CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE

PHARMACEUTICAL QUALITY SYMPOSIUM 2021: Innovations in a Changing World

FDA U.S. FOOD & DRUG ADMINISTRATION

www.fda.gov/CDERSBIA

OCT 26-27, 2021

Version 5 – Updated September 27, 2021

For files and resources, please visit
The Event Page on SBIAevents.com

AGENDA

All times are Eastern (EDT UTC-4)
View Start Time on World Clock

DAY ONE: Tuesday, October 26, 2021

8:50 – 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 – 9:10

Keynote

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

9:10 – 9:20

PQS Keynote

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

Your SBIA Hosts for Day One

Renu Lal, PharmD
LCDR, USPHS*, Pharmacist*
SBIA | DDI | OCOMM | CDER

Forest "Ray" Ford, Jr., PharmD
CAPT, USPHS, *Pharmacist*
SBIA | DDI | OCOMM | CDER

Learning from the COVID-19 Public Health Emergency

9:20 – 9:35

Regulation of Pharmaceutical Quality in the U.S.

This presentation covers the meaning and importance of pharmaceutical quality and describes the role of FDA's Office of Pharmaceutical Quality (OPQ), within the Center for Drug Evaluation and Research, in regulating pharmaceutical quality.

Lucinda Buhse
Deputy Director for Operations
Office of Pharmaceutical Quality (OPQ) | CDER

DAY ONE: Tuesday, October 26, 2021

Learning from the COVID-19 Public Health Emergency

9:35 - 9:55

Policy Updates on Pharmaceutical Quality

This overview provides an update on the latest policy developments related to pharmaceutical quality, including guidance development and matters related to COVID-19.

Laurie Graham
Director
Division of Internal Policies and Programs (DIPAP)
Office of Policy for Pharmaceutical Quality (OPPQ)
OPQ | CDER

9:55 – 10:25

FDA's Facility Oversight

FDA staff from the Office of Pharmaceutical Quality and the Office of Regulatory Affairs will explain how they are working together to evaluate and inspect pharmaceutical manufacturing facilities and will provide considerations for facility management when interacting with the FDA.

Stelios Tsinontides
Director
Office of Pharmaceutical Manufacturing Assessment (OPMA)
OPQ | CDER

Nancy Rolli
Deputy Director
Office of Pharmaceutical Quality Operations (OPQO)
Office of Regulatory Affairs (ORA)

10:25 – 10:50

Panel Questions & Discussion

Lucinda Buhse, Laurie Graham, Stelios Tsinontides, Nancy Rolli

10:50 - 11:05: BREAK

11:05 - 12:05

FDA Leaders Panel Discussion

In this live moderated forum, FDA leaders will discuss what global regulators and industry have done related to manufacturing and quality in response to the COVID-19 public health emergency that were positive developments, and what could and should continue long after the end of the pandemic.

Moderator:

Ashley Boam
Director
OPPQ | OPQ | CDER

Michael Kopcha
Director
OPQ | CDER

Theresa Mullin
Associate Director for Strategy
Office of the Center Director (OCD) | CDER

Don Ashley
Director
Office of Compliance (OC) | CDER

Elizabeth Miller
Assistant Commissioner
Office of Medical Products and Tobacco Operations (OMPTO)
ORA

12:05 - 12:35 PM: LUNCH BREAK

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DAY ONE: Tuesday, October 26, 2021

Innovations at FDA

12:35 – 12:50

Integrated Quality Assessment (IQA): Aligned Teams

This presentation will describe advances in the team-based integrated quality assessment of regulatory submissions including the creation of "aligned teams" to strengthen and streamline the assessment process.

Don Henry
Director
Office of Program and Regulatory Operations (OPRO)
OPQ | CDER

12:50 – 1:05

Knowledge-Aided Assessment and Structured Application (KASA): Part 1

The first presentation on this topic will cover KASA's development and implementation for the quality assessment of new and generic drug applications, including drug substance, drug product, and manufacturing (process/facilities).

