Presentation Published Relating to GDUFA Research in Fiscal Year 2019

1. Babiskin, A. *Use of PBPK Model to Evaluate Impact of Ophthalmic Drug Product's Critical Quality Attributes on BA/BE Assessment.* Presentation at 2019 American Society for Clinical Pharmacology and Therapeutics (ASCPT), Pre-Conference: PBPK Modeling for the Development and Approval of Locally Acting Products. Washington DC, Mar. 13, 2019.
2. Bolger, M. *Developing PBPK for Ocular Delivery.* Presentation at 2019 American Society for Clinical Pharmacology and Therapeutics (ASCPT), Pre-Conference: PBPK Modeling for the Development and Approval of Locally Acting Products. Washington DC, Mar. 13, 2019.
3. Bulitta, J. and Hochhaus, G. *Studies to Further Establish PK As Central Tool for a Streamlined Approval of Generic Inhalation Drugs*. Presentation at FY2019 Generic Drug Research Public Workshop. Silver Spring, MD, May 1, 2019.Kozak, D. *Advantages and Challenges in Implementing New Analytical Methods That Arise from Regulatory Science Initiatives*. Presentation at FY2019 Generic Drug Research Public Workshop. Silver Spring, MD, May 1, 2019.
4. Byron, P. *Bioequivalence Assessment for Inhalation Products*. Presentation at AAPS Pharmsci 360. Washington, DC, Nov. 6, 2018.
5. Choi, J., Choi, S., Hoffman, E., O'Shaughenessy, P., Castro, M., Delvadia, R., Walenga, R., Babiskin, A., and Lin, C. *Assessment of Effects of Selective Airway Luminal Expansion on Inhaled Particle Deposition in Severe Asthmatic Human Lungs - A Numerical Study*. Presentation at Georgia World Congress Center. Atlanta, GA, Nov. 19, 2018.
6. Conti, D. *Considerations for Pre-ANDA Meeting Requests for Orally Inhaled and Nasal Drug Products.* Presentation at 2019 Small Business and Industry Assistance (SBIA) Workshop. College Park, MD, Sept. 26, 2019.
7. Conti, D. *Emerging Concepts and New Technologies for Bioequivalence of Orally Inhaled and Nasal Drug Products*. Presentation at ATS International Conference. Dallas, TX, May 19, 2019.
8. Conti, D. *Overview of Complex Generic Inhalation, Nasal and Auto- Injector Drug-Device Combination Products.* Presentation at Drug Information Association (DIA) Annual Meeting, Combination Products. Silver Spring, MD, Oct. 9, 2018.
9. Drescher, S. *Characterizing the Time-Course of Lung Absorption Via Population Pharmacokinetic Modeling.* Presentation at Drug Delivery to the Lungs Conference. Edinburgh, UK, Dec. 13, 2018.
10. Fang, L. *Model-Informed Drug Development for Long-Acting Injectable Products*. Presentation at ACCP Annual Meeting. Chicago, IL, Sept. 16, 2019.
11. Fang, L. *PK and Statistical Considerations for Steady State Bioequivalence Studies - FDA Perspective.* Presentation at Scientists Advancing Affordable Medicines (SAAM) Conference. Rockville, MD, Apr. 4, 2019.
12. Fang, L. *PK/PD Meta-Analysis of Abuse Deterrent Opioid Drug Products: PSG Development, Research and ANDA Assessment.* Presentation at 2019 Small Business and Industry Assistance (SBIA) Workshop: Complex Drug Product Development, College Park, MD, Sep. 26, 2019.
13. Feng, W. *Complex Particle Morphology in Propofol Emulsions: Effect of Manufacturing Process*. AAPS PharmSci 360. Washington DC, Nov 4-7, 2018.
14. Ghosh, P. *Bioequivalence Fundamentals for Generic Topical Dermatological Drug Products*. Presentation at Innovations in Dermatological Sciences. Somerset, NJ, Sept. 9, 2019.
15. Ghosh, P. *FDA Initiatives to Stimulate Innovation and Imporve Patient Access to Generic Topical & Transdermal Products Part Li*. Presentation at Wellman Center for Photomedicine. Massachusetts, MA, Apr. 23, 2019.

16. Ghosh, P. *In Vitro Data Analysis Issues: IVPT Analyses and Other Challenges*. Presentation at Scientists Advancing Affordable Medicines. Baltimore, MD, Oct. 18, 2018.
17. Jiang, X. *Understanding FDA's Rules and Expectations Surrounding Q1/Q2 Determinations*. Presentation at Scientists Advancing Affordable Medicines. Baltimore, MD, Oct. 18, 2018.
