Presentations Relating to GDUFA Science and Research in Fiscal Year 2021

1. Ajjarapu S. *Impact of Fractional Solubility on Drug Permeation from Topical Formulations.* Presentation at The American Association of Pharmaceutical Scientists (AAPS) PharmSci 360. Virtual Meeting, Nov. 04, 2020.
2. Ajjarapu S. *Influence of Metamorphosis on the Performance of Topical Formulations.* Presentation at The American Association of Pharmaceutical Scientists (AAPS) Topical and Transdermal Community. Virtual Meeting, Mar. 26, 2021.
3. Alam K, and Tsakalozou E. *Challenges and Considerations with Model-based Virtual Bioequivalence Assessments for Generic Dermatological Products, Part 2.* Presentation at the 2021 Small Business and Industry (SBIA) Workshop. Virtual Meeting, Sep. 22, 2021.
4. Alam K. *Research Overview and Regulatory Experience on Mechanistic Modeling for Generic Dermatological Drug Products.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop: Regulatory Utility of Mechanistic Modeling to Support Alternative Bioequivalence Approaches. Virtual Meeting, Sep. 30, 2021.
5. Al-Ghabeish M. *Advancement in the In-Vitro Evaluation of Abuse-Deterrent Formulations for Opioid Analgesics: Research and Assessment Perspectives.* Presentation at the 2021 Small Business and Industry (SBIA) Workshop. Virtual Meeting, Sep. 21, 2021.
6. Al-Ghabeish M. *Advancement in the In-Vitro Evaluation of Abuse-Deterrent Formulations for Opioid Analgesics: Research and Assessment Perspectives.* Presentation at the 2021 Small Business and Industry (SBIA) Workshop. Virtual Meeting, Sep. 22, 2021.
7. Arora S. *Integrating Topical Drug Product Quality Attributes Within Physiologically-based Pharmacokinetic Models.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) PharmSci 360 Webinar. Virtual Meeting, Oct. 24, 2020.
8. Arora S. *Modeling Derma Drug Absorption from Complex Semisolid Formulations: Insights from Multi-Phase, Multi-Layer MechDermA Model.* Presentation at The American Association of Pharmaceutical Scientists (AAPS) Topical and Transdermal Community. Virtual Meeting, Feb. 26, 2021.
9. Arora S. *Modeling Dermal Drug Absorption from Complex Semisolid Formulations: Insights from Multi-Phase, Multi-Layer MechDermA Model.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) Topical and Transdermal Community. Virtual Meeting, Feb. 26, 2021.
10. Babiskin A. *Regulatory Perspective: Challenges and Opportunities to Enhance Model Sharing upon Regulatory Use.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop: Regulatory Utility of Mechanistic Modeling to Support Alternative Bioequivalence Approaches. Virtual Meeting, Sep. 30, 2021.
11. Bajaj R. *Screening Oral Excipients against P-glycoprotein.* Presentation at the 4th International Conference on Applied Biochemistry and Biotechnology (ABB) 2021. Virtual Meeting, Aug. 11, 2021.
12. Ballard B. *Device Considerations from User Interface Perspective: Comparative Analyses.* Presentation at the 2020 Association for Accessible Medicines (AAM): GRx+Biosims Conference. Virtual Meeting, Nov. 10, 2020.
13. Belsey N. *Imaging Formulated Product Performance Using Optical Spectroscopy.* Presentation at the UK Surface Analysis Forum (UKSAF) Meeting. Virtual Meeting, Jan. 05, 2021.
14. Bielski E. *The Impact of Actuator Device Design on Metered Dose Inhaler (MDI) In Vitro Performance.* Presentation at the 2020 Association for Accessible Medicines (AAM): GRx+Biosims Conference. Virtual Meeting, Nov. 09, 2020.

15. Boc S. *Product-Specific Considerations for Alternative Bioequivalence (BE) Approaches to Comparative Clinical Endpoint BE Studies.* Presentation at the 2021 Small Business and Industry (SBIA) Workshop. Virtual Meeting, Sep. 22, 2021.
16. Boyce H. *Establishing Bioequivalence for "Additional Strengths" of Oral Modified-Release Drug Products.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) Pharmsci 360. Virtual Meeting, Oct. 28, 2020.
