Version 9 – Updated August 25, 2020

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AGENDA

All times are Eastern (EDT UTC-4)

August 25 & 26: CDER Sessions: NDA & BLA - Post Approval Considerations

August 27 & 28: CDRH Sessions

DAY ONE: CDER: Tuesday, August 25, 2020

8:50 – 9:10

Welcome

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

9:10 – 9:50

Plenary

This presentation will provide an overview of the U.S. Food and Drug Administration's (FDA's) initiatives involving real-word data (RWD) and real-world evidence (RWE). The presenters will discuss regulatory frameworks for RWE with regard to drugs, biologics, and devices. The speakers will discuss opportunities and challenges when using RWD focusing specifically on the use of RWE to support regulatory decisions in the FDA's efforts to explore the potential for leveraging the vast amount of data generated in the health care system to protect and promote the public health.

John Concato
Deputy Director
Office of Medical Policy Initiatives
CDER

Soma Kalb
Director
Division of Clinical Evaluation and Analysis 1: Clinical Science and Quality
Office of Clinical Evaluation and Analysis
Office of Product Evaluation and Quality
Center for Devices and Radiological Health (CDRH)

9:50– 9:55

Day One Overview

Host: **Forest "Ray" Ford, Jr.**
CAPT, USPHS
Pharmacist
DDI | OCOMM

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

DAY ONE: CDER: Tuesday, August 25, 2020

9:55 - 10:45

New Drugs Regulatory Program Modernization -Restructure of the Office of New Drugs

In 2017, the Center for Drug Evaluation and Research embarked on an initiative to modernize the New Drugs Regulatory Program to better serve the patients as well as better support staff in their work to carry out the Center's mission-To protect and promote health by making sure that human drugs are safe and effective for their intended use, that they meet established quality standards, and that they are available to patients. One key component of the Modernization included a reorganization of the New Drugs Regulatory Program, which required a restructuring of the Office of New Drugs and corresponding changes in the Office of Translational Sciences (OTS) and Office of Pharmaceutical Quality (OPQ). This new organization created offices that align interrelated disease areas with clearer and more focused areas of expertise. This presentation will provide information on the reorganized Office of New Drugs, its new offices, divisions and current leadership.

Judit Milstein
Chief, Project Management Staff
Division of Regulatory Operations for Specialty Medicine
Office of Regulatory Operations (ORO) | OND

10:45 - 11:00: BREAK

11:00 - 12:00

So, Your NDA Was Approved – Now What?! Post-approval Responsibilities and Obligations

This presentation will provide participants with a cursory overview of applicant responsibilities following NDA approval. This presentation will initially discuss the requirements that apply to all NDA applications and then focus on some additional post-approval activities that can occur, including changes to an existing NDA, submission of supplements, and potential additional postmarketing obligations (e.g., PMCs, PMRs, REMS, etc.).

Lawrence Allan
Regulatory Health Project Manager
Business Process Operations Staff
Office of New Drugs (OND) | CDER

12:00 - 1:00 PM: LUNCH BREAK

1:00 - 1:40

Overview of Postmarketing Drug Safety Reporting Requirements

This presentation will provide participants with a regulatory foundation related to postmarketing drug safety reporting requirements. It will also highlight the importance of submitting accurate, reliable, and timely safety data to FDA.

Kelley M. Simms
CDR, USPHS
Regulatory Policy Analyst
Office of Surveillance and Epidemiology (OSE) | CDER

1:40 - 2:20

Drug Shortages

The mission of the Drug Shortage Staff (DSS) is to prevent, mitigate, and help resolve shortages as well as perform outreach to professional organizations, patient groups, the public, and other stakeholders. Additionally, DSS facilitates prevention and resolution of shortages by working with key stakeholders from the FDA, other government agencies, industry, and the public. Drug shortages can have serious effects on patients who may experience treatment delays, receive alternative treatments that are not as effective or well-tolerated, or forgo treatment. These outcomes can prolong patient suffering, contribute to disease progression, and result in other adverse health outcomes that reduce patient well-being and increase morbidity. Mitigating and preventing drug shortages is a priority for FDA.

