Presentations Relating to GDUFA Science and Research in Fiscal Year 2022

1. Abuznait A. *Expectations and Common Deficiencies with IVRT Studies Submitted in ANDAs for Ophthalmic Emulsion Products.* Presentation at the FDA-CRCG Workshop on In Vitro Release Testing and In Vitro In Vivo Correlation of Complex Ophthalmic, Injectable, Implantable, and Inserted Products. Virtual Meeting, Jun. 29, 2022.

2. Al Ghabeish M. *In Vitro Assessments that Support In Vitro Binding Studies in Demonstrating Bioequivalence of Locally Acting Gastrointestinal Drugs.* Presentation at the Small Business and Industry (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 21, 2022.

3. Alam K. *Mechanistic Modeling of Complex Injectables: Recommendations to Navigate Regulatory Challenges.* Presentation at the Small Business and Industry Assistance (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 20, 2022.

4. Ayral G. *Novel Model-Integrated Designs for Bioequivalence Studies of LAI Products: A Complete Framework with the MonolixSuite.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop: Establishing the Suitability of Model-Integrated Evidence to Demonstrate Bioequivalence for Long-Acting Injectable and Implantable Drug Products. Virtual Meeting, Nov. 30, 2021.

5. Ballard B. *Future Challenges: Electronic Devices, Drug Use Related Software, and Impacts on Generic Development and Substitution.* Presentation at the Small Business and Industry (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 21, 2022.

6. Ballard B. *Pre - ANDA Evaluation of Drug Delivery Device Constituents.* Presentation at the Fiscal Year (FY) 2022 Generic Drug Science and Research Initiatives Public Workshop. Virtual Meeting, May. 10, 2022.

7. Batchelor H, Pawar G, Wu F, Zhao L, Fang L, Burckart G, Feng K, and Mousa Y. *Risk Factors Related to Relative Bioavailability Studies for Pediatric Products.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2021. Philadelphia, PA, Oct. 18, 2021.

8. Bengston K. *FDA Product-Specific Guidance Program Overview.* Presentation at the Small Business and Industry (SBIA) 2022: Generic Drug Forum. Virtual Meeting, Apr. 27, 2022.

9. Boc S. *Alternative BE Approaches and Considerations for Nasal Products.* Presentation at the Small Business and Industry Assistance (SBIA) 2022 Workshop: Advancing Generic Drug Development: Translating Science to Approval. Virtual Meeting, Sep. 21, 2022.

10. Boyce H. *Bridging the Difference: Case Studies that Demonstrate Bioequivalence Assessments for Approved Suitability Petitions.* Presentation at the Small Business and Industry (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 21, 2022.

11. Burgess D. *IVRT Method Development for API Suspension Products and Validation with In Vivo Model.* Presentation at the FDA-CRCG Workshop on In Vitro Release Testing and In Vitro In Vivo Correlation of Complex Ophthalmic, Injectable, Implantable, and Inserted Products. Virtual Meeting, Jun. 29, 2022.

12. Chan I. *Comparative-Use Human Factors Studies for ANDA Products.* Presentation at the Fiscal Year (FY) 2022 Generic Drug Science and Research Initiatives Public Workshop. Virtual Meeting, May. 10, 2022.

13. Chen K. *High Resolution 19F qNMR Reveals Mass-balanced Drug Phase Distribution in Oil-in-Water Nano-Emulsion Formulations.* Presentation at the USP qNMR Summit 2021 (qNMR Summit 6.0). Virtual Meeting, Oct. 06, 2021.

14. Dhapare S, Murphy S, Sandell D, Winner L, Sheth P, Hallinger M, Svensson M, Conti D, Oguntimein O, Bulitta J, and Hochhaus G. *Effects of Formulation and Actuator Design on Spray Velocity of Mometasone Furoate Metered Dose Inhalers.* Presentation at the Respiratory Drug Delivery (RDD) 2022. Orlando, Florida, May. 01, 2022.

15. Dhapare S. *Effects of Realistic In Vitro Test Factors on the Aerosol Properties of Metered-Dose Inhalers (MDIs).* Presentation at the Drug Delivery to the Lungs (DDL) 2021. Virtual Meeting, Dec. 08, 2021.

16. Donnelly M. *Regulatory Challenges with Pharmacokinetic (PK) Bioequivalence (BE) Studies for Drugs Containing Endogenous Compounds.* Presentation at the Scientists Advancing Affordable Medicines Workshop 2022. Virtual Meeting, Apr. 27, 2022.

17. Ducharme M. *Model-Integrated BE Approaches for Long-Acting Injectables.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop: Establishing the Suitability of Model-Integrated Evidence to Demonstrate Bioequivalence for Long-Acting Injectable and Implantable Drug Products. Virtual Meeting, Nov. 30, 2021.

