Presentations Relating to GDUFA Science and Research in Fiscal Year 2020

1. Al-Ghabeish, M. *Formulation Challenges Facing Naloxone Intranasal Solution*. Presentation at American Association of Pharmaceutical Scientists (AAPS) 2019 PharmSci 360. San Antonio, TX, Nov. 5, 2019.
2. Arora, S. *Biopharmaceutic in Vitro In Vivo Extrapolation (IVIV_E) Informed PBPK Model of Ritonavir Norvir Tablet Absorption in Humans Under Fasted and Fed Conditions*. Presentation at Simcyp Consortium Members Webinar. Jun. 18, 2020.
3. Arora, S*. Formulation Drug Product Quality Attributes Additions in Dermal PBPK Model*. Presentation at the 10th Annual Simcyp Virtual Seminar. Webinar, Oct. 24, 2019.
4. Arora, S. *Modeling Dermal Drug Absorption from Complex Semisolid Formulations: Insights from Multi-Phase, Multi-Layer MechDerm A Model*. Presentation at the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI) and FDA Co-Sponsored Topical Drug Development: Evolution of Science and Regulatory Policy II Workshop. Virtual Meeting, Jul. 23, 2020.
5. Arora, S., Patel, N., Polak, S., Jamei, M., Tsakalozou, E., Ghosh, P., Alam, K., Liu, X., Namjoshi, S., Grice, J., Mohammed, Y., and Roberts, M. *Simulating the Effect of Propylene Glycol on Acyclovir (Zovirax Cream, 5%) Permeation Across the Skin Using a Physiologically Based Pharmacokinetic (PBPK) Model of In Vitro Flow-Through Skin Permeation*. Presentation at 2020 Controlled Release Society (CRS) Annual Meeting. Virtual Meeting, Jun. 29, 2020.
6. Babiskin, A. *Assessing Bioequivalence for Generic Extended Release Formulations.* Presentation at the American Professional Society of ADHD and Related Disorders (APSARD) 2020 Annual Meeting. Washington, DC, Jan. 18, 2020.
7. Bielski, E. *Advancements in In Vitro Studies for Alternative Bioequivalence (BE) Approaches to Comparative Clinical Endpoint BE Studies.* Presentation at CDER Small Business and Industry (SBIA) 2020 Regulatory Education for Industry (REdI): Advancing Innovative Science in Generic Drug Development Workshop. Virtual Meeting, Sept. 30, 2020.
8. Bielski, E., *The Effects of Formulation Factors and Actuator Design on Mometasone Furoate Metered Dose Inhaler In Vitro Aerosolization Performance.* Presentation at Respiratory Drug Delivery 2020 Conference. Virtual Meeting, Apr. 26, 2020.
9. Brown, J. *Real-World Data Approaches for Early Detection of Potential Safety and Effectiveness Signals for Generic Substitution: A Metoprolol Extended Release Case Study.* Presentation at American College of Clinical Pharmacology (ACCP) 2020 Virtual Journal Club. Orlando, FL, Mar. 12, 2020.
10. Burgess, D. *Development of IVIVCs for Complex Parenteral Products.* Presentation at 3rd Long-Acting Injectables & Implantables Conference. La Jolla, CA, Feb. 6, 2020.
11. Burgess, D. *In Vitro Release Testing and In Vitro In Vivo Correlation of PLGA Based Drugs: Challenges to Solutions.* Presentation at Equivalence of Complex Long Acting Drugs Workshop at 2020 Controlled Release Society (CRS) Annual Meeting. Virtual Workshop, Jul. 1-2, 2020.
12. Chazin H. *Postmarket Surveillance of Generic Drugs: Opportunities for GDUFA Research.* Presentation at FY2020 Generic Drug Regulatory Science Initiatives Public Workshop. Virtual Meeting, May 4, 2020.
13. Chen, X., Hooker, A., Nyberg, H., Karlsson, M., and Hooker, A. *Model-Based Bioequivalence Evaluation for Ophthalmic Products Using Model Averaging Approaches.* Presentation at American Conference on Pharmacometrics (ACoP10) Conference. Orlando, FL, Oct. 22, 2019.
14. Choe, S. *Keynote.* Presentation at FY2020 Generic Drug Regulatory Science Initiatives Public Workshop. Virtual Meeting, May 4, 2020.

