

Publications Relating to GDUFA Science and Research in Fiscal Year 2022

1. Abdullah A, Sommers C, Hawes J, Rodriguez J, and Yang K. *Tandem Mass Spectrometric Sequence Characterization of Synthetic Thymidine-Rich Oligonucleotides*. Journal of Mass Spectrometry. 57(4): e4819. <https://doi.org/10.1002/jms.4819>. PMID: 35347805.
2. Alfaifi A, Hosseini S, Esmaeili A, Walenga R, Babiskin A, Schuman T, Longest W, Hindle M, and Golshahi L. *Anatomically Realistic Nasal Replicas Capturing the Range of Nasal Spray Drug Delivery in Adults*. International Journal of Pharmaceutics. (2022) 622: 121858. <https://doi.org/10.1016/j.ijpharm.2022.121858>. PMID: 35643344.
3. Ansar S, Jiang W, and Mudalige T. *Analysis of Verteporfin Liposomal Formulations for Phospholipids and Phospholipid Degradation Products by Liquid Chromatography-mass Spectrometry (LC-MS)*. Journal of Pharmaceutical and Biomedical Analysis. (2022) 208. <https://doi.org/10.1016/j.jpba.2021.114473>. PMID: 34814079.
4. Arora S, Clarke J, Tsakalozou E, Ghosh P, Alam K, Grice J, Roberts M, Jamei M, and Polak S. *Mechanistic Modeling of In Vitro Skin Permeation and Extrapolation to In Vivo for Topically Applied Metronidazole Drug Products Using a Physiologically Based Pharmacokinetic Model*. Molecular Pharmaceutics. (2022) 19(9): 3139-3152. <https://doi.org/10.1021/acs.molpharmaceut.2c00229>. PMID: 35969125.
5. Bachhav S, Sheth P, Sandell D, Svensson M, Bhagwat S, Conti D, Oguntiemein O, Dhapare S, Saluja B, Winner L, Bulitta J, and Hochhaus G. *Systematic Evaluation of the Effect of Formulation Variables on In Vitro Performance of Mometasone Furoate Suspension-Metered Dose Inhalers*. The AAPS Journal. (2021) 24(1): 9. <https://doi.org/10.1208/s12248-021-00638-1>. PMID: 34874508.
6. Backman P, Cabal A, Clark A, Ehrhardt C, Forbes B, Hastedt J, Hickey A, Hochhaus G, Jiang W, Kassinos S, Kuehl P, Prime D, Son Y, Teague S, Tehler U, and Wylie J. *iBCS: 2. Mechanistic Modeling of Pulmonary Availability of Inhaled Drugs versus Critical Product Attributes*. (2022) 19(7): 2040-2047. <https://doi.org/10.1021/acs.molpharmaceut.2c00112>. PMID: 35609877.
7. Bao Q, Wang X, Zou Y, Wang Y, and Burgess D. *In Vitro Release Testing Method Development for Long-Acting Injectable Suspensions*. International Journal of Pharmaceutics. (2022) 622(121840). <https://doi.org/10.1016/j.ijpharm.2022.121840>. PMID: 35595043.
8. Beig A, Ackermann R, Wang Y, Schutzman R, and Schwendeman S. *Minimizing the Initial Burst of Octreotide Acetate from Glucose Star PLGA Microspheres Prepared by the Solvent Evaporation Method*. International journal of pharmaceutics. (2022) 624(121842). <https://doi.org/10.1016/j.ijpharm.2022.121842>. PMID: 35609832.
9. Bellantone R, Shah K, Patel P, Kaplan M, Xu X, Li V, Newman B, and Kaisar M. *Cyclosporine Release and Distribution in Ophthalmic Emulsions Determined by Pulsatile Microdialysis*. International Journal of Pharmaceutics. (2022) 615. <https://doi.org/10.1016/j.ijpharm.2022.121521>. PMID: 35093461.
10. Brito J, Deng Y, Ross J, Choi N, Graham D, Qiang Y, Rantou E, Wang Z, Zhao L, Shah N, and Lipska K. *Association Between Generic-to-Generic Levothyroxine Switching and Thyrotropin Levels Among US*

Adults. JAMA Internal Medicine. (2022) 182(4): 418-425.
