DAY ONE: Keynote, Plenary, and CDER Sessions: Monday, July 19, 2021

8:40–9:00

Welcome

Brenda Stodart, PharmD, BCGP, RAC
CAPT, USPHS
Director, Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM) | CDER

9:00–9:20

Keynote

Janet Woodcock, MD
 Acting Commissioner of Food and Drugs
 Food and Drug Administration

9:20–10:20

Plenary

This plenary session will reflect on FDA’s use of Emergency Use Authorizations (EUAs) and other resources in making drug, device, and biological products available to support the public health response to the COVID-19 pandemic.

An emergency use authorization, or EUA, is a regulatory pathway that allows FDA to help strengthen the nation’s public health protections by facilitating the availability and use of medical countermeasures needed during public health emergencies. Under this pathway, FDA may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives.

10:20–10:35 AM: BREAK
**DAY ONE: CDER Sessions: Monday, July 19, 2021**

### Your CDER Hosts

**Host:** Renu Lal, PharmD  
*LCDR, USPHS Pharmacist*  
DDI | OCOMM

**Q&A Moderator:** Lisa Misevicz  
*Health Communications Specialist*  
SBIA | DDI | OCOMM | CDER

### 10:35 - 11:05

**OND Reorganization and the New Drugs Regulatory Program Modernization**

This presentation will review the Office of New Drugs (OND) new organizational structure which was implemented via a 2020 reorganization. We will also discuss the impetus for this action and its connection to the New Drugs Regulatory Program Modernization. We will cover details of the prior and new structure, address additional New Drugs Regulatory Program Modernization initiatives and workstreams currently undergoing implementation, and those also on the horizon.

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

### 11:05 - 11:15

**ANDA Efforts Related to COVID-19**

This session will serve to explain the Generic Drug Program’s efforts to facilitate marketing of generic drug products for potential treatment and supportive therapies for patients with to COVID-19.

**John Ibrahim, PharmD**  
*Associate Director for Regulatory Affairs (ADRA)*  
Office of Regulatory Operations (ORO)  
Office of Generic Drugs (OGD) | CDER

### 11:15 - 11:50

**Resource Capacity Planning: How CDER is Modernizing Resource Planning Capabilities**

This session will discuss how CDER is working to develop a unified and trusted resource management capability to foster innovation and maximize operational performance, facilitating a flow of products to patients first in the world in order to protect and promote public health, and meet our commitments to the American public.

**Alison Lyndaker**  
*Operations Research Analyst*  
Resource Capacity Planning Staff  
Office of Program and Strategic Analysis (OPSA)  
CDER

### 11:50 - 12:50 PM: LUNCH BREAK

### 12:50 - 1:25

**CDER NextGen Portal**

The CDER NextGen Portal is an integrated cloud solution based on common standards for collaboration. The portal enables sponsors to submit Drug Shortages Notifications to the FDA CDER with validated product information. Provide options for non eCTD submissions to submit Research INDs, Type III DMFs, EUA, and exempted human drug applications to the FDA. This collaboration capability continues to reduce regulatory overhead for sponsors, academia, research institute, medical doctors, and small businesses. In addition, the solution substantially reduces the amount of paper submissions and improves overall digital transformation and operational efficiency.

**Seyoum Senay**  
*Supervisory Operations Research*  
Division of Data Management Services and Solutions (DDMSS)  
Office of Business Informatics (OBI)  
Office of Strategic Programs (OSP) | CDER
### Electronic Common Technical Document (eCTD)

The presentation will focus on eCTD and discuss any recent updates to guidance and specifications. Content will also include common errors, frequently asked questions, and information about the Technical Rejection Criteria for Study Data (TRC).

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

### Product Quality Considerations for Emergency Use Authorizations (EUAs)

Learn more about emergency use authorizations – what they are, the process to submit EUAs, and the expectations for chemistry, manufacturing, and controls information in an EUA submission.

**Wendy Wilson-Lee, PhD**  
Division Director, Division of New Drug Products II  
Office of New Drug Products (ONDP)  
Office of Pharmaceutical Quality (OPQ) | CDER

### Strategies to Address Potential Medication Errors for EUA Products for COVID-19

This session describes examples of medication errors and strategies to address them to increase the safe use of drug products under development for COVID that is related to the product design, labeling, and/or packaging.

