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

DAY ONE: Tuesday, September 20, 2022

8:00 – 8:15
Welcome
Brenda Stodart, PharmD, MS, BCGP, RAC
CAPT, USPHS
Director, Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM)
Center for Drug Evaluation and Research CDER

8:15 – 8:30
Keynote
Robert Califf, MD
Commissioner of Food and Drugs
Food and Drug Administration

Your SBIA Hosts for Day One
Forest "Ray" Ford, PharmD, BCPS
CAPT, USPHS
DDI | OCOMM | CDER
Renu Lal, PharmD
LCDR, USPHS
DDI | OCOMM | CDER
Nora Lim, PharmD, BCPS
LT USPHS, Pharmacist
SBIA | DDI | OCOMM | CDER
### DAY ONE: Tuesday, September 20, 2022

**Session 1A: Peptide Immunogenicity Risk and Impurity Assessment Considerations**

Session Leads: **Darby Kozak, PhD**, Deputy Director | DTP I | ORS | OGD | CDER & **Cameron Smith, PhD**, Branch Chief | LBB II | DLBP I | OLDP | OPQ | CDER

<table>
<thead>
<tr>
<th>Time</th>
<th>Title</th>
<th>Presenter</th>
<th>Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:30 – 8:50</td>
<td>Guidance for Peptide Products and Assessing Immunogenicity Risk</td>
<td>Eric Pang, PhD</td>
<td>Senior Chemist</td>
</tr>
<tr>
<td>8:50 – 9:10</td>
<td>Common Deficiencies Associated with Comparative Peptide Impurity Profile Studies and Qualification of Impurity Levels and Proposed Limits</td>
<td>Yili Li, PhD</td>
<td>Chemist</td>
</tr>
<tr>
<td>9:10 – 9:30</td>
<td>Assessing Impurities to Inform Peptide Immunogenicity Risk: Developing Informative Studies</td>
<td>Daniela Verthelyi, MD, PhD</td>
<td>Chief, Laboratory of Immunology</td>
</tr>
<tr>
<td>9:30 – 10:00</td>
<td>Session 1A: Q&amp;A Panel</td>
<td>Eric Pang, Yilli Li, Daniela Verthelyi and Cameron Smith, PhD, Branch Chief</td>
<td>LBB II</td>
</tr>
<tr>
<td>10:00 – 10:10: BREAK</td>
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</table>
DAY ONE: Tuesday, September 20, 2022

Session 1B: Oligonucleotide Active Pharmaceutical Ingredient (API) Sameness and Impurity Assessment Considerations

Session Leads: Darby Kozak, PhD, Deputy Director | DTP I | ORS | OGD | CDER & Cynthia Sommers, MS, Branch Chief | DCDA | OTR | OPQ | CDER

10:10 – 10:30
Oligonucleotides: Current Thinking and Analytical Challenges Identified in the Nusinersen PSG Development

Deyi Zhang, PhD
Senior Chemist
DTP I | ORS | OGD | CDER

10:30 – 10:50
In-Depth Impurity Assessment of Synthetic Oligonucleotides Enabled by High Resolution Mass Spectrometry

Kui Yang, PhD
Senior Research Scientist
DCDA | OTR | OPQ | CDER

10:50 – 11:10
Session 1B: Q&A Panel

Deyi Zhang, Kui Yang, and Daniela Verthelyi, MD, PhD, Chief, Laboratory of Immunology, DBRR III | OBP | OPQ | CDER
Likan Liang, PhD, Branch Chief, LBB V | DLBP II | OLDP | OPQ | CDER

All times shown are Eastern (EDT UTC-5)
# DAY ONE: Tuesday, September 20, 2022

## Session 2: Drug-Device Combination Products with a Focus on Devices

**Session Leads:** Stephanie Soukup, MD, *Physician*, DCR | OSCE | OGD | CDER & Katharine Feibus, MD, *Team Lead*, DTP I | ORS | OGD | CDER