<https://doi.org/10.1001/jamainternmed.2022.0045>. PMID: 35226058.

11. Brito J, Wang Z, and Lipska K. *Considerations for Generic-to-Generic Levothyroxine Switching-Reply*. JAMA Internal Medicine. (2022) 182(8): 887. <https://doi.org/10.1001/jamainternmed.2022.1990>. PMID: 35666533.
12. Burrows V, and Luke M. *The History of Dermatology and Dermatologists at the US Food and Drug Administration*. Dermatologic Clinics. (2022) 40(3): 237-248. <https://doi.org/10.1016/j.det.2022.03.001>. PMID: 35750408.
13. Capecelatro J, Longest W, Boerman C, Sulaiman M, and Sundaresan S. *Recent Developments in the Computational Simulation of Dry Powder Inhalers*. Advanced Drug Delivery Reviews. (2022) 188. <https://doi.org/10.1016/j.addr.2022.114461>. PMID: 35868587.
14. Chari S, Sridhar K, and Kleinstreuer C. *Effects of Subject-Variability on Nasally Inhaled Drug Deposition, Uptake, and Clearance*. Journal of Aerosol Science. (2022) 165: 106021. <https://doi.org/10.1016/j.jaerosci.2022.106021>.
15. Chen K. *2D NMR Peak Profiling to Compare Chemical Differences between Batches of Pentosan Polysulfate Sodium*. Journal of Pharmaceutical and Biomedical Analysis. (2022) 211: 114589. <https://doi.org/10.1016/j.jpba.2022.114589>. PMID: 35038672.
16. Clark A, Wang R, Qin Y, Wang Y, Zhu A, Lomeo J, Bao Q, Burgess D, Chen J, Qin B, Zou Y, and Zhang S. *Assessing Microstructural Critical Quality Attributes in PLGA Microspheres by FIB-SEM Analytics*. Journal of Controlled Release. (2022) (349): 580-591. <https://doi.org/10.1016/j.jconrel.2022.06.066>. PMID: 35803326.
17. Dave S, Kleinstreuer C, and Chari S. *An Effective PBPK Model Predicting Dissolved Drug Transfer from a Representative Nasal Cavity to the Blood Stream*. Journal of Aerosol Science. (2022) 160: 105898. <https://doi.org/10.1016/j.jaerosci.2021.105898>.
18. Dhapare S, Mohan A, Newman B, Svensson M, Elfman P, Sandell D, Winner L, Berger S, Bulitta J, and Hochhaus G. *Effects of Realistic In Vitro Test Factors on the Aerosol Properties of Metered-Dose Inhalers (MDIs)*. Drug Delivery to the Lungs. 32.
19. Dutta R, Kolanjiyil A, Golshahi L, and Longest P. *Development of a CFD-PK Nasal Spray Model with In Vivo Human Subject Validation*. Respiratory Drug Delivery (RDD) 2022. (2022) 1: 483-488.
20. Elfakhri K, Niu M, Ghosh P, Ramezanli T, Raney S, Ahmed S, Willett D, Yilmaz H, Ashraf M, and Zidan A. *Physicochemical and Structural Evaluation of Microparticles in Tretinoin Topical Gels*. International Journal of Pharmaceutics. (2022). <https://doi.org/10.1016/j.ijpharm.2022.121748>. PMID: 35427749.
21. El-Gendy N, Bertha C, El-Shafy M, Gaglani D, Babiskin A, Bielski E, Boc S, Dhapare S, Fang L, Feibus K, Kaviratna A, Li B, Luke M, Ma T, Newman B, Walenga R, and Zhao L. *Scientific and Regulatory Activities Initiated by the U.S. Food and Drug Administration to Foster Approvals of Generic Dry Powder Inhalers: Quality Perspective*. Advanced Drug Delivery Reviews. (2022) 189(114519). <https://doi.org/10.1016/j.addr.2022.114519>. PMID: 36038083.

22. Esmaeili A, Hosseini S, Wilkins J, Alfaifi A, Dhapare S, Walenga R, Newman B, Schuman T, Longest P, Hindle M, and Golshahi L. *In Vitro Evaluation of Regional Drug Deposition in Nasal Airways of Children Using Realistic Anatomical Replicas*. Respiratory Drug Delivery (RDD) 2022. 1: 493-498.