18. Dutta R, Kolanjiyil A, Golshahi L, and Longest W. *Development of a CFD PK Nasal Spray Model with In Vivo Human Subject Validation.* Presentation at the Respiratory Drug Delivery (RDD) 2022. Orlando, Florida, May. 02, 2022.

19. Edginton A, Yun E, and Hamadeh A. *Physiologically-Based Pharmacokinetic Pediatric Skin Model.* Presentation at the 14th European Paediatric Formulation Initiative (EuPFI) Conference 2022). Rome, Italy, Sep. 21, 2022.

20. Esmaeili A, Hosseini S, Wilkins J, Alfaifi A, Dhapare S, Walenga, Newman B, Schuman T, Edwards D, Longest W, Hindle M, and Golshahi L. *In Vitro Evaluation of Regional Drug Deposition in Nasal Airways of Children Using Realistic Anatomical Replicas.* Presentation at the Respiratory Drug Delivery (RDD) 2022. Orlando, Florida, May. 02, 2022.

21. Evans C. *Advanced Techniques for Measuring Cutaneous Pharmacokinetics Using Pharmacokinetic Tomography.* Presentation at the Society for Investigative Dermatology (SID) Annual meeting. Portland, Oregon, May. 20, 2022.

22. Fang L. *Is Bioequivalence Established in Adults Relevant for Pediatrics?* Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2021. Philadelphia, Pennsylvania, Oct. 17, 2021.

23. Fehrenbach H. *Opportunities to Leverage Device Functional Assessment for Classifying and Evaluating User Interface Differences.* Presentation at the Fiscal Year (FY) 2022 Generic Drug Science and Research Initiatives Public Workshop. Virtual Meeting, May. 10, 2022.

24. Feibus K. *Drug-Device Combination Products.* Presentation at the Fiscal Year (FY) 2022 Generic Drug Science and Research Initiatives Public Workshop. Virtual Meeting, May. 10, 2022.

25. Feng K. *Application of Quantitative Modeling and Simulations to Bioequivalence Determination for Long-Acting Injectables – Sharing Research Progress and Regulatory Experience.* Presentation at the Small Business and Industry Assistance (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 20, 2022.

26. Feng K. *Model-based Bridging to Establish Bioequivalence with a Discontinued Reference Listed Product.* Presentation at the 2022 American College of Clinical Pharmacology (ACCP) Annual Meeting. Bethesda, Maryland, Sep. 24, 2022.

27. Fitzgerald M. *Industry Perspective: Incorporation of BE Modeling and LAI Development Challenges.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop: Establishing the Suitability of Model-Integrated Evidence to Demonstrate Bioequivalence for Long-Acting Injectable and Implantable Drug Products. Virtual Meeting, Nov. 30, 2021.

28. Gajjar P. *A Model-Integrated Pathway to Explore Bioequivalence of LAI Products: Studies Using Paliperidone Palmitate.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop: Establishing the Suitability of Model-Integrated Evidence to Demonstrate Bioequivalence for Long-Acting Injectable and Implantable Drug Products. Virtual Meeting, Nov. 30, 2021.

29. Ghosh P, and Luke M. *Characterization Based Approaches for Establishing Bioequivalence Locally Acting Drug Products Applied to the Skin.* Presentation at the 5th Annual Global Bioequivalence Harmonization Initiative Meeting. Amsterdam, Netherlands, Sep. 29, 2022.

30. Ghosh P, and Luke M. *Cutaneous Pharmacokinetic Based Approaches for Establishing Bioequivalence Locally Acting Drug Products Applied to the Skin.* Presentation at the 5th Annual Global Bioequivalence Harmonization Initiative Meeting. Amsterdam, Netherlands, Sep. 29, 2022.

31. Ghosh P. *Identification of Research Needs During Product Development Prior to ANDA Submission.* Presentation at the Fiscal Year 2022 GDUFA Public Workshop. Virtual Meeting, May. 09, 2022.

32. Ghosh P. *Overview FDA's Generic Drug Research Topical Dermatological Drug Products.* Presentation at the Society for Investigative Dermatology (SID) Annual meeting. Portland, Oregon, May. 20, 2022.

33. Ghosh P. *Product Development Considerations and Bioequivalence Strategies for Generic Topical Products.* Presentation at the Drug Information Association (DIA) 2022 Annual Meeting. Chicago, Illinois, Jun. 22, 2022.

34. Ghosh P. *Translating Scientific Advances to Regulatory Methods Assessment of Cutaneous Pharmacokinetics.* Presentation at the Innovations in Dermatological Sciences Conference. Virtual Meeting, Sep. 29, 2022.

35. Gobburu J. *Accelerating LAI Generic Development Using Model-Integrated Bioequivalence.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop:

Establishing the Suitability of Model-Integrated Evidence to Demonstrate Bioequivalence for Long-Acting Injectable and Implantable Drug Products. Virtual Meeting, Nov. 30, 2021.

