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 – 9:15  
Keynote  
Janet Woodcock, MD  
Acting Commissioner of Food and Drugs  
Food and Drug Administration

9:15 – 9:30  
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

9:30 – 9:45  
Regulation of Pharmaceutical Quality in the U.S.  
Lucinda Buhse  
Deputy Director for Operations  
Office of Pharmaceutical Quality (OPQ) | CDER

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.
**DAY ONE: Tuesday, October 26, 2021**

**Learning from the COVID-19 Public Health Emergency**

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<tr>
<th>Time</th>
<th>Session Title</th>
<th>Speaker(s)</th>
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<tbody>
<tr>
<td>9:45 - 10:05</td>
<td><strong>Policy Updates on Pharmaceutical Quality</strong></td>
<td>Laurie Graham, Director Division of Internal Policies and Programs (DIPAP) Office of Policy for Pharmaceutical Quality (OPPQ) OPQ</td>
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<td>10:05 – 10:40</td>
<td><strong>FDA’s Facility Oversight</strong></td>
<td>Stelios Tsinontides, Director Office of Pharmaceutical Manufacturing Assessment (OPMA) Nancy Rolli, Deputy Director Office of Pharmaceutical Quality Operations (OPQO) Office of Regulatory Affairs (ORA)</td>
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<td>10:40 – 11:00</td>
<td><strong>Panel Questions &amp; Discussion</strong></td>
<td>Lucinda Buhse, Laurie Graham, Stelios Tsinontides, Nancy Rolli</td>
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<td>11:00 - 11:10: BREAK</td>
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<td>11:10 - 12:10</td>
<td><strong>FDA Leaders Panel Discussion</strong></td>
<td>Michael Kopcha, Director OPPQ</td>
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<td>12:10 - 12:35 PM: LUNCH BREAK</td>
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### DAY ONE: Tuesday, October 26, 2021

#### Innovations at FDA

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<tr>
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<th>Event Description</th>
<th>Presenter/Title/Office</th>
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<td>12:35 – 12:55</td>
<td><strong>Integrated Quality Assessment (IQA): Aligned Teams</strong>&lt;br&gt;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.</td>
<td>Don Henry&lt;br&gt;Director&lt;br&gt;Office of Program and Regulatory Operations (OPRO)&lt;br&gt;OPQ</td>
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<td>12:55 – 1:10</td>
<td><strong>Knowledge-Aided Assessment and Structured Application (KASA): Part 1</strong>&lt;br&gt;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).</td>
<td>Ee-Sunn “Joanne” Chia&lt;br&gt;Division Director&lt;br&gt;Division of New Drug Products III (DNDP III)&lt;br&gt;Office of New Drugs Products (ONDP)&lt;br&gt;OPQ</td>
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<td>1:10 – 1:25</td>
<td><strong>Knowledge-Aided Assessment and Structured Application (KASA): Part 2</strong>&lt;br&gt;The second presentation on this topic will cover KASA’s development and implementation for the quality assessment of biologics license applications.</td>
<td>Joel Welch&lt;br&gt;Associate Director for Science&lt;br&gt;Office of Biotechnology Products (OBP)&lt;br&gt;OPQ</td>
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<td>1:25 – 1:50</td>
<td><strong>Quality Surveillance Dashboard (QSD)</strong>&lt;br&gt;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.</td>
<td>Alex Viehmann&lt;br&gt;Division Director&lt;br&gt;Division of Quality Intelligence II&lt;br&gt;Office of Quality Surveillance (OQS)&lt;br&gt;Office of Pharmaceutical Quality (OPQ)</td>
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<td>1:50 – 2:15</td>
<td><strong>Panel Questions and Discussion</strong>&lt;br&gt;Don Henry, Ee-Sunn “Joanne” Chia, Joel Welch, Alex Viehmann</td>
<td>Don Henry, Ee-Sunn “Joanne” Chia, Joel Welch, Alex Viehmann</td>
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<td>2:15 – 2:25: BREAK</td>
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### Innovations at FDA

**2:25 – 2:45**

**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

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**2:45 – 3:00**

**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

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**3:00 - 3:20**

**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

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**3:20 – 3:45**

**Panel Questions and Discussion**

Brian Hasselbalch, Jennifer Maguire, Francis Godwin

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**3:45 PM: DAY ONE ADJOURN**
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
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

All times shown are Eastern (EDT UTC-4)
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