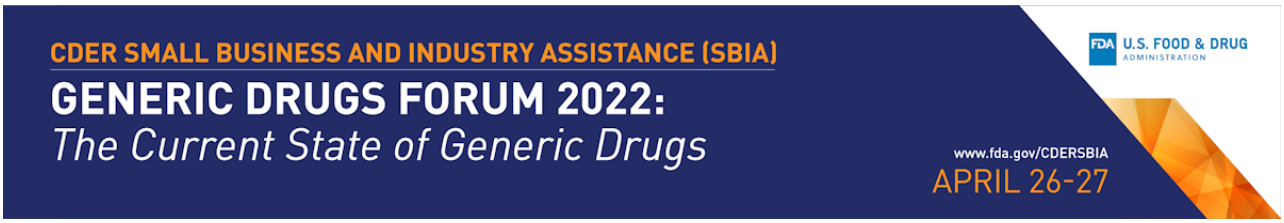


Version 9 – Updated April 21, 2022

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

*Add Event to Your Calendar*

# AGENDA

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

## DAY ONE: Tuesday, April 26, 2022

8:15 – 8:30

### Administrative Overview

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

8:30 – 8:45

### Keynote

**Janet Woodcock**
*Principal Deputy Commissioner*
Office of the Commissioner
U.S. Food and Drug Administration

8:45 – 9:00

### Office of Generic Drugs (OGD) Keynote

**Sally Choe**
*Director*
Office of Generic Drugs (OGD) | CDER

9:00 – 9:15

### Office of Pharmaceutical Quality (OPQ) Keynote

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

# DAY ONE: Tuesday, April 26, 2022

## Your SBIA Hosts for Day One

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

9:15 – 9:35

## Use of Knowledge-Aided Assessment and Structured Application (KASA) in Drug Product Assessment

This presentation will focus on how Knowledge-Aided Assessment and Structured Application (KASA) is used in the assessment of drug product information submitted in Abbreviated New Drug Applications (ANDA).

**Peter Capella**
*Director*
Division of Immediate and Modified Release Products II (DIMRPII)
Office of Life Cycle Products (OLDP) | OPQ | CDER

9:35 – 9:55

## Use of Knowledge-Aided Assessment and Structured Application (KASA) in Drug Product Manufacturing Assessment

This presentation will focus on how Knowledge-Aided Assessment and Structured Application (KASA) is used in the assessment of drug product manufacturing information submitted in Abbreviated New Drug Applications (ANDA).

**Rakhi Shah**
*Associate Director*
Office of Pharmaceutical Manufacturing Assessment (OPMA)
OPQ | CDER

9:55 – 10:15

## Use of Knowledge-Aided Assessment and Structured Application (KASA) in Biopharmaceutics Assessment

This presentation will focus on how Knowledge-Aided Assessment and Structured Application (KASA) is used in the assessment of biopharmaceutical information submitted in Abbreviated New Drug Applications (ANDA).

**Kimberly Raines**
*Branch Chief*
Division of Biopharmaceutics
Office of New Drug Products (ONDP), OPQ | CDER

10:15 – 10:35

## Integrated Drug Product Assessment: Expectations

This presentation will highlight common drug product issues and deficiencies for generic applications and illustrate typical approaches to resolve the same using sample case studies.

**Mayra Pineiro Sanchez**
Senior Pharmaceutical Quality Assessor
Division of Immediate and Modified Release Products II
OLDP | OPQ | CDER

10:35 – 10:55

## Questions & Panel Discussion

**Peter Capella, Rakhi Shah, Kimberly Raines, Mayra Pineiro Sanchez**

**10:55 - 11:05: BREAK**

All times shown are Eastern (EST UTC-4)

# DAY ONE: Tuesday, April 26, 2022

11:05 – 11:15

## ANDA Program Annual Public Stats and What they Mean: Office of Generic Drugs

The audience will learn of FDA's Generic Drug Program successes in 2021, such as generic drug and first generic drug approvals and tentative approvals, COVID-19 related work, and other activities that support the generic drug industry and patient interests.

