FDA Office of Generic Drugs Office of Research & Standards (ORS)
Presentations by External Collaborators and ORS Staff in Fiscal Year 2016

1. Alloush J, Jones J, Polli J, Michel S, Kane M. Evaluation Of Biomarkers In Healthy Subjects Treated With Generic And Reference Sodium Ferric Gluconate, 2016 Research Day - University of Maryland School of Pharmacy, Baltimore, MD, April 22, 2016.
2. Alloway R. Generic Tacrolimus: Good Medicine or Cheap Fix?? Results of U01 study comparing tacrolimus brand and the 2 most disparate generics in renal and liver transplant recipients, University of Cincinnati Liver Transplant Patient Support Group, Cincinnati, OH, August, 2016.
3. Alloway R. Pharmacokinetic Studies of Tacrolimus in Transplant Patients, FDA-JHU CERSI workshop: Substitutability of Generic Drugs: Perception and Reality, Silver Spring, MD, November 18, 2016.
4. Andhariya JV, Shen J, Choi S, Wang Y, Qu W, Zou Y, Burgess DJ. Research Highlight Talk in the session "Manufacture, Characterization, Stability, and Regulatory Aspect, Controlled Release Society Annual Meeting, Seattle, WA, July 17-20, 2016.
5. Azimi M, Longest PW, Shur J, Price R, Hindle M. Clinically relevant in vitro tests for the assessment of innovator and generic nasal spray products, Drug Delivery to the Lungs, Edinburgh, Scotland, December 7-9, 2016.
6. Behafarid F, Brasseur JG, Vijayakumar G, Jayaraman B, Wang Y. Computational Studies of Drug Release, Transport and Absorption in the Human Intestines, 69th Annual Meeting of the American Physical Society (APS) Division of Fluid Dynamics, Boston, MA, November 20-22, 2016.
7. Boyce H, Hoag SW. Analysis of polyethylene oxide in sintered pharmaceutical tablets by transmission Raman spectroscopy, SCIX Conf, Minneapolis, MN, Sept 18-23, 2016.
8. Bunge AL, Guy RH. Evidence From In Vivo Skin Stripping Studies: Utility For Evaluating Topical Bioavailability, Fifteenth International Conference on Perspectives in Percutaneous Penetration, La Grande Motte, France, March 30, 2016.
9. Burgess DJ. In Vitro-In Vivo Correlation for Complex Drug Products and In Vitro/In Vivo Stability Issues, Peking University, Beijing, China, June, 2016.
10. Chen J, Fang L, Pu X, Wang Y, Pan Y, Lu D, Jiang X, Stier E, Li BV, Zhao L. Methodology Advancement on Dose-scale Analysis to Assess Pharmacodynamics Equivalence, American Conference of Pharmacometrics, Seattle, WA, October, 2016.
11. Cheng N, Banerjee T, Qian J, Hansen RA. Association Of Authorized Generic Marketing With Prescription Drug Spending On Antidepressants From 2000 To 2011, APhA Annual Meeting & Exposition, Baltimore, MD, October 29-November 2, 2016.
12. Choi S. An Update on FDA's Research Program for Ophthalmic Generic Products, Controlled Release Society Annual Meeting, Seattle, WA, July 19, 2016.
13. Choi S. Alternative Approaches to Demonstrate Bioequivalence of Ophthalmic Products and the Role of Regulatory Science, AAPS 2016, Denver, CO, November 12, 2016.
14. Das S, Pu X, Jiang X, Tung R, Ting TY, Polli JE. Frequency of Generic Brittleness in Epilepsy Patients, NIPTE conference, Breckenridge, CO, July 12-15, 2016.

15. Daubresse M, Lee CY, Moechtar M, Dutcher S, Romanelli R, Segal JB. Predictors Of Generic Thyroid Hormone Utilization Among The Commercially Insured, International Society for Pharmacoepidemiology Mid-Year Meeting Baltimore, MD, April 10-12, 2016.
16. Delgado-Charro MB. Recent Advances On Topical, Transdermal And Nail Drug Delivery, Spanish-Portuguese Conference on Controlled Drug Delivery "Revolutionary Approaches in Nanomedicine Development, Granada, Spain, January 21, 2016.
17. Fang L. Establishing the Bioequivalence (BE) for Pediatric Formulations: OGD Perspective, Challenges and Strategies to Facilitate Formulation Development of Pediatric Drug Products; a symposium sponsored by the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI), College Park, MD, June 8, 2016.
18. Gelder TV, Jiang W. Do High Risk Transplant Recipients Take Higher Risk When Treated With Generic Tacrolimus? American Transplant Congress, Boston, MA, June 11-15, 2016.
