**AGENDA**

All times are Eastern (EST UTC-5)

For files and resources, please visit [The Event Page on SBIAnvents.com](http://www.fda.gov/cder/sbia)

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**DAY ONE: Wednesday, March 3, 2021**

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<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Presenter(s)</th>
<th>Role(s)</th>
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<tbody>
<tr>
<td>7:45 – 8:05</td>
<td><strong>Administrative Overview</strong></td>
<td>Brenda Stodart</td>
<td>CAPT, USPHS, <strong>Director</strong>, Small Business and Industry Assistance (SBIA)**Division of Drug Information (DDI)</td>
</tr>
<tr>
<td>8:05 – 8:20</td>
<td><strong>Welcome</strong></td>
<td>Lawrence Yu</td>
<td>Director, Office of New Drug Products (ONDP), Office of Pharmaceutical Quality (OPQ)</td>
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<tr>
<td>8:20 – 8:25</td>
<td><strong>Session Introduction</strong></td>
<td>Erin Skoda</td>
<td>Branch Chief (Acting), Division of Lifecycle API, ONDP, OPQ, CDER</td>
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**Your SBIA Hosts for Day One**

<table>
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<tr>
<th>Name</th>
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<tr>
<td>Forest &quot;Ray&quot; Ford, Jr.</td>
<td><strong>CAPT, USPHS, Pharmacist</strong></td>
<td>DDI, OCOMM, CDER</td>
</tr>
<tr>
<td>Lisa Misevicz</td>
<td><strong>Health Communications Specialist</strong></td>
<td>SBIA, DDI, OCOMM, CDER</td>
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## DAY ONE: Wednesday, March 3, 2021

### 8:25 – 8:55

**Introduction to the DMF Review Process**

The DMF review process from a timeline perspective with an emphasis on key takeaways from the workshop will be covered.

**Erin Skoda**  
*Branch Chief (Acting)*  
*Division of Lifecycle API*  
*ONDP | OPQ | CDER*

### 8:55 – 9:25

**Administrative Aspects of Managing a DMF**

We will discuss the administrative timeline of a DMF from requesting a pre-assigned DMF number to progression of status from pending to active and subsequent submissions with advice on administrative aspects of managing a DMF.

**Vathsala Selvam**  
*Technical Information Specialist*  
*Division of Lifecycle API*  
*ONDP | OPQ | CDER*

### 9:25 – 9:50

**Q&A Panel**

**Erin Skoda, Vathsala Selvam, David Skanchy**

### 9:50 - 10:05: BREAK

### 10:05 – 10:30

**Managing Electronic DMF Submissions**

Information to manage a DMF in eCTD format including electronic submission requirements, metrics, best practices, frequently asked questions, and where to obtain help will be covered.

**Jonathan Resnick**  
*Project Management Officer*  
*Cloud Collaboration Capability Team*  
*Division of Data Management Services and Solutions*  
*Office of Business Informatics (OBI) | CDER*

### 10:30 – 10:45

**Drug Master Files from a GDUFA II User Fee Perspective**

Information about DMF user fee assessment including fee requirement, payment, best practices, frequently asked questions, and where to obtain help will be covered.

**Hanah Pham**  
*Commander, USPHS*

**Evelyn Hong**  
*Lieutenant Commander, USPHS*

*Division of User Fee Management and Budget Formulation (DUFMBF)*  
*Office of Management (OM) | CDER*

### 10:45 – 11:10

**Timely Consult and Early Information Request (TCIR) Process for Drug Master Files (DMFs)**

Background and data on the TCIR process for DMFs, which could have a substantial positive impact on the overall ANDA approval process, is discussed.