Emily Thakur
Team Leader
Drug Shortage Staff
CDER

2:20 - 2:35 PM: BREAK

DAY ONE: CDER: Tuesday, August 25, 2020

2:35 – 3:15

Enhanced Drug Distribution Security – DSCSA Implementation Updates

This presentation will provide participants with implementation updates on supply chain security requirements under the Drug Supply Chain Security Act (DSCSA).

Connie Jung
CAPT, USPHS
Senior Advisor for Policy
Office of Compliance
Office of Drug Security, Integrity, and Response (ODSIR) | CDER

3:15 – 3:55

CDER Export Certificate Program

This presentation introduces the viewer to the CDER Export Certificate Program. This presentation will cover the following: general information about the program; what are export certificates; provide an overview of CDER's electronic application submission process using our electronic platform, CDER Export Certification Application and Tracking System (CDEReCATS); and how to apply for a CDER export certificate. In addition, the presentation will outline the benefits associated with using CDEReCATS as well as tips for the applicant to ensure the application submitted is complete and accurate.

William Jones
Technical Information Specialist
Exports Certificates and Compliance Team
Imports Exports Compliance Branch
Division of Global Drug Distribution and Policy
ODSIR | OC | CDER

3:55 PM: DAY ONE ADJOURN

DAY TWO: CDER: Wednesday, August 26, 2020

9:30 – 9:40

Day Two Overview

Host: **Forest "Ray" Ford, Jr.**
CAPT, USPHS
Pharmacist
DDI | OCOMM

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

9:40 – 10:00

SBIA - Program Overview

Learn more about the broad array of learning products and other resources available from CDER's Small Business and Industry Assistance program.

Renu Lal
LCDR, USPHS
Pharmacist
SBIA | DDI | OCOMM

10:00 – 10:30

Post-Approval Submission of Promotional Materials to the Office of Prescription Drug Promotion

This presentation will cover the fundamentals of submitting promotional materials to the Office of Prescription Drug Promotion (OPDP) following product approval. We will focus on topics such as launch and non-launch promotional materials, Subpart E and H submissions, and resubmissions and/or amendments. The goal of this presentation is to improve understanding of the post-approval submission requirements as it relates to promotional materials and OPDP in order to be consistent with the relevant regulations and to address the challenges that may occur during this process.

Robert Nguyen
Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP) CDER

10:30 - 10:45: BREAK

10:45 – 11:45

How to meet FDA's Requirement for Electronic Submission of an Application and Study Data

Electronic Submissions Update
This highly useful presentation covers a wide range of electronic submission topics, including recent updates to the eCTD guidance, how to submit electronically, and address eCTD validations that can result in a technical rejection if study data is not submitted in conformance with the eCTD and Study Data guidance. We will cover frequent questions to the eSub Team, when to use CDER's Next Gen Portal, and CDER's progress to further automate the inbound process to put your submission in the hands of the reviewoffice quicker.

Jonathan Resnick
Cloud Collaboration Capability Team
Division of Data Management Services and Solutions (DDMSS)
Office of Business Informatics (OBI)
Office of Strategic Programs (OSP) | CDER

Study Data Technical Rejection Criteria
Study Data Standards listed in the FDA Data Standards Catalog are required for clinical and nonclinical studies that started after December 17, 2016 (for ANDA, NDA and BLA) or December 17, 2017 (for Commercial IND). Based on the Technical Rejection Criteria for Study Data (TRC) conformance analysis conducted by FDA on submissions that contain study data received by the Agency, FDA updated TRC to provide more clarification. FDA also developed supporting tools to help Industry meet study data requirements, including the Study Data Self-Check Worksheet. These efforts are expected to improve conformance rates over time by making it clearer and easier for industry to meet FDA's studyElectronic

Heather Crandall
Cloud Collaboration Capability Team
DDMSS | OBI | OSP

11:45 - 12:45: LUNCH BREAK

All times shown are Eastern (EDT UTC-4)

DAY TWO: CDER: Wednesday, August 26, 2020

12:45 – 1:15

Overview of post-approval Chemistry, Manufacture, and Controls (CMC) changes to NDAs

The presentation will discuss regulations and guidances for making post-approval changes, including ICH Q12 and comparability protocols. It will also cover type of submissions to FDA for post-approval changes and opportunities available for guidance from FDA.