18. Ghosh, P. *Innovation and Harmonization of Bioequivalence Standards for Generic Topical and Transdermal Products*. Presentation at 2019 Small Business and Industry Assistance (SBIA) Workshop. College Park, MD, Sept. 25, 2019.
19. Gong, X. *Regulatory Considerations on Dose-scale Analysis in Assessing Pharmacodynamic Equivalence*. Presentation at 2019 SBIA Complex Generic Drug Product Development Workshop. College Park, MD, Sept. 26, 2019.
20. Hu, M. *Equivalence Criteria for In Vitro BE Tests for Locally Acting Drug Products: The Earth Mover's Distance Approach.* Presentation at Scientists Advancing Affordable Medicines (SAAM) Conference. Rockville, MD, April. 4, 2019.
21. Reisfeld, B. *Enhancing the Reliability, Efficiency, and Usability of Bayesian Population PBPK Modeling.* Presentation at 2018 American Conference on Pharmacometrics (ACoP) 9 Meeting. San Diego, CA, Oct. 10, 2018.
22. Gobburu, J. *Population Pharmacokinetic and Pharmacodynamic, Dose Toxicity Modeling and Simulation for Narrow Therapeutic Index (NTI) Drugs.* Presentation at 2018 American Conference on Pharmacometrics (ACoP) 9 Meeting. San Diego, CA, Oct. 10, 2018.
23. Hochhaus, G. and Bulitta, J. *Pharmacokinetic Comparison of Locally Acting Dry Powder Inhalers*. Presentation at DIA Combination Products. Silver Spring, MD, Oct. 9, 2018.
24. Hochhaus, G. *Regulatory Implications of Device Changes Later in Drug Development*. Presentation at AAPS Pharmsci 360. Washington, DC, Nov. 7, 2018.
25. Hochhaus, G., Bulitta, J., Price, R., Shur, J., and Hindle, M. *Using PBPK to Link Systemic PK to Local Delivery in the Lung.* Presentation at 2019 Annual Meeting, American Society for Clinical Pharmacology and Therapeutics (ASCPT) Pre-Conference. Washington, DC, Mar. 13, 2019.
26. Jiang, W. *Advanced Analytical Methods to Characterize Liposome Drug Products.* Joint Eurpopean Commission Joint Research Center (JRC), National Institute of Standards and Technology (NIST) Workshop on Characterization Methods and Standards for Nanoparticles in Medical Products. Ispra, Italy. Dec. 3, 2018.
27. Jiang, W. *Complex Injectable and Implantable Drug Products: Bioequivalence Considerations.* 4th FDA/PQRI Conference on Advancing Product Quality: Patient-Centric Product Design, Drug Development, and Manufacturing. Rockville, MD. April 9-11, 2019.
28. Jiang, W. *Regulating Generic Nanotechnology Drug Products: Guidances and Standards.* Global Summit for Regulatory Science. Lago Maggiore. Lago Maggiore, Italy. Sept. 25, 2019.
29. Jiang, X. *Follow Up Discussion on FDA Peptide Guidance after Public Comments*. Presentation at Unites States Pharmacopeia (USP) Workshop on Synthetic Therapeutic Peptides. Rockville, MD, Nov. 5, 2018.
30. Karlsson, M., Chen, X., and Hooker, A. *Development of Model-Informed Bioequivalence Evaluation Strategies for Long-Acting Injectable Products (LAI)*. Presentation at ACCP Annual Meeting. Chicago, IL, Sept. 16, 2019.
31. Kozak, D. *Advantages and Challenges in Implementing New Analytical Methods That Arise from Regulatory Science Initiatives*. Presentation at FY2019 Generic Drug Research Public Workshop. Silver Spring, MD, May 1, 2019.

32. Kozak, D. *Generic Ophthalmic Drug Products, Physical Characteristics, And Bioequivalence*. Presentation at Association for Ocular Pharmacology and Therapeutics. New Orleans, LA, March 10, 2019.
33. Kurumaddali, A. *A Semi-Physiological Approach for Evaluating the Sensitivity of Pharmacokinetics to Detect Differences in Regional Lung Deposition of Orally-Inhaled Drug Products (Oidps).* Presentation at ACCP Annual Meeting. Chicago, IL, Sept. 16, 2019.
34. Kuzma, B. *Estimation of in-Vivo Percutaneous Permeation (Flux) and Cumulative Amount Input of Metronidazole Formulations in Mini-Pigs' Dermis*. Presentation at Gordon Research Conference. Barcelona, Spain, Aug. 12, 2019.