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<thead>
<tr>
<th>Time</th>
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<th>Speaker</th>
<th>Department</th>
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<tbody>
<tr>
<td>11:10</td>
<td>Comparing Device User Interfaces and Seeking Advice in the Pre-ANDA Period</td>
<td>Kathryn Hartka, Pharm D, PhD</td>
<td>DTP I</td>
</tr>
<tr>
<td>11:30</td>
<td>Conducting a Comparative Analysis When the RLD is Not Available</td>
<td>Stephanie Soukup, MD</td>
<td>DCR</td>
</tr>
<tr>
<td>11:50</td>
<td>Future Challenges: Electronic Devices, PDURS, Impacts on Generic Development and Substitution</td>
<td>Betsy Ballard, MD</td>
<td>Medical Officer</td>
</tr>
<tr>
<td>12:10</td>
<td>Session 2: Q&amp;A Panel</td>
<td>Kathryn Hartka, Stephanie Soukup, Betsy Ballard, Lisa Bercu, JD, CDR Andrew Fine, PharmD, Katharine Feibus, MD</td>
<td>DTP I</td>
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<tr>
<td>12:40</td>
<td>PM: LUNCH BREAK</td>
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### DAY ONE: Tuesday, September 20, 2022

**Session 3: Simple Injectables**

Session Leads: Bing Cai, PhD, Director, DLBP | OLDP | OPQ | CDER & Yan Wang, PhD, Team Lead, DTP | ORS | OGD | CDER

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<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker &amp; Position</th>
<th>Affiliations</th>
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<tbody>
<tr>
<td>1:15 – 1:35</td>
<td><strong>Q1/Q2 Assessment and Requirements for Biowaiver of Injectables</strong></td>
<td>Xinran Li, PhD, Staff Fellow</td>
<td>DB II</td>
</tr>
<tr>
<td>1:35 – 1:55</td>
<td><strong>Current Thinking and Research On In Vitro Only Approaches for Injectable Suspensions of Drug Substances – A Scientific Discussion</strong></td>
<td>Bin Qin, PhD, Staff Fellow</td>
<td>DTP</td>
</tr>
<tr>
<td>1:55 – 2:10</td>
<td><strong>Challenges and Considerations in Developing In Vitro Release Testing Methods for Parenteral Suspensions</strong></td>
<td>William Smith, PhD, Research Fellow</td>
<td>DPQR</td>
</tr>
<tr>
<td>2:10 – 2:35</td>
<td><strong>MAPP 5019.1 - Allowable Excess Volume/Content in Injectable Drug and Biological Products</strong></td>
<td>Hongna Wang, PhD, Chemist</td>
<td>DIPAP</td>
</tr>
<tr>
<td>2:35 – 3:05</td>
<td><strong>Session 3: Q&amp;A Panel</strong></td>
<td>Xinran Li, Bin Qin, William Smith, Hongna Wang, and Utpal Munshi, PhD, Director, DBI</td>
<td>DBI</td>
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<td>David Anderson, PhD, Branch Chief, DMAII</td>
<td>OPMA</td>
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<td>Janice Brown, MS, Branch Chief, DIPAP</td>
<td>OPPQ</td>
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#### Break

3:05 – 3:15 PM:  **BREAK**
DAY ONE: Tuesday, September 20, 2022

Session 4: Scientific Challenges and Advancements of Long-Acting Injectables

Session Leads: Lucy Fang, PhD, Deputy Director, DQMM | ORS | OGD | CDER & Bing Li, PhD, Associate Director for Science, OB | OGD | CDER

3:15 – 3:35
Q1/Q2 Challenges from a BE Assessment Perspective
Dapeng Cui, PhD
Pharmacologist
DBI | OB | OGD | CDER

3:35 – 3:55
Application Of Quantitative Modeling and Simulations to BE Determination for Long-Acting Injectables – Sharing Research Progress and Regulatory Experience
Kairui (Kevin) Feng, PhD
Senior Chemical Engineer
DQMM | ORS | OGD | CDER

3:55 – 4:15
Mechanistic Modeling of Complex Injectables: Recommendations to Navigate Regulatory Challenges
Khondoker Alam, PhD
Senior Pharmacologist
DQMM | ORS | OGD | CDER

4:15 – 4:35
Recommendation of Partial Area Under the Curve Metrics in Product- Specific Guidances for Long-Acting Injectable Drug Products
Sherin Thomas, PhD
Pharmacologist
DQMM | ORS | OGD | CDER

4:35 – 5:05
Session 4: Q&A Panel
Dapeng Cui, Kairui (Kevin) Feng, Khondoker Alam, Sherin Thomas and

Hao Zhu, PhD, Deputy Director, DPM | OCP | OTS | CDER
Lucy Fang, PhD, Deputy Director, DQMM | ORS | OGD | CDER
Bing Li, PhD, Associate Director for Science, OB | OGD | CDER

5:05 – 5:10
Day One Closing Remarks
Lei Zhang, PhD
Deputy Director
ORS | OGD | CDER
### DAY TWO: Wednesday, September 21, 2022