**Iilun Murphy**
*Deputy Director*
Clinical & Regulatory Affairs
OGD | CDER

11:15 – 11:35

## ANDA Program Public Stats and What they Mean: Office of Regulatory Operations (ORO)

ORO will present salient ANDA program statistics covering publicly reported monthly and quarterly reports, as well as performance metrics.

**Robert Berger**
*Analytics Team*

**David Holovac**
*Analytics Team*

**Russell Storms**
*Associate Director for Analytics*

**Edward (Ted) Sherwood**
*Director*

Office of Regulatory Operations (ORO)
OGD | CDER

11:35 – 11:45

## ANDA Program Public Stats and What they Mean: Office of Generic Drug Policy (OGDP)

OGDP will present ANDA program public statistics related to Competitive Generic Therapy (CGT) Approval and FDARA 807 reports.

**Andrew Coogan**
*LCDR*, USPHS
Division of Legal and Regulatory Support (DLRS)
OGDP | CDER

11:45 – 11:55

## ANDA Program Public Stats and What they Mean: Office of Lifecycle Drug Products (OLDP)

This talk includes salient ANDA program stats covering metrics related to supplements, inspections using alternate tools, etc.

**Derek Smith**
*Deputy Director*
OPMA | OPQ | CDER

11:55 – 12:15

## Questions & Panel Discussion

**Iilun Murphy, Edward Sherwood, Andrew Coogan, Derek Smith, Geoffrey Wu**

**12:15 – 12:45: LUNCH BREAK**

All times shown are Eastern (EST UTC-4)

# DAY ONE: Tuesday, April 26, 2022

12:45 – 1:15

## Culture of Quality

These presentations will focus on the importance and approaches for ensuring data integrity and data quality in submissions for generic drug applications.

**Nilufer Tampal**
*Associate Director for Scientific Quality*
Immediate Office | Office of Bioequivalence (OB) |
OGD | CDER

**Shujun Chen**
Senior Pharmaceutical Quality Assessor
Division of Pharmaceutical Manufacturing II (DPMII)
OPMA | OPQ | CDER

1:15 – 1:35

## Data Integrity Issues in ANDA Submissions

This is an opportunity to learn about data integrity issues in ANDA submissions and the preventive action to assure data integrity and data quality.

**Minglei Cui**
*CDR*, USPHS
*Team Leader*, Division of Bioequivalence II (DBII)
OB | OGD | CDER

1:35 – 1:55

## Data Integrity Issues from BA/BE Clinical Site Inspections: Case Studies and OSIS Evaluation

This presentation will focus on the potential impact of documentation, or lack thereof, on data integrity of BA/BE clinical studies

**Cynthia (Yiyue) Zhang**
*Senior Staff Fellow*
Division of New Drug Study Integrity (DNDSI)
Office of Study Integrity and Surveillance Session (OSIS)
Office of Translational Sciences (OTS) | CDER

**1:55 – 2:05: BREAK**

2:05 – 2:25

## Analytical Data Integrity: Looking Beyond the Obvious

This presentation will focus on data integrity issues observed at analytical sites.

**Kara Scheibner**
*Pharmacologist*
Division of Generic Drug Study Integrity (DGDSI)
OSIS | OTS | CDER

2:25 – 2:45

## Data Integrity in Pharmacology/Toxicology Studies

Hear a discussion of a case study where data integrity issues were identified in Pharmacology/Toxicology studies submitted to the Office of Generic Drugs

**Victoria Keck**
*Team Leader*
Division of Pharmacology/Toxicology Review (DPTR)
Office of Safety and Clinical Evaluation (OSCE)
OGD | CDER

# DAY ONE: Tuesday, April 26, 2022

2:45 – 3:05

## Role of Data Integrity in Drug Applications

Data integrity breaches impact both the availability of marketed products as well as the approvability of new products. This presentation will describe the impact of data integrity on drug applications, data integrity remediation considerations, and case study from regulatory submission.

