Version 8, October 9, 2019
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FDA Acronyms & Abbreviations - CDER Guidance Documents

AGENDA

(Jump to Day Two)

Day One: Wednesday, October 16, 2019

7:15 a.m. Registration Opens

8:00 - 8:15: Administrative Announcements — **Jeff Kelly**

8:15 - 8:30

Welcome

Brenda Stodart
Captain, United States Public Health Service
Director, Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM)
Center for Drug Evaluation & Research (CDER)

8:30 - 8:45

Keynote from the Center for Drug Evaluation and Research (CDER)

Patrizia Cavazzoni
Deputy Center Director for Operations
CDER

8:45 – 9:00

Keynote from the Office of Pharmaceutical Quality (OPQ)

Michael Kopcha
Director
Office of Pharmaceutical Quality (OPQ) | CDER

Day One: Wednesday, October 16, 2019

SESSION 1: Manufacturing and the Quality Assessment of Applications

9:00 – 9:25

The Quality Assessment of Different Application Types

The FDA will explain the role of the quality assessment in the face of different application types – NDAs, ANDAs, BLAs.

Lawrence Yu
Deputy Director
OPQ | CDER

9:25 – 9:50

Application Manufacturing Assessment

Learn what the FDA means by the term 'manufacturing assessment,' the value of integrating facility assessment and inspection, and why it is important for application approval.

Mahesh Ramanadham
Office of Process and Facilities (OPF)
OPQ | CDER

9:50 – 10:10

Policy Initiatives for Pharmaceutical Quality

The FDA will present the latest policy initiatives and explain how they will impact pharmaceutical quality.

Ashley Boam
Director
Office of Policy for Pharmaceutical Quality (OPPQ)
OPQ | CDER

10:10 – 10:35

Panel Questions & Discussion

Lawrence Yu, Mahesh Ramanadham, Ashley Boam

10:35 - 10:50: BREAK

10:50 – 11:15

How Does FDA Execute Preapproval and Postapproval Inspections?

This topic will address how the FDA carries out preapproval and postapproval inspections in the field and explain some common pitfalls.

Rakhi Shah
OPF | OPQ | CDER

11:15 – 11:40

Integration of Assessment and Inspection: Small Molecule Case Studies

FDA will present case studies of small molecule drug products illustrating some of the benefits of integrated facility assessment and inspection and acknowledge some of the challenges.

Allison Aldridge
OPF | OPQ | CDER

11:40 – 12:05

Integration of Assessment and Inspection: Biological Products Case Studies

FDA will present case studies of biological products illustrating some of the benefits of integrated facility assessment and inspection and acknowledge some of the challenges.

Candace Gomez-Broughton
OPF | OPQ | CDER

Day One: Wednesday, October 16, 2019

12:05 – 12:30

Panel Questions & Discussion

Rakhi Shah, Allison Aldridge, Candace Gomez-Broughton

12:30 - 1:45 p.m. LUNCH & NETWORKING - On your own. Click HERE for onsite dining options

SESSION 2: Quality Beyond Application Approval

1:45 – 2:10

The Future of FDA's Quality Assessment and Knowledge Management

This presentation will describe the FDA's Knowledge-Aided Assessment and Structured Application (KASA) innovation which links application assessment with lifecycle knowledge management.

Geoffrey Wu
Office of Lifecycle Drug Products (OLDP)
OPQ | CDER

2:10 – 2:30

Postapproval Change Management: ICH Q12 and Established Conditions

This discussion will cover new policies surrounding manufacturing changes for approved products.

Bhagwant Rege
OLDP | OPQ | CDER

2:30 - 3:00

Panel Questions & Discussion

Geoffrey Wu, Bhagwant Rege

3:00 - 3:15: BREAK

3:15 – 3:35

Pharmaceutical Quality Surveillance Program

The FDA will describe their surveillance program for quality oversight of CDER-regulated drugs and discuss innovative tools and approaches that advance this program.

Lucinda (Cindy) Buhse
Director
Office of Surveillance (OS)
OPQ | CDER

3:35 – 3:55

Quality-Related Enforcement Actions and Trends

This session will address recent trends and enforcement actions related to quality issues throughout the industry.

Francis Godwin
Director
Office of Manufacturing Quality (OMQ)
Office of Compliance (OC) | CDER

3:55 – 4:10

The Importance of Quality Metrics and Quality Culture

FDA will present on its developing quality metrics program and explain the importance of Quality Culture in manufacturing.

Tara Gooen
OPPQ | OPQ | CDER

Day One: Wednesday, October 16, 2019

4:10 – 4:30

Panel Questions & Discussion

Cindy Buhse, Tara Gooen, Francis Godwin

4:30 p.m. - DAY ONE ADJOURN

4:30 - 6:00 PM: NETWORKING OPPORTUNITY

Onsite attendees are invited to gather at THE HOTEL's Lobby Bar to continue the conversation with fellow attendees.