36. Golshahi L, Alfaifi A, Hosseini S, Esmaeili A, Hindle M, Longest W, and Schuman T. *Leveraging In Vitro Bioequivalence Tests for Locally-Acting Suspension Nasal Sprays with Three Anatomically-Correct Replicas of Human Nasal Airways Representing Intersubject Variability.* Presentation at the Respiratory Drug Delivery (RDD) 2022. Florida, Orlando, May. 02, 2022.

37. Gong Y. *Alternative Model-Based Data Analysis Approach to Demonstrate Bioequivalence.* Presentation at the Small Business and Industry Assistance (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 21, 2022.

38. Guy R. *Dermatopharmacokinetics: Modelling, Assessment and Optimization.* Presentation at the Innovations in Dermatological Sciences Conference. Virtual Meeting, Sep. 29, 2022.

39. Hakeem S. *Overview of Pre-ANDA Meeting Program.* Presentation at the Small Business and Industry (SBIA) 2022: Generic Drug Forum. Virtual Meeting, Apr. 27, 2022.

40. Hamadeh A, and Troutman J. *Mechanistic in Silico Inference of Dermal Absorption for Chemical Risk Assessment.* Presentation at the ScitoVation Webinar. Virtual Meeting, Mar. 08, 2022.

41. Hartka K. *Comparing Device User Interfaces and Seeking Advice in the Pre-ANDA Period.* Presentation at the Small Business and Industry Assistance (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 20, 2022.

42. Hochhaus G, Amini E, Berger S, Shur J, Kurumaddali A, Schilling U, Jiao Y, Drescher S, Seay B, Baumstein S, Abu Hasan M, Oguntimein O, Carrasco C, Winner L, Delvadia R, Saluja B, Price R, Conti D, Dhapare S, Newman B, and Bulitta J. *Evaluating Particle Size Differences of Suspension-based Nasal Sprays Through In Vitro and Pharmacokinetic Approaches.* Presentation at the Respiratory Drug Delivery (RDD) 2022. Orlando, Florida, May. 02, 2022.

43. Holtgrewe N. *In Vitro Characterization of Nasal Powder Drug Products.* Presentation at the Small Business and Industry Assistance (SBIA) 2022 Workshop: Advancing Generic Drug Development: Translating Science to Approval. Virtual Meeting, Sep. 21, 2022.

44. Hooker A. *Model-Integrated Methods and Innovative Study Designs for Generic LAI Product Development and Regulatory Assessment.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop: Establishing the Suitability of Model-Integrated Evidence to Demonstrate Bioequivalence for Long-Acting Injectable and Implantable Drug Products. Virtual Meeting, Nov. 30, 2021.

45. Hooker A. *Research Related to Model Master Files to Establish the Concept and Details for Practical Implementation of Model- Integrated BE Packages in Regulatory Submissions.* Presentation at the Fiscal Year (FY) 2022 Generic Drug Science and Research Initiatives Public Workshop. Virtual Meeting, May. 09, 2022.

46. Hu M. *Leveraging Artificial Intelligence (AI) and Machine Learning (ML) to Support Generic Drug Development and Regulatory Efficiency.* Presentation at the International Consortium for Innovation and Quality in Pharmaceutical Development - Workshop 2022. Virtual Meeting, Sep. 15, 2022.

47. Hu M. *Leveraging Artificial Intelligence (AI) and Machine Learning (ML) to Support Regulatory Efficiency – Current Progress.* Presentation at the Fiscal Year (FY) 2022 GDUFA Public Workshop. Virtual Meeting, May. 09, 2022.

48. Jiang W. *Bioequivalence Evaluation of Narrow Therapeutic Index Drugs - Rationales for the Current Regulatory Approach by U.S. FDA.* Presentation at the 5th Annual Global Bioequivalence Harmonization Initiative Meeting. Amsterdam, Netherland, Sep. 29, 2022.

49. Jiang W. *Complex Generics Containing Nanomaterials: Developments in 2021 and 2022.* Presentation at the 13th European Foundation for Clinical Nanomedicine Annual Summit. Virtual Meeting, May. 02, 2022.

50. Jiang W. *How can Scientific Advancements Help Align Global Development of Complex Generic Products.* Presentation at the Fiscal Year (FY) 2022 Generic Drug Science and Research Initiatives Public Workshop. Virtual Meeting, May. 09, 2022.

51. Jiang W. *U.S. FDA Recommendation on Bioequivalence Demonstration of Topical Drug Products.* Presentation at the 5th Annual Global Bioequivalence Harmonization Initiative Meeting. Amsterdam, Netherland, Sep. 29, 2022.