**Sevan Kolejian, PharmD, MBA, BCPPS**  
Team Leader  
Division of Medication Error Prevention and Analysis I (DMEPAI)  
Office of Medication Error Prevention and Risk Management (OMEPRM)  
Office of Surveillance and Epidemiology (OSE) | CDER

### Clinical Pharmacology Regulatory Sciences in Drug Development and Precision Medicine: Current Status and Emerging Trends

In the regulatory setting, clinical pharmacology focuses on the impact of intrinsic and extrinsic factors on inter-patient and intra-subject variability in drug exposure and response. This translational science contributes to the understanding of the benefit-risk profile in individual patients and the development of relevant therapeutic monitoring and management strategies.

Clinical pharmacology also plays a major role in the development and qualification of drug development tools. Some recent examples will be presented to illustrate the important roles of clinical pharmacology in drug development and evaluation. In addition, emerging trends in clinical pharmacology regulatory sciences will be discussed, including the Model-Informed Drug Development (MIDD) pilot program, the use of real-world data to generate real-world evidence, and leveraging advances in basic, biomedical, and clinical science into useful tools for drug development and evaluation.

Continued advances in clinical pharmacology can be the basis of more rational and efficient drug development and improved access to new drug treatments that are tailored to the patient to achieve better efficacy and safety.

**Qi Liu, PhD, MStat, FCP**  
Associate Director for Innovation & Partnership  
Office of Clinical Pharmacology (OCP)  
Office of Translational Sciences (OTS) | CDER
## Day Two Welcome and Overview

**Host:** Forest "Ray" Ford, Jr., PharmD  
CAPT, USPHS  
Pharmacist  
Small Business and Industry Assistance (SBIA)  
Division of Drug Information (DDI)  
Office of Communications (OCOMM) | CDER

**Q&A Moderator:** Lisa Misevicz  
Health Communications Specialist  
SBIA | DDI | OCOMM | CDER

### 9:00 – 10:15

**CDER's Role in Public Health Emergency Response and Medical Countermeasure Development**

This session will provide a general overview of how CDER, as part of a regulatory agency, executes emergency preparedness and response for public health incidents, including medical countermeasure (MCM) development programs and FDA’s tools and authorities for facilitating the availability of MCMs for emergency preparedness and response. In addition to reviewing specific CDER responses to past public health emergencies, the session will highlight some of CDER’s public health actions targeted for the current COVID-19 pandemic response.

**Andrea Gormley, PharmD**  
LCDR, USPHS  
Associate Director for Regulatory Affairs

**Kelly Ngan, PharmD**  
CDR, USPHS  
Team Leader  
Counter-Terrorism and Emergency Coordination Staff (CTECS)  
Office of Center Director (OCD) | CDER

### 10:15 – 10:55

**Where Do We Go From Here? How the Ombudsman Can Help**

Anyone having interactions with CDER should find our staff professional and helpful and our decisions based on sound science and policy. However, as you interact with CDER, there may be instances when you feel stuck, unheard, misunderstood, or wonder if you are being treated fairly. The CDER Ombudsman offers an informal, confidential, and neutral environment to hear your concerns and discuss options for a path forward.

**Virginia Behr**  
Ombudsman  
Office of Executive Programs (OEP) | CDER

### 10:55 - 11:15: BREAK

### 11:15 – 11:45

**COMMUNICATION Best Practices – Interacting with Regulatory Project Managers in the Office of Regulatory Operations**

This presentation will introduce participants to the Office of Regulatory Operations within CDER’s Office of New Drugs and will describe several communication best practices when interacting with the Regulatory Project Managers, who manage OND applications (e.g., investigational new drug applications).

**Jacqueline Ware, PharmD**  
CAPT, USPHS  
Chief of Project Management Staff (acting)  
Neurology 2 RPM Group  
Division of Regulatory Operations for Neuroscience and  
Deputy Director, Office of Regulatory Operations (ORO) | OND | CDER
DAY TWO: CDER Sessions: Tuesday, July 20, 2021

11:45 – 12:15
Communications in a Global Pandemic
This presentation will focus on the various communications channels employed in OCOMM’s role in FDA’s mission to serve public health.