15. Clarke, J. and Roberts, M. *Predicting Dermal Absorption in Diseased or Damaged Skin Using PBPK Modelling*. Presentation at Certara Simcyp Workshop. Princeton, NJ, Dec. 13, 2019.
16. Clarke, J. *Formulation Drug Product Quality Attributes Additions in Dermal PBPK Model*. Presentation at the 10th Annual Simcyp Virtual Seminar. Webinar, Oct. 24, 2019.
17. Dhapare, S., *The Effects of Formulation Factors and Actuator Design on Spray Pattern and Plume Geometry of Mometasone Furoate Metered Dose Inhalers.* Presentation at Respiratory Drug Delivery 2020 Conference. Virtual Meeting, Apr. 26, 2020.
18. Fang, L. *Data Analysis and Model-Based Bioequivalence Breakout Session*. Presentation at FY2020 Generic Drug Regulatory Science Initiatives Public Workshop. Virtual Meeting, May 4, 2020.
19. Fang, L. *Model-informed Drug Development for Long-acting Injectable Products.* Presentation at 2020 American College of Clinical Pharmacy (ACCP) Annual Meeting. Virtual Meeting, Sept. 21 - 23, 2020.
20. Feng, X. *Evaluation of Abuse-Deterrent Characteristics of Tablets Prepared via Hot-Melt Extrusion.* Presentation at 3rd Annual Extrusion End User Forum, Rutgers University, Piscataway, NJ, Oct. 31, 2019.
21. Garner, J. *Poly(lactide-co-glycolide) Semi-Solvent Separation: A Tale of Many Polymers in One.* Presentation at Equivalence of Complex Long Acting Drugs Workshop at 2020 Controlled Release Society (CRS) Annual Meeting. Virtual Meeting, Jul. 1-2, 2020.
22. Ghosh, P. *Non-Invasive Raman Spectroscopy-Based Bioequivalence Approaches*. Presentation at CDER Small Business and Industry (SBIA) 2020 Regulatory Education for Industry (REdI): Advancing Innovative Science in Generic Drug Development Workshop. Virtual Meeting, Sept. 30, 2020.
23. Ghosh, P., Luke, M., Tsakalozou, E., and Simamora, P. *Bioequivalence of Generic Topical Dermatological Drug Products*. Presentation at Association for Accessible Medicines (AAM): Generic + Biosimilar Medicines Conference (GBMC) 2019. Bethesda, MD, Nov. 6, 2019.
24. Golshahi, L. *Pathways to Establish Bioequivalence and Facilitate Development of Innovative and Generic Intranasal Drug Delivery Products: In Vitro Anatomically Correct Nasal Models*. Presentation at 3rd Annual Inhalation & Respiratory Drug Delivery. Webinar, Sept. 30, 2020.
25. Golshahi, L., Manniello, M., Hosseini, S., Alfaifi, A., Schuman, T., Hindle, M., Longest, W., and Sandell, D. *In Vitro Bioequivalence Testing of Nasal Sprays Using Multiple Anatomically Correct Nasal Airway Models*. Presentation at Respiratory Drug Delivery 2000 Conference. Virtual Meeting, Apr. 26, 2020.
26. Gomeni, R. *Drug-Disease Modeling Approach to Describe the Relationship Between Long-Acting Methlyphenidate Exposure and Clinical Response.* Presentation at the American Professional Society of ADHD and Related Disorders (APSARD) 2020 Annual Meeting. Washington, DC, Jan. 18, 2020.
27. Gong, X. *Alternatives to F2 Testing for Dissolution Similarity – F2 Bootstrapping and Multivariate Statistical Distance (MSD) Method*. Presentation at CDER Small Business and Industry (SBIA) 2020 Regulatory Education for Industry (REdI): Advancing Innovative Science in Generic Drug Development Workshop. Virtual Meeting, Sept. 30, 2020.
28. Guo, C. *Developing and Validating Advanced Microscopy Methods for Supporting Complex Product Equivalence.* Presentation at CDER Small Business and Industry (SBIA) 2020 Regulatory Education for Industry (REdI): Advancing Innovative Science in Generic Drug Development Workshop. Virtual Meeting, Sept. 29, 2020.
29. Hamadeh, A. *A Workflow for Mechanistic Dermal Model Optimization and In vitro-In vivo Inference.* Presentation at the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI) and FDA Co-Sponsored Topical Drug Development: Evolution of Science and Regulatory Policy II Workshop. Virtual Meeting, Jul. 23, 2020.