23. Fanse S, Bao Q, Zou Y, Wang Y, and Burgess D. *Effect of Crosslinking on the Physicochemical Properties of Polydimethylsiloxane-Based Levonorgestrel Intrauterine Systems*. International Journal of Pharmaceutics. (2021) 609(121192). <https://doi.org/10.1016/j.ijpharm.2021.121192>. PMID: 34666142.
24. Fanse S, Bao Q, Zou Y, Wang Y, and Burgess D. *Impact of Polymer Crosslinking on Release Mechanisms from Long-Acting Levonorgestrel Intrauterine Systems*. International Journal of Pharmaceutics. (2022) 612. <https://doi.org/10.1016/j.ijpharm.2021.121383>. PMID: 34919997.
25. Garner J, Skidmore S, Hadar J, Park H, Park K, Otte A, Jhon Y, Xu X, Qin B, and Wang Y. *Scanning Analysis of Sequential Semisolvent Vapor Impact to Study Naltrexone Release from Poly(lactide-co-glycolide) Microparticles*. Molecular Pharmaceutics. <https://doi.org/10.1021/acs.molpharmaceut.2c00595>. PMID: 36166409.
26. Garner J, Skidmore S, Hadar J, Park H, Park K, Qin B, and Wang Y. *Surface Analysis of Sequential Semi-Solvent Vapor Impact (SAVI) for Studying Microstructural Arrangements of Poly(lactide-co-glycolide) Microparticles*. Journal of Controlled Release. 350: 600-612. <https://doi.org/10.1016/j.jconrel.2022.08.052>. PMID: 36057396.
27. Ghosh P, Raney S, and Luke M. *How Does the Food and Drug Administration Approve Topical Generic Drugs Applied to the Skin?* Dermatologic Clinics. (2022) 40(3): 279-287. <https://doi.org/10.1016/j.det.2022.02.003>. PMID: 35750411.
28. Golshahi L, Alfaifi A, Hosseini S, Esmaeili A, Hindle M, Longest P, 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*. Respiratory Drug Delivery (RDD) 2022. (2022) 1: 37-46.
29. Gong X, Hu M, Basu M, and Zhao L. *Heterogeneous Treatment Effect Analysis Based on Machine-Learning Methodology*. CPT: Pharmacometrics & Systems Pharmacology. (2021) 10(11): 1433-1443. <https://doi.org/10.1002/psp4.12715>. PMID: 34716669.
30. Gong X, Hu M, Liu J, Kim G, Xu J, McKee A, Palmby T, Claro R, and Zhao L. *Decoding Kinase-Adverse Event Associations for Small Molecule Kinase Inhibitors*. Nature Communications. (2022) 13(1): 4349. <https://doi.org/10.1038/s41467-022-32033-5>. PMID: 35896580.
31. Gong Y, Feng K, Zhang P, Lee J, Pan Y, Zhang Z, Ni Z, Bai T, Yoon M, Li B, Kim C, Fang L, and Zhao L. *Quantitative Methods and Modeling to Assess COVID-19 Interrupted In Vivo Pharmacokinetic Bioequivalence Studies with Two Reference Batches*. CPT Pharmacometrics Systems Pharmacology. (2022) 11(7): 833-842. <https://doi.org/10.1002/psp4.12795>. PMID: 35411692.
32. Guhl M, Mercier F, Hofmann C, Sharan S, Donnelly M, Feng K, Sun W, Sun G, Stella G, Zhao L, Fang L, Mentre F, Comets E, and Bertrand J. *Impact of Model Misspecification on Model-Based Tests in PK Studies with Parallel Design: Real Case and Simulation Studies*. Journal of Pharmacokinetics and Pharmacodynamics. (2022) 49(5): 557-577. <https://doi.org/10.1007/s10928-022-09821-z>. PMID: 36112338.

33. Hamadeh A, Troutman J, Najjar A, and Edginton A. *A Mechanistic Bayesian Inferential Workflow for Estimation of In Vivo Skin Permeation from In Vitro Measurements*. Journal of Pharmaceutical Sciences. (2022) 111(3): 838-851. <https://doi.org/10.1016/j.xphs.2021.11.028>. PMID: 34871561.