James-Denton (JD) Wyllie
Director
Office of Communications (OCOMM)
CDER

12:15 - 1:15: LUNCH BREAK

1:15 – 1:45
Regulatory Policy: Role in Guiding Decision Making in CDER
This session will describe how regulatory policy guides decision making in CDER, explain the Office of Regulatory Policy’s role in facilitating regulatory policy objectives in CDER, and discuss CDER’s approach to developing and coordinating policy making on a rapid basis in response to the COVID-19 public health emergency. The session will address, among other things, topics relating to CDER’s policy governance, COVID-19 guidance development, and emergency use authorization disclosure and transparency.

Stefanie Kraus, JD, MPH
Senior Regulatory Counsel
Division of Regulatory Policy II
Office of Regulatory Policy (ORP)
CDER

1:45 – 2:25
Role of the Product Jurisdiction Team in the Medical Product Development Process
This session will describe the role the CDER Product Jurisdiction Team plays in identifying products as drug, devices, biological products or combination products, facilitating intercenter coordination for CDER-led combination products, and developing guidance and policy related to the combination products CDER regulates. In addition, this session will include an overview of how the CDER Product Jurisdiction Team coordinates with the Office of Combination Products, as well as the CDRH and CBER Jurisdiction Officers.

Kristina Lauritsen, PhD
CDER Combination Products Regulatory Policy Advisor
OEP | CDER

2:25 – 2:45: BREAK

2:45 – 3:25
Post FDA Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency
Early in the COVID-19 public health emergency, FDA recognized that the pandemic was impacting the conduct of clinical trials of medical products and creating challenges in accomplishing protocol-specified procedures. FDA also recognized that COVID-19 illness and COVID-19 control measures would lead to protocol modifications and cause unavoidable protocol deviations.

In response, the Agency published FDA Guidance on Conducting Clinical Trials of Medical Products During the COVID-19 Public Health Emergency and opened a Clinicaltrialconduct-COVID19@fda.hhs.gov mailbox to respond to questions from stakeholders. The guidance—which was subsequently updated several times based on mailbox inquiries—provides general considerations to assist sponsors in promoting the safety of trial participants, maintaining compliance with good clinical practice, and minimizing risks to trial integrity.

John Concato, MD, MS MPH
Associate Director of Real World Evidence Analytics (Acting)
Office of Medical Policy (OMP) | CDER
FDA's Bioresearch Monitoring (BIMO) program is responsible for monitoring all aspects of the conduct and reporting of FDA-regulated research to ensure trials are being conducted in a way that ensures the reliability of data used in regulatory decision making and that the rights of participants in FDA-regulated research are being protected. The COVID-19 Public Health Emergency reduced the ability to conduct on-site inspections and led to the development of alternative approaches to inform decisions regarding pending applications.
8:30 – 8:45

**CDRH Sessions Welcome**

_Elias Mallis_

_Director_

_Division of Industry and Consumer Education (DICE)_

_Office of Communication and Education (OCE)_

_FDA Center for Devices and Radiological Health (CDRH)_

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8:45 – 9:25

**Demystifying Medical Device Regulations**

This presentation will provide an introduction to the basics of medical device regulation. Presentation topics include the following: the FDA’s role in regulating medical devices; the definition of a medical device and some basics about device classification; and, the primary steps to bring a new product to market, including the different types of premarket regulatory submissions an applicant may send to the FDA.