30. Han, L. *The Potential of Pharmacokinetic Bioequivalence (BE) Studies in Detecting Regional Deposition with Orally Inhaled Drug Products*. Presentation at CDER Small Business and Industry (SBIA) 2020 Regulatory Education for Industry (REdI): Advancing Innovative Science in Generic Drug Development Workshop. Virtual Meeting, Sept. 30, 2020.
31. Hochhaus, G. *Dissolution Methods for Orally Inhaled Drug Products*. Presentation at United States Pharmacopoeial (USP) 2019 Workshop. Bethesda, MD, Dec. 12, 2019.
32. Hochhaus, G. *In Vitro Testing - Predictive of In Vivo Performance of OIDPs.* Presentation at American Association of Pharmaceutical Scientists (AAPS) and The European Federation for Pharmaceutical Sciences (EUFEPS), FDA Co-Sponsored Global Bioequivalence Harmonization Initiative (GBHI): 4th International Workshop. Bethesda, MD, Dec. 13, 2019.
33. Hochhaus, G. *Precilinical Models for Pulmonary Delivery*. Presentation at American Association of Pharmaceutical Scientists (AAPS) 2019 Pharmsci360. San Antonio, TX, Nov. 6, 2019.
34. Hochhaus, G., *Unraveling the Pulmonary Fate of Fluticasone and Friends: Meeting the Physiologic and Pharmacokinetic Challenge.* Presentation at Respiratory Drug Delivery 2020 Conference. Virtual Meeting, Apr. 26, 2020.
35. Hooker, A., Nyberg, H., Karlsson, M., and Chen, X. *Development and Comparison of Model-Based Bioequivalence Analysis Methods on Sparse Data.* Presentation at American Conference on Pharmacometrics (ACoP10) Conference. Orlando, FL, Oct. 22, 2019.
36. Hu, M. *Quantitative Methods for Determining Equivalence of Particle Size Distributions.* Presentation at CDER Small Business and Industry (SBIA) 2020 Regulatory Education for Industry (REdI): Advancing Innovative Science in Generic Drug Development Workshop. Virtual Meeting, Sept. 29, 2020.
37. Jiang, W. *Bioequivalence Assessment for Long-Acting Injectables (LAIs) - FDA Regulatory Perspectives.* Presentation at American Association of Pharmaceutical Scientists (AAPS) and The European Federation for Pharmaceutical Sciences (EUFEPS), FDA Co-Sponsored Global Bioequivalence Harmonization Initiative (GBHI): 4th International Workshop. Bethesda, MD, Dec. 12, 2019.
38. Jiang, W. *Complex Drug Product Landscape*. Presentation at Product Quality Research Institute Biopharmaceutical Technical Committee 2020 Webinar Series. Webinar, Apr. 28, 2020.
39. Kakhi, M. *Prediction of Respimat, Inhaler Spray: Co-Flow Air Behavior*. Presentation at 15th Openfoam Workshop. Arlington, VA, Jun. 25, 2020.
40. Kozak, D. *GDUFA Regulatory Science Research on In Vitro Bioequivalence Methods*. Presentation at FY2020 Generic Drug Regulatory Science Initiatives Public Workshop. Virtual Meeting, May 4, 2020.
41. Kozak, D. *Navigating Formulation Assessments: From General Q1/Q2 Inquiries to Supporting Complex Excipient Sameness.* Presentation at CDER Small Business and Industry (SBIA) 2020 Regulatory Education for Industry (REdI): Advancing Innovative Science in Generic Drug Development Workshop. Virtual Meeting, Sept. 29, 2020.
42. Kozak, D., Cai, B., and Babiskin, A. *Complex Generic Drug Products (CGDPs) with Complex Formulations Including Nanotechnology Products.* Presentation at Association for Accessible Medicines (AAM): Generic + Biosimilar Medicines Conference (GBMC) 2019. Bethesda, MD, Nov. 6, 2019.
43. Kuzma, B*. In-Vivo Flux: A Breakthrough in IVIVC of Topical Dermatological Formulations.* Presentation at American Association of Pharmaceutical Scientists (AAPS) 2019 PharmSci360. San Antonio, TX, Nov. 6, 2019.