52. Jones A, Chung H, and Kozak D. *Decoding the Guidance: Considerations for Waiver Requests for pH Adjusters in Generic Drug Products Intended for Parenteral, Ophthalmic, or Otic Use.* Presentation at the CDER Small Business & Industry Assistance (SBIA) Webinar. Virtual Meeting, Aug. 10, 2022.

53. Kohojkar A. *Industry Perspective: Regulatory Challenges in Development of Generic Long-Acting Injectables.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop: Establishing the Suitability of Model-Integrated Evidence to Demonstrate Bioequivalence for Long-Acting Injectable and Implantable Drug Products. Virtual Meeting, Nov. 30, 2021.

54. Kolanjiyil A, Golshahi L, and Longest W. *On the Importance of Liquid Motion in Nasal Spray Delivery.* Presentation at the Respiratory Drug Delivery (RDD) 2022. Orlando, Florida, May 02, 2022.

55. Kozak D, and Xu X. *Approaches Using Proactive Research in Support of Product-Specific Guidance (PSG) Development.* Presentation at the Small Business and Industry Assistance (SBIA) 2022: Generic Drug Forum. Virtual Meeting, Apr. 27, 2022.

56. Kozak D. *A Scientific and Regulatory Overview of IVRT: Current Considerations and Challenges.* Presentation at the FDA-CRCG Workshop on In Vitro Release Test and In Vitro In Vivo Correlation of Complex Ophthalmic, Injectable, Implantable, and Inserted Products. Virtual Meeting, Jun. 29, 2022.

57. Kozak D. *Formulation Considerations for In Vitro Characterization Based Approaches of Locally Acting Complex Generic Drug Products.* Presentation at the GRx+ Biosims Virtual Conference: Science and Regulatory Learning Track. Virtual Meeting, Nov. 08, 2021.

58. Kuzma B. *Novel Methodologies to Assess Cutaneous Bioavailability and Bioequivalence: Dermal Microdialysis and Coherent Raman Imaging.* Presentation at the Innovations in Dermatological Sciences Conference. Virtual Meeting, Sep. 29, 2022.

59. Lemke M. *URRA and Root Cause Analysis: The Secret Ingredients for Effective Comparative Use Human Factors Studies.* Presentation at the Fiscal Year (FY) 2022 Generic Drug Science and Research Initiatives Public Workshop. Virtual Meeting, May. 10, 2022.

60. Li Y. *Common Deficiencies Associated with Comparative Peptide Impurity Profile Studies and Qualification of Impurity Levels and Proposed Limits.* Presentation at the Small Business and Industry (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 20, 2022.

61. Lionberger R. *Complex Generics Town Hall.* Presentation at the 2021 Association for Accessible Medicines (AAM): GRx+Biosims. Virtual Meeting, Nov. 10, 2021.

62. Lionberger R. *Critical Roles of Excipients in the Development of Generic Drug Products.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2021. Philadelphia, Pennsylvania, Oct. 17, 2021.

63. Lionberger R. *Suitability Petitions Enable Generics.* Presentation at the Small Business and Industry (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 21, 2022.

64. Luke M. *Advancing the Science of how Topically Applied Drugs Penetrate the Skin and Clinical Relevance - the Viewpoint of an FDA Dermatologist.* Presentation at the Dermatology Innovation Forum - an Advancing Innovation in Dermatology Conference. Virtual Meeting, Jun. 24, 2022.

65. Luke M. *Drug Device Combination Products and Similarity.* Presentation at the 2021 Association for Accessible Medicines (AAM): GRx+Biosims Conference. Virtual Meeting, Nov. 08, 2021.

66. Luke M. *FDA and Dermatology - Topical Drug Products: New Paradigm for Generics.* Presentation at the International Dermatology Outcome Measures (IDEOM) 2021 Annual Meeting. Virtual Meeting, Nov. 19, 2021.

67. Luke M. *FDA and the Dermatologist - The Basics about FDA and a New Paradigm for Generic Topical Drug Bioequivalence.* Presentation at the American Academy of Dermatology Annual Meeting 2022. Boston, Massachusetts, Mar. 27, 2022.

68. Mohan A, Dhapare S, Newman B, Svensson M, Elfman P, Winner L, Bulitta J, and Hochhaus G. *The Effects of Inhalation Flow Rate on Aerodynamic Particle Size Distribution of Commercial Solution and Suspension Metered Dose Inhalers.* Presentation at the Respiratory Drug Delivery (RDD) 2022. Orlando, Florida, May. 02, 2022.

69. Mohan A. *The Effects of Inhalation Flow Rate on Aerodynamic Particle Size Distribution of Commercial Solution and Suspension Metered Dose Inhalers (MDIs).* Presentation at the Respiratory Drug Delivery (RDD) 2022. Orlando, Florida, May. 01, 2022.

70. Newman B. *Nasal Products: Current Landscape and Recent Advancements.* Presentation at the Small Business and Industry Assistance (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 21, 2022.