_Suggested pre-requisites:_

- Overview of Device Regulation
- How to Study and Market Your Device

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9:25 – 10:05

**Accelerating Medical Device Innovation with Regulatory Tools**

_Edward Margerrison, PhD_

_Director_

_Office of Science and Engineering Laboratories (OSEL)_

_CDRH_

_Edward Margerrison, PhD_  
_Director_  
_Office of Science and Engineering Laboratories (OSEL)_  
_CDRH_

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

_Suggested pre-requisites:_

- Catalog of Regulatory Science Tools to Help Assess New Medical Devices
- Accelerating Medical Device Innovation with Regulatory Science Tools
- How the FDA Uses Science to Speed Medical Device Innovation

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10:05 - 10:25: BREAK
**DAY THREE: CDRH Sessions: Wednesday, July 21, 2021**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Presenter</th>
<th>Title / Positions</th>
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<tbody>
<tr>
<td>10:25 - 11:05</td>
<td><strong>Q-Sub Program: What Is It and Best Practices</strong></td>
<td>Susannah Gilbert, MS</td>
<td>Policy Analyst/Q-Submission Program Lead Division of Regulatory Programs 1 (DRP1)</td>
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<td>Office of Product Evaluation and Quality (OPEQ) CDRH</td>
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<td>11:05 - 11:45</td>
<td><strong>The 510(k) Program - Overview and Program Updates</strong></td>
<td>Geeta Pamidimukkala, MS</td>
<td>Deputy Director (Acting) DRP1</td>
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<td>11:45 - 12:45</td>
<td><strong>LUNCH BREAK</strong></td>
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<td>12:45 – 1:25</td>
<td><strong>The 510(k) Program - How to Determine an Effective Predicate Device</strong></td>
<td>Melissa Hall, MS</td>
<td>Consumer Safety Officer PPB</td>
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<td>1:25 - 2:05</td>
<td><strong>Bioresearch Monitoring Sponsor Inspections</strong></td>
<td>Adam Donat, MS, JD</td>
<td>Deputy Director Division of Clinical Evidence and Analysis 1 OPEQ</td>
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<td>Office of Clinical Evidence and Analysis (OCEA)</td>
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<td>2:05 - 2:25 PM</td>
<td><strong>BREAK</strong></td>
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**Q-Sub Program: What Is It and Best Practices**

The Q-Submission Program provides a mechanism for submitters to request feedback or a meeting with the FDA at different points along the total product life cycle for a device. This session will discuss the evolution of the Q-Submission Program and outline some of the specific Q-Submission types. The presentation will also highlight some best practices and resources that can be used during the Q-Submission process.

**The 510(k) Program - Overview and Program Updates**

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

**The 510(k) Program - How to Determine an Effective Predicate Device**

This session will discuss the 510(k) program as it relates to the choice of a predicate device. We'll review key factors to consider when choosing a predicate and we'll walk through the process of selecting an effective predicate device through a case study.

**Bioresearch Monitoring Sponsor Inspections**

FDA's Bioresearch Monitoring (BIMO) program is a comprehensive program of on-site inspections and data audits designed to monitor all aspects of the conduct and reporting of FDA regulated research. This session will provide an overview of the regulatory roles and responsibilities of sponsors of medical device research, as well as unique considerations for sponsor-investigators. It will also discuss BIMO inspection metrics, what to expect during an inspection, and close with tips for facilitating a successful inspection.
## DAY THREE: CDRH Sessions: Wednesday, July 21, 2021

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<tr>
<td>2:25 – 2:35</td>
<td>Postmarket Introduction</td>
<td>Joseph Tartal&lt;br&gt;Deputy Director&lt;br&gt;DICE</td>
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<td>2:35 – 3:15</td>
<td>Management Responsibilities at a Glance</td>
<td>Vidya Gopal, MS&lt;br&gt;Consumer Safety Officer&lt;br&gt;Postmarket and Consumer Branch (PCB)&lt;br&gt;DICE</td>
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<td>3:15 – 3:55</td>
<td>CAPA at a Glance</td>
<td>Tonya A. Wilbon&lt;br&gt;Branch Chief&lt;br&gt;PCB</td>
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<td>3:55 – 4:00</td>
<td>CDRH Day One Closing Remarks</td>
<td>Joseph Tartal&lt;br&gt;Deputy Director&lt;br&gt;DICE</td>
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### Management Responsibilities at a Glance

Management Controls is one of the seven key quality indicators using the subsystem approach and is one of the major subsystems that serve as the basic foundation of a firm’s quality system. This presentation will explain the essential elements identified in the Quality System Regulation and the International Organization for Standardization (ISO) 13485: 2016 for Management activities that ensure adequate resources are provided and that an effective quality system has been implemented and is monitored.