34. Hastedt J, Backman P, Cabal A, Clark A, Ehrhardt C, Forbes B, Hickey A, Hochhaus G, Jiang W, Kassinos S, Kuehl P, Prime D, Son Y, Teague S, Tehler U, and Wylie J. *iBCS: 1. Principles and Framework of an Inhalation-Based Biopharmaceutics Classification System*. Molecular Pharmaceutics. (2022) 19(7): 2032-2039. <https://doi.org/10.1021/acs.molpharmaceut.2c00113>. PMID: 35576168.
35. Hochhaus G, Amini E, Berger S, Shur J, Kurumaddali A, Schilling U, Jiao Y, Drescher S, Seay B, Baumstein S, Abu Hasan M, Oguntiemein 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*. Respiratory Drug Delivery (RDD) 2022. (2022) 1: 47-54.
36. Holley C, Cedrone E, Donohue D, Neun B, Verthelyi D, Pang E, and Dobrovolskaia M. *An In Vitro Assessment of Immunostimulatory Responses to Ten Model Innate Immune Response Modulating Impurities (IIRMIs) and Peptide Drug Product, Teriparatide*. Molecules. (2021) 26(24): 7461. <https://doi.org/10.3390/molecules26247461>. PMID: 34946542.
37. Jung N, Namjoshi S, Mohammed Y, Grice J, Benson H, Raney S, Roberts M, and Windbergs M. *Application of Confocal Raman Microscopy for the Characterization of Topical Semisolid Formulations and their Penetration into Human Skin Ex Vivo*. Pharmaceutical Research. (2022) 39(5): 935-948. <https://doi.org/10.1007/s11095-022-03245-7>. PMID: 35411509.
38. Kolanjiyil A, Alfaifi A, Aladwani G, Golshahi L, and Longest W. *Importance of Spray-Wall Interaction and Post-Deposition Liquid Motion in the Transport and Delivery of Pharmaceutical Nasal Sprays*. Pharmaceutics. (2022) 14(5): 956. <https://doi.org/10.3390/pharmaceutics14050956>. PMID: 35631539.
39. Kolanjiyil A, Golshahi L, and Longest P. *On the Importance of Liquid Motion in Nasal Spray Delivery*. Respiratory Drug Delivery (RDD) 2022. (2022) 1: 515-520.
40. Kolanjiyil A, Hosseini S, Alfaifi A, Farkas D, Walenga R, Babiskin A, Hindle M, Golshahi L, and Longest P. *Validating CFD Predictions of Nasal Spray Deposition: Inclusion of Cloud Motion Effects for Two Spray Pump Designs*. Aerosol Science and Technology. (2022) 56(4): 305 - 322. <https://doi.org/10.1080/02786826.2021.2011830>.
41. Koo B, Liu Y, Abboud M, Qin B, Wu Y, Choi S, Kozak D, and Zheng J. *Characterizing How Size Distribution and Concentration Affect Echogenicity of Ultrasound Contrast Agents*. Ultrasonics. (2023) 127. <https://doi.org/https://doi.org/10.1016/j.ultras.2022.106827>. PMID: 36063769.
42. Kuehster L, Jhon Y, Wang Y, Smith W, Xu X, Qin B, Zhang F, and Lynd N. *Stochastic and Deterministic Analysis of Reactivity Ratios in the Partially Reversible Copolymerization of Lactide and Glycolide*. Macromolecules. (2022) 55(16): 7171–7180. <https://doi.org/https://doi.org/10.1021/acs.macromol.2c00757>.
43. Kuzma B, Senemar S, Ramezanli T, Ghosh P, Raney S, and Stagni G. *The Dose-Duration Effect on Cutaneous Pharmacokinetics of Metronidazole from Topical Dermatological Formulations in*

- Yucatan Mini-Pigs*. European Journal of Pharmaceutics and Biopharmaceutics. (2022) 175: 43-52. [https://doi.org/https://doi.org/10.1016/j.ejpb.2022.05.001](https://doi.org/10.1016/j.ejpb.2022.05.001).
44. Le Merdy M, Alqaraghuli F, Tan M, Walenga R, Babiskin A, Zhao L, and Lukacova V. *Clinical Ocular Exposure Extrapolation for Ophthalmic Solutions Using PBPK Modeling and Simulation*. Pharmaceutical Research. <https://doi.org/10.1007/s11095-022-03390-z>. PMID: 36151444.