#### Session 5: In Vitro Binding Study for Locally Acting GI Drug Products

**Session Leads:** Wei-Jhe Sun, PhD, Pharmacologist, DTP II | ORS | OGD | CDER & Nilufer Tampal, PhD, Acting Associate Director of Scientific Quality, OB | OGD | CDER

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<th>Time</th>
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<th>Presenter(s)</th>
<th>Roles/Departments</th>
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<tbody>
<tr>
<td>8:15 – 8:35</td>
<td>In-Vitro Binding Studies for Bioequivalence Demonstration</td>
<td>Wei-Jhe Sun, PhD</td>
<td>Pharmacologist, DTP II</td>
</tr>
<tr>
<td>8:35 – 8:55</td>
<td>Assessing API “Sameness”</td>
<td>Hongmei Li, PhD</td>
<td>Senior Pharmaceutical Quality Assessor, LBB1</td>
</tr>
<tr>
<td>8:55 – 9:15</td>
<td>In Vitro Assessments that Support In Vitro Binding Studies in Demonstrating Bioequivalence of Locally Acting Gastrointestinal Drugs</td>
<td>Manar Al-Ghabeish, PhD</td>
<td>Staff Fellow, DTP II</td>
</tr>
<tr>
<td>9:15 – 9:35</td>
<td>Common Deficiencies and Case Studies of In-Vitro Binding Bioequivalence Studies</td>
<td>Hongfei Zhou, PhD</td>
<td>Pharmacologist, DB III</td>
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DAY TWO: Wednesday, September 21, 2022

9:35 – 10:05

Session 5: Q&A Panel
Wei-Jhe Sun, Hongmei Li, Manar Al-Ghabeish, Hongfei Zhou and Hongling Zhang, PhD, Division Director, DB II | OB | OGD | CDER

10:05 – 10:15 AM: BREAK

Session 6: Complex Generics: Current Challenges and Scientific Advancements for Nasal Products
Session Leads: Bryan Newman, PhD, Team Lead, DTP I | ORS | OGD | CDER & Changning Guo, PhD, Supervisory Chemist, DCDA | OTR | OPQ | CDER

10:15 – 10:35
Nasal Products: Current Landscape and Recent Advancements
Bryan Newman, PhD
Team Lead
DTP I | ORS | OGD | CDER

10:35 – 10:55
Alternative BE Approaches and Considerations for Nasal Products
Susan Boc, PhD
Scientific Researcher
DTP I | ORS OGD | CDER

10:55 – 11:15
Mechanistic Modeling and Realistic In Vitro Models to Facilitate Development of Generic Nasal Drug Products
Ross Walenga, PhD
Senior Chemical Engineer
DQMM | ORS | OGD | CDER

11:15 – 11:35
In Vitro Characterization of Nasal Powder Drug Products
Nick Holtgrewe, PhD
Chemist
DCDA | OTR | OPQ | CDER
### Session 6: Q&A Panel

Bryan Newman, Ross Walenga, Nick Holtgrewe, and Ke Ren, PhD, *Supervisory Pharmacologist*, DB III | OB | OGD | CDER

### Session 7: Quantitative Methods – Study Design, Model-integrated BE Approaches

**Session Leads:** Liang Zhao, PhD, *Director*, DQMM | ORS | OGD | CDER & Zhen Zhang, PhD, *Senior Pharmacologist*, DB I | OB | OGD | CDER

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<tr>
<th>Time</th>
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<th>Speaker</th>
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<tbody>
<tr>
<td>1:00 – 1:20</td>
<td>Alternative Model-Based Data Analysis Approach to Demonstrate BE</td>
<td>Yuqing Gong, PhD</td>
<td>DQMM</td>
</tr>
<tr>
<td>1:20 – 1:40</td>
<td>Evaluation and Application of New/Novel Data Imputation Approaches to Support BE Assessment</td>
<td>Jing Wang, PhD</td>
<td>Research Fellow</td>
</tr>
<tr>
<td>1:40 – 2:00</td>
<td>Challenges And Opportunities on Using Oral PBPK To Support Risk Assessment and Biowaiver in Regulatory Submissions</td>
<td>Fang Wu, PhD</td>
<td>Senior Pharmacologist/Scientific Lead</td>
</tr>
<tr>
<td>2:00 – 2:20</td>
<td>Dermal PBPK Modeling for a Transdermal Delivery System to Assess the Impact of the Application Site on In Vivo Performance</td>
<td>Eleftheria Tsakalozou, PhD</td>
<td>Senior Pharmacologist</td>
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## DAY TWO: Wednesday, September 21, 2022