Ee-Sunn "Joanne" Chia
Division Director
Division of New Drug Products III (DNDP III)
Office of New Drugs Products (ONDP)
OPQ | CDER

1:05 – 1:20

Knowledge-Aided Assessment and Structured Application (KASA): Part 2

The second presentation on this topic will cover KASA's development and implementation for the quality assessment of biologics license applications.

Joel Welch
Associate Director for Science
Office of Biotechnology Products (OBP)
OPQ | CDER

1:20 – 1:35

Quality Surveillance Dashboard (QSD)

The FDA will introduce an interactive application that provides a framework for consistent assessment of CDER-regulated facilities through reporting, data exploration, and analytics to facilitate data-driven decisions and proactive detection of potential quality signals.

Alex Viehmann
Division Director
Division of Quality Intelligence II
Office of Quality Surveillance (OQS)
Office of Pharmaceutical Quality (OPQ) | CDER

1:35 – 2:00

Panel Questions and Discussion

Don Henry, Ee-Sunn "Joanne" Chia, Joel Welch, Alex Viehmann

2:00 – 2:15: BREAK

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DAY ONE: Tuesday, October 26, 2021

Innovations at FDA

2:15 – 2:35

The Importance of International Harmonization

The FDA will explain the importance of regulatory harmonization and convergence and share the latest FDA efforts to promote and engage in international harmonization.

Brian Hasselbalch
Deputy Director
OPPQ | OPQ | CDER

2:35 – 2:55

Quality-Related Compliance Updates and Innovations

This talk will address updates and innovations related to facility compliance and enforcement actions for quality issues, as well as general trends, throughout the industry.

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

2:55 - 3:15

Quality Management Maturity (QMM)

The FDA will describe a vision for the development and implementation of a transparent QMM program and present findings from recent QMM pilot programs.

Jennifer Maguire
Director
OQS |OPQ | CDER

3:15 – 3:35

CARES Act: Volume NextGen Reporting Portal

This presentation will discuss the creation of a portal to collect annually, amount of listed drugs and biological products by registrants and explain how FDA will curate and report the data.

Obinna Ugwu-Oju
Division Director
Division of Quality Data Science (DQDS)
OQS | OPQ | CDER

3:35 – 4:00

Panel Questions and Discussion

Brian Hasselbalch, Jennifer Maguire, Francis Godwin, Obinna Ugwu-Oju

4:00 PM: DAY ONE ADJOURN

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DAY TWO: Wednesday, October 27, 2021

8:45 – 8:55

Welcome

Renu Lal, PharmD
LCDR, USPHS, Pharmacist
Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM) | CDER

Your SBIA Hosts for Day Two

Renu Lal, PharmD
LCDR, USPHS, *Pharmacist*
SBIA | DDI | OCOMM | CDER

Forest "Ray" Ford, Jr., PharmD
CAPT, USPHS, *Pharmacist*
SBIA | DDI | OCOMM | CDER

A Foundation of Science

8:55 – 9:15

Control of Nitrosamine Impurities in Human Drugs

The FDA will present the science driving the regulation of nitrosamine impurities in drugs, including angiotensin receptor blockers, metformin, and ranitidine.

Jason Rodriguez
Division Director
Division of Complex Drug Analysis
Office of Testing and Research (OTR)
OPQ | CDER

9:15 – 9:35

Research Fueling Approvals: A Case Study of Glucagon

FDA research and assessment staff will describe laboratory research and explain how it directly enabled the regulatory approval of the first generic glucagon product for the treatment of severe hypoglycemia.

Ilan Geerlof-Vidavsky
Chemist
Division of Pharmaceutical Analysis (DPA)
OTR | OPQ | CDER

Cameron Smith
Supervisory Chemist
Division of Liquid-Based Products (DLBP)
Office of Lifecycle Drug Products (OLDP)
OPQ | CDER

9:35 – 9:55

Research Fueling Approvals: A Case Study of Enteral Feeding Tubes

FDA research and assessment staff will describe laboratory research and explain how it directly enabled the guidance for industry oral drug products administered via enteral feeding tube.