44. Liao, K., Copeland, C., Myung, J., Kozak, D., and Stavis, S. *Liposomal Doxorubicin Under Microconfinement and Microscopy.* Presentation at American Association of Pharmaceutical Scientists (AAPS) 2019 PharmSci 360. San Antonio, TX, Nov. 5, 2019.

45. Lionberger, R. *Generics for Long-Acting Injectables: Building a Pathway to Success.* Presentation at 2020 Controlled Release Society (CRS) Annual Meeting. Virtual Meeting, Jul. 1, 2020.
46. Lionberger, R. *Update on GDUFA Science and Research.* Presentation at CDER Small Business and Industry (SBIA) 2020 Regulatory Education for Industry (REdI): Advancing Innovative Science in Generic Drug Development Workshop. Virtual Meeting, Sept. 29, 2020.
47. Lionberger, R. *Workshop Introduction.* Presentation at FY2020 Generic Drug Regulatory Science Initiatives Public Workshop. Virtual Meeting, May 4, 2020.
48. Lukacova, V. *What Does It Take to Develop a PBPK Model That Mimics In Vivo Behavior of LAIs.* Presentation at 3rd Long-Acting Injectables & Implantables Conference. La Jolla, CA, Feb. 6, 2020.
49. Luke, M. *Modernization and Harmonization of Bioequivalence Standards for Generic Topical and Transdermal Products.* Presentation at Association for Accessible Medicines (AAM): Generic + Biosimilar Medicines Conference (GBMC) 2019. Bethesda, MD, Nov. 6, 2019.
50. Luke, M.C. *Bioequivalence of Transdermal Systems*. Podium Presentation at AAPS/EUFEPS/FDA Co-sponsored Global Bioequivalence Harmonization Initiative (GBHI): 4th International Workshop. Bethesda, MD, Dec. 12, 2019.
51. Luke, M.C. *Drug-Device Combination Products Breakout Session*. Presentation at FY2020 Generic Drug Regulatory Science Initiatives Public Workshop. Virtual Meeting, May 4, 2020.
52. Meng, H. *Quantitative Methods for Determining Equivalence of Particle Size Distributions.* Presentation at CDER Small Business and Industry (SBIA) 2020 Regulatory Education for Industry (REdI): Advancing Innovative Science in Generic Drug Development Workshop. Virtual Meeting, Sept. 29, 2020.
53. Mentre, F., Loingeville, F., Rakez, M., Nguyen, T., Bertrant, J., Mollenhoff K., Dette, H., Sharan, S., Sun, G., Grosser, S., Zhao, L., and Fang, L. *Model-Based Statistical Approaches for Pharmacokinetic Bioequivalence Studies with Sparse Sampling and Extension to Two-Stage Designs.* Presentation at American Conference on Pharmacometrics (ACoP10) Conference. Orlando, FL, Oct. 22, 2019.
54. Nahid S. Kamal, Sarah Ibrahim, Celia N. Cruz, Muhammad Ashraf, Ahmed S. Zidan, *Development of a Novel In Vitro Model to Predict Risk of Skin-to-Skin Drug Transfer During Transdermal Hormonal Replacement Therapy*. Rapid-Fire Presentation at American Association of Pharmaceutical Scientists (AAPS) 2019 PharmSci 360. San Antonio, TX, Nov. 4, 2019.
55. Newman, B., Dhapare, S., Walenga, R., and Feng, K. *Addressing the Challenges with Orally Inhaled and Nasal Drug Products (OINDPs) Through the Pre-ANDA Meeting Process*. Podium Presentation at Generic + Biosimilar Medicines Conference (GBMC) 2019. Bethesda, MD, Nov. 6, 2019.
56. Pang, E. *Non-Clinical Evaluation of Comparative Immunogenicity Risk of Complex Peptide Products.* Presentation at CDER Small Business and Industry (SBIA) 2020 Regulatory Education for Industry (REdI): Advancing Innovative Science in Generic Drug Development Workshop. Virtual Meeting, Sept. 29, 2020.
57. Park, K. *PLGA Polymers: The Very Familiar Strangers in Drug Delivery.* Presentation at Equivalence of Complex Long Acting Drugs Workshop at 2020 Controlled Release Society (CRS) Annual Meeting. Virtual Meeting, Jul. 1-2, 2020.
58. Puttrevu, S. K. *PBPK Modeling of Transdermal Selegiline Disposition Discrepancy in Special Populations*. Presentation at American Association of Pharmaceutical Scientists (AAPS) 2019 Pharmsci360. San Antonio, TX, Nov. 4, 2019.