### Session 7: Q&A Panel

Yuqing Gong, Jing Wang, Fang Wu, Eleftheria Tsakalozou, and Zhen Zhang, PhD, Senior Pharmacologist, DB I | OB | OGD | CDER

Stella Grosser, PhD, Director, DB VIII | OB | OTS | CDER

### 2:50 – 3:00 PM: BREAK

### Session 8: Enabling Generics: Changes to Suitability Petitions in GDUFA III

Session Leads: Lei Zhang, PhD, Deputy Director, ORS | OGD | CDER & Susan Levine, JD, Deputy Director, DPD | OGDP | OGD | CDER

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<tr>
<th>Time</th>
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</table>
| 3:00 – 3:20 | Suitability Petitions Enable Generics           | Robert Lionberger, PhD  
Director  
ORS | OGD | CDER                                      |
| 3:20 – 3:35 | Suitability Petitions: A Policy Perspective   | Susan Levine, JD  
Deputy Director  
DPD | OGDP | OGD | CDER                                      |
| 3:35 – 3:55 | Best Practices for Submitting a Suitability Petition | Rosanne Pagaduan, PharmD  
Supervisory Pharmacist  
DFR | ORO | OGD | CDER                                      |
| 3:55 – 4:20 | Bridging the Difference: Bioequivalence Assessments for Suitability Petitions | Pamela Dorsey, PhD  
Pharmacologist  
DB III | OB | OGD | CDER                                      |
|        |                                                    | Heather Boyce, PhD  
Acting Team Lead  
DTP II | ORS | OGD | CDER                                      |
**DAY TWO: Wednesday, September 21, 2022**

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<tr>
<td>4:20 – 4:50</td>
<td><strong>Session 8: Q&amp;A Panel</strong></td>
<td>Robert Lionberger, Susan Levine, Rosanne Pagaduan, Pamela Dorsey, Heather Boyce and CDR Andrew Fine, PharmD, Senior Advisor, DCR</td>
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<td>Arlene Figueroa, JD, Regulatory Counsel, DLRS</td>
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<tr>
<td>4:50 – 5:00</td>
<td><strong>Closing Remarks</strong></td>
<td>Robert Lionberger, PhD, Director</td>
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<tr>
<td>5:00:</td>
<td>ADJOURN WORKSHOP</td>
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List of Acronyms Used in This Document:

Center for Drug Evaluation and Research (CDER)
Division of Bioequivalence I (DB I)
Division of Bioequivalence II (DB II)
Division of Biometrics VIII (DB VIII)
Division of Biotechnology Review and Research III (DBRR III)
Division of Clinical Review (DCR)
Division of Complex Drug Analysis (DCDA)
Division of Filing Review (DFR)
Division of Internal Policies and Programs (DIPAP)
Division of Legal & Regulatory Support (DLRS)
Division of Liquid-Based Products I (DLBP I)
Division of Liquid-Based Products II (DLBP II)
Division of Microbiology Assessment II (DMA II)
Division of Pharmacometrics (DPM)
Division of Policy Development (DPD)
Division of Product Quality Research (DQPR)
Division of Quantitative Methods & Modeling (DQMM)
Division of Therapeutic Performance I (DTP I)
Division of Therapeutic Performance II (DTP II)
Division of Translational and Precision Medicine (DTPM)
Doctor of Medicine (MD)
Doctor of Philosophy (PhD)
Food and Drug Administration (FDA)
Liquid-Based Branch II (LBB II)
Liquid-Based Branch V (LBB V)
Master of Science (MS)
Office of Bioequivalence (OB)
Office of Biostatistics (OB)
Office of Biotechnology Products (OBP)
Office of Clinical Pharmacology (OCP)
Office of Generic Drug Policy (OGDP)
Office of Generic Drugs (OGD)
Office of Lifecycle Drug Products (OLDP)
Office of Pharmaceutical Manufacturing Assessment (OPMA)
Office of Pharmaceutical Quality (OPQ)
Office of Policy for Pharmaceutical Quality (OPPQ)
Office of Regulatory Operations (ORO)
Office of Research and Standards (ORS)
Office of Safety & Clinical Evaluation (OSCE)
Office of Testing & Research (OTR)
Office of Translational Sciences (OTS)