**Suggested pre-requisite:**
- Management Controls

### CAPA at a Glance

The Corrective and Preventive Action (CAPA) subsystem is critical to the health of a firm’s overall quality system. It is part of the feedback and monitoring mechanisms used in a quality system to identify and correct quality problems. This presentation will explain the requirements identified in the Quality System Regulation and the International Organization for Standardization (ISO) 13485: 2016 for CAPA activities that ensure corrective and preventive action have been implemented. The attendees will learn about the similarities and differences of these requirements.

**Suggested pre-requisite:**
- Corrective and Preventive Action Basics

### CDRH Day One Closing Remarks

Joseph Tartal<br>Deputy Director<br>DICE | OCE | CDRH

### 4:00 PM: DAY THREE ADJOURN
DAY FOUR: CDRH Sessions: Thursday, July 22, 2021

8:30 – 8:45

**CDRH Day Two Welcome & Overview**

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8:45 – 9:25

**Medical Device Single Audit Program (MDSAP) Overview**

The Medical Device Single Audit Program allows recognized Auditing Organizations (AOs) to conduct a single audit of a medical device manufacturer (MDM) that will satisfy the relevant requirements of participating Regulatory Authorities (RAs). The RAs currently participating in MDSAP include the Therapeutic Goods Administration of Australia (TGA), Brazil's Agência Nacional de Vigilância Sanitária (ANVISA), Health Canada, Japan's Pharmaceuticals and Medical Devices Agency (PMDA), and the U.S. Food and Drug Administration (FDA). This presentation will provide a brief update on the program and an in-depth look on how each Regulatory Authority utilizes MDSAP Audit Reports and Certifications within their jurisdiction.

Suggested pre-requisites:
- Medical Device Single Audit Program Frequently Asked Questions
- Introduction to the MDSAP Program
- Overview of the MDSAP Audit Process

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<th>Jake Dyer, PE, PMP</th>
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<td>Lieutenant Commander, USPHS</td>
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<td>Senior Regulatory Officer</td>
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<td>Regulatory Inspections and Audits Team</td>
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<td>Division of Regulatory Programs 2 (DRP2)</td>
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9:25 – 10:05

**Public MAUDE Database Overview**

The Manufacturer and User Facility Device Experience (MAUDE) database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers. This presentation will provide an overview of MAUDE and walkthrough on how to navigate the database.

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<th>Fariba Maramkhah, MS</th>
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<td>Consumer Safety Officer</td>
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<td>Monitoring eMDR Helpdesk</td>
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<td>Division of Regulatory Programs 3 (DRP3)</td>
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10:05 - 10:25: BREAK

10:25 – 11:05

**Additive Manufacturing of Medical Devices**

Additive Manufacturing (AM), also referred to as 3D Printing, refers to a suite of manufacturing technologies which builds parts one layer at a time. This presentation will cover the multiple AM Technologies that are used to manufacture medical devices and the kinds of medical devices that are made use AM technologies. This presentation will conclude with a brief summary of CDRH’s Guidance “Technical Considerations for Additively Manufactured Medical Devices.”

Suggested pre-requisite
- Technical Considerations for Additive Manufactured Medical Devices

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<tr>
<th>Matthew Di Prima, PhD</th>
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<tr>
<td>Research Materials Scientist</td>
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<td>Additive Manufacturing Program Area Coordinator</td>
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<td>Division of Applied Mechanics (DAM)</td>
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DAY FOUR: CDRH Sessions: Thursday, July 22, 2021

11:05 – 11:45

**FDA Review of Class I and II Recalls**

This presentation will share the results of an in-depth analysis of Class I and Class II recalls and provide considerations for the application of those results to the medical device industry. The application considerations will include best practices and corrective actions feedback for industry. This presentation will provide insights from our recent review of Class I and Class II recalls that may assist industry in navigating recalls in the future.