Hasmukh B. Patel
Director
Division of Post-Marketing Activities 1
Office of Lifecycle Drug Products (OLDP)
Office of Pharmaceutical Quality (OPQ) | CDER

1:15 – 1:45

Lifecycle Changes to Chemistry, Manufacture, and Controls in NDAs – FDA Perspective

The real journey of a new drug's Lifecycle begins only after the regulatory approval for that drug entity. Often referred to as post-approval (or post-marketing) is when the applicants start to focus on the economics of the manufacturing and marketing for a given product and indication. Many changes are made to the Chemistry and Manufacturing Controls without changing the fundamental active ingredient. This talk will focus on the types of changes, and regulatory implications for those changes with case studies.

Ramesh Raghavachari
Chief, Branch I
Division of Post-Marketing Activities I
OLDP | OPQ | CDER

1:45 – 2:00: BREAK

2:00 – 2:30

Post Approval Regulatory Consideration for Changes to Manufacturing Process and Facilities

This presentation will discuss post approval changes related to manufacturing process and facilities during the continued process verification stage, including modifying the approved manufacturing process, adding or removing a manufacturing line, replacing the current equipment with a new equipment, and changing of manufacturing site/location. Examples will be given for each change and will discuss the appropriate type of submissions (PAS, CBE0, CBE30, or Annual Report) that would be typically expected based on the changes.

Rose Xu
Quality Assessment Lead (Acting)
Office of Pharmaceutical Manufacturing Assessment (OPMA)
OPQ | CDER

2:30 – 3:00

Q&A Panel Discussion

Hasmukh B. Patel, Ramesh Raghavachari and **Rose Xu**

3:00 – 3:50

FDA Drug Manufacturing Inspections

This presentation will discuss the purposes, conduct, and expectations of FDA drug manufacturing inspections. Attendees will learn how to prepare for, host, and respond to such inspections, as well as their potential consequences.

Russell K. Riley
Compliance Officer
Office of Regulatory Affairs (ORA)
Division of Pharmaceutical Quality Operations III

3:50 PM: DAY TWO ADJOURN

All times shown are Eastern (EDT UTC-4)

DAY THREE: CDRH: Thursday, August 27, 2020

8:55 – 9:15

Welcome

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

9:15 - 10:00

Plenary

This presentation will provide an overview of the U.S. Food and Drug Administration's (FDA's) initiatives involving real-word data (RWD) and real-world evidence (RWE). The presenters will discuss regulatory frameworks for RWE with regard to drugs, biologics, and devices. The speakers will discuss opportunities and challenges when using RWD focusing specifically on the use of RWE to support regulatory decisions in the FDA's efforts to explore the potential for leveraging the vast amount of data generated in the health care system to protect and promote the public health.

John Concato
Deputy Director
Office of Medical Policy Initiatives
CDER

Soma Kalb
Director
Division of Clinical Evaluation and Analysis 1: Clinical Science and Quality
Office of Clinical Evaluation and Analysis (OCEA)
Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH)

10:00 - 10:15: BREAK

10:15 - 10:25

CDRH Day One Overview

Elias Mallis
Director
Division of Industry and Consumer Education (DICE)
Office of Communication and Education (OCE)
CDRH

10:25 - 11:05

Getting Started: CDRH Resources for You

The Center for Devices and Radiological Health (CDRH) provides resources to help the medical device industry understand the regulatory requirements and process for marketing Medical Devices in the United States. This presentation will provide helpful resources and tips for finding and using these resources, including tips for searching Medical Device Databases. This presentation will highlight two key educational resources: Device Advice, a website that contains comprehensive regulatory information and CDRH Learn, a website that contains multimedia modules on regulatory programs and key topics. The primary goal of this presentation is to empower the Medical Device Industry to locate and utilize CDRH's resources for Medical Devices.

