FDA Office of Generic Drugs Office of Research & Standards (ORS)
Presentations by External Collaborators and ORS Staff in Fiscal Year 2017

1. Choi S. Regulatory Science Update, FDA Small Business Regulatory Education for Industry (REdI): Generic Drugs Forum, Silver Spring, MD, April 4, 2017.
2. Choi S. GDUFA Research And Regulatory Initiatives For Complex Ophthalmic Products,505b2 and Generics Workshop, Somerset, NJ, September 21, 2017.
3. Choi S. Generic Drug Regulatory Research: In Vitro Equivalence Testing, IFPAC, Rockville, MD, March 02, 2017.
4. Choi S. Impact of Excipient Grade (Q1/Q2) on the Bioequivalence of Generic Drug Products, FDA-USP Workshop on Standards for Pharmaceutical Products, Rockville, MD, February 27, 2017.
5. Fan, J. Regulatory Experience with Mechanistic Oral Absorption Modeling and Simulation for Formulation Development and Bioequivalence Evaluation, IFPAC, Rockville, MD, March 2, 2017.
6. Heisig M. Parameter Sensitivity Analysis of a Two-Dimensional Skin Diffusion Model, International Multigrid Conference, Bruchsal, Germany, December 5-9, 2017.
7. Jiang W. Evolving Regulatory Sciences for Generic Drugs, ASQ509 Biomed/Biotech SIG Meeting, Rockville, MD, July, 2017.
8. Jiang W. Excipients in Parenteral Drug Products, FDA-USP Workshop on Standards for Pharmaceutical Products, Rockville, MD, February 27-28, 2017.
9. Jiang W. Characterizations of Nanomaterials, 2017 Carolina Nanoformulation Workshop, Chapel Hill, NC, March 13, 2017.
10. Jiant W. Tacrolimus Intra-Patient Variability Determined from Daily Trough Levels in Adherent Kidney and Liver Transplant Recipients, 2017 American Transplant Congress, Chicago, IL, April 30, 2017.
11. Kesselheim AS. Variations in Use of Generic Drugs By Patient Characteristics in the United States: Evidence from the Medical Expenditure Panel Survey, Academy Health 2017 Annual Research Meeting, New Orleans, LA, June 25-27, 2017.
12. Liang, Z. Assessing Excipients Impact on Drug Absorption by Physiologically Based Pharmacokinetic Modeling, FDA-USP Workshop on Standards for Pharmaceutical Products, Rockville, MD, February 27-28, 2017.
13. Lionberger, R. Generic Drug Equivalence Standards for Topical Dermatological Products, American Academy of Dermatology 75th Annual Meeting: FDA Hot Topics - The Evolving Regulatory Landscape, Orlando, FL, March 3-7, 2017.
14. Luke M, Raney S, Ghosh P, Dandamudi S. A Case Study with Acyclovir, a Complex Topical Dermatologic Drug Product, OGD Science Forum, Silver Spring, MD, March, 2017.
15. Markham L. Equivalence of Locally-Acting Drug Products, GDUFA Research Public Workshop, Silver Spring, MD, May 03, 2017.
16. Martins F, Patel N, Jamei M, Polak S. Development and validation of a dermal PBPK model for prediction of the hair follicular absorption of caffeine: Application of the Simcyp MechDermA model, 14th European ISSX Meeting Organizing Committee, Cologne, Germany, June 26-29, 2017.