 45. Lee J, Feng K, Conti D, Walenga R, Wientjes M, Wang H, Newman B, Han L, Dhapare S, Bielski E, Babiskin A, Wu F, Donnelly M, Kim M, Jiang W, Luke M, Fang L, and Zhao L. *Considerations for the Forced Expiratory Volume in 1 Second-Based Comparative Clinical Endpoint Bioequivalence Studies for Orally Inhaled Drug Products*. Clinical Pharmacology and Therapeutics. (2022) 112(5): 982-989. <https://doi.org/10.1002/cpt.2553>. PMID: 35133652.
 46. Lex T, Rodriguez J, Zhang L, Jiang W, and Gao Z. *Development of In Vitro Dissolution Testing Methods to Simulate Fed Conditions for Immediate Release Solid Oral Dosage Forms*. The AAPS Journal. (2022) 24(2): 40. <https://doi.org/10.1208/s12248-022-00690-5>. PMID: 35277760.
 47. Liang J, Koo B, Wu Y, Manna S, N, Patel M, Park J, Kozak D, Wang Y, and Zheng J. *Characterization of Complex Drug Formulations using Cryogenic Scanning Electron Microscopy (Cryo-SEM)*. Current Protocols. (2022) 2(4). <https://doi.org/10.1002/cpz1.406>. PMID: 35384403.
 48. Liu X, Cheruvu H, Anissimov Y, Van Der Hoek J, Tsakalozou E, Ni Z, Ghosh P, Grice J, and Roberts M. *Percutaneous Absorption of Steroids from Finite Doses: Predicting Urinary Excretion from In Vitro Skin Permeation Testing*. International Journal of Pharmaceutics. (2022) 625(122095). <https://doi.org/10.1016/j.ijpharm.2022.122095>. PMID: 35961420.
 49. Madabushi R, Seo P, Zhao L, Tegenge M, and Zhu H. *Review: Role of Model-Informed Drug Development Approaches in the Lifecycle of Drug Development and Regulatory Decision-Making*. Pharmaceutical Research. (2022) 39(8): 1669-1680. <https://doi.org/10.1007/s11095-022-03288-w>. PMID: 35552984.
 50. Martinez M, Sinko B, Wu F, Flanagan T, Borbas E, Tsakalozou E, and Giacomini K. *A Critical Overview of the Biological Effects of Excipients (Part I): Impact on Gastrointestinal Absorption*. The AAPS Journal. (2022) 24(3): 60. <https://doi.org/10.1208/s12248-022-00711-3>. PMID: 35501614.
 51. Martinez M, Wu F, Sinko B, Brayden D, Grass M, Kesisoglou F, Stewart A, and Sugano K. *A Critical Overview of the Biological Effects of Excipients (Part II): Scientific Considerations and Tools for Oral Product Development: Scientific Considerations and Tools for Product Development*. The AAPS Journal. 24(3). <https://doi.org/10.1208/s12248-022-00713-1>. PMID: 35501528.
 52. Marx R, Lee J, Svirkin Y, Yoon S, Landrau N, Kaisar M, Qin B, Park J, Alam K, Kozak D, Wang Y, Xu X, Zheng J, and Rivnay B. *Physicochemical Surrogates for In Vitro Toxicity Assessment of Liposomal Amphotericin B*. International Journal of Pharmaceutics. 628. <https://doi.org/10.1016/j.ijpharm.2022.122273>. PMID: 36228881.
 53. Miao L, Wu F, Yang X, Mousa Y, Ramamoorthy A, Lee S, Raines K, Zhang L, and Seo P. *Application of Solubility and Dissolution Profile Comparison for Prediction of Gastric pH-Mediated Drug-Drug Interactions*. The AAPS Journal. (2022) 24(1): 35. <https://doi.org/10.1208/s12248-022-00684-3>. PMID: 35166814.

54. 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*. Respiratory Drug Delivery (RDD) 2022. (2022) 1: 417-422.
55. Mosley S, Kim S, Rouby N, Lingineni K, Vozmediano V, Gong Y, Chen Y, Estores D, Feng K, Kim H, Kinjo M, Langaae T, Li Z, Schