MEETING AGENDA

October 2, 2017

8:00 – 8:40 am  Registration

8:40 – 8:45 am  Welcome and Logistics
   Liang Zhao, PhD, MBA, U.S. Food & Drug Administration

8:45 – 9:00 am  Introduction and Objectives of the Workshop
   Kathleen “Cook” Uhl, MD, U.S. Food & Drug Administration

Session 1  Global Regulatory Convergence and Harmonization for Generic Drugs and Opportunities for the Use of Quantitative Methods

9:00 – 9:05 am  Session Opening
   Moderator: April Braddy, PhD, U.S. Food & Drug Administration

Unit I  Global Regulatory Harmonization for Generic Drugs

9:05 – 9:15 am  ICH Reform and Future Directions
   Amanda Roache, BS, U.S. Food & Drug Administration

9:15 – 9:25 am  ICH for Generic Drugs: The FDA Perspective
   Zili Li, MD, MPH, U.S. Food & Drug Administration

9:25 – 9:35 am  FDA Commissioner Remarks
   Scott Gottlieb, MD, U.S. Food & Drug Administration

9:35 – 9:45 am  IGBA – The International Generic and Biosimilar Industry Voice for Regulatory Convergence and Harmonization
   Nicholas Cappuccino, PhD, International Generic and Biosimilar Medicines Association

9:45 – 9:55 am  CFDA Reform and Membership at ICH
   Xinyu Weng, PhD, China Food & Drug Administration

9:55 – 10:05 am  CDSCO – Generic Drug Regulations and Regulatory Convergence
   Ranga Chandrashekar, MPharm, LLB, Central Drugs Standard Control Organization
10:05 – 10:15 am  **COFEPRIS Experience on Generics and International Harmonization**  
Enrique Perret for Mario Alanis Garza, PhD, Federal Commission for the Protection against Sanitary Risk

10:15 – 10:25 am  **WHO: Initiatives and Progress Towards Harmonization**  
Anthony Fake, PhD, World Health Organization

10:25 – 10:35 am  **Break**

**Unit II**  **Use of Quantitative Methods in Generic Drug Development and Regulatory Decision Making**

10:35 – 10:55 am  **Leveraging Quantitative Methods and Modeling to Modernize Generic Drug Development and Review from the FDA perspective**  
Liang Zhao, PhD, MBA, U.S. Food & Drug Administration

10:55 – 11:15 am  **Quantitative Methods and Generic Drugs: Current Approaches and Future Directions in Health Canada**  
Danika Painter, PhD, Health Canada

11:15 am – 12:15 pm  **Panel Discussion and Public Hearing**  
Amanda Roache, BS (FDA), Zili Li, MD, MPH (FDA), Nicholas Cappuccino, PhD (IGBA), Xinyu Weng, PhD (CFDA), Ranga Chandrashekhar, MPharm, LLB (CDSCO), Joel Rogozinski for Mario Alanis Garza, PhD (COFEPRIS), Anthony Fake, PhD (WHO), Liang Zhao, PhD, MBA (FDA), Danika Painter, PhD (Health Canada), Tania Teixeira, PharmD (EMA)

12:15 – 1:15 pm  **Lunch** (not provided)

**Session 2**  **Model Informed Drug Development and Review for Complex and Locally Acting Products**

1:15 – 1:20 pm  **Session Opening**  
Myong-Jin “MJ” Kim, PharmD, U.S. Food & Drug Administration

1:20 – 1:40 pm  **Partial AUCs 2.0 – Improved Metrics for Assessing Bioequivalence on Mixed Release Mode (IR/ER) Drug Products**  
Charlie DiLiberti, MS, Montclair Bioequivalence Services, LLC

1:40 – 2:00 pm  **Model-based Method to Identify Critical PK Measures for Equivalence of Complex Products**  
Yaning Wang, PhD, U.S. Food & Drug Administration
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<tr>
<th>Time</th>
<th>Topic</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>2:00 – 2:20 pm</td>
<td>Leveraging Quantitative Methods in Reviewing Complex/Locally Acting Products</td>
<td>Lanyan “Lucy” Fang, PhD, U.S. Food &amp; Drug Administration</td>
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<td>2:20 – 2:40 pm</td>
<td>Considerations for Bioequivalence Evaluation of Nanoparticulate/Molecular Medicine</td>
<td>Jessie Au, PharmD, PhD, Institute of Quantitative Systems Pharmacology</td>
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<td>2:40 – 2:50 pm</td>
<td>Break</td>
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<td>2:50 – 3:10 pm</td>
<td>Model-based Approaches as Guidance to Bioequivalence Decision Making: Design and Analysis Considerations</td>
<td>Andrew Hooker, PhD, Uppsala University</td>
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<td>3:10 – 3:30 pm</td>
<td>Strengths and Weaknesses of Population PK Analyses for the Assessment of Bioequivalence of Complex and Locally Acting Products</td>
<td>Murray Ducharme, PharmD, DPH, Learn and Confirm, Inc.</td>
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<td>3:30 – 4:30 pm</td>
<td>Panel Discussion and Public Hearing</td>
<td>Charlie DiLiberti, MS, (Montclair Bioequivalence Services), Yaning Wang, PhD (FDA), Lanyan “Lucy” Fang, PhD (FDA), Jessie Au, PharmD, PhD (IQSP), Andrew Hooker, PhD (Uppsala U), Murray Ducharme, PharmD, DPH (Learn and Confirm), John Peters, MD (FDA), Robert Lionberger, PhD (FDA), Markham Luke, MD, PhD (FDA), Stella Grosser, PhD (FDA), Li Li, PhD (CFDA), Sarah Yim, MD (FDA), Dale Conner, PharmD (FDA), Shiew-Mei Huang, PhD (FDA)</td>
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<td>4:30 – 4:40 pm</td>
<td>Day 1 Closing Announcements</td>
<td>John Peters, MD, U.S. Food &amp; Drug Administration</td>
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Leveraging Quantitative Methods and Modeling to Modernize Generic Drug Development and Review

FDA White Oak – Building 31, Great Room (Rm.1503 B/C)
October 2-3, 2017

MEETING AGENDA

October 3, 2017

8:00 – 8:30 am  Registration

Session 3  Emerging Quantitative Methodologies and Their Use in Product Lifecycle Management

8:30 – 8:35 am  Session Opening
Moderator Unit I: Liang Zhao, PhD, MBA, U.S. Food & Drug Administration
Moderator Unit II: Andreas Schick, PhD, U.S. Food & Drug Administration

Unit I  Emerging Quantitative Methods and Modeling to Transform Generic Drug Review and Development

8:35 – 8:55 am  Is There a Potential to Apply Bayesian Approach in Generic Development and Approval?
Carl Peck, MD, University of California, San Francisco and NDA Partners, LLC

8:55 – 9:15 am  Using Quantitative Methods and Modeling to Transform Generic Drug Development and Review
Rob Lionberger, PhD, U.S. Food & Drug Administration

9:15 – 9:35 am  Narrow Therapeutic Index: Time to Redefine?
Joga Gobburu, PhD, MBA, University of Maryland

9:35 – 10:25 am  Panel Discussion and Public Hearing
Carl Peck, MD (UCSF and NDA Partners), Robert Lionberger, PhD (FDA), Joga Gobburu, PhD, MBA (U Maryland), Robert Bies, PharmD, PhD (SUNY at Buffalo), John Peters, MD (FDA), Dale Conner, PharmD (FDA), Stella Grosser, PhD (FDA), Murray Ducharme, PharmD, DPH (Learn and Confirm), Danika Painter, PhD (Health Canada)
10:25 – 10:35 am  Break

Unit II  Understanding Generic Drug Competition via Pharmacoeconomics and Big Data

10:35 – 10:55 am  Challenges in Maintaining Competition in Small Generic Drug Markets, Part I  
Ernst Berndt, PhD, Massachusetts Institute of Technology

10:55 – 11:15 am  Challenges in Maintaining Competition in Small Generic Drug Markets, Part II  
Rena Conti, PhD, University of Chicago

11:15 – 11:35 am  Prediction of the First ANDA Submission for NCEs Utilizing Machine Learning Methodology  
Meng Hu, PhD, U.S. Food & Drug Administration

11:35 am – 12:15 pm  Panel Discussion and Public Hearing  
Ernst Berndt, PhD (MIT), Rena Conti, PhD (U Chicago), Robert Lionberger, PhD (FDA), Meng Hu, PhD (FDA), John Peters, MD (FDA), Liang Zhao, PhD, MBA (FDA), Kathleen Miller, PhD (FDA)

12:15 – 1:15 pm  Lunch (not provided)

Session 4  Model-Guided Signal Detection in Post-Marketing Stage

1:15 – 1:20 pm  Session Opening  
Moderator: Howard Chazin, MD, MBA, U.S. Food & Drug Administration

1:20 – 1:40 am  A Model- and Systems-Based Approach to Efficacy and Safety Questions Related to Generic Substitution  
Stephan Schmidt, PhD, FCP, University of Florida

1:40 – 2:00 pm  Real World Pragmatic Studies: Pharma Perspective and a Recent Example  
Cynthia Huang Bartlett, MD, MBA, Pfizer Oncology

2:00 – 2:20 pm  Using the Sentinel System to Assess Generic Drug Safety in the Post-Approval Setting  
Tyler Coyle, MD, U.S. Food & Drug Administration
2:20 – 2:40 pm  Use of Regulatory Science Research to Support Post-marketing Surveillance of Generic Drug Products
    Sarah Dutcher, PhD, U.S. Food & Drug Administration

2:40 – 2:50 pm  Break

2:50 – 3:50 pm  Panel Discussion and Public Hearing
    Howard Chazin, MD, MBA (FDA), Stephan Schmidt, PhD, FCP (U Florida), Cynthia Huang Bartlett, MD, MBA (Pfizer), Tyler Coyle, MD (FDA), Sarah Dutcher, PhD (FDA), Rob Lionberger, PhD (FDA), John Peters, MD (FDA), Rajnikanth Madabushi, PhD (FDA)

3:50 – 4:00 pm  Closing Remarks
    Robert Lionberger, PhD, U.S. Food & Drug Administration