71. Niu M. *The Role of Microparticles and Other Excipients in the Complexity of Certain Topical Drug Products.* Presentation at the Excipient World Conference & Expo 2022. Kissimmee, Florida, May. 03, 2022.

72. O'Connor T. *Characterization of Excipients in Complex Dosage Forms – FDA Research Highlights.* Presentation at the Fiscal Year (FY) 2022 Generic Drug Science and Research Initiatives Public Workshop. Virtual Meeting, May. 09, 2022.

73. Pang E. *Guidance for Peptide Products and Assessing Immunogenicity Risk.* Presentation at the Small Business and Industry (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 20, 2022.

74. Park E. *Bioequivalence Considerations for IVRT Methods for Ophthalmic Products.* Presentation at the FDA-CRCG Workshop on In Vitro Release Testing and In Vitro In Vivo Correlation of Complex Ophthalmic, Injectable, Implantable, and Inserted Products. Virtual Meeting, Jun. 29, 2022.

75. Patel H. *Practical Considerations Related to IVPT Studies for Topical Products Submitted in ANDAs.* Presentation at the Small Business and Industry Assistance (SBIA) 2022: Best Practices for Topical Generic Product Development and ANDA Submission. Virtual Meeting, Aug. 11, 2022.

76. Pellowe M, and Sjogren E. *Virtual Bioequivalence Workflow.* Presentation at the Population Approach Group Europe (PAGE) 2022 Annual Meeting. Ljubljana, Slovenia, June. 28, 2022.

77. Privitera M. *Building a Taxonomy for Consistent Determination of Design Differences in Combination Products.* Presentation at the Fiscal Year (FY) 2022 Generic Drug Science and Research Initiatives Public Workshop. Virtual Meeting, May. 10, 2022.

78. Qin B. *Current Thinking and Research On In Vitro Only Approaches for Injectable Drug Substance Suspensions-A Scientific Discussion.* Presentation at the Small Business and Industry Assistance (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 20, 2022.

79. Qin B. *Regulatory Uses of IVRT Studies on Complex Generic Ophthalmic, Injectable, Implantable, and Inserted Products.* Presentation at the FDA-CRCG Workshop on In Vitro Release Test and In Vitro In Vivo Correlation of Complex Ophthalmic, Injectable, Implantable, and Inserted Products. Virtual Meeting, Jun. 29, 2022.

80. Qu H. *Challenges and Opportunities of using AF4 for Characterizing High Molecular Mass PEO in Abuse-Deterrent Formulations.* Presentation at the 22nd International Symposium on Field- and Flow-Based Separations. Riverside, California, Sep. 12, 2022.

81. Ramezanli T. *Practical Considerations for IVRT Studies with Topical Drug Products Submitted in ANDAs.* Presentation at the Small Business and Industry Assistance (SBIA) 2022: Best Practices for Topical Generic Product Development and ANDA Submission. Virtual Meeting, Aug. 11, 2022.

82. Ramezanli T. *Therapeutic Equivalence of Compositionally Different Topical Products: Correlation of Product Characteristics with Sensorial Attributes.* Presentation at the Innovations in Dermatological Sciences Conference. Virtual Meeting, Sep. 29, 2022.

83. Raney S. *A Regulatory Perspective on Physicochemical, Structural, and Performance Characterization of Topical Semisolid Products.* Presentation at the 17th International Perspectives in Percutaneous Penetration Conference (PPP2022). La Grande Motte, France, Apr. 20, 2022.

84. Raney S. *GDUFA Funded Development of Efficient Bioequivalence Approaches for Topical Generics.* Presentation at the Drug Information Association (DIA) 2022 Annual Meeting. Chicago, Illinois, Jun. 22, 2022.

85. Raney S. *GDUFA Science and Research Program.* Presentation at the Society for Investigative Dermatology (SID) Annual meeting. Portland, Oregon, May. 20, 2022.

86. Raney S. *Scientific and Regulatory Considerations for Q3 Characterization of Topical Products.* Presentation at the Small Business and Industry Assistance (SBIA) 2022: Best Practices for Topical Generic Product Development and ANDA Submission. Virtual Meeting, Aug. 11, 2022.

87. Raney S. *The Critical Impact of Excipients on the Physicochemical and Structural Characteristics of Topical Drug Products.* Presentation at the Excipient World Conference & Expo 2022. Kissimmee, Florida, May. 03, 2022.

88. Roberts M. *Advanced Techniques for Characterizing the Form & Function of Topical Dermatological Drug Products.* Presentation at the Society for Investigative Dermatology (SID) Annual Meeting. Portland, Oregon, May. 20, 2022.

89. Senemar S. *New developments in the Assessment of Cutaneous Bioavailability and Bioequivalence of Topical Dermatological Drug Products Using Dermal Microdialysis.* Presentation at the The Center for Dermal Research. Virtual Meeting, Jun. 06, 2022.