**Byeongtaek Oh**
*Staff Fellow*
Division of Pharmaceutical Manufacturing I (DPMI)
OPMA | OPQ | CDER

3:05 – 3:45

## Data Integrity Q&A and Panel Session

**Nilufer Tampal, Shujun Chen, Minglei Cui, Cynthia Zhang, Kara Scheibner, Victoria Keck, Byeongtaek Oh** and **Partha Roy**
*Director*
OB | OGD | CDER

**Dave Coppersmith**
*Regulatory Counsel*
Division of Policy Development (DPD)
Office of Generic Drug Policy (OGDP) | OGD | CDER

3:45 – 3:55

## Day One Closing

**3:55: DAY ONE ADJOURN**

All times shown are Eastern (EST UTC-4)

## DAY TWO: Wednesday, April 27, 2022

8:30 – 8:40

### Administrative Overview

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

8:40 – 9:00

### Nitrosamines in Drug Products – An Update

This presentation will focus on Nitrosamines in drug products, what is known so far, and the risk mitigation.

**Andre Raw**
*Senior Science and Policy Advisor*
OLDP | OPQ | CDER

9:00 – 9:20

### Common Manufacturing Related Deficiencies for Liquid Products

This presentation will highlight common liquid drug product manufacturing deficiencies and illustrate typical approaches to resolve the same using sample case studies.

**Jinong (Jenn) Li**
*Chemist*
OPMA | OPQ | CDER

9:20 – 9:40

### Questions & Panel Discussion

**Andre Raw, Jenn Li**

9:40 – 10:00

### Generic Drug Development and Globally Divergent Regulations

Learn about OGD Global Affairs' path to harmonization through rigorous dialogue, gap analysis and negotiations. OGD Global Affairs identifies opportunities and challenges as those national regulations are being developed and implemented positioning regulators proactively on the path of convergence. Includes discussion of the Generic Drug Cluster and ICH M13.

**Sarah Ibrahim**
*Associate Director for Global Generic Drug Affairs*
OGD | CDER

10:00 – 10:20

### Overview of the Product-Specific Guidance (PSG) Program

FDA will provide an overview of the Product-Specific Guidance (PSG) program and its role in facilitating generic drug development.

**Karen Bengtson**
*Lead Regulatory Health Project Manager*
ORS | OGD | CDER

**10:20 – 10:30: BREAK**

All times shown are Eastern (EST UTC-4)

## DAY TWO: Wednesday, April 27, 2022

10:30 – 10:50

### Approaches Using Proactive Research in Support of Product Specific Guidance (PSG) Development

Product-Specific Guidances (PSGs) provide recommendations on individual drug products to the pharmaceutical industry for developing generic drug products. This talk will describe the approaches in support of PSG development.

**Darby Kozak**
*Deputy Director*
Division of Therapeutic Performance I (DTP I)
ORS | OGD | CDER

**Xiaoming Xu**
*Branch Chief*
Office of Testing and Research (OTR)
OPQ | CDER

10:50 – 11:10

### Questions & Panel Discussion

**Sarah Ibrahim, Karen Bengtson, Xiaoming Xu, Darby Kozak** and

**Lei Zhang**
*Deputy Director*
ORS | OGD | CDER

11:10 – 11:30

### Review of Bio-INDs in the Office of Generic Drugs

This presentation will provide an overview of the regulations underlying Bio-INDs, a discussion of roles and responsibilities consistent with MAPP 5210.5 reflecting the recent OGD reorganization, and advice to sponsors regarding content and review of Bio-INDs.

**Michael Spagnola**
*Clinical Team Leader*
Division of Clinical Safety and Surveillance (DCSS)
OSCE | OGD | CDER

11:30 – 11:50

### Overview of Pre-ANDA Meetings

FDA will provide an overview on how to request and conduct product development pre-ANDA meetings and share tips on best practices in preparing an effective meeting package. An overview of other pre-submission communications to facilitate generic drug development for complex products and support submission of high quality approvable ANDAs will be presented.