59. Qin, B. *Bioequivalence of Long Acting Injectable (LAI) Suspensions: Current Perspective and Future Directions.* Presentation at Equivalence of Complex Long Acting Drugs Workshop at 2020 Controlled Release Society (CRS) Annual Meeting. Virtual Meeting, Jul. 1-2, 2020.
60. Ramezanli, T. *In Vivo Dermal Microperfusion & Microdialysis Bioequivalence Approaches*. Presentation at CDER Small Business and Industry (SBIA) 2020 Regulatory Education for Industry

(REdI): Advancing Innovative Science in Generic Drug Development Workshop. Virtual Meeting, Sept. 30, 2020.

61. Raney, S. *A Generic Drugs Perspective on the Use of In Vitro Assessment Methods: Bridging Results from the Maximum Use Trials with Sunscreen Reformulations.* Presentation at New York Society of Cosmetic Chemists Meeting. Iselin, NJ, Jan. 29, 2020.
62. Raney, S. *Advances in Topical Bioequivalence Assessments: Characterization-Based Approaches.* Presentation at the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI) and FDA Co-Sponsored Topical Drug Development: Evolution of Science and Regulatory Policy II Workshop. Virtual Meeting, Jul. 23, 2020
63. Raney, S. *When Do Formulation Differences in Topical Dosage Forms Impact Their Function: Emerging Insights and Implications for Bioequivalence Approaches*. Presentation at CDER Small Business and Industry (SBIA) 2020 Regulatory Education for Industry (REdI): Advancing Innovative Science in Generic Drug Development Workshop. Virtual Meeting, Sept. 30, 2020.
64. Roberts, M. *Mathematical Modeling of Skin Absorption and Transport*. Presentation at American Association of Pharmaceutical Scientists (AAPS) Topical and Transdermal Free Webinar. Webinar, Feb. 7, 2020.
65. Schwendeman, S. *A Cage Model to Understand the Impact of Raw Materials on Formulation Performance In Vitro and In Vivo*. Presentation at Equivalence of Complex Long Acting Drugs Workshop at 2020 Controlled Release Society (CRS) Annual Meeting. Virtual Meeting, Jul. 1-2, 2020.
66. Sharan, S. *Model-Informed and Model-Integrated Approaches in BE Assessment of Long Acting Injectable Products.* Presentation at CDER Small Business and Industry (SBIA) 2020 Regulatory Education for Industry (REdI): Advancing Innovative Science in Generic Drug Development Workshop. Virtual Meeting, Sept. 30, 2020.
67. Sinner, F. *Use of Skin Pharmacokinetics (PK) & Pharmacodynamics (PD) in Drug Development.* Presentation at American Association of Pharmaceutical Scientists (AAPS) Topical and Transdermal Free Webinar. Webinar, Jan. 10, 2020.
68. Spencer, T., Biederman, J., Faraone, S., Childress, A., Gomeni, R., Babiskin, A., and Fang, L. *Comparative, Crossover PD Study of Different Formulations of Extended Release MPH*. Presentation at the American Professional Society of ADHD and Related Disorders (APSARD) 2020 Annual Meeting. Washington, DC, Jan. 18, 2020.
69. Spires, J. *Computational Modeling of Absorption from Complex Topical Formulations*. Presentation at the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI) and FDA Co-Sponsored Topical Drug Development: Evolution of Science and Regulatory Policy II Workshop. Virtual Meeting, Jul. 23, 2020.
70. Tsakalozou E. *Bioequivalence of Generic Topical Dermatological Drug Products*. Presentation at Generic + Biosimilar Medicine Conference / Complex Product Workshop, Bethesda, MD, Nov. 2019.
71. Tsakalozou, E. *Physiologically-based Pharmacokinetic Modeling to Guide Study Design and Product Development for Generic Dermatological Products*. Presentation at CDER Small Business and Industry (SBIA) 2020 Regulatory Education for Industry (REdI): Advancing Innovative Science in Generic Drug Development Workshop. Virtual Meeting, Sept. 30, 2020.
72. Turner, D. *Exploiting Dual Solid State PBPK Tools to Assess the Bio(in)equivalence of Tacrolimus Amorphous Formulations with Various Degrees of Crystallization Arising During Storage*. Presentation at 8th IAPC Meeting. Split, Croatia. Sept. 11, 2019.