Day Two: Thursday, October 17, 2019

7:30 a.m. Registration Opens

8:05 - 8:15: Administrative Announcements — **Jeff Kelly**

8:15 - 8:25

Welcome

Forest "Ray" Ford, Jr.
DDI | OCOMM | CDER

SESSION 3: Emerging Technologies and the FDA

8:25 – 8:40

Interacting with CDER's Emerging Technology Program

This session will provide detail on how to best interact with the Emerging Technology Program when a company is developing an innovation in pharmaceutical design and manufacturing - whether a company is large or small.

Sau (Larry) Lee
Director
Office of Testing and Research (OTR)
OPQ | CDER

8:40 – 9:00

Policy Considerations for Continuous Manufacturing

The FDA will explain policy considerations surrounding the implementation of continuous manufacturing and provide updates on international harmonization surrounding continuous manufacturing.

Rapti Madurawe
OPF | OPQ | CDER

Tara Gooen
OPPQ | OPQ | CDER

9:00 – 9:20

Continuous Manufacturing of Drug Product: Case Studies

This session will focus on continuous manufacturing and common issues seen in applications using continuous manufacturing for drug product.

Arwa El Hagrasy
OPF | OPQ | CDER

9:20 – 9:40

Continuous Manufacturing of Drug Substance: Case Studies

This session will focus on continuous manufacturing and common issues seen in applications using continuous manufacturing for drug substance.

Vani Mathur Richards
OPF | OPQ | CDER

9:40 – 10:10

Panel Questions & Discussion

Larry Lee, Rapti Madurawe, Tara Gooen, Arwa El Hagrasy, Vani Mathur Richards

10:10 - 10:25: BREAK

Day Two: Thursday, October 17, 2019

10:25 – 10:45

Emerging Technologies for Biologics: Multi-Attribute Method

This session will describe emerging technologies the FDA is seeing related to biologics and will describe in-depth the multi-attribute method for quality control.

Sarah Rogstad
OTR | OPQ | CDER

10:45 – 11:05

FDA Research Supporting Emerging Technologies with Case Studies

This session will discuss how the FDA uses intramural and extramural research to support its Emerging Technology Program. The FDA will provide examples of applying this research to application assessment.

Thomas O'Connor
OTR | OPQ | CDER

11:05 – 11:25

Extramural Research Supporting Emerging Technologies

An investigator on an FDA-sponsored research project will discuss research related to emerging technologies in pharmaceutical design and manufacturing.

Salvatore Mascia
CEO
Continuus

11:25 – 11:45

Panel Questions & Discussion

Sarah Rogstad, Thomas O'Connor, Salvatore Mascia

11:45 - 1:00 p.m. LUNCH & NETWORKING - On your own. Click HERE for onsite dining options

SESSION 4: Happenings in Biologics: Biosimilars and Transition Biological Products

1:00 – 1:30

FDA's Biosimilars Program

An overview of the FDA's biosimilars program including statutory requirements with a focus on the role quality plays in assessing biosimilar products.

Leila Hann
Science Policy Analyst
Office of Therapeutic Biologics and Biosimilars (OTBB)
Office of New Drugs (OND) | CDER

1:30 – 1:55

Biosimilars Manufacturing Issues with Case Studies

FDA will address the importance of having quality manufacturing to support a biosimilar application. This is a key driver for biosimilar approvals.

Rachel Novak
Office of Biotechnology Products (OBP)
OPQ | CDER

1:55 – 2:20

Data Quality Expectations for Biosimilars with Case Studies

FDA will address the importance of having quality data to support a biosimilar application as it relates to demonstrating analytical similarity.

Merry Christie
OBP | OPQ | CDER

Day Two: Thursday, October 17, 2019

2:20 – 2:50

Panel Questions & Discussion

Leila Hann, Rachel Novak, Merry Christie

2:50 – 3:05: BREAK

3:05 – 3:25

The "Deemed to be a License" Provision of the BPCI Act

FDA will provide an overview of the statutory "transition" provision and related FDA guidance that is intended to facilitate planning for the March 23, 2020, transition date.

Janice Weiner
Office of Regulatory Policy (ORP)
CDER

3:25 – 3:45

Quality Considerations for Transition Biological Products

This session covers certain chemistry, manufacturing, and controls (CMC) requirements applicable to biological products regulated under the PHS Act that may differ in some respects from requirements for drug products regulated under the FD&C Act.

Leslie Rivera Rosado
OBP | OPQ | CDER

3:45 – 4:05

Panel Questions & Discussion

Janice Weiner, Leslie Rivera Rosado, Susan Kirshner

4:05 PM: ADJOURN

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