**Susan Hakeem**
*Regulatory Health Project Manager*
ORS | OGD | CDER

11:50 – 12:05

### Questions & Panel Discussion

**Michael Spagnola, Susan Hakeem, Karen Bengtson**

**12:05 - 12:35: LUNCH BREAK**

All times shown are Eastern (EST UTC-4)

# DAY TWO: Wednesday, April 27, 2022

12:35 – 12:55

## Best Practices and Strategies for Communication with FDA

This talk will focus on best practices and strategies for communication with FDA during ANDA assessment.

**Robert Gaines**
*Deputy Director*
Office of Program and Regulatory Operations (OPRO)
OPQ | CDER

**Warren Simmons**
*LT*, USPHS
*Regulatory Project Manager*
ORP | OGD | CDER

12:55 – 1:15

## Division of Filing Review: Best Practices for ANDA and Controlled Correspondence Submissions

The Division of Filing Review will provide an overview of common deficiencies found during filing review and recommend best practices for submitting controlled correspondences and substantially complete ANDAs.

**Peter Enos**
*Filing Reviewer*, Division of Filing Review (DFR)
ORO | OGD | CDER

**Elizabeth Kim**
*LCDR*, USPHS
*Controls Coordinator,* DFR
ORO | OGD | CDER

1:15 – 1:30

## Questions & Panel Discussion

**Robert Gaines, Warren Simmons, Peter Enos, Elizabeth Kim,** and **Julia Lee**
*Deputy Director*
DFR | ORO | OGD | CDER

1:30 – 1:50

## Project Management of Premarket and Postmarket Generic Drug Safety

Participants will hear from the regulatory health project manager's perspective: the collaborative approaches used to managing generic drug safety issues across OGD and CDER; clinical reviews of serious adverse events from premarket bioequivalence/bioavailability (BA/BE) studies; and get introduced to OGD/DCSS's role in the postmarket safety process outlined in the Newly Identified Safety Signal (NISS) MAPP.

**Tu-Van Lambert**
*Senior Regulatory Health Project Manager*
Division of Clinical Safety and Surveillance
OSCE | OGD | CDER

1:50 – 2:10

## Best Practices for Conducting Comparative Analyses in ANDAs

This presentation will help participants understand key principles for conducting comparative analyses, review user-interface considerations for specific categories of products and provide tips for user interface assessment during product development.

**Andrew Fine**
*CDR*, USPHS
*Senior Advisor*
Division of Clinical Review (DCR)
OSCE | OGD | CDER

All times shown are Eastern (EST UTC-4)

## DAY TWO: Wednesday, April 27, 2022

2:10 – 2:25

### Questions & Panel Discussion

**Tu-Van Lambert, Andrew Fine**

**2:25 – 2:35: BREAK**

2:35 – 2:55

### Use of Alternate Tools for Inspections During the COVID-19 Pandemic

This talk will describe the Agency's experience in performing Record Reviews and Remote Interactive Evaluations (RIE) of manufacturing facilities *in lieu* of the pre-approval inspections during travel restriction caused by public health emergency.

**Haitao Li**
*Branch Chief*

**Alexander Gontcharov**
*Staff Fellow*

OPMA | OPQ | CDER

2:55 – 3:15

### Office of Quality Surveillance (OQS) and the Assessment of Pharmaceutical Quality Systems (PQS) in support of ICH Q12

This talk will focus on Assessment of Pharmaceutical Quality Systems (PQS) by the Office of Quality Surveillance (OQS).

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

3:15 – 3:35

### OPQ Policy Update - Guidance ICH Q12 Technical Considerations for Pharmaceutical Product Lifecycle Management

This talk will provide a policy update to ICH Q12.

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

3:35 – 3:55

### Questions & Panel Discussion

**Alexander Gontcharov, Haitao Li, Alex Viehmann, Ashley Boam**

3:55 – 4:00

### Day Two Closing

**4:00: ADJOURN**

All times shown are Eastern (EST UTC-4)