73. Turner, D. *Updates to the Simcyp Simulator's ADAM / M-ADAM Models*. SIMCYP webinar. Jan. 29, 2020.

74. Tyner, K. *Interplay of Voluntary Consensus Standards and Regulations: Opportunities and Lessons Learned: A US-FDA Perspective.* Presentation at American National Standards Institute (ANSI) Nanotechnology Standards Panel. Washington, DC, Oct. 16, 2019.
75. Tyner, K. *Regulatory Research Supporting the Development of Drug Products Containing Nanomaterials A US-FDA Perspective.* Presentation at The National Institute for Pharmaceutical Technology and Education (NIPTE) Annual Meeting. Washington, DC, Oct. 3, 2019.
76. Vitry, P., Maciel Tabosa, A., Belsey, N., Tsikritsis, D., Woodman, T., Bunge, A., Delgado-Charro, M., and Guy, R. *Assessing the Skin Pharmacokinetics of Topical Drugs, and the Bioequivalence of Topical Drug Products, Using Non-Invasive Techniques*. Presentation at Biological and Pharmaceutical Applications of CRS microscopy. Odense, Denmark, Dec. 3, 2019.
77. Walenga, R. *Bridging the Gap Between Regional Deposition and Systemic Pharmacokinetic Data of OINDPs with Modeling and Simulation*. Presentation at CDER Small Business and Industry (SBIA) 2020 Regulatory Education for Industry (REdI): Advancing Innovative Science in Generic Drug Development Workshop. Virtual Meeting, Sept. 30, 2020.
78. Walenga, R. *Role of Computational Fluid Dynamics and Physiologically-Based Pharmacokinetic Modeling in Development of Orally Inhaled and Nasal Drug Products.* Presentation at University of Texas-El Paso Student Seminar. El Paso, TX, May 11, 2020.
79. Wang, Y. *Bioequivalence of Polymeric Long Acting Drugs.* Presentation at Equivalence of Complex Long Acting Drugs Workshop at 2020 Controlled Release Society (CRS) Annual Meeting. Virtual Meeting, Jul. 1-2, 2020.
80. Wang, Y. *In Vitro Bioequivalence Methods Breakout Session*. Presentation at FY2020 Generic Drug Regulatory Science Initiatives Public Workshop. Virtual Meeting, May 4, 2020.
81. Wang, Y. *In Vitro Release Testing for Complex Generics: A Bioequivalence Perspective.* Presentation at CDER Small Business and Industry (SBIA) 2020 Regulatory Education for Industry (REdI): Advancing Innovative Science in Generic Drug Development Workshop. Virtual Meeting, Sept. 29, 2020.
82. Willett, D. R., Yang, Y. *In Vitro Characterizations of Topical and Transdermal Drug Products from the Product Quality Assessment Perspective*. Presentation at USP Workshop. Rockville, MD, Dec. 19, 2019.
83. Willett, D. R., Yilmaz, H., Wokovich, A. M., Zidan, A., Rodriguez, J. D., Keire, D. *Raman Mapping and Multivariate Image Analysis for Characterization of Transdermal Delivery Systems*. Presentation at Federation of Analytical Chemistry and Spectroscopy Societies (FACSS) SciX 2019. Palm Springs, CA, Oct. 19, 2019.
84. Willett, D. R., Yilmaz, H., Xi, W., Zidan, A., Yang, Y., and Rodriguez, J. D. *High Resolution Spectroscopic Imaging for Complex Pharmaceutical Dosage Forms*. Presentation at IFPAC Annual Meeting 2020, Bethesda, MD, Feb. 20, 2020.
85. Witzmann, K. *GDUFA Regulatory Science and Research on Generic Drug-Device Combination Products*. Presentation at FY2020 Generic Drug Regulatory Science Initiatives Public Workshop. Virtual Meeting, May 4, 2020.
86. Wu, F. *Application of PBPK Modeling in Regulatory Submission: FDA Experience on Generic Drugs*. Presentation at 2019 AAPS PharmSci360. San Antonio, Texas, Nov 6, 2019.
87. Wu, F. *Using Physiologically-Based Pharmacokinetic Absorption Modeling to Support Biopharmaceutics Classification System Class 3 Drug Waiver*. Presentation at CDER Small Business and Industry (SBIA) 2020 Regulatory Education for Industry (REdI): Advancing Innovative Science in Generic Drug Development Workshop. Virtual Meeting, Sept. 30, 2020.\
88. Xu, X. *Look & See: Innovative Research to Address Regulatory Challenges in Complex Ophthalmic Drug Products*. Presentation at 2020 Controlled Release Society (CRS) Annual Meeting. Virtual Meeting, Jun. 30, 2020.

89. Xu, X. *Developing and Validating Commonly Employed Particle Sizing Methods to Support Bioequivalence and Product Quality*. Presentation at CDER Small Business and Industry (SBIA) 2020 Regulatory Education for Industry (REdI): Advancing Innovative Science in Generic Drug Development Workshop. Virtual Meeting, Sept. 29, 2020.
90. Xu, X. *Regulatory Consideration and Research to Evaluate Abuse Deterrence Properties of Opioid Drug Products*. Presentation at NIPTE Research Conference, Crystal City, VA, October 2-4, 2019.
91. Yang, K. *Characterization and Quality Control of Synthetic Oligonucleotide Therapeutics by Mass Spectrometry: The Current and the Future*. Presentation at 68th ASMS Conference on Mass Spectrometry. Virtual Meeting, Jun. 1, 2020.
92. Zhang, D. *Considerations for Abbreviated New Drug Application of Generic Peptide Drug Products.* Presentation at TIDES US 2020 Workshop #3: FDA Draft Guidance on ANDA Filings for Peptides. Virtual Meeting, Sept. 15, 2020.
93. Zhang, D. *Considerations in Developing Generic Peptide and Oligonucleotide Drug Products.* Presentation at United States Pharmacopeia (USP) 2019 Workshop. Rockville, MD, Nov. 4, 2019.
94. Zhang, L. *Closing Remarks.* Presentation at CDER Small Business and Industry (SBIA) 2020 Regulatory Education for Industry (REdI): Advancing Innovative Science in Generic Drug Development Workshop. Virtual Meeting, Sept. 30, 2020.
95. Zhang, L. *Newly Approved Complex Drug Products and Potential Challenges to Generic Drug Development.* Presentation at FY2020 Generic Drug Regulatory Science Initiatives Public Workshop. Virtual Meeting, May 4, 2020.
96. Zhang, Y. *Biopharmaceutics Classification System Class 3 Waiver*. Presentation at CDER Small Business and Industry (SBIA) 2020 Regulatory Education for Industry (REdI): Advancing Innovative Science in Generic Drug Development Workshop. Virtual Meeting, Sept. 30, 2020.
97. Zhao, L. *FEV1 Based Bioequivalence Study for Inhaled Corticosteroids*. Presentation at AAPS/EUFEPS/FDA Co-Sponsored Global Bioequivalence Harmonization Initiative (GBHI): 4th International Workshop. Bethesda, MD, Dec. 12, 2019.
98. Zhao, L. *Generating Model-Integrated Evidence for Developing & Approving Complex Generic LAI Products.* Presentation at 2020 American College of Clinical Pharmacy (ACCP): Applying Pharmaceutics Precision Dosing in the Lifecycle of Long-Acting Injectable Products: Drug Development, Regulatory Approval & Clinical Practice. Virtual Workshop, Sept. 21, 2020.
99. Zhao, L. *Leveraging Modeling and Simulation to Make Regulatory Impacts for Long-Acting Generic Drug Approvals.* Presentation at Equivalence of Complex Long Acting Drugs Workshop at 2020 Controlled Release Society (CRS) Annual Meeting. Virtual Meeting, Jul. 2, 2020.
100. Zhao, L. *Quantitative Methods and Modeling to Support GDUFA Regulatory Science Research Program*. Presentation at FY2020 Generic Drug Regulatory Science Initiatives Public Workshop. Virtual Meeting, May 4, 2020.
101. Zhao, L. *Regulatory Challenges and Opportunities for Model-Based Approaches for Patient Pharmacokinetic (PK) Studies with Sparse Sampling Design*. Presentation at American Conference on Pharmacometrics (ACoP10) Conference. Orlando, FL, Oct. 22, 2019.
102. Zidan, A. *Risk Assessment of Drug Recrystallization in Transdermal Delivery System*. Presentation at American Association of Pharmaceutical Scientists (AAPS) 2019 PharmSci 360, San Antonio, TX, Nov. 5, 2019.