Donna Headlee
Branch Chief, Premarket Programs Branch
DICE | OCE | CDRH

All times shown are Eastern (EDT UTC-4)

DAY THREE: CDRH: Thursday, August 27, 2020

11:05 - 11:45

Benefit-Risk Throughout the Medical Device Lifecycle: Premarket, Postmarket, and Compliance

Kimberly Brown Smith
Assistant Director (Acting)
Clinical and Scientific Policy Staff
OPEQ | CDRH

The FDA is charged with ensuring that medical products are safe and effective for their use. CDRH focuses on ensuring that medical devices are high quality, which means that they are introduced to the market, and remain on the market, only when the benefit of their use outweighs the risk. As such, CDRH review staff take a benefit-risk approach to every assessment they perform, such as for a marketing application, a recall or correction, or an inspectional observation. Although the specific factors reviewers use for those assessments vary by situation, there are many common threads. Dr. Brown Smith will outline CDRH's overall benefit-risk approach, illustrate how it varies among different regulatory contexts, and provide examples of how benefit-risk determinations can change regulatory outcome.

Suggested pre-requisites:

- Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications (Guidance)
- Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics (Guidance)
- Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions (Guidance)
- Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions (Guidance)

11:45 - 12:45: LUNCH BREAK

All times shown are Eastern (EDT UTC-4)

DAY THREE: CDRH: Thursday, August 27, 2020

12:45 – 1:25

510k Device Modifications: Case Study

This session will describe things to consider when conducting a risk-based assessment for device modifications, detail the common types of modifications that may require a 510(k), and provide a detailed walk-through of a specific case study with in-depth discussion of each decision point in the Technology, Engineering, and Performance Changes 510(k) modifications flowchart (Flowchart B).

Suggested pre-requisite:

- Deciding When to Submit a 510(k) for a Change to an Existing Device (Webinar)

Melissa Hall
Consumer Safety Officer
Premarket Programs Branch
DICE | OCE | CDRH

1:25 - 2:05

A New Way to 510k: The Safety and Performance Based Pathway

This session will provide an overview of the new Safety and Performance Based Pathway for 510(k) submissions as well as relevant guidance documents. The session will describe some of the unique aspects of this particular 510(k) pathway, including the device types appropriate for the pathway, the types of information that can be provided in a submission, and plans to expand the pathway in the future.

Jason Ryans
Guidance and Policy Analyst
Regulation, Guidance and Policy Staff
OPEQ | CDRH

2:05 - 2:20 PM: BREAK

2:20 – 3:00

De Novo Classification: An Alternative Pathway to Market for New Device Types

The De Novo classification pathway was created more than 20 years ago as an alternative pathway to market for new device types that normally would require an approved Premarket Approval (PMA) before they can be legally marketed in the United States. However, only relatively recently has it been seen as a viable route to market. The De Novo Program is also an important component of CDRH's vision to promote medical device innovation and to bring high quality, safe and effective medical devices to US patients. This session will provide an overview of De Novo classification, identify the types of medical devices that are eligible for this pathway, explain the criteria that must be met to be classified into Class I or Class II, and share best practices for the creation and submission of a De Novo classification request to the FDA.

Suggested pre-reading:

- De Novo Classification Process (Evaluation of Automatic Class III Designation) (Guidance)
- Classify Your Medical Device (Device Advice)

Sergio de del Castillo
De Novo Program Lead
Division of Regulatory Programs 1: Submission Support
Office of Regulatory Programs
OPEQ | CDRH

All times shown are Eastern (EDT UTC-4)

DAY THREE: CDRH: Thursday, August 27, 2020

3:00 – 3:40

Considering Cybersecurity in Device Development and Factors Influencing Successful Premarket Review

Challenges in security are a solid reality in today's medical device environment. Ten years ago, cybersecurity risks were less often mitigated in medical device design and infrequently considered during premarket review. In the intervening years, FDA has taken several steps to improve cybersecurity across the medical device ecosystem. This presentation will focus on premarket activities related to cybersecurity and FDA's expectations for supporting documentation, with an eye to factors that can also improve postmarket response to cybersecurity challenges.