Meredith Andress, MPH
Recall Coordinator, Division 2
Office of Medical Devices and Radiological Health (OMDRHO)
Office of Regulatory Affairs (ORA)

11:45 – 11:55

**Closing for CDRH Sessions**

Joseph Tartal
Deputy Director
DICE | OCE | CDRH

11:55 – 12:45: LUNCH BREAK
DAY FOUR: CBER Sessions: Thursday, July 22, 2021

AGENDA

All times are Eastern (EDT UTC-5)

**12:45 – 12:55**

**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)

**12:55 – 1:25**

**Introduction to the Office of Tissues and Advanced Therapies (OTAT)**

This presentation will describe the structure, regulatory responsibilities, and mission of the Office of Tissues and Advanced Therapies (OTAT).

**Wilson Bryan, MD**  
*Director*  
OTAT | CBER

**1:25 – 2:20**

**21 CFR Part 1271 (known as the "Tissue Rule"): HCT/P Regulatory Framework**

Scott Brubaker  
*Director*  
Division of Human Tissues (DHT)  
OTAT | CBER  
Safa Karandish  
*Consumer Safety Officer*  
DHT | OTAT | CBER

Part 1 of this presentation will outline regulations in 21 CFR Part 1271 and policy considerations when manufacturing includes human cells, tissues, or cellular or tissue-based products (HCT/Ps) and "Tissue Rule" applicability to product development.

Part 2 of this presentation will outline regulations and policies related to donor eligibility determination including exemptions and alternatives under 21CFR 1271.155.

**2:20 – 2:30**: BREAK

**2:30 – 3:10**

**Overview of Product Development for Advanced Therapies under 351 Pathway**

Jennifer Hsu Albert, BSN, RN  
*Regulatory Project Manager*  
Division of Regulatory Project Management (DRPM)  
OTAT | CBER

This presentation will cover the basics of biologics submissions, review the life-cycle of biological products from Investigational New Drug (IND) to Biological License Application (BLA), and familiarize the audience with FDA/Sponsor meeting procedures for development of biologics.
### DAY FOUR: CBER Sessions: Thursday, July 22, 2021

**3:10 – 3:30**

**Cellular Therapies: Manufacturing Control and Comparability Considerations for Cellular Therapy Products**  
This presentation will describe complexities and unique challenges of manufacturing cell therapy products and discuss lifecycle approaches to controlled manufacturing and demonstration of product comparability after a significant manufacturing change.  

**Thomas Finn, PhD**  
 Produkt Quality Reviewer  
 Division of Cellular and Gene Therapies (DCGT)  
 OTAT | CBER

**3:30 – 3:50**

**Using Consensus Standards in Regulatory Submissions for Biological Products**  
The presentation will describe how consensus standards that leverage the expertise available to external Standards Development Organizations may be applied to develop best practices and explicit methods to support regulatory submissions for biological products.  

**Malcolm Moos, MD, PhD**  
 Senior Investigator and Product Quality Reviewer  
 DCGT | OTAT | CBER

**3:50 – 4:05**

**Question & Answer for Two Above Sessions**  

**4:05 – 4:15: BREAK**

**4:15 - 4:45**

**Preclinical Development Considerations for Cellular Therapies**  
This presentation will provide an overview of preclinical study design considerations for cellular therapy products and expectations for early phase clinical trials.  

**Danielle Brooks, PhD**  
 Pharmacology/Toxicology Reviewer  
 DCEPT | OTAT | CBER

**4:45 – 5:15**

**Development of Cellular Therapies: Clinical Perspective**  
This presentation will describe cellular therapies and discuss clinical considerations for the development of these products.  

**Elizabeth Hart, MD**  
 Chief, General Medicine Branch 1  
 DCEPT | OTAT | CBER

**5:15 – 5:30**

**Question & Answer for Two Above Sessions**  

**5:30 – 5:35**

**CBER Day One Closing Remarks**  

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

**5:35 PM: DAY FOUR ADJOURN**
**DAY FIVE: CBER Sessions: Friday, July 23, 2021**

### 8:30 – 8:35
**CBER Day Two Welcome & Overview**

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

### 8:35 – 8:50
**Expeditied Programs for Development of Advanced Therapies**
This presentation will discuss Fast Track Designation, Breakthrough Therapy Designation, Regenerative Medicine Advanced Therapy Designation, Rolling review and Priority review for BLA.