90. Shakleya D. *Analytical Regulatory Considerations for Different Pharmaceutical Drug Matrices.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2021. Virtual Meeting, Oct. 17, 2021.

91. Shakleya D. *Case Study: Non-standard Matrices Considerations - Ocular Implant.* Presentation at the 23rd Annual Land O' Lakes Bioanalytical Conference. Virtual Meeting, Jul. 13, 2022.

92. Sinner F. *Advanced Techniques for Measuring Cutaneous Pharmacokinetics In Vivo Using Microdialysis Dermal Open Flow Microperfusion.* Presentation at the Society for Investigative Dermatology (SID) Annual meeting. Portland, Oregon, May. 20, 2022.

93. Sinner F. *Learnings from Accessing the Dermis Vivo: from Topical Bioequivalence to Biomarker Research.* Presentation at the 17th International Perspectives in Percutaneous Penetration Conference (PPP2022). La Grande Motte, France, Apr. 20, 2022.

94. Smith C, and Geerlof-Vidavsky I. *Research Fueling Approvals: A Case Study of Glucagon.* Presentation at the Small Business Investor Assistance (SBIA) 2021. Virtual Meeting, Oct. 27, 2021.

95. Smith W. *Assessing Morphological Variation in Liposomal Drug Products using Asymmetrical Flow Field-Flow Fractionation.* Presentation at the 22nd International Symposium on Field- and Flow-Based Separations. Riverside, California, Sep. 11, 2022.

96. Smith W. *Challenges and Considerations in Developing In Vitro Release Testing Methods for Parenteral Suspensions.* Presentation at the Small Business Investor Assistance (SBIA) 2022: Advancing Generic Drug Development: Translating Science to Approval. Virtual Meeting, Sep. 20, 2022.

97. Smith W. *Developing Discriminatory IVRT Methods for Injectable Suspensions: Start with Why.* Presentation at the FDA-CRCG Workshop on In Vitro Release Test and In Vitro-In Vivo Correlation of Complex Ophthalmic, Injectable, Implant Products. Virtual Meeting, Jun. 29, 2022.

98. Smith W. *Impact of Particle Flocculation on Particle Size Determination and Implications on Dissolution and Bioavailability of Injectable Suspensions.* Presentation at the International Forum on Process Analytical Chemistry (IFPAC) 2022. Virtual Meeting, Jun. 14, 2022.

99. Soukup S. *Approach to a Comparative Analysis When the RLD is Unavailable.* Presentation at the Small Business and Industry (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 20, 2022.

100. Soukup S. *Conducting a Comparative Analysis When the RLD is Not Available.* Presentation at the Small Business and Industry (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 20, 2022.

101. Srinivasan C, and Li Y. *Research Fueling Approval: A Case Study of Ferumoxytol.* Presentation at the Small Business & Industry Assistance (SBIA) 2021: Pharmaceutical Quality Symposium Workshop: Innovations in a Changing World. Virtual Meeting, Oct. 27, 2021.

102. Sun W. *In Vitro Binding Studies for Bioequivalence Demonstration.* Presentation at the Small Business and Industry Assistance (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 21, 2022.

103. Thomas S. *Recommendation of Partial Area Under the Curve (pAUC) Metrics in Product-Specific Guidance for Long-Acting Injectable (LAI) Drug Products.* Presentation at the Small Business and Industry (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 20, 2022.

104. Tiffner K, Boulgaropoulos B, Birngruber T, Bodenlenz M, Lackner B, Raml R, and Sinner F. *Promising Technologies: Continuous Skin Sampling Methods for Cutaneous PK-Based Bioequivalence Assessment.* Presentation at the 5th conference on The Global Harmonization Initiative. Amsterdam, Netherlands, Sep. 29, 2022.

105. Tsakalozou E. *Dermal PBPK Modeling for a Transdermal Delivery System to Assess the Impact of the Application Site on In Vivo Performance.* Presentation at the Small Business and Industry Assistance (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 21, 2022.

106. Tsakalozou E. *Leveraging Dermal Physiologically-based Pharmacokinetic Modeling and Simulation Approaches for the Approval of a Generic Diclofenac Sodium Topical Gel.* Presentation at the Simcyp Scientific Webinar Series. Virtual Meeting, Dec. 08, 2021.

107. Van Osdol B, and Spires J. *In Silico QbD for Dermal Topical Formulations via TCAT Model Simulations.* Presentation at the Simulations Plus Model Informed Drug Development (MIDD) +22. Virtual Meeting, Feb. 17, 2022.

108. Verthelyi D. *Assessing Impurities to Inform Peptide Immunogenicity Risk: Developing Informative Studies.* Presentation at the Small Business and Industry (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 20, 2022.