Suggested pre-requisite:

- FDA Cybersecurity

Lisa Simone
Cybersecurity Program Manager
All Hazards Response and Cybersecurity
Division of All Hazards Response, Science and Strategic Partnerships
Office of Strategic Partnerships and Technology Innovation
CDRH

3:40 – 3:45

Closing Remarks

Elias Mallis
Director
DICE | OCE | CDRH

3:45 PM: DAY THREE ADJOURN

All times shown are Eastern (EDT UTC-4)

DAY FOUR: CDRH: Friday, August 28, 2020

8:40 – 9:00

Day Four Overview

Joseph Tartal
Deputy Director
DICE | OCE | CDRH

9:00 – 9:40

Design Controls: Case Study

How do you adequately design a medical device? This presentation will walk through a case study example to educate you on how to implement effective design controls, while also reviewing both the 21 CFR 820.30 regulatory requirements and best practices. Learn how to leverage your resources to minimize the need for design changes post production.

Joseph Tartal
Deputy Director
DICE | OCE | CDRH

Suggested pre-requisite:

- Design Controls (CDRH Learn)

9:40 – 10:20

Production and Process Controls: Case Study

Production and process controls are a key part of the Quality System for medical device manufacturing. They help ensure that you manufacture products that meet pre-determined specifications and build the products you said you were going to build. This presentation will use a case study to review the principles of production and process controls.

Vidya Gopal
Consumer Safety Officer
Postmarket and Consumer Branch
DICE | OCE | CDRH

Suggested pre-requisite:

- Production and Process Controls (CDRH Learn)
- Production and Process Controls, Part 2 (CDRH Learn)

10:20 - 10:35: BREAK

10:35 – 11:15

Case for Quality

What is FDA's Case for Quality, why is it important, and what are the current efforts? This presentation will cover the results of the program to date and how participants may benefit. Finally, the presentation will cover upcoming programs and activities participants may want to join

Francisco Vicenty
Program Manager, Case for Quality
Compliance and Quality Staff
OPEQ | CDRH

All times shown are Eastern (EDT UTC-4)

DAY FOUR: CDRH: Friday, August 28, 2020

11:15 – 12:00

Medical Device Single Audit Program (MDSAP)

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.

Kenneth Chen
LCDR, USPHS
Senior Regulatory Officer
Medical Device Single Audit Program Team
Regulatory Inspections and Audits Team
Division of Regulatory Programs 2: Establishment Support
Office of Regulatory Programs
OPEQ | CDRH

12:00 - 1:00: LUNCH BREAK

1:00 – 1:40

Risk Management Within A Quality System

What are risk management activities? Should I conduct risk management activities during the design or production and process control activities for my medical device? This presentation will address these questions and provide tools for conducting risk management activities within a quality management system.

Tonya Wilbon
Chief, Postmarket and Consumer Branch
DICE | OCE | CDRH

1:40 – 2:20

eMDR System Overview and Submission Walkthrough

CDRH requires manufacturers and importers to submit Medical Device Reports (MDRs) of adverse events electronically using eSubmitter. This presentation will provide an overview of electronic medical device reporting (eMDR) and how adverse event data are received and stored in CDRH. It will also include a complete walkthrough of an eMDR submission using eSubmitter and WebTrader.

Suggested pre-requisite

- Overview of Medical Device Reporting (CDRH Learn)
- Medical Device Reporting for Mandatory Reporters (CDRH Learn)

Evan Jacobs
Product Owner, Electronic Medical Device Reporting (eMDR)
Division of Regulatory Programs 3: Market Intelligence
Office of Regulatory Programs
OPEQ | CDRH

2:20 - 2:35: BREAK

2:35 – 3:15

FDA Medical Device Inspections

This session will familiarize manufacturers with the procedures and processes that FDA's Office of Medical Devices and Radiological Health Operations uses to conduct inspections of medical device facilities in the United States and Worldwide. You will learn what to expect before, during and after your inspection.

Laureen Genuisz
Acting Director, Foreign Branch Operations
Office of Medical Device and Radiological Health Operations, Division 1
Office of Regulatory Affairs | CDRH

All times shown are Eastern (EDT UTC-4)

DAY FOUR: CDRH: Friday, August 28, 2020

3:15 – 3:20

Closing Remarks

Joseph Tartal
Deputy Director
DICE | OCE | CDRH

3:20 PM: DAY FOUR ADJOURN