17. Boyce H. *Pharmacokinetics of Milled Oxycodone Hydrochloride Tablet Products Following Nasal Insufflation in Nondependent, Recreational Opioid Users.* Presentation at the National Institute for Pharmaceutical Technology and Education Annual Scientific Conference. Virtual Meeting, Dec. 09, 2020.
18. Chang R. *Quality Considerations for Injectable Drug-Device Combination Products in Abbreviated New Drug Applications (ANDAs).* Presentation at the 2020 Association for Accessible Medicines (AAM): GRx+Biosims Conference. Virtual Meeting, Nov. 10, 2020.
19. Chopra P. *Challenges in the Approval of Complex Otic & Ophthalmic Generic Products: Quality Perspectives.* Presentation at the 2021 Small Business and Industry Assistance (SBIA) Workshop, Advancing Generic Drug Development: Translating Science to Approval. Virtual Meeting, Sep. 21, 2021.
20. Conti D. *Considerations for Pre-ANDA Meeting Requests and Case Scenario Setup: Device Constituent of Hypothetical BREATHEATOL Drug Product.* Presentation at the 2020 Association for Accessible Medicines (AAM): GRx+Biosims Conference. Virtual Meeting, Nov. 10, 2020.
21. Conti D. *Device Considerations for Pre-ANDA Meeting Requests for Complex Drug-Device Combination Products.* Presentation at the 2020 Association for Accessible Medicines (AAM): GRx+Biosims Conference. Virtual Meeting, Nov. 09, 2020.
22. Conti D. *Emerging Concepts and New Technologies for Bioequivalence of Orally Inhaled and Nasal Drug Products.* Presentation at the American Thoracic Society (ATS) International Conference. Virtual Meeting, May. 14, 2021.
23. Conti D. *Introduction to Session 4: Device Considerations for Complex Drug-Device Combination Products.* Presentation at the 2020 Association for Accessible Medicines (AAM): GRx+Biosims Conference. Virtual Meeting, Nov. 10, 2020.
24. Dhapare S, Newman B, Svensson M, Elfman P, Sandell D, Winner L, Bulitta J, and Hochhaus G. *Factors Influencing Plume Characteristics of Metered Dose Inhalers (MDIs) Following Passage through Bio-relevant Mouth-Throat Models.* Presentation at the Respiratory Drug Delivery (RDD) 2021 Virtual Conference. Virtual Meeting, May. 04, 2021.
25. Dhapare S. *Demonstrating Bioequivalence with Inhalation Spray Drug Products.* Presentation at the 2021 Small Business and Industry (SBIA) Workshop. Virtual Meeting, Sep. 22, 2021.
26. Evans C. *Imaging and Quantifying Topical Drug Uptake in Human Tissue.* Presentation at the Society of Photo-Optical Instrumentation Engineers (SPIE) Photonics West 2021. Virtual Meeting, Mar. 06, 2021.
27. Evans C. *Multiphoton Chemical Imaging to Assess Dermal Pharmacokinetics and Pharmacodynamics.* Presentation at the Society of Photo-Optical Instrumentation Engineers (SPIE) Photonics West 2021. Virtual Meeting, Mar. 06, 2021.
28. Evans C. *SRS Pharmacokinetic Tomography.* Presentation at the Great Scientific Exchange (SCIX) 2021. Virtual Meeting, Sep. 26, 2021.
29. Feng K. *Applications and Lessons Learned for Conducting Adaptive Designs in Generic Drug Development.* Presentation at the 2021 Small Business and Industry (SBIA) Workshop. Virtual Meeting, Sep. 21, 2021.
30. Frost M. *Product-Specific Guidance Fundamentals from a Clinical Perspective.* Presentation at the 2021 Small Business and Industry (SBIA) Webinar. Virtual Meeting, May. 05, 2021.

31. Frost M. *Protecting Participants in Bioequivalence Studies for Abbreviated New Drug Applications During the COVID-19 Public Health Emergency.* Presentation at the 2021 Small Business and Industry (SBIA) Workshop. Virtual Meeting, Sep. 21, 2021.
32. Ghosh P. *Advanced Technologies and Evolving Paradigms: Characterization of Topical Semisolid Dosage Forms.* Presentation at the Innovations in Dermatological Sciences Annual Conference 2021. Virtual Meeting, Sep. 29, 2021.
33. Ghosh P. *Evaluation of Cutaneous Pharmacokinetics The Past, The Present, and The Future.* Presentation at the Society of Photo-Optical Instrumentation Engineers (SPIE) Photonics West 2021. Virtual Meeting, Mar. 06, 2021.
34. Ghosh P. *Panel Discussion: IVPT Data Challenges and Statistical Analysis.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop: In Vitro Release Test (IVRT) and In Vitro Permeation Test (IVPT) Methods: Best Practices and Scientific Considerations for ANDA Submissions. Virtual Meeting, Aug. 18, 2021.
35. Ghosh P. *Theoretical Principles and Best Practices In Vitro Permeation Testing (IVPT).* Presentation at the 2021 Small Business and Industry (SBIA) Workshop. Virtual Meeting, Sep. 22, 2021.
36. Ghosh P. *Towards Building a Dermal Model for BE Assessment: The Role of Drug Product Characterization & Performance Data.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop: Regulatory Utility of Mechanistic Modeling to Support Alternative Bioequivalence Approaches. Virtual Meeting, Sep. 30, 2021.
37. Gong Y. *Alternative BE Approaches for Data Analysis Due To COVID-19 Related Study Interruptions.* Presentation at the 2021 Small Business and Industry (SBIA) Workshop. Virtual Meeting, Sep. 21, 2021.
38. Guy R. *Prediction, Assessment and Optimisation of Drug Delivery into and through the Skin.* Presentation at the Leo Foundation Center for Cutaneous Drug Delivery. Virtual Meeting, Mar. 01, 2021.
39. Hochhaus G, and Bulitta J. *Pharmacokinetic Comparison of Locally Acting Nasal Suspension Spray Products.* Presentation at the DIA/FDA Complex Generic Drug-Device Combination Products Conference 2020. Virtual Meeting, Oct. 19, 2020.
40. Hochhaus G. *Dissolution Methodologies.* Presentation at the 2021 International Society for Aerosols in Medicine (ISAM) Conference. Virtual Meeting, May. 25, 2021.
41. Hu M. *Development of a Data/Text Analytics Tool to Enhance Quality and Efficiency of Bioequivalence Assessment.* Presentation at the FDA Science Forum. Virtual Meeting, May. 26, 2021.
42. Hu M. *Utility of Artificial Intelligence to Facilitate the Development and Regulatory Assessment of Complex Generic Drugs.* Presentation at the 2021 Small Business and Industry (SBIA) Workshop. Virtual Meeting, Sep. 21, 2021.
43. Ince I, and Dallmann A. *Predictive Performance of PBPK Dose Estimates for Pediatric Trials.* Presentation at the M-CERSI "Pediatric Dose Selection" Conference. Virtual Meeting, Oct. 22, 2020.
44. Jiang W. *Advances in Iron Colloid Products: Product-Specific Guidance Discussion.* Presentation at the 2021 Small Business and Industry (SBIA) Workshop. Virtual Meeting, Sep. 21, 2021.
45. Jiang W. *Complex Drug Products Containing Nanomaterials.* Presentation at the 12th European Foundation for Clinical Nanomedicine Annual Summit. Virtual Meeting, Oct. 27, 2020.
46. Jiang W. *FDA Bioequivalence Standards.* Presentation at the 2021 Pharmaceutical Outcomes & Policy Seminar. Virtual Meeting, Mar. 06, 2021.
47. Jiang W. *Global Bioequivalence Requirements for Orally Inhaled Drug Products (OIDPs).* Presentation at The American Association of Pharmaceutical Scientists (AAPS) Bay Lung Therapeutics Symposium. Virtual Meeting, Jul. 29, 2021.

48. Jiang W. *Liposome Guidance.* Presentation at the Nanotechnology Task Force NanoDay. Virtual Meeting, Oct. 09, 2020.
49. Kelchen M. *"No Difference" Standard vs. Q1/Q2 Sameness for Topical Drug Products.* Presentation at the 2021 Small Business and Industry (SBIA) Workshop. Virtual Meeting, Sep. 22, 2021.
50. Kelchen M. *An FDA Perspective on the Comparative Analyses of Critical Material, Quality, and Design Attributes for Topical, Transdermal, Rectal, and Vaginal Drug-Device Combination Products.* Presentation at the DIA/FDA Complex Generic Drug-Device Combination Products Conference 2020. Virtual Meeting, Oct. 20, 2020.
51. Kim M. *Non-Complex Drug Products and Product-Specific Guidances.* Presentation at the 2021 Small Business and Industry (SBIA) Webinar. Virtual Meeting, May. 05, 2021.
52. Kozak D. *Advanced Analytical Methods in Generic Drug Development and Approval.* Presentation at the Controlled Release Society (CRS) Annual Meeting. Virtual Meeting, Jul. 25, 2021.
53. Kozak D. *Ophthalmic Generic Drug Development and Approval: Challenges and Recent Research.* Presentation at the FDA Webinar on Complex Ophthalmic Formulations. Virtual Meeting, Aug. 05, 2021.
54. Kuzma B. *Recent Advancements in Dermal Microdialysis to Assess Topical Bioavailability and Bioequivalence.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) Topical Transdermal Community Webinar. Virtual Meeting, Apr. 30, 2021.
55. Le C. *Overview of the FDA Product-Specific Guidance (PSG) Program.* Presentation at the 2021 Small Business and Industry (SBIA) Webinar. Virtual Meeting, May. 05, 2021.
56. Lee J. *Quantitative Methods and Modeling to Support Bioequivalence Evaluation of Orally Inhaled and Nasal Drug Products (OINDPs).* Presentation at the 2020 Association for Accessible Medicines (AAM): GRx+Biosims Conference. Virtual Meeting, Nov. 10, 2020.
57. Li Y. *Advances in Iron Colloid Products: Quality Considerations When Conducting Comparability Studies.* Presentation at the 2021 Small Business and Industry Assistance (SBIA) Workshop, Advancing Generic Drug Development: Translating Science to Approval. Virtual Meeting, Sep. 21, 2021.
58. Lionberger R. *Introductory Remarks.* Presentation at the Non-clinical Immunogenicity Assessment of Generic Peptide Products: Development, Validation, and Sampling Workshop. Virtual Meeting, Jan. 26, 2021.
59. Liu X, Sulaiman M, Kolehmainen J, Ozel A, and Sundaresan S. *Modeling Complex Particle Interactions in Dry Powder Inhaler.* Presentation at the 2020 Virtual American Institute of Chemical Engineer (AIChE) Meeting. Virtual Meeting, Nov. 20, 2020.
60. Longest W, and Dutta R. *Case Study: Predicting Regional Lung Deposition of Pharmaceutical Aerosols with CFD.* Presentation at the "FDA and the Center for Research on Complex Generics (CRCG) Workshop: Regulatory Utility of Mechanistic Modeling to Support Alternative Bioequivalence Approaches". Virtual Meeting, Sep. 30, 2021.
61. Luke M. *Product-Specific Guidances for Complex Generic Drugs.* Presentation at the 2021 Small Business and Industry (SBIA) Webinar. Virtual Meeting, May. 05, 2021.
62. Murthy N. *Role of Excipients in Dermal and Transdermal Delivery of Drugs.* Presentation at the Controlled Release Society (CRS) Annual Meeting. Virtual Meeting, Jul. 25, 2021.
63. Newman B. *Overview of Complex Generic Inhalation and Nasal Drug-Device Combination Products.* Presentation at the DIA/FDA Complex Generic Drug-Device Combination Products Conference 2020. Virtual Meeting, Oct. 19, 2020.
64. Newman B. *Overview of Complex Generic Orally Inhaled Drug Products.* Presentation at the 2021 PBPK Public Workshop. Virtual Meeting, Sep. 30, 2021.

65. Pang E, and Vertheryi D. *Overview: Non-clinical Immunogenicity Assessment of Generic Peptide Products.* Presentation at the Non-clinical Immunogenicity Assessment of Generic Peptide Products: Development, Validation, and Sampling Workshop 2021. Virtual Meeting, Jan. 26, 2021.
66. Qin B. *Injectable Suspensions: Tools and Methods Bridging The In Vivo and In Vitro Gap.* Presentation at the 2021 Small Business and Industry (SBIA) Workshop. Virtual Meeting, Sep. 21, 2021.
67. Ramezanli T. *Development of Efficient Alternative Bioequivalence Approaches for Topical Dermatological Drug Products.* Presentation at the Innovations in Dermatological Sciences Annual Conference 2021. Virtual Meeting, Sep. 29, 2021.
68. Ramezanli T. *IVRT Method Development, Validation, and Transfer Theoretical Principles and Practical Challenges.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop: In Vitro Release Test (IVRT) and In Vitro Permeation Test (IVPT) Methods: Best Practices and Scientific Considerations for ANDA Submissions. Virtual Meeting, Aug. 18, 2021.
69. Ramezanli T. *Theoretical Principles and Best Practices In Vitro Release Testing (IVRT).* Presentation at the 2021 Small Business and Industry (SBIA) Workshop. Virtual Meeting, Sep. 22, 2021.
70. Raney S. *In Vitro Permeation Test (IVPT) Fundamentals: Scientific and Practical Considerations.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop: In Vitro Release Test (IVRT) and In Vitro Permeation Test (IVPT) Methods: Best Practices and Scientific Considerations for ANDA Submissions. Virtual Meeting, Aug. 18, 2021.
71. Raney S. *In Vitro Release Test (IVRT) Fundamentals: Scientific and Practical Considerations.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop: In Vitro Release Test (IVRT) and In Vitro Permeation Test (IVPT) Methods: Best Practices and Scientific Considerations for ANDA Submissions. Virtual Meeting, Aug. 18, 2021.
72. Raney S. *Overview of Breakout Session on Topical Drug Products: Workshop on Complex Generic Drug Products (CGDPs).* Presentation at the 2020 Association for Accessible Medicines (AAM): GRx+Biosims Conference. Virtual Meeting, Nov. 10, 2020.
73. Raney S. *Physicochemical, Structural, and Performance Characterization of Topical Semisolid Products.* Presentation at the Florida Chapter Society of Cosmetic Chemists Sunscreen Symposium 2021. Virtual Meeting, Sep. 25, 2021.
74. Raney S. *Use of Q3 Characterization Tests for Topical Semisolid Drug Products.* Presentation at the 2021 Small Business and Industry (SBIA) Workshop. Virtual Meeting, Sep. 22, 2021.
75. Rantou E. *Statistical Considerations in Assessing BE of IVPT Data.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop: In Vitro Release Test (IVRT) and In Vitro Permeation Test (IVPT) Methods: Best Practices and Scientific Considerations for ANDA Submissions. Virtual Meeting, Aug. 18, 2021.
76. Raofi S. *Nasal Pharmacokinetic Study of Abuse-Deterrent Oxycodone HCl ER Products Following Insufflation of Physically Manipulated Products.* Presentation at the 2021 Small Business and Industry (SBIA) Workshop. Virtual Meeting, Sep. 21, 2021.
77. Sarago C. *GDUFA II: Pre-ANDA Program and Meetings for Complex Generic Products.* Presentation at the 2021 Small Business and Industry (SBIA) Generic Drug Forum. Virtual Meeting, Apr. 28, 2021.
78. Sharan S. *Long-Acting Complex Generic Drug Products with Nanotechnology.* Presentation at the 2020 Association for Accessible Medicines (AAM): GRx+Biosims Conference. Virtual Meeting, Nov. 10, 2020.
79. Spires J. *PBPK Modeling of Dermal Penetration from Topical Formulations.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop: Regulatory Utility of Mechanistic Modeling to Support Alternative Bioequivalence Approaches. Virtual Meeting, Sep. 30, 2021.

80. Stinchcomb A. *IVPT Studies with Topical and Transdermal Products.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop: In Vitro Release Test (IVRT) and In Vitro Permeation Test (IVPT) Methods: Best Practices and Scientific Considerations for ANDA Submissions. Virtual Meeting, Aug. 18, 2021.
81. Sulaiman M, Liu X, Kolehmainen J, Ozel A, and Sundaresan S. *Powder Fluidization in Dry Powder Inhalers.* Presentation at the American Institute of Chemical Engineer (AIChE) Meeting. Virtual Meeting, Nov. 20, 2020.
82. Sun W, and Wang R. *Generic Oral Modified Release Drug Products: Establishing Bioequivalence for Additional Strengths.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) Seminar. Virtual Meeting, Dec. 10, 2020.
83. Tabosa A. *Assessing Topical Drug Bioavailability in the Skin Using Raman Spectroscopy.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) PharmSci 360. Virtual Meeting, Nov. 04, 2020.
84. Tan M. *GDUFA Research Update on Mechanistic Modeling Approaches for Generic Ophthalmic, Nasal, Implant and Injectable Drug Products.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop: Regulatory Utility of Mechanistic Modeling to Support Alternative Bioequivalence Approaches. Virtual Meeting, Sep. 30, 2021.
85. Tan M. *Physiologically-based Pharmacokinetic Modeling to Support Generic Ophthalmic Product Development and Regulatory Decision Making.* Presentation at the 2021 Small Business and Industry (SBIA) Workshop. Virtual Meeting, Sep. 21, 2021.
86. Tsakalozou E, and Alam K. *Challenges and Considerations with Model-based Virtual Bioequivalence Assessments for Generic Dermatological Products, Part 1.* Presentation at the 2021 Small Business and Industry (SBIA) Workshop. Virtual Meeting, Sep. 22, 2021.
87. Tsakalozou E. *Scientific and Regulatory Considerations on Dermal PBPK Modeling for Virtual Bioequivalence Assessments and Decision-making.* Presentation at the 2021 PBPK Public Workshop. Virtual Meeting, Sep. 30, 2021.
88. Walenga R. *Abbreviated New Drug Application (ANDA) and Pre-ANDA Experience with Orally Inhaled Drug Product (OIDP) Modeling.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop: Regulatory Utility of Mechanistic Modeling to Support Alternative Bioequivalence Approaches. Virtual Meeting, Sep. 30, 2021.
89. Walenga R. *Computational Fluid Dynamics (CFD) Modeling for Optimization of Device Design and Understanding of Product Performance.* Presentation at the 2020 Association for Accessible Medicines (AAM): GRx+Biosims Conference. Virtual Meeting, Nov. 10, 2020.
90. Walenga R. *In Silico and Experimental Methods to Support Generic Nasal Drug Product (NDP) Development.* Presentation at the Respiratory Drug Delivery (RDD) 2021 Virtual Conference. Virtual Meeting, May. 07, 2021.
91. Wang Y. *Advanced Imaging and Data Analysis to Support Structure Similarity of Polymeric Formulations.* Presentation at the 2021 Small Business and Industry (SBIA) Workshop. Virtual Meeting, Sep. 22, 2021.
92. Wang Y. *Bioequivalence of Intravaginal Rings and Intrauterine Systems: Current Perspective and Future Directions.* Presentation at the DIA/FDA Complex Generic Drug-Device Combination Products Conference 2020. Virtual Meeting, Oct. 20, 2020.
93. Wang Y. *Regulatory and Scientific Considerations on Characterizations of Complex Polymeric Excipients.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) Pharmsci 360. Virtual Meeting, Oct. 30, 2020.
94. Weng Y, Hu M, Zhao L, Wang C, Shen M, and Gong X. *Developing a Statistical Approach to Facilitate Sameness Assessment of Complex Heterogenous Active Pharmaceutical Ingredients.* Presentation at the 2021 Joint Statistical Meetings. Virtual Meeting, Aug. 08, 2021.

95. Witzmann K. *Complex Generic Drug-Device Inhalation Products and User Interface Sameness: Successful Outcomes.* Presentation at the DIA/FDA Complex Generic Drug-Device Combination Products Conference 2020. Virtual Meeting, Oct. 19, 2020.
96. Wu F. *PBPK Absorption Modeling and Virtual Bioequivalence to Support Generic Drug Development and Regulatory Decision Making for Oral Products.* Presentation at the 2021 Small Business and Industry (SBIA) Workshop. Virtual Meeting, Sep. 21, 2021.
97. Xu X. *Connecting the Dots: Particle Size, Drug Distribution and Drug Release in Nanoemulsions.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) Webinar. Virtual Meeting, May. 07, 2021.
98. Xu X. *Supporting the Development of Drug Products Containing Nanomaterials: Guidance, Trends and Research.* Presentation at the NIPTE Annual Conference. Virtual Meeting, Dec. 08, 2020.
99. Xu X. *Supporting the Development of Drug Products Containing Nanomaterials: Guidance, Trends, and Research.* Presentation at the Advancing Measurement Technologies and Standards for Nanomedicine Virtual Workshop. Virtual Meeting, Jun. 15, 2021.
100. Xu X. *Supporting the Development of Drug Products Containing Nanomaterials: Trends, Guidances, and Voluntary Consensus Standards.* Presentation at the USP Nanomaterial Working Group Meeting. Virtual Meeting, Oct. 16, 2020.
101. Xu X. *Understanding Drug Release from Multivesicular Liposomes.* Presentation at the NanoDay Symposium. Virtual Meeting, Oct. 09, 2020.
102. Yang K, Abdullah A, Sommers C, and Rodriguez J. *Resolving Impurity Isomers in Synthetic Oligonucleotides by High Resolution Mass Spectrometry.* Presentation at the International Foundation Process Analytical Chemistry (IFPAC) 2021. Virtual Meeting, Feb. 28, 2021.
103. Yoon M. *Model-Integrated Evidence for BE Assessment of Complex Generic Drugs.* Presentation at the 2021 Small Business and Industry (SBIA) Workshop. Virtual Meeting, Sep. 22, 2021.
104. Zhang D. *Considerations in Submitting Abbreviated New Drug Application of Generic Peptide Drug Products.* Presentation at the TIDES USA 2021 Workshop #5: FDA Guidance on ANDA Submission for Peptides. Virtual Meeting, Sep. 20, 2021.
105. Zhang L, and Lee S. *Role of Regulatory Science in Generic Drug Development and Application Assessment.* Presentation at the GDUFA III Stakeholder Meeting. Virtual Meeting, Nov. 17, 2020.
106. Zhang L. *Opening Remarks.* Presentation at the 2021 Small Business and Industry (SBIA) Webinar. Virtual Meeting, May. 05, 2021.
107. Zhao C. *Challenges in the Approval of Complex Otic and Ophthalmic Generic Products: Bioequivalence Perspectives.* Presentation at the 2021 Small Business and Industry Assistance (SBIA) Workshop, Advancing Generic Drug Development: Translating Science to Approval. Virtual Meeting, Sep. 21, 2021.
108. Zhao L. *Application of Quantitative Clinical Pharmacology in the Development of Long-Acting Injectable (LAI) Drug Products.* Presentation at the Product Quality Research Institute (PQRI) 2021 Webinar. Virtual Meeting, Apr. 08, 2021.
109. Zhao L. *Computational Pharmaceutics: Scientific Gaps and Forthcoming Research to Modernize Regulatory Science.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) Seminar. Virtual Meeting, Dec. 11, 2020.
110. Zhao L. *Quantitative Methods and Modeling to Evaluate Alternative Approaches for COVID-19 Interrupted Bioequivalence Studies.* Presentation at the 2020 Association for Accessible Medicines (AAM): GRx+Biosims Conference. Virtual Meeting, Nov. 09, 2020.
111. Zhao L. *Regulatory Perspective: What Can Be a Model Master File and How to Share It?.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop: Regulatory Utility of Mechanistic Modeling to Support Alternative Bioequivalence Approaches. Virtual Meeting, Sep. 30, 2021.

112. Zidan A. *Diffusion Cell Apparatus: Scientific Principles and Practical Challenges I.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop, In Vitro Release Test (IVRT) and In Vitro Permeation Test (IVPT) Methods: Best Practices and Scientific Considerations for ANDA Submissions. Virtual Meeting, Aug. 18, 2021.
113. Zidan A. *Recent Research Related to Q3 Characterization of Topical Products Containing Porous Microparticles.* Presentation at the 2021 Small Business and Industry (SBIA) Workshop. Virtual Meeting, Sep. 21, 2021.