109. Vonbriesen T. *Insufficient Published Literature Related to the Usability of Device Constituent Parts.* Presentation at the Fiscal Year (FY) 2022 Generic Drug Science and Research Initiatives Public Workshop. Virtual Meeting, May. 10, 2022.

110. Walenga R. *Mechanistic Modeling and Realistic In Vitro Models to Facilitate Development of Generic Nasal Drug Products.* Presentation at the Small Business and Industry Assistance (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 21, 2022.

111. Walenga R. *Modeling of CNS Delivery for Nose-to-Brain Targeted Drug Products.* Presentation at the Society for Computational Fluid Dynamics of the Nose Airway (SCONA) 2022 Virtual Meeting. Virtual Meeting, Jan. 28, 2022.

112. Wang J. *Advance in Data Imputation Approach to Support BE Assessment.* Presentation at the Small Business and Industry Assistance (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 21, 2022.

113. Wang J. *Evaluation and Application of New/Novel Data Imputation Approaches to Support BE Assessment.* Presentation at the Small Business and Industry Assistance (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 21, 2022.

114. Wang Y. *From Bench to Approval: The Role of GDUFA Research in Promoting Complex Generics.* Presentation at the Fiscal Year (FY) 2022 Generic Drug Science and Research Initiatives Public Workshop. Virtual Meeting, May. 06, 2022.

115. Wu F. *Bioequivalence Evaluation of Pediatric Products Using Physiologically Based Pharmacokinetic Modeling.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2021. Philadelphia, PA, Oct. 18, 2021.

116. Wu F. *Challenges and Opportunities when Using Oral PBPK to Support Risk Assessment and Biowaiver in Regulatory Submissions.* Presentation at the Small Business and Industry Assistance (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 21, 2022.

117. Wu F. *Using a Physiologically Based Pharmacokinetic Absorption Model to Establish Dissolution Bioequivalence Safe Space for Oseltamivir in Adult and Pediatric Populations.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2021. Philadelphia, Pennsylvania, Oct. 15, 2021.

118. Xu X. *Identify Research Needs to Accelerate Product-Specific Guidances (PSGs) Development for Complex Products.* Presentation at the FY22 GDUFA Public Workshop. Virtual Meeting, May. 09, 2022.

119. Xu X. *In Vitro Drug Release Test for Complex Formulations.* Presentation at the UConn's American Association of Pharmaceutical Sciences (AAPS) Student Chapter Webinar. Virtual Meeting, Mar. 11, 2022.

120. Xu X. *In Vitro Release Test for Complex Drug Products: Start with Why.* Presentation at the 2022 National Institute for Pharmaceutical Technology and Education (NIPTE) Research Conference: Accelerating the Drug Development Program. Virtual Meeting, Dec. 02, 2021.

121. Xu X. *Regulatory Perspective and Quality Considerations on Drug Products Containing Nanomaterials: Guidance and Research.* Presentation at the ACS POLY Workshop. Virtual Meeting, Feb. 21, 2022.

122. Xu X. *Research to Support the Development Product-Specific Guidances (PSGs) for Complex Products.* Presentation at the Small Business & Industry Assistance (SBIA) Generic Drug Forum. Virtual Meeting, Apr. 27, 2022.

123. Xu X. *Thinking Outside the Box: A Regulatory Perspective on Innovation through Flow Processes.* Presentation at the 22nd International Symposium on Field- and Flow-Based Separations. Riverside, California, Sep. 12, 2022.

124. Xu X. *Thinking Outside the Box: Adaptive Perfusion Method to Study Drug Release from Emulsions.* Presentation at the FDA-CRCG Workshop on In Vitro Release Test and In Vitro-In Vivo Correlation of Complex Ophthalmic, Injectable, Implant Products. Virtual Meeting, Jun. 29, 2022.

125. Yang K. *In-depth Impurity Assessment of Synthetic Oligonucleotides Enabled by High Resolution Mass Spectrometry.* Presentation at the Small Business and Industry Assistance (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 20, 2022.

126. Yang K. *In-depth Impurity Profiling of Synthetic Oligonucleotides by High Resolution Mass Spectrometry.* Presentation at the 7th USP Workshop on Therapeutic Peptides and Oligonucleotides. Virtual Meeting, Feb. 28, 2022.

127. Yang K. *Mass Spectrometry-based Characterization of Synthetic Oligonucleotides and Structurally Related Impurities.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2021. Virtual Meeting, Oct. 17, 2021.

128. Yoon M. *Model-Integrated Bioequivalence Establishment: Long-Acting Injectable Drug Products.* Presentation at the 2021 Association for Accessible Medicines (AAM): GRx+Biosims Conference. Virtual Meeting, Nov. 10, 2021.