**Niloofar Kennedy, MS**  
Regulatory Project Manager  
DRPM | OTAT | CBER

### 8:50 – 9:15
**Practical Applications for Regenerative Medicine Advanced Therapy Designation**
The presentation will highlight the key features of FDA’s Expedited Programs and will discuss OTAT’s experience with Regenerative Medicine Advanced Therapy designations thus far.

**Tejashri Purohit-Sheth, MD, FACAAI, CQIA**  
Director  
DCEPT | OTAT | CBER

### 9:15 – 9:30
**Question & Answer for Two Above Sessions**

**Niloofar Kennedy** and **Tejashri Purohit-Sheth**

### 9:30 – 10:00
**Development of Gene Therapies from Product Quality Perspective: Genetically Modified Cells**
This presentation will discuss product testing for genetically modified cellular products, with a focus on product characterization studies and potency assay development across the product lifecycle.

**Graeme Price, PhD**  
Product Quality Reviewer  
DCGT | OTAT | CBER

### 10:00 – 10:30
**Chemistry, Manufacturing, and Control Considerations for In Vivo Gene Therapy Products**
This presentation will focus on the chemistry, manufacturing, and control considerations for in vivo gene therapy products including adeno-associated virus vectors and in vivo genome editing products.

**Anna Kwilas, PhD**  
Product Quality Team Lead  
DCGT | OTAT | CBER

### 10:30 – 10:45
**Question & Answer for Two Above Sessions**

**Graeme Price** and **Anna Kwilas**

### 10:45 – 10:55: BREAK
### Preclinical Development Considerations for Gene Therapies

This presentation will include an overview of preclinical study design considerations for gene therapy products and expectations for early phase clinical trials.

Daniel Urban, PhD  
Pharmacology/Toxicology Reviewer  
DCEPT | OTAT | CBER

### Clinical Development of Gene Therapies: Genetically Modified Cellular and Cancer Immunotherapies

This presentation will give a clinical perspective on gene therapy product development for the treatment of cancer with a focus on investigational new drug applications evaluated by FDA and important considerations in clinical trial designs.

Asha Das, MD  
Medical Officer  
DCEPT | OTAT | CBER

### Clinical Development for In-Vivo Gene Therapy Products

This presentation will summarize basic knowledge about gene therapy (GT) and GT products, important principles on efficient clinical development of these treatments, and regulatory requirements and flexibility for developing GT for rare diseases.

Lei Xu, MD, PhD  
Chief, General Medicine Branch 2  
DCEPT | OTAT | CBER

### Question & Answer for Three Above Sessions

Daniel Urban, Asha Das and Lei Xu

### Medical Devices in CBER

This presentation will describe the types of medical devices regulated by CBER and applicable regulatory considerations.

Andrea Gray, PhD  
Devices and Combination Products Team Lead  
Cell Therapy Branch  
DCGT | OTAT | CBER

### Immunogenicity of Protein Therapeutics

This presentation will outline the development of proteins to treat deficiency disorders. It will also discuss current research and approach to management of inhibitory antibodies which may develop in response to protein therapeutics.

Basil Golding, MD, MBChB  
Director  
Division of Plasma Protein Therapeutics  
OTAT | CBER
**DAY FIVE: CBER Sessions: Friday, July 23, 2021**

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<tr>
<th>Time</th>
<th>Session</th>
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<tr>
<td>3:00 – 3:50</td>
<td><strong>Cell and Gene Therapy Products: Inspectional Experience</strong></td>
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<td>The presentation will provide an overview of cell and gene therapy</td>
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<td>(CGT) manufacturing challenges, applicable regulatory requirements, and</td>
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<td>FDA approach to manufacturing facility inspections. Frequency analysis</td>
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<td>and examples of inspectional observations at CGT facilities will be</td>
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<td><strong>Ekaterina Allen</strong></td>
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<td>3:50 – 3:55</td>
<td><strong>CBER &amp; Conference Closing Remarks</strong></td>
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<td><strong>Larissa Lapteva, MD, MHS, MBA</strong></td>
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<td>3:55 PM</td>
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