**Jayani Perera**  
*Chemist*  
*Division of Lifecycle API*  
*ONDP | OPQ | CDER*
**DAY ONE: Wednesday, March 3, 2021**

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<tr>
<td>11:10 - 11:40</td>
<td><strong>Effective Communication Strategies for Drug Master Files (DMF)</strong></td>
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|            | Critical pathways, modes, types, and timing of communications during the DMF and application lifecycle along with advice and best practices from an FDA perspective on maximizing the effectiveness of these communications will be covered. | David Skanchy  
Commander, USPHS  
Director, Division of Lifecycle API  
ONDP | OPQ | CDER |
|            |                                                                        | Benjamin Danso  
Commander, USPHS  
Lead DMF Project Manager  
Office of Program and Regulatory Operations (OPRO)  
| OPQ | CDER |
| 11:40 - 12:00 | **Q&A Panel**                                                          |
|            | Jonathan Resnick, Hanah Pham, Evelyn Hong, Jayani Perera, David Skanchy, Benjamin Danso |
| 12:00 – 1:00: | **LUNCH BREAK**                                                      |
| 1:00 – 1:30 | **Poster Presentations: Responses to Submitted Questions**              |
|            | NOTE: Poster Presentations will be made available for viewing before the Workshop. Please visit the Workshop Event Page for information on how to view the presentations and submit questions. | Poster Presenters |
| 1:30 – 1:35 | **Manufacturing Session Introduction**                                 |
|            | Erin Skoda  
Branch Chief (Acting)  
Division of Lifecycle API  
ONDP | OPQ | CDER |
| 1:35 – 2:00 | **Drug Substance Facilities – Hidden and Critical Intermediate**       |
|            | This presentation covers critical intermediates and how to avoid DMF hidden facilities in order to prevent delays in referencing application approvals. | Wei Liu  
Senior Pharmaceutical Quality Assessor  
Division of Lifecycle API  
ONDP | OPQ | CDER |
|            |                                                                        | Cassandra Abellard  
Quality Assessor/ Consumer Safety Officer  
Division of Pharmaceutical Manufacturing  
Office of Pharmaceutical Manufacturing Assessment (OPMA)  
| OPQ | CDER |
## DAY ONE: Wednesday, March 3, 2021

### 2:00 – 2:25

**ICH Q11 Q&A, a Supporting Document for the Selection and Justification of Starting Materials**

This presentation will provide key concepts and clarification for starting materials selection based on ICH Q11 Q&A.

Anita Tiwari  
*Senior Pharmaceutical Quality Assessor*  
Division of Lifecycle API  
ONDP | OPQ | CDER

### 2:25 - 2:40

**Q&A Panel**

Wei Liu, Cassandra Abellard, Anita Tiwari, David Skanchy

### 2:40 – 2:55: BREAK

### 2:55 – 3:20

**Common Issues Related to LC and GC Methods in Type II DMFs**

This presentation will focus on commonly observed issues related to LC and GC analytical procedures and validation.

Xinghua Wu  
*Chemist*  
Division of Lifecycle API  
ONDP | OPQ | CDER

### 3:20 – 3:45

**Process Validation and ICH Q7**

This presentation covers manufacturing validation data from an FDA review perspective.

David Amspacher  
*Chemist*  
Division of Lifecycle API  
ONDP | OPQ | CDER

### 3:45 – 4:10

**Regulatory Considerations in Demonstrating Complex API Sameness**

Regulatory strategies to show API sameness of complex APIs in generic drug product will be discussed.

Bapu R. Gaddam  
*Chemist*  
Division of Lifecycle API  
ONDP | OPQ | CDER

### 4:10 – 4:40

**Q&A Panel**

Xinghua Wu, David Amspacher, Bapu R. Gaddam, David Skanchy
DAY ONE: Wednesday, March 3, 2021

4:40 – 4:45
Day One Closing

Erin Skoda
Branch Chief (Acting)
Division of Lifecycle API
ONDP | OPQ | CDER

4:45: DAY ONE ADJOURN
DAY TWO: Thursday, March 4, 2021

8:05 – 8:15
Administrative Overview
Lisa Misevicz
Health Communications Specialist
SBIA | DDI | OCOMM | CDER

8:15 – 8:20
Welcome & Session Introduction
Ramnarayan Randad
Branch Chief
Division of Lifecycle API
ONDP | OPQ | CDER

Your SBIA Hosts for Day Two
Forest "Ray" Ford, Jr.
CAPT, USPHS, Pharmacist
DDI | OCOMM | CDER
Lisa Misevicz
Health Communications Specialist
SBIA | DDI | OCOMM | CDER

8:20 – 8:50
Regulatory Considerations for Impurity Qualification: ICH Q3A/Q3C/Q3D, RLD & MDD
Hongbiao Liao
Chemist
Division of Lifecycle API
ONDP | OPQ | CDER

8:50 – 9:20
ICH M7(R1) – Chemistry and Manufacturing Control (CMC) Perspective on Hazard Assessment
Barbara O. Scott
Chemist
Division of Lifecycle API
ONDP | OPQ | CDER

9:20 – 9:45
Application of (Q)SAR and Expert Knowledge for ICH M7 Impurity Classification
Naomi L. Kruhlak
Scientific Lead
Computational Toxicology Consultation Service (CTCS)
Division of Applied Regulatory Science (DARS)
Office of Translational Sciences (OTS) | CDER

9:45 – 10:15
Q&A Panel
Hongbiao Liao, Barbara O. Scott, Naomi L. Kruhlak

10:15 – 10:30: BREAK

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DAY TWO: Thursday, March 4, 2021

10:30 – 10:55

**Safety Evaluation of Drug Substance Impurities in Generics**

The OGD-Pharmacology/Toxicology (Pharm/Tox) process for safety evaluation of impurities in drug substances is described and illustrated with case studies, emphasizing critical elements considered in safety evaluations, and commonly occurring deficiencies in DMFs.

**Chanchal Gupta**  
*Pharmacology/Toxicology Reviewer*  
Division of Clinical Review (DCR)  
Office of Bioequivalence (OB)  
Office of Generic Drugs (OGD) | CDER

10:55 – 11:20

**Nitrosamines: Where Are We Now?**

We will discuss the Agency’s current thinking on nitrosamine risk mitigation.

**Deborah F. Johnson**  
*Branch Chief*  
Division of Lifecycle API  
ONDP | OPQ | CDER

11:20 – 11:50

**Q&A Panel**

**Chanchal Gupta, Deborah F. Johnson**  
and **Sruthi King**  
*Associate Director of Pharmacology/Toxicology*  
Division of Clinical Review (DCR)  
Office of Bioequivalence (OB) | OGD | CDER

11:50 - 12:50: LUNCH BREAK

12:50 – 1:20

**Poster Presentations: Responses to Submitted Questions**

**Poster Presenters**

**NOTE:** Poster Presentations will be made available for viewing before the Workshop. Please visit the Workshop Event Page for information on how to view the presentations and submit questions.

1:20 – 1:25

**Life Cycle Session Introduction**

**Ramnarayan Randad**  
*Branch Chief*  
Division of Lifecycle API  
ONDP | OPQ | CDER

1:25 – 1:50

**API Facility Inspections**

The presentation will cover an overview of FDA’s inspection program, approach to various types of inspections, recent compliance trends, and certain API-specific scenarios.

**Jay Jariwala**  
*Team Leader, Division of Drug Quality*  
Office of Manufacturing Quality  
Office of Compliance | CDER
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| 1:50 – 2:15  | Drug Substance Postapproval Changes Guidance: Determination of Impurity Profile Equivalence | Brian Connell  
Senior Pharmaceutical Quality Assessor  
Division of Lifecycle API  
ONDP | OPQ | CDER |
| 2:15 – 2:30  | Q&A Panel                                                               | Jay Jariwala, Brian Connell                                                |
| 2:30 – 2:45  | BREAK                                                                   |                                                                            |
| 2:45 – 3:10  | Common CMC Issues in Type II DMFs and How to Avoid Them                  | Wei Liu  
Senior Pharmaceutical Quality Assessor  
Division of Lifecycle API  
ONDP | OPQ | CDER |
| 3:10 – 3:35  | Modernizing Drug Substance Assessment through KASA                        | Larisa Wu  
Associate Director for Science and Communications (Acting)  
ONDP | OPQ | CDER |
| 3:35 – 4:05  | Q&A Panel                                                               | Wei Liu, Larisa Wu, David Skanchy                                           |
| 4:05 – 4:15  | Day Two Closing                                                           | David Skanchy  
Commander, USPHS  
Director, Division of Lifecycle API  
ONDP | OPQ | CDER |
| 4:15         | ADJOURN                                                                  |                                                                            |

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