129. Yoon M. *Model-Integrated Evidence for Bioequivalence Assessment of Long-Acting Injectables from a Generic Drug Perspective.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop: Establishing the Suitability of Model-Integrated Evidence to Demonstrate Bioequivalence for Long-Acting Injectable and Implantable Drug Products. Virtual Meeting, Nov. 30, 2021.

130. Zhang D. *Developing Product-Specific Guidances on Oligonucleotides for Generic Drug Development.* Presentation at the 7th USP Workshop on Therapeutic Peptides and Oligonucleotides. Virtual Meeting, Feb. 28, 2022.

131. Zhang D. *Oligonucleotides: Current Thinking and Analytical Challenges Identified in the Nusinersen PSG Development.* Presentation at the Small Business and Industry (SBIA) 2022: Advancing Generic Drug Development Workshop: Translating Science to Approval. Virtual Meeting, Sep. 20, 2022.

132. Zhang F. *Melt-Extruded Dexamethasone Ophthalmic Implants: Process, Structure and In Vitro Drug Release.* Presentation at the 12th American Drug Delivery Formulation Summit. San Diego, California, Sep. 26, 2022.

133. Zhang F. *Melt-extruded Dexamethasone Ophthalmic Implants-Process, Structure, and In Vitro Drug Release.* Presentation at the FDA-CRCG Workshop on In Vitro Release Testing and In Vitro In Vivo Correlation of Complex Ophthalmic, Injectable, Implantable, and Inserted Products. Virtual Meeting, Jun. 29, 2022.

134. Zhang L, and Tampal N. *Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA.* Presentation at the Small Business and Industry (SBIA) 2022: BE Studies with PK Endpoints for Drugs Submitted Under an ANDA. Virtual Meeting, Feb. 24, 2022.

135. Zhang L. *Complex Drug Products and Potential Challenges to Generic Drug Development.* Presentation at the FDA-USP Quarterly Meeting. Virtual Meeting, May. 10, 2022.

136. Zhang L. *Regulatory Research on the Effect of Excipients on Drug Absorption.* Presentation at the American Society for Clinical Pharmacology and Therapeutics (ASCPT) 2021 Membrane Transporter Community Meeting. Virtual Meeting, Jan. 11, 2022.

137. Zhang S. *Advanced Imaging Technologies and AI Based Image Analysis for Mechanistic Characterization and Prediction of Complex Drug Release.* Presentation at the FDA-CRCG Workshop on In Vitro Release Testing and In Vitro In Vivo Correlation of Complex Ophthalmic, Injectable, Implantable, and Inserted Products. Virtual Meeting, Jun. 29, 2022.

138. Zhang Y. *Essential Elements of BCS III-Based Biowaiver Request.* Presentation at the Small Business and Industry Assistance (SBIA) 2022: Regulatory Best Practices for Global Access to Medicines Workshop. Virtual Meeting, Aug. 18, 2022.

139. Zhao L. *Applications and Advance in Using Modeling and Simulation (MS) to Support Drug Product Life Cycle Management.* Presentation at the DIA China Clinical Pharmacology Seminar. Virtual Meeting, Jul. 10, 2022.

140. Zhao L. *Best Practices to Leverage Model-Integrated Evidence and Model Master File Packages to Bring Complex Generics to Market.* Presentation at the Fiscal Year (FY) 2022 Generic Drug Science and Research Initiatives Public Workshop. Virtual Meeting, May. 09, 2022.

141. Zhao L. *Impact of Modeling and Simulation on Drug Product Life Cycle Management.* Presentation at the International Symposium in Quantitative Pharmacology (ISQP) 2021 Annual Meeting. Virtual Meeting, Nov. 04, 2021.

142. Zhao L. *Leveraging Model-Integrated Evidence for Generic Drug Development and Approval.* Presentation at the 5th Annual Global Bioequivalence Harmonization Initiative Meeting. Amsterdam, Netherlands, Sep. 28, 2022.

143. Zhao L. *Overview of GDUFA II-funded Modeling and Simulation Grants/Contracts.* Presentation at the American Conference on Pharmacometrics (ACoP) 2021 Annual Public Workshop. Virtual Meeting, Nov. 08, 2021.

144. Zhao L. *Risk Assessment and Management for Formulation Change Using Model Integrated Approach.* Presentation at the 2021 Association for Accessible Medicines (AAM): GRx+Biosims Conference. Virtual Meeting, Nov. 08, 2021.

145. Zidan A. *Microstructure (Q3) Characterization Approaches for Demonstration of BE of Locally Acting Drug Products.* Presentation at the Generics + Biosimilars Conference 2021. Virtual Meeting, Nov. 08, 2021.

146. Zidan A. *Research and Innovation to Support the Availability of Topical Dermatological Products in the US.* Presentation at the Drug Information Association (DIA) 2022 Annual Meeting. Chicago, Illinois, Jun. 22, 2022.