Version 8 – Updated September 21, 2022

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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

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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

8:30 – 8:50

Guidance for Peptide Products and Assessing Immunogenicity Risk

Eric Pang, PhD
Senior Chemist
DTP I | ORS | OGD | CDER

8:50 – 9:10

Common Deficiencies Associated with Comparative Peptide Impurity Profile Studies and Qualification of Impurity Levels and Proposed Limits

Yili Li, PhD
Chemist
LBB II | DLBP I | OLDP | OPQ | CDER

9:10 – 9:30

Assessing Impurities to Inform Peptide Immunogenicity Risk: Developing Informative Studies

Daniela Verthelyi, MD, PhD
Chief, Laboratory of Immunology
DBRR III | OBP | OPQ | CDER

9:30 – 10:00

Session 1A: Q&A Panel

Eric Pang, Yilli Li, Daniela Verthelyi and
Cameron Smith, PhD, *Branch Chief,* LBB II | DLBP I | OLDP | OPQ | CDER

10:00 – 10:10: BREAK

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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

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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

11:10 – 11:30

Comparing Device User Interfaces and Seeking Advice in the Pre-ANDA Period

Kathryn Hartka, Pharm D, PhD
Pharmacologist
DTP I | ORS | OGD | CDER

11:30 – 11:50

Conducting a Comparative Analysis When the RLD is Not Available

Stephanie Soukup, MD
Physician
DCR | OSCE | OGD | CDER

11:50 – 12:10

Future Challenges: Electronic Devices, PDURS, Impacts on Generic Development and Substitution

Betsy Ballard, MD
Medical Officer
DTP I | ORS | OGD | CDER

12:10 – 12:40

Session 2: Q&A Panel

Kathryn Hartka, Stephanie Soukup, Betsy Ballard, and

Lisa Bercu, JD, *Regulatory Counsel,* DPD | OGDP | OGD | CDER
Markham Luke, MD, PhD, *Director,* DTP I | ORS | OGD | CDER
CDR Andrew Fine, PharmD, Senior Advisor, DCR | OSCE | OGD | CDER
Katharine Feibus, MD, *Team Leader,* DTP I | ORS | OGD | CDER

12:40 – 1:15 PM: LUNCH BREAK

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DAY ONE: Tuesday, September 20, 2022

Session 3: Simple Injectables

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

1:15 – 1:35

Q1/Q2 Assessment and Requirements for Biowaiver of Injectables

Xinran Li, PhD
Staff Fellow
DB II | OB | OGD | CDER

1:35 – 1:55

Current Thinking and Research On In Vitro Only Approaches for Injectable Suspensions of Drug Substances– A Scientific Discussion

Bin Qin, PhD
Staff Fellow
DTP I | ORS | OGD | CDER

1:55 – 2:10

Challenges and Considerations in Developing In Vitro Release Testing Methods for Parenteral Suspensions

William Smith, PhD
Research Fellow
DPQR | OTR | OPQ | CDER

2:10 – 2:35

MAPP 5019.1 - Allowable Excess Volume/Content in Injectable Drug and Biological Products

Hongna Wang, PhD
Chemist
DIPAP | OPPQ | OPQ | CDER

2:35 – 3:05

Session 3: Q&A Panel

Xinran Li, Bin Qin, William Smith, Hongna Wang, and

Utpal Munshi, PhD, *Director,* DBI | OB | OGD | CDER
David Anderson, PhD, *Branch Chief,* DMAII | OPMA | OPQ | CDER
Janice Brown, MS, *Branch Chief*, DIPAP | OPPQ | OPQ | CDER

3:05 – 3:15 PM: BREAK

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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

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DAY TWO: Wednesday, September 21, 2022

8:00 – 8:15

Day Two SBIA Overview

Forest "Ray" Ford, PharmD, BCPS
CAPT, USPHS
DDI | OCOMM | CDER

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 Scientifc Quality*, OB | OGD | CDER

8:15 – 8:35

In-Vitro Binding Studies for Bioequivalence Demonstration

Wei-Jhe Sun, PhD
Pharmacologist
DTP II | ORS | OGD | CDER

8:35 – 8:55

Assessing API “Sameness”

Hongmei Li, PhD
Senior Pharmaceutical Quality Assessor
LBB1 | DLBPI | OLDP | OPQ | CDER

8:55 – 9:15

In Vitro Assessments that Support In Vitro Binding Studies in Demonstrating Bioequivalence of Locally Acting Gastrointestinal Drugs

Manar Al-Ghabeish, PhD
Staff Fellow
DTP II | ORS | OGD | CDER

9:15 – 9:35

Common Deficiencies and Case Studies of In-Vitro Binding Bioequivalence Studies

Hongfei Zhou, PhD
Pharmacologist
DB III | OB | OGD | CDER

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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

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DAY TWO: Wednesday, September 21, 2022

11:35 – 12:05

Session 6: Q&A Panel

Bryan Newman, Ross Walenga, Nick Holtgrewe, and

Ke Ren, PhD, *Supervisory Pharmacologist*, DB III | OB | OGD | CDER

12:05 - 1:00: LUNCH BREAK

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

1:00 – 1:20

Alternative Model-Based Data Analysis Approach to Demonstrate BE

Yuqing Gong, PhD
Pharmacologist
DQMM | ORS | OGD | CDER

1:20 – 1:40

Evaluation and Application of New/Novel Data Imputation Approaches to Support BE Assessment

Jing Wang, PhD
Research Fellow
DQMM | ORS | OGD | CDER

1:40 – 2:00

Challenges And Opportunities on Using Oral PBPK To Support Risk Assessment and Biowaiver in Regulatory Submissions

Fang Wu, PhD
Senior Pharmacologist/Scientific Lead
DQMM | ORS | OGD | CDER

2:00 – 2:20

Dermal PBPK Modeling for a Transdermal Delivery System to Assess the Impact of the Application Site on In Vivo Performance

Eleftheria Tsakalozou, PhD
Senior Pharmacologist
DQMM | ORS | OGD | CDER

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DAY TWO: Wednesday, September 21, 2022

2:20 – 2:50

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

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

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DAY TWO: Wednesday, September 21, 2022

4:20 – 4:50

Session 8: Q&A Panel

Robert Lionberger, Susan Levine, Rosanne Pagaduan, Pamela Dorsey, Heather Boyce
and
CDR Andrew Fine, PharmD, *Senior Advisor*, DCR | OSCE | OGD | CDER
Arlene Figueroa, JD, *Regulatory Counsel*, DLRS | OGDP | OGD | CDER

4:50 – 5:00

Closing Remarks

Robert Lionberger, PhD
Director
ORS | OGD | CDER

5:00: ADJOURN WORKSHOP

All times shown are Eastern (EDT UTC-5)

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)