**

**Larissa Lapteva, MD, MHS, MBA**  
*Associate Director*  
 DCEPT | OTAT | CBER

8:40 – 9:20

**Post-marketing Surveillance and REMS for CBER Products**

This presentation will provide an overview of pharmacovigilance activities and include examples of post-marketing studies and risk evaluation and mitigation strategies (REMS) for CBER-regulated products.

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

9:20 – 9:45

**CBER Sentinel (BEST) System**

This presentation will describe and discuss the Biologics Effectiveness and Safety (BEST) System in CBER.

**Joyce Obidi, PhD**  
*Health Scientist*  
 CBER Surveillance Team  
 OBPV | CBER

9:45 – 10:05

**Question & Answer Session**

**Meghna Alimchandani and Joyce Obidi**

**10:05 – 10:20: BREAK**

10:20 – 10:45

**FDA Regulatory Oversight for Xenotransplantation Products**

This presentation will describe the evolution of FDA policy and regulatory requirements for xenotransplantation products. It will also discuss the risks associated with the use of xenotransplantation with a focus on screening and control of donor animals and sample collection and archiving of patient and animal samples for various purposes.

**Judy Arcidiacono, MS**  
*Regulatory Liaison*  
 OTAT | CBER

10:45 – 11:15

**Chemistry, Manufacturing and Controls (CMC) Considerations for Xenotransplantation Products**

This presentation will discuss CMC considerations for the characterization and safety testing of xenotransplantation products.

**Archana Siddam, PhD**  
*CMC Reviewer*  
 Cell Therapies Branch (CTB)  
 DCGT | OTAT | CBER

**DAY FIVE: CBER Sessions: Friday, June 10, 2022**

11:15 – 11:35

**Xenotransplantation Products: Approach to Clinical Development**

This presentation will highlight regulatory expectations for safe clinical development of products intended for xenotransplantation.

**Patricia Beaston, MD, PhD**  
*Medical Officer*  
 DCEPT | OTAT | CBER

11:35 – 11:55

**Question & Answer Session**

**Judy Arcidiacono, Archana Siddam, and Patricia Beaston**

**11:55 – 1:00: LUNCH BREAK**

1:00 – 1:30

**OTAT’s Stakeholder Outreach and Patient Engagement Program**

This presentation will include a brief overview of stakeholder engagement at OTAT, with a focus on patient outreach and education efforts in the regenerative medicine space.

**Anne Rowzee, PhD**  
*Associate Director for Policy*  
 Stakeholder Outreach and Engagement  
 OTAT | CBER

1:30 – 2:00

**The CBER Advanced Technologies Team**

The Center for Biologics Evaluation and Research (CBER) recently established the CBER Advanced Technologies Team (CATT) to encourage the adoption of advanced technologies to modernize biopharmaceutical manufacturing of complex biologics. This presentation will discuss the rationale for establishing the CATT program, its mission and objectives, the mechanism for interacting with CATT, and CBER experience with the program thus far.

**Manuel Osorio, PhD**  
*Senior Scientist for Emerging Technologies and Medical Countermeasures*  
 Office of Center Director  
 CBER

2:00 – 2:20

**Overview of FDA-EMA Parallel Scientific Advice Program for The Center for Biologics Evaluation and Research (CBER)**

The Parallel Scientific Advice Program (PSAP) provides a concurrent review and exchange of advice from the U.S. Food and Drug Administration (FDA) and the European Medicine Agency (EMA) to sponsors on scientific issues during the development of new medicinal products (i.e., new human drugs and biologics). This presentation will provide an overview of the program for the Center for Biologics Evaluation and Research.

**Crystal Melendez MT, RN, BSN, DCPM**  
*Regulatory Health Project Manager*  
 DRPM | OTAT | CBER

2:20 – 2:40

**Question & Answer Session**

**Anne Rowzee, Manuel Osorio, and Crystal Melendez**

**2:40 – 3:00: BREAK**

## DAY FIVE: CBER Sessions: Friday, June 10, 2022

3:00 – 3:30

### Medical Devices in CBER

This presentation will provide an overview of the types of medical devices reviewed in CBER and delivery device considerations for biological products.

**Alyssa Kitchel, PhD**

*Device Team Lead*  
Tissue Engineering Branch  
DCGT | OTAT | CBER

3:30 – 4:00

### Safety-Related Impurities in Plasma-Derived Products

This presentation will discuss examples of serious adverse events associated with impurities in plasma-derived products and manufacturing control strategies that mitigate these patient safety risks.

**Mikhail Ovanesov, PhD**

*Research Biologist, Principal Investigator*  
Division of Plasma Protein Therapeutics (DPPT)  
OTAT | CBER

4:00 – 4:25

### Common Mistakes in Demonstrating Analytical Method Suitability

This presentation will discuss analytical method validation and common mistakes encountered in regulatory submissions.

**Emnet Yitbarek, PhD**

*Analytical Chemist*  
Division of Biologic Standards and Quality Control (DBSQC)  
Office of Compliance and Biologics Quality (OCBQ)  
CBER

4:25 – 4:45

### Question & Answer Session

**Alyssa Kitchel, Mikhail Ovanesov, and  
Emnet Yitbarek**

4:45 – 4:50

### CBER & Conference Closing Remarks

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

*Associate Director*  
DCEPT | OTAT | CBER

**4:50 PM: CONFERENCE ADJOURN**