35. Li, M. *Dose-Scale (Emax) Modeling in Pharmacodynamic Bioequivalence Studies - FDA Perspective*. Presentation at 2019 Scientists Advancing Affordable Medicines (SAAM) Conference. Rockville, MD, Apr. 4, 2019.
36. Lin, CL. *CFD Lung Models for Drug Delivery*. Presentation at 2019 American Society for Clinical Pharmacology and Therapeutics (ASCPT), Pre-Conference: PBPK Modeling for the Development and Approval of Locally Acting Products. Washington, DC, Mar. 13, 2019.
37. Lionberger, R. *Closing Remarks*. Presentation at Drug Information Association (DIA) Annual Meeting, Combination Products. Silver Spring, MD, Oct. 10, 2018.
38. Lionberger, R. *Critical Roles for Locally Acting PBPK in Regulatory Decisions*. Presentation at 2019 American Society for Clinical Pharmacology and Therapeutics (ASCPT), Pre-Conference: PBPK Modeling for the Development and Approval of Locally Acting Products. Washington, DC, Mar. 13, 2019.
39. Luke, M. Horizon Scanning for Generic Combination Drug-Device Products. Presentation at 2018 FDA/DIA Complex Generic Drug-Device Combination Products Workshop. Silver Spring, MD, Oct. 10, 2018.
40. Luke, M. *Generic Drugs and Their Role in Bringing Next Generation Products: An FDA Perspective.* Presentation at Association for Ocular Pharmacology and Therapeutics. New Orleans, LA, March 10, 2019.
41. Luke, M. *Generic Drugs for Dermatology*. Presentation at FDA Symposium at the 2019 AAD Annual Meeting. White Oak, MD, Mar. 3, 2019.
42. Luke, M., K., W., and Conti, D. *Generic Drug Development for Respiratory Products, US Food and Drug Administration Update*. Presentation at ATS International Conference. Dallas, TX, May 19, 2019.
43. Manna, S. *Mechanistic Understanding of In Vitro Drug Release of Bupivacaine from Multivesicular Liposomes.* AAPS PharmSci 360. Washington DC, Nov 4-7, 2018.
44. Manna, S. *Significance of Cryo-Scanning Electron Microscopy (Cryo-SEM) in Evaluating the Morphology of Multivesicular Liposomes*. Microscopy and Microanalysis. Portland, OR. Aug 2, 2019.
45. Murthy, S. N. *Effect of Excipients on the In Vitro Permeation of Drugs from Topical Products*. Presentation at AAPS Pharmsci 360. Washington, DC, Nov. 7, 2018.
46. Newman, B. PSG *Recommendations and Updates for Oindps.* Presentation at 2019 Small Business and Industry Assistance (SBIA) Workshop. College Park, MD, Sept. 26, 2019.
47. Patel, N. *PBPK Modeling of Dermally Applied Drug Products to Support Clinical Development and Regulatory Assessment.* Presentation at 2019 American Society for Clinical Pharmacology and Therapeutics (ASCPT), Pre-Conference: PBPK Modeling for the Development and Approval of Locally Acting Products. Washington, DC, Mar. 13, 2019.

48. Przekwas, A., German, C., and Garimella, T. *An Integrated Multiscale-Multiphysics Modeling Ocular Drug Delivery and Pharmacokinetics Pharmacological Protection and Treatment*. Presentation at 2019 American Society for Clinical Pharmacology and Therapeutics (ASCPT), Pre-Conference: PBPK Modeling for the Development and Approval of Locally Acting Products. Washington, DC, Mar. 13, 2019.
49. Qin, B. *Characterization and Comparative Evaluation Strategies to Demonstrate Complex Excipient Sameness*. Presentation at 2019 Small Business and Industry Assistance (SBIA) Workshop. College Park, MD, Sept. 25, 2019.
50. Ramezanli, T. *Best Practices & Efficient Strategies for Generic Topical Product Development*. Presentation at 2019 Small Business and Industry Assistance (SBIA) Workshop. College Park, MD, Sept. 25, 2019.
51. Ramezanli, T. *Bioquivalence of Topical Products Scientific Consideration*. Presentation at PQRI Conference of Advancing Product Quality. Rockville, MD, Apr. 9, 2019.
52. Ramezanli, T. *How to structure efficient development programs for Generic topical drug products*. Presentation at Innovations in Dermatological Sciences. Somerset, NJ, Sept. 9, 2019.
53. Raney, S. *A Generic Perspective on the Use of In Vitro Assessment Methods*. Presentation at Topical Drug Development – Evolution of Science and Regulatory Policy Workshop sponsored by the University of Maryland Center of Excellence in Regulatory Science. Baltimore, MD, July 30, 2019.
