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 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

2:00 – 2:20 pm	**Leveraging Quantitative Methods in Reviewing Complex/Locally Acting Products** Lanyan "Lucy" Fang, PhD, U.S. Food & Drug Administration
2:20 – 2:40 pm	**Considerations for Bioequivalence Evaluation of Nano-particulate/Molecular Medicine** Jessie Au, PharmD, PhD, Institute of Quantitative Systems Pharmacology
2:40 – 2:50 pm	**Break**
2:50 – 3:10 pm	**Model-based Approaches as Guidance to Bioequivalence Decision Making: Design and Analysis Considerations** Andrew Hooker, PhD, Uppsala University
3:10 – 3:30 pm	**Strengths and Weaknesses of Population PK Analyses for the Assessment of Bioequivalence of Complex and Locally Acting Products** Murray Ducharme, PharmD, DPH, Learn and Confirm, Inc.
3:30 – 4:30 pm	**Panel Discussion and Public Hearing** 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)
4:30 – 4:40 pm	**Day 1 Closing Announcements** John Peters, MD, U.S. Food & Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

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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