19. Hansen RA, Qian J, Berg RL, Linneman JG, Seoane-Vazquez E, Dutcher S, Raofi S, Page CD, Peissig P. Comparison of outcomes following a switch from a brand to an authorized vs independent generic drug, 32nd International Conference on Pharmacoepidemiology and Therapeutic Risk Management, Dublin, Ireland, August 25-28, 2016.
20. Heisig M. Modelling the effect of an ethanol/water vehicle on transient percutaneous penetration – a computational parameter study, TechSim Workshop, October, 2016.
21. Hocchaus G. Correlating the In Vitro Dissolution Behavior of Inhalation and Nasal Drug Products With In Vivo Performance: Pitfalls And Potential Solutions Using The Transwell System, International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS) / Respiratory Drug Delivery (RDD) Conference, Phoenix, AZ, April 17-21, 2016.
22. Jiang W. FDA perspectives on determining equivalence of Generic Complex drug products, New York Academy of Science Workshop: Equivalence of Complex Drug Products: Scientific and Regulatory Challenges, NYC, NY, November 9, 2016.
23. Jiang W. FDA town hall update on generic AEDs, American Epilepsy Society (AES), Houston, TX, December 5, 2016.
24. Jiang W. Nanotechnology drug products: Liposomes, 2016 Global summit of regulatory science, Bethesda, MD, September 7, 2016.
25. Jiang X. Generic Drugs and GDUFA Regulatory Science at FDA, Pacific Northwest National Laboratory, Bellevue, WA, July 14, 2016.
26. Jiang X. Regulatory Considerations for Complex Drug Substances Including Peptides, Controlled Release Society Annual Meeting, Seattle, WA, July 16, 2016.
27. Jiang X. Regulatory Science under the Generic Drug User Fee Act of 2012 (GDUFA), American Chemical Society National Meeting & Exposition, San Diego, CA, March 14, 2016.
28. Kanfer I. The Development And Application Of Surrogate Methods To Assess Bioequivalence Of Topical Generic Products Intended For Local Action,3rd Bioequivalence Summit: Ensure Regulatory Compliance When Demonstrating the Bioequivalence of New Dosage Forms, Delivery Methods and Biosimilars, Boston, MA, September 26, 2016.
29. Kannan R, Chen ZJ, Singh N, Przekwas A, Delvadia R, Tian G. A Multiscale Framework For Computational Inhalation Pharmacology, 2nd International Conference on Respiratory & Pulmonary Medicine, Chicago, IL, October 17-19, 2016.

30. Kitabi EN. A Signal to Noise Ratio Classification System of Drugs to Investigate Generic Drug Ineffectiveness Claims, American College of Clinical Pharmacology (ACCP), Bethesda, MD, September 25-27, 2016.
31. Lapteva L. Drug Product Development in Autoimmune Renal Diseases: Regulatory Perspective, International Society of Nephrology, April 6, 2016.
32. Lapteva L. Generic Drug Product Development: Regulatory Perspective, 2016 Annual Conference American Thoracic Society, San Francisco, CA, May 16, 2016.
33. Lionberger R. Challenges in Bioequivalence for Locally Acting Products, 2016 AAPS Workshop on Locally-Acting Drug Products: Bioequivalence Challenges and Opportunities, Denver, CO, November 12, 2016.
34. Lionberger R. Introduction to FDA's draft guidance on the General Principles for Evaluation of Abuse Deterrence of Generic Solid Oral Opioid Drug Products, Public Meeting on Pre-Market Evaluation of Abuse-deterrent properties of Opioid Drug Products, College Park, MD, October 31, 2016.
35. Lionberger R. Role of PBPK based virtual trials modelling in generic product development, 2016 AAPS Annual Meeting, Denver, CO, November 15, 2016.
36. Lionberger R. Scientific Agenda Update and Complex Product Discussion, GPhA Fall Technical Meeting, Bethesda, MD, October 26, 2016.
37. Longest W, Rygg A, Hindle M. Bioequivalence Testing: Can Systemic Pharmacokinetic Profiles From Corticosteroid Nasal Sprays Be Used To Elucidate Local Drug Deposition Within The Nose? Respiratory Drug Delivery 2016, Silver Spring, MD, April 17-21, 2016.
38. Luke M. Generic Drugs: A Primer and Perspective from FDA, SAPA, Washington DC, September 27, 2016.
39. Matsson E. Drug Interaction Assessment in Drug Development and Regulatory Approval, American Society for Clinical Pharmacology and Therapeutics, San Diego, CA, March 8, 2016.
40. Meng A, Trame MN, Schmidt S, Fang L, Lesko LJ. Application of pharmacokinetic/pharmacodynamics modeling to simulate potential differences in bioequivalence between generic and brand name gabapentin products, American Society of Clinical Pharmacology and Therapeutics Annual Meeting, San Diego CA, March, 2016.
41. Murthy N. Characterizing Failure Modes And Critical Quality (Q3) Attributes Of Semi-Solid Topical Drug Products, International Conference on Perspectives in Percutaneous Penetration La Grande Motte, France, March 30, 2016.
42. Murthy SN. Beyond Q1/Q2—Comparing the Arrangement of Matter (Q3) and Performance, The American Association of Pharmaceutical Scientists (AAPS) Annual Meeting, Denver, CO, November 12, 2016.
43. Nägel A, Heisig M, Wittum G. Mathematical Models for Skin Penetration, 5th Galenus-Workshop, Berlin, Germany, November, 2016.
44. Page D. Machine Learning For Adverse Drug Event Detection, 2nd Seattle Symposium on Health Care Data Analytics, Seattle, WA, October 23-26, 2016.
45. Patel N, Martins F, Cristea S, Salem F, Abduljalil K, Jamei M, Polak S. PBPK Modelling of Dermal Drug Absorption and Population Variability Simcyp MPML MechDermA Model, Pharmacokinetics UK Annual Meeting, London, UK, November, 2016.

46. Patela N, Cristeaa S, Jameia M, Salema F, Polaka S. Mechanistic Modelling Of Dermal Drug Absorption Using Simcyp MPML MechDermA Model Rationale Behind Model Development, Its Shape And Performance, Skin Forum Annual Meeting, London, UK, June, 2016.
47. Polak S. Mechanistic modelling of dermal drug absorption using Simcyp MPML MechDermA model rationale behind model development, its shape and performance, Skin Forum Meeting, London, UK, June, 2016.
48. Polli JE, et al. Bioequivalence in Epilepsy Patients and Assessment of Generic Brittleness, Johns Hopkins CERSI Substitutability of Generic Drugs: Perceptions and Reality, Baltimore, MD, November 18, 2016.
49. Polli JE, et al. Exploring Generic Brittleness in Epilepsy Patients, American Epilepsy Society (AES), Houston, TX, December 5, 2016.
50. Polli JE. Non-Inferiority Assessment for Iron-Carbohydrate Complexes, 2016 Research Day - University of Maryland School of Pharmacy, Baltimore, MD, April 22, 2016.
51. Qian J, Hansen R, Surry D, Howard J, Kiptanui Z, and Harris I. Disclosure Of Industry Payments To Prescribers: Industry Payments Might Be A Factor Impacting Generic Drug Prescribing,32nd International Conference on Pharmacoepidemiology &Therapeutic Risk Management, Dublin, Ireland, August 25-28, 2016.
52. Raney SG. Dosage Form And Function: Bioavailability And Bioequivalence Implications For Topical Dermatological Products, AAPS 2016, Denver, CO, November 12, 2016.
53. Raney SG. The Matter Of Medicine-Does Form Follow Function Or Vice Versa? Rutgers Center for Dermal Research Workshop: The Role of Topical Semi-solid Microstructure on Product Performance and Functionality, Piscataway, NJ, May 24, 2016.
54. Ren W, Kelm G, Choi S, Kozak D, Absar M, Wang Y, Chow E, Walenga R, Li SK. Low Volume Dissolution Devices for Long Acting Periodontal Drug Products, AAPS 2016, Denver, CO, November 13-17, 2016.
55. Roberts MS. Topical Semisolid Drug Product Critical Quality Attributes (Q3 Characterization) With Relevance To Topical Bioequivalence, International Conference on Perspectives in Percutaneous Penetration La Grande Motte, France, March 30, 2016.
56. Romanelli RJ, Nimbal V, Segal JB. Provider-Level Variation And Determinants Of Outpatient Generic Prescribing In A Mixed-Payer Healthcare System, 22nd Annual Health Care Systems Research Network Conference, Atlanta, GA, April 13-16, 2016.
57. Schroeter JD. Prediction II: Computational Fluid Dynamics, as part of a workshop titled Bridging the Gap from Science to Clinical Efficacy: Imaging, Modelling, and Physiology of Aerosols and the Lung, International Society for Aerosols in Medicine Conference, Munich, Germany, May 30-June 3, 2016.
58. Shin S. In Vitro And In Vivo Evaluation Of Three Fentanyl Transdermal Delivery Systems In Conjunction With Transient Heat Exposure, AAPS 2016, Denver, CO, November 08, 2016.
59. Shur J. The Development of Predictive Dissolution Methods for Orally Inhaled Drug Products, IPAC-RS 2016 Symposium, Scottsdale, AZ, April 21, 2016.