Alicia Hoover
Chemist
DPA | OTR | OPQ | CDER

Namrata Trivedi
Chemist
Division of Immediate and Modified Release Products III (DIMRPIII)
OLDP | OPQ | CDER

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DAY TWO: Wednesday, October 27, 2021

A Foundation of Science

9:55 – 10:15

Research Fueling Approvals: A Case Study of Ferumoxytol

FDA research and assessment staff will describe laboratory research and explain how it directly enabled the regulatory approval of a generic ferumoxytol product for the treatment of iron deficiency anemia.

Charudharshini Srinivasan
Research Scientist, Staff Fellow
Division of Product Quality Research (DPQR)
OTR | OPQ | CDER

Yiwei Li
Supervisory Chemist
Division of Pharmaceutical Manufacturing Assessment III (DPMAIV)
OMPA | OPQ | CDER

10:15 – 10:45

Panel Questions and Discussion

Jason Rodriguez, Ilan Geerlof-Vidavsky, Cameron Smith, Alicia Hoover, Namrata Trivedi Charudharshini Srinivasan, Yiwei Li

10:45 - 11:00: BREAK

11:00 – 11:20

Keeping Products Safe for Consumers

This presentation will describe how science drives regulatory actions to protect consumers from unsafe products, including some hand sanitizers marketed during the COVID-19 public health emergency.

Connie Ruzicka
Lab Chief
DPA | OTR | OPQ | CDER

11:20 - 11:40

The State of Pharmaceutical Quality

The FDA will discuss findings from its latest Report on the State of Pharmaceutical Quality and describe how they are used to improve quality surveillance.

Neil Stiber
Associate Director for Science and Communication
OQS | OPQ | CDER

11:40 – 12:00

Panel Questions and Discussion

Connie Ruzicka, Neil Stiber

12:00 – 12:30 PM: LUNCH BREAK

12:30 – 12:45

Emerging Technology Program 2.0

This talk will outline the next generation of CDER's Emerging Technology Program to enhance program efficiency and encourage and support industry adoption of advanced manufacturing technologies.

Sau "Larry" Lee
Deputy Director of Science
OPQ | CDER

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DAY TWO: Wednesday, October 27, 2021
Advancing Advanced Manufacturing

12:45 – 1:05

Addressing the Advanced Manufacturing Regulatory Framework

This presentation will share FDA efforts to identify and address gaps and pain points in the current regulatory framework related to advanced manufacturing (e.g., continuous, distributed, point-of-care, and AI-controlled manufacturing technologies).

Adam Fisher
Acting Associate Director of Science and Outreach
OPQ | CDER

1:05 – 1:25

Panel Questions and Discussion

Sau "Larry" Lee, Adam Fisher

1:25 – 1:40: BREAK

1:40 – 2:00

FDA's Advanced Manufacturing Product Development Science Program

FDA will describe the development of an intramural and extramural research program to generate foundational knowledge to support assessment, guidance and policy development, surveillance, and training related to advanced pharmaceutical manufacturing.

Thomas O'Connor
Division Director
Division of Product Quality Research
OTR | OPQ | CDER

2:00 – 2:20

Extramural Advanced Manufacturing Product Development Science: Continuus

An FDA-sponsored investigator will present research related to the continuous manufacturing of human pharmaceuticals.

Ernie Penachio
Vice President of Technical Operations
Continuus Pharmaceuticals

2:20 – 2:40

Industry Development of Advanced Manufacturing: On Demand Pharmaceuticals

An industry leader will describe the commercial development of the 'Pharmacy on Demand' platform, an advanced, miniaturized, and automated suite of pharmaceutical manufacturing systems.

John Lewin
Chief Medical Officer
On Demand Pharmaceuticals, Inc.

2:40 – 3:05

Panel Questions and Discussion

Thomas O'Connor, Ernie Penachio, John Lewin

3:05 – 3:15

Closing Words from the Office of Pharmaceutical Quality

Michael Kopcha

3:15 PM: DAY TWO ADJOURN

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