17. Martins F, Patel N, Salem F, Jamei M, Polak S. Multi-phase Multi-layer MechDermA model: Development, verification and application of a PBPK-PD model of dermal absorption for transdermal product assessment. Multi-phase Multi-layer MechDermA model: Development, verification and application of a PBPK-PD model of dermal absorption for transdermal product assessment, Gordon Research Conference on the Barrier Function of Mammalian Skin, Waterville Valley, NH, August 13-18, 2017.
18. Martins F. PBPK Modelling of Dermal Drug Absorption and Population Variability Simcyp MPML MechDermA model, University of Bath, Bath, UK, January, 2017.
19. Myung JH. Assessing Particle Counting Techniques to Improve the Regulatory Review of Complex Colloidal Drug Products, ACS Colloids and Surface Science Symposium, New York, NY, July 10, 2017.
20. Polak S, Patel N, Martins F, Salem F, Jamei M. Predicting diclofenac systemic and synovial fluid concentrations after dermal application using the Multi-Phase Multi-Layer MechDermA PBPK model, Population Approach Group of Europe (PAGE) Annual Meeting, Budapest, Hungary, June, 2017.
21. Polak S. Mechanistic Modelling of Dermal Drug Absorption using Simcyp MPML MechDermA Model Rationale Behind Model Development, Its Shape and Performance, Presentation to FDA, Silver Spring, MD, March 24, 2017.
22. Polli JE, et al. Bioequivalence in Epilepsy Patients and Assessment of Generic Brittleness, IFPAC, North Bethesda, MD, March, 2017.
23. Pottel J, Algaa E, Irwin J, Shoichet B. Activity Of Inactive Ingredients: Foundations For Innovation In Drug Excipients, ACS, Washington, DC, August 20-24, 2017.
24. Qian J, Hansen R, Frank G, Howard J, Kiptanui Z, Harris I. Key Groups Influencing Generic Drug Use in the US: the Nature and Extend of Their Influence, ISPOR 22nd Annual International Meeting, Boston, MA, May 20-24, 2017.
25. Qian J, Hansen R, Surry D, Howard J, Kiptanui Z, Harris I. Understanding Global Influencers of Generic Drug Use among Older Adults, 21st International Association of Gerontology and Geriatrics (IAGG) World Congress, San Francisco, CA, July 23-27, 2017.
26. Qian J, Hansen R, Frank G, Mishuk A, Howard J, Kiptanui Z, and Harris I. The Association between Patient Sociodemographic Characteristics and Generic Drug Use – a Systematic Review and Meta-analysis, ISPOR 22nd Annual International Meeting, Boston, MA, May 20-24, 2017.
27. Raney S. Facilitating Patient Access to High Quality Generics: A Case Study in Regulatory Science, American Academy of Dermatology Annual Meeting Forum on FDA Hot Topics: The Evolving Regulatory Landscape, Orlando, FL, March, 2017.
28. Raney S. In Vitro Characterizations of Topical Semisolid Dosage Forms, 3rd PQRI/FDA Conference on Advancing Product Quality, Rockville, MD, March, 2017.
29. Raney SG. Cutaneous Pharmacokinetics and pharmacodynamics for the 21st Century,7th AGAH Dermatology Product Development Workshop, Bethesda, MD, May 12, 2017.
30. Raney SG. Why Do We Call Excipients in Topical Products Inactive Ingredients? FDA-USP Workshop on Standards for Pharmaceutical Products, Rockville, MD, February, 2017.

31. Shin SH. Evaluation of Level A In Vitro In Vivo Correlations (IVIVC) for Nicotine and Fentanyl Transdermal Delivery Systems(TDS) with Transient Heat Exposure by Using Multiple Approaches, 2017 Barrier Function of Mammalian Skin (GRS), Waterville Valley, NH, August 12, 2017.
32. Shoichet B. An Open Access Excipients Database and Its Use to Investigate Their Possible Biological Targets, FDA-USP Workshop on Standards for Pharmaceutical Products, Rockville, MD, February 27-28, 2017.
33. Shoichet B. An Open Access Excipients Database and Its Use to Investigate Their Possible Biological Targets, USCPT Meeting, Washington DC, Mar 17, 2017.
34. Sinner F. Innovative Dermal PK and PD: In Vivo Proof-of-Mechanism to Clinical Dermal Bioequivalence using Open Flow Microperfusion,7th AGAH Dermatology Product Development Workshop, Bethesda, MD, May 12, 2017.
35. Stern ST. Nanomedicine Pharmacokinetics and Bioanalytical Methods to Measure Drug Release, 11th World Drug Delivery Summit, Baltimore, MD, October 16, 2017.
36. Ting TY. The Story of Generic AED Equivalence Testing – How the Epilepsy Community Made a Difference, Ammon's Horn Society Meeting, sponsored by Abilities Network/Epilepsy Foundation Chesapeake Region, Chevy Chase, MD,42864, 2017.
37. Wittayanukorn S, Dutcher S, Zhao L, Babiskin A. Pattern of market exclusivity and the entry of abbreviated new drug applications, ISPOR 22th Annual International Meeting, Boston, MA, May 20-24, 2017.
38. Witzmann KA. Impact Of Excipients On Inhalation Drug Products, FDA & USP Workshop on Standards of Pharmaceutical Products: Critical Importance of Excipients in Product Development – Why Excipients are Important Now and In the Future, Rockville, MD, February 28, 2017.
39. Yeoh T, Singh B, Dick L, Milewski M, Mitragotri S, Donnelly R. Heat Effects and IVIVC in Transdermal and Topical Drug Delivery, Transdermal & Intradermal Drug Delivery Systems, Philadelphia, PA, September 28-29, 2017.