60. Sinner F. Dermal Open Flow Microperfusion (DoFM) for the Bioequivalence Assessment of Topical Products Based on Skin PK, International Conference and Expo on Generic Drug Market and Contract Manufacturing, Barcelona, Spain, November 07, 2016.

61. Sinner F. In-vivo Open Flow Microperfusion for Evaluating Topical Bioavailability, Fifteenth International Conference on Perspectives in Percutaneous Penetration, La Grande Motte, France, March 30, 2016.
62. Stinchcomb AL. Bioavailability And Bioequivalence Of Products Applied To The Skin, Third Bioequivalence Summit: Ensure Regulatory Compliance When Demonstrating the Bioequivalence of New Dosage Forms, Delivery Methods and Biosimilars, Boston, MA, September 26, 2016.
63. Stinchcomb AL. Ivivc In Transdermal Drug Delivery: Streamlining The Drug Approval Process, Transdermal and Intradermal Drug Delivery Systems 2016: Advanced Design, Development and Delivery of Skin-Mediated Therapies and Vaccines, Philadelphia, PA, May 24, 2016.
64. Suh M, Kastellorizios M, Qu W, Wang Y, Choi S, Burgess DJ. Research Highlight Talk in the session "Parenteral Systemic Delivery of Biopharmaceuticals: Overcoming Product Development and Regulatory Challenges", Controlled Release Society Annual Meeting, Seattle, WA, July, 2016.
65. Vinks AA. Evaluating Transplant Donor And Recipient Pharmacogenetics And Its Impact On Variability In Tacrolimus And Metabolite Pharmacokinetics, American Transplant Congress, Boston, MA, June 11-15, 2016.
66. Wang Y. Challenges in Evaluating Bioequivalence of Generic Microsphere Drug Products, Controlled Release Society Annual Meeting, Seattle, WA, July 16, 2016.
67. Wen H. Overview of Inactive Ingredients, Lyo Synergy Session of NIPTE and LyoHub, Rockville, MD, September 19, 2016.
68. Wittayanukorn S, Babiskin A, Dutcher S, Pu X, Hu M, Zhao L, Lionberger R. Patterns of Bioequivalence Recommendations and Trends of Abbreviated New Drug Approval over Time, ISPOR, Washington, DC, May 21-25, 2016.
69. Zee J, Bello GA, Oguntimein M, Beil C, Li Q, Park J, Saulles AD, Goel S, Balkrishnan R, Fava M, Sharma, Robert M Merion P, Leichtman AB. Comparison of the Effects of Brand Name Versus Generic Immunosuppressants on Long-Term Graft Failure Risk Among US Kidney Transplant Recipients: Analysis of SRTR and Medicare Claims Data, 2016 The Transplantation Society Conference, Hong Kong, August 18-23, 2016.
70. Zhang D. Upcoming Guidance for Submitting Synthetic Peptides as ANDAs Referencing NDA Peptides of rDNA Origin, USP Workshop on Synthetic Therapeutic Peptide - Regulations and Standards and Quality, Rockville, MD, November 15, 2016.
71. Zhang D. Scientific Considerations in Submitting Synthetic Peptide Drug Products as ANDAs Referencing Peptide Drug products of rDNA origin,3rd USP Workshop on Synthetic Therapeutic Peptides - Regulations, Standards and Quality, Rockville, MD, November 14-15, 2016.
72. Zhang X. One Health Initiative: In silico modeling: examples in human health, One Health Webinar, Silver Spring, MD, July 28, 2016.
73. Zhang X. Physiologically Base Pharmacokinetic and Absorption Modeling and Simulation, Cases Studies USP workshop: Computer Modeling – In vitro and In vivo studies, Rockville, MD, October 23, 2016.
74. Zhang X. The Science of Therapeutic Equivalence, UCSF-CERSI lecture, San Francisco, CA, September 1, 2016.

75. Zhao L. Foundations of PK comparisons of generic opioids to RLDs with labeling describing abuse-deterrent properties, FDA Public Meeting (Pre-market Evaluation of AD Properties of Opioid Drug Products), College Park, MD, Oct 31, 2016.
76. Zhao L. Regulatory considerations for equivalence evaluation of parenteral drug delivery systems, 2016 AAPS Annual Meeting, Denver, CO, November 12, 2016.
77. Zhao L. Scientific And Regulatory Background For The Revised Bioequivalence Requirements For NTI, Steep Exposure-Response, And Drugs With Complex PK Profiles, 2016 AAPS Annual Meeting, Denver, CO, November 15, 2016.
78. Zhao L. The Utility of Modeling and Simulation in Understanding Locally Acting Drug Delivery, 2016 AAPS Workshop on Locally-Acting Drug Products: Bioequivalence Challenges and Opportunities, Denver, CO, November 13, 2016.