

SMALL BUSINESS AND INDUSTRY ASSISTANCE

REGULATORY EDUCATION FOR INDUSTRY (REdI)

First annual conference with drugs, devices, and biologics.



JULY 19-23, 2021
VIA WEBCAST | www.fda.gov/CDERSBIA

Version 9 – Updated July 17, 2021

For files and resources, please visit
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AGENDA

All times are Eastern (EDT UTC-5)

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July 19-20

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July 22-23

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.

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)

10:20 - 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*

DAY ONE: CDER Sessions: Monday, July 19, 2021

1:25 - 2:00

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

2:00 - 2:20 PM: BREAK

2:20 – 3:00

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

3:00 – 3:40

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

3:40 – 4:20

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

4:20 PM: DAY ONE ADJOURN

DAY TWO: CDER Sessions: Tuesday, July 20, 2021

8:45 – 9:00

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
 Project Management and Emergency Coordination
 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 a 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

DAY TWO: CDER Sessions: Tuesday, July 20, 2021

3:25 – 4:05

OSI's Role in the Drug Development Process and the Impact of COVID-19

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.

Laurie Muldowney, MD

Deputy Director

Office of Scientific Investigations (OSI)
Office of Compliance (OC) | CDER

4:05 PM: DAY TWO ADJOURN

DAY THREE: CDRH Sessions: Wednesday, July 21, 2021

AGENDA

All times are Eastern (EDT UTC-5)

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July 22-23

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)

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.

Diane Nell, PhD

Consumer Safety Officer
Premarket Programs Branch (PPB)
DICE | OCE | CDRH

Suggested pre-requisites:

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

9:25 – 10:05

Accelerating Medical Device Innovation with Regulatory Tools

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.

Edward Margerrison, PhD

Director
Office of Science and Engineering Laboratories
(OSEL)
CDRH

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](#)

10:05 - 10:25: BREAK

DAY THREE: CDRH Sessions: Wednesday, July 21, 2021

10:25 - 11:05

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.

Susannah Gilbert, MS
Policy Analyst/Q-Submission Program Lead
 Division of Regulatory Programs 1 (DRP1)
 Office of Regulatory Programs (ORP)
 Office of Product Evaluation and Quality (OPEQ)
 CDRH

11:05 - 11:45

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.

Geeta Pamidimukkala, MS
Deputy Director (Acting)
 DRP1 | ORP | OPEQ | CDRH

11:45 - 12:45: LUNCH BREAK

12:45 – 1:25

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.

Melissa Hall, MS
Consumer Safety Officer
 PPB | DICE | OCE | CDRH

Suggested pre-requisites:

- [The 510\(k\) Program](#)
- [How is My Medical Device Classified?](#)
- [Case Study: How is My Medical Device Classified?](#)
- [The 510\(k\) Program: Evaluating Substantial Equivalence in Premarket Notifications \[510\(k\)\]](#)

1:25 - 2:05

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.

Adam Donat, MS, JD
Deputy Director
 Division of Clinical Evidence and Analysis 1
 Office of Clinical Evidence and Analysis (OCEA)
 OPEQ | CDRH

2:05 - 2:25 PM: BREAK

DAY THREE: CDRH Sessions: Wednesday, July 21, 2021

2:25 – 2:35

Postmarket Introduction

Joseph Tartal
Deputy Director
DICE | OCE | CDRH

2:35 – 3:15

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.

Vidya Gopal, MS
Consumer Safety Officer
Postmarket and Consumer Branch (PCB)
DICE | OCE | CDRH

Suggested pre-requisite:

- [Management Controls](#)

3:15 – 3:55

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.

Tonya A. Wilbon
Branch Chief
PCB | DICE | OCE | CDRH

Suggested pre-requisite:

- [Corrective and Preventive Action Basics](#)

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, July 22, 2021

8:30 – 8:45

CDRH Day Two Welcome & Overview

Joseph Tartal
Deputy Director
DICE | OCE | CDRH

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.

Jake Dyer, PE, PMP
Lieutenant Commander, USPHS
Senior Regulatory Officer
Regulatory Inspections and Audits Team
Division of Regulatory Programs 2 (DRP2)
ORP | OPEQ | CDRH

Suggested pre-requisites:

- [Medical Device Single Audit Program Frequently Asked Questions](#)
- [Introduction to the MDSAP Program](#)
- [Overview of the MDSAP Audit Process](#)

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.

Fariba Maramkhah, MS
Consumer Safety Officer
Monitoring eMDR Helpdesk
Division of Regulatory Programs 3 (DRP3)
ORP | OPEQ | CDRH

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."

Matthew Di Prima, PhD
Research Materials Scientist
Additive Manufacturing Program Area Coordinator
Division of Applied Mechanics (DAM)
OSEL | CDRH

Suggested pre-requisite

- [Technical Considerations for Additive Manufactured Medical Devices](#)

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

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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

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.

Scott Brubaker

Director

Division of Human Tissues (DHT)

OTAT | CBER

Safa Karandish

Consumer Safety Officer

DHT | OTAT | CBER

2:20 – 2:30: BREAK

2:30 – 3:10

Overview of Product Development for Advanced Therapies under 351 Pathway

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.

Jennifer Hsu Albert, BSN, RN

Regulatory Project Manager

Division of Regulatory Project Management (DRPM)

OTAT | CBER

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
Product 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

Thomas Finn and Malcolm Moos

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

Danielle Brooks and Elizabeth Hart

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

Expedited 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.

Niloofer 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, FACA, CQIA
Director
 DCEPT | OTAT | CBER

9:15 – 9:30

Question & Answer for Two Above Sessions

Niloofer 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

DAY FIVE: CBER Sessions: Friday, July 23, 2021

10:55 – 11:15

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

11:15 – 11:40

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

11:40 – 12:05

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

12:05 – 12:30

Question & Answer for Three Above Sessions

Daniel Urban, Asha Das and Lei Xu

12:30 – 1:30: LUNCH BREAK

1:30 – 2:10

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

2:10 – 3:00

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, MBBCh
Director
 Division of Plasma Protein Therapeutics
 OTAT | CBER

DAY FIVE: CBER Sessions: Friday, July 23, 2021

3:00 – 3:50

Cell and Gene Therapy Products: Inspectional Experience

The presentation will provide an overview of cell and gene therapy (CGT) manufacturing challenges, applicable regulatory requirements, and FDA approach to manufacturing facility inspections. Frequency analysis and examples of inspectional observations at CGT facilities will be presented.

Ekaterina Allen

Lead Consumer Safety Officer

Division of Manufacturing and Product Quality (DMPQ)

Office of Compliance and Biologics Quality (OMPQ)

CBER

3:50 – 3:55

CBER & Conference Closing Remarks

Larissa Lapteva, MD, MHS, MBA

Associate Director

DCEPT | OTAT | CBER

3:55 PM: CONFERENCE ADJOURN