AGENDA
All times are Eastern (EST UTC-4)

DAY ONE: Tuesday, April 26, 2022

8:30 – 8:45
Administrative Overview
Brenda Stodart
CAPT, USPHS
Director, Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI)
Office of Communications (OCOMM) | CDER

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

Your SBIA Hosts for Day One
Forest "Ray" Ford, Jr.
CAPT, USPHS, Pharmacist
DDI | OCOMM | CDER
## DAY ONE: Tuesday, April 26, 2022

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<tr>
<th>Time</th>
<th>Presentation</th>
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<tr>
<td>9:15 – 9:35</td>
<td><strong>Use of Knowledge-Aided Assessment and Structured Application (KASA) in Drug Product Assessment</strong>&lt;br&gt;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).&lt;br&gt;Peter Capella&lt;br&gt;Director&lt;br&gt;Division of Immediate and Modified Release Products II (DIMRPII)&lt;br&gt;Office of Life Cycle Products (OLDP)</td>
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<td>9:35 – 9:55</td>
<td><strong>Use of Knowledge-Aided Assessment and Structured Application (KASA) in Drug Product Manufacturing Assessment</strong>&lt;br&gt;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).&lt;br&gt;Rakhi Shah&lt;br&gt;Associate Director&lt;br&gt;Office of Pharmaceutical Manufacturing Assessment (OPMA)</td>
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<tr>
<td>9:55 – 10:15</td>
<td><strong>Use of Knowledge-Aided Assessment and Structured Application (KASA) in Biopharmaceutics Assessment</strong>&lt;br&gt;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).&lt;br&gt;Kimberly Raines&lt;br&gt;Branch Chief&lt;br&gt;Division of Biopharmaceutics&lt;br&gt;Office of New Drug Products (ONDP)</td>
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<td>10:15 – 10:35</td>
<td><strong>Integrated Drug Product Assessment: Expectations</strong>&lt;br&gt;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.&lt;br&gt;Mayra Pineiro Sanchez&lt;br&gt;Senior Pharmaceutical Quality Assessor&lt;br&gt;Division of Immediate and Modified Release Products II&lt;br&gt;OLDP</td>
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<tr>
<td>10:35 – 10:55</td>
<td><strong>Questions &amp; Panel Discussion</strong>&lt;br&gt;Peter Capella, Rakhi Shah, Kimberly Raines, Mayra Pineiro Sanchez</td>
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10:55 - 11:05: BREAK
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.

Edward (Ted) Sherwood
Director
ORO

Russell Storms
Associate Director for Analytics
ORO

David Holovac
Analytics Team
ORO

Robert Berger
Analytics Team
ORO

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 | OPO | CDER

11:55 – 12:15
Questions & Panel Discussion

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

12:15 – 12:45:
LUNCH BREAK
DAY ONE: Tuesday, April 26, 2022

12:45 – 1:15
**Culture of Quality**
This presentation will focus on data integrity issues, specifically related to lessons learned from the Agency’s experience with Panexcell/Synchron.

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 Inspections: Looking Beyond the Obvious to Uncover Data Integrity Issues**
This presentation will focus on data integrity issues, experiences and observations for analytical sites, including Panexcell/Synchron.

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

**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**
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**

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

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

9:00 – 9:20
**Common Manufacturing Related Deficiencies for Liquid Products**

Jinong (Jenn) Li
Chemist
OPMA | OPQ | CDER

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

9:20 – 9:40
**Questions & Panel Discussion**

Andre Raw, Jenn Li

9:40 – 10:00
**Generic Drug Development and Globally Divergent Regulations**

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

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.

10:00 – 10:20
**Overview of the Product-Specific Guidance (PSG) Program**

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

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

10:20 – 10:30: BREAK
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<th>Time</th>
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<tbody>
<tr>
<td>10:30 – 10:50</td>
<td><strong>Approaches Using Proactive Research in Support of Product Specific Guidance (PSG) Development</strong></td>
<td>Xiaoming Xu: Branch Chief, Office of Testing and Research (OTR), OPQ</td>
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<td>11:50 – 11:10</td>
<td><strong>Questions &amp; Panel Discussion</strong></td>
<td>Sarah Ibrahim, Karen Bengtson, Xiaoming Xu, Darby Kozak and Lei Zhang: Deputy Director, ORS</td>
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<td>11:10 – 11:30</td>
<td><strong>Review of Bio-INDs in the Office of Generic Drugs</strong></td>
<td>Michael Spagnola: Clinical Team Leader, Division of Clinical Safety and Surveillance (DCSS), OSCE</td>
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<td>11:30 – 11:50</td>
<td><strong>Overview of Pre-ANDA Meetings</strong></td>
<td>Susan Hakeem: Regulatory Health Project Manager, ORS</td>
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<td>11:50 – 12:05</td>
<td><strong>Questions &amp; Panel Discussion</strong></td>
<td>Michael Spagnola, Susan Hakeem, Karen Bengtson</td>
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<td>12:05 - 12:35</td>
<td><strong>LUNCH BREAK</strong></td>
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### Best Practices and Strategies for Communication with FDA

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| 12:35 – 12:55 | 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 |

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

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| 12:55 – 1:15 | 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 |

### Questions & Panel Discussion

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<tr>
<td>1:15 – 1:30</td>
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<td><strong>Robert Gaines, Warren Simmons, Peter Enos, Elizabeth Kim</strong></td>
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### Project Management of Premarket and Postmarket Generic Drug Safety

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| 1:30 – 1:50 | 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 |

### Best Practices for Conducting Comparative Analyses in ANDAs

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| 1:50 – 2:10 | 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 |
**DAY TWO: Wednesday, April 27, 2022**

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<td><strong>Questions &amp; Panel Discussion</strong></td>
<td>Tu-Van Lambert, Andrew Fine</td>
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<td><strong>BREAK</strong></td>
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<td>2:25 – 2:55</td>
<td><strong>Use of Alternate Tools for Inspections During the COVID -19 Pandemic</strong></td>
<td>Alexander Gontcharov</td>
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<td>Haitao Li</td>
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<td>Branch Chief</td>
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<td>OPMA</td>
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<td>2:55 – 3:15</td>
<td><strong>Office of Quality Surveillance (OQS) and the Assessment of Pharmaceutical Quality Systems (PQS) in support of ICH Q12</strong></td>
<td>Alex Viehmann</td>
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<td>Division Director</td>
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<td>3:15 – 3:35</td>
<td><strong>OPQ Policy Update - Guidance ICH Q12 Technical Considerations for Pharmaceutical Product Lifecycle Management</strong></td>
<td>Ashley Boam</td>
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<td><strong>Questions &amp; Panel Discussion</strong></td>
<td>Alexander Gontcharov, Haitao Li, Alex Viehmann, Ashley Boam</td>
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<td>3:55 – 4:00</td>
<td><strong>Day Two Closing</strong></td>
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