54. Raney, S. *FDA Initiatives to Stimulate Innovation and Imporve Patient Access to Generic Topical & Transdermal Products Part I*. Presentation at Wellman Center for Photomedicine. Massachusetts, MA, Apr. 23, 2019.
55. Raney, S. *Research Activities, Scientific Advances, & Modernization of Bioequivalence Standards for Generic Topical and Transdermal Products*. Presentation at 2019 Small Business and Industry Assistance (SBIA) Workshop. College Park, MD, Sept. 25, 2019.
56. Rantou, E. *Statistical Issues with Aberrant IVRT/IVPT Data – FDA Perspective.* Presentation at Scientists Advancing Affordable Medicines (SAAM) Conference. Rockville, MD April 4, 2019.
57. Rantou, E. *Using R for Generic Drug Evaluation and SABE R-Package for Assessing Bioequivanlence of Topical Dermatological Products.* Presentation at R in Pharma Conference. Boston, MA, Aug. 2, 2019.
58. Roberts, M. *PBPK Models of the Skin*. Presentation at 2019 American Society for Clinical Pharmacology and Therapeutics (ASCPT), Pre-Conference: PBPK Modeling for the Development and Approval of Locally Acting Products. Washington, DC, Mar. 13, 2019.
59. Rodriguez, J. *Development of Enhanced Analytical Tools for Evaluation of Complex Generic Products*. Presentation at FY2019 Generic Drug Research Public Workshop. Silver Spring, MD, May 1, 2019.
60. Schoroeter, J. *Exploring the Relationship Between Suspension and Solution MDI Formulation Variables and Predicted Lung Deposition.* Presentation at RDD Asia 2018. Kerala, India, Nov. 16, 2018.
61. Schroeter, J. D. *Local and Systemic Absorption Predictions of Nasal Inhaled Corticosteroids: A Combined Approach.* Presentation at AAPS Pharmsci 360. Washington, DC, Nov. 6, 2018.
62. Sharan, S. *Application of Modeling and Simulation in Establishing Appropriate Bioequivalence Limits for Long Acting Intrauterine Product*. Presentation at DIA Complex Drug-Device Generic Combination Products Meeting. Silver Spring, MD, Oct. 9, 2018.

63. Sharan, S. *Application of Quantitative Clinical Pharmacology (QCP) in Development of Long Acting Injectable Products.* Presentation at 2019 Small Business and Industry Assistance (SBIA) Workshop. College Park, MD, Sept. 25, 2019.
64. Sharan, S. *Opportunities and Challenges for Modeling and Simulation in Development of Long-Acting Injectable Drug Products*. Presentation at ACCP Annual Meeting. Chicago, IL, Sept. 16, 2019.
65. Shukla, S., Thomas, S., Hammell, D., Bunge, A., Hassan, H., and Stinchcomb, A. *Impact of Operator Variability on the Reproducibility of Tape Stripping Results*. Presentation at Gordon Research Conference. Barcelona, Spain, Aug. 12, 2019.
66. Singh, N. *A Predictive Multiscale Computational Tool for Simulation of Lung Absorption and Pharmacokinetics and Optimization of Pulmonary Drug Delivery*. Presentation at 2018 American Conference on Pharmacometrics (ACoP) 9 Meeting. San Diego, CA, Oct. 10, 2018.
67. Sinner, F. *In-Vivo Skin PK Testing for New and Generic Topical Dermatological Drug Development*. Presentation at European Federation for Pharmaceutical Sciences. Frankfurt, Germany, Mar. 6, 2019.
68. Stavis, S.M., *A Multifunctional Microstructure for Microscope Calibration and Nanoparticle Characterization*. Conference on Electron, Ion, and Photon Beam Technology and Nanofabrication. Minneapolis, MN. May 29, 2019.
69. Tsakalozou, E. *Physiologically-based Pharmacokinetic Modeling and Simulation Approaches: Best Practices for Regulatory Applications Related to Locally-acting Generic Drugs.* Presentation at 2019 Small Business and Industry Assistance (SBIA), Complex Generic Drug Product Development Workshop. College Park, MD, Sept. 26, 2019.
70. Tsakalozou, E. *Physiologically-Based Pharmacokinetic Modeling for the Development of Dermatological Drug Products and Its Regulatory Impact*. Presentation at 2019 American Society for Clinical Pharmacology and Therapeutics (ASCPT), Pre-Conference: PBPK Modeling for the Development and Approval of Locally Acting Products. Washington, DC, Mar. 13, 2019.
71. Tyner, K. *Regulatory Research Supporting the Development of Drug Products Containing Nanomaterials: A US FDA Perspective*. Global Summit for Regulatory Science. Lago Maggiore, Italy. Sept. 25, 2019.
72. Urtti, A. *Bioequivalence Assessment for Complex Ophthalmic Products*. Presentation at AAPS Pharmsci 360. Washington, DC, Nov. 6, 2018.
73. Vince, B.D. *Nasal PK Study of Abuse-Deterrent Opioid Products Following Insufflation of Physically Manipulated Products.* Presentation at 2019 Annual Meeting, American Society for Clinical Pharmacology and Therapeutics (ASCPT). Washington, DC, Mar. 15, 2019.
74. Walenga, R. *Impact of Orally Inhaled and Nasal Drug Product PBPK Models on Product Development and Regulatory Decision Making*. Presentation at 2019 American Society for Clinical Pharmacology and Therapeutics (ASCPT), Pre-Conference: PBPK Modeling for the Development and Approval of Locally Acting Products., Washington, DC, Mar. 13, 2019.
75. Walenga, R. *Computational Fluid Dynamics Modeling of Nasally Administered Drug Products in Regulatory Science Research at the U.S. Food and Drug Administration*. Presentation at Society for Computational Fluid Dynamics of the Nose and Airway (SCONA) 2019. Chicago, IL, June 5, 2019.
76. Walenga, R. *Credibility Establishment for Computational Fluid Dynamics Models of*

Complex Generic Drug Delivery. Presentation at 2019 Small Business and Industry Assistance (SBIA), Complex Generic Drug Product Development Workshop. College Park, MD, Sept. 26, 2019.

77. Walenga, R. *Impact of Orally Inhaled and Nasal Drug Product PBPK Models on Product Development and Regulatory Decision Making*. Public Presentation (Unknown Location). Washington, DC, Mar. 13, 2019.
78. Walenga, R. *Role of Computational Fluid Dynamics and Physiologically-Based Pharmacokinetic Modeling in Development of Orally Inhaled and Nasal Drug Products*. Presentation at Design of Medical Devices Conference. Minneapolis, MN, Apr. 16, 2019.
79. Walenga, R.L. *Computational Fluid Dynamics Modeling of Nasally Administered Drug Products in Regulatory Science Research at The U.S. Food and Drug Administration.* Presentation at the 2019 Society for Computational Fluid Dynamics of the Nose and Airway (SCONA). Chicago, IL, Jun. 5, 2019.
80. Witzmann, K. *Comparative Analyses: Device and User Interface Considerations*. Presentation at 2019 Small Business and Industry Assistance (SBIA) Complex Generic Drug Product Development Workshop. College Park, MD, Sept. 26, 2019.
81. Witzmann, K. *Critical Importance of Excipients in Generic Product Development- Now and in the Future*. Public Presentation (Unknown Location). Edinburgh, Scotland, Dec. 13, 2018.
82. Wu, F. *Biopharmaceutics and Bioequivalence A day in Life*. Presentation at AAPS forum. Boston, Massachusetts, May. 6, 2019.
83. Zhang, D. Characterization and Comparative Evaluation Strategies to Demonstrate Complex API Sameness. Presentation at 2019 Small Business and Industry Assistance (SBIA) Workshop. College Park, MD, Sept. 25, 2019.
84. Zhao, L. *Craft the Art of Using Quantitative Methods and Modeling for Drug Development.* Presentation at 2018 Annual Meeting for Professional Committee of Pharmacometrics. Changsha, China, Nov. 17, 2018.
85. Zhao, L. *Overview of GDUFA-funded Modeling and Simulation Grants/Contracts.* Presentation at 2018 American Conference on Pharmacometrics (ACoP) 9 Meeting. San Diego, CA, Oct. 10, 2018
86. Zhao, L. *General Overview: The Use of Quantitative Methods and Modeling to Facilitate Generic Drug Development and Regulatory Assessment*. Presentation at 2019 Small Business and Industry Assistance (SBIA) Workshop. College Park, MD, Sept. 25, 2019.
87. Zhao, L. *Quantitative Analysis of Opioid ADF PK/ PD*. Presentation at 2019 Annual Meeting, American Society for Clinical Pharmacology and Therapeutics (ASCPT), Science at Sunrise Session. Washington, DC, Mar. 15, 2019.
88. Zhao, L. *Review of Quantitative Modelling of Complex Products*. Presentation at Workshop on Quantitative Evaluation of the Quality of Inhalable Products. Beijing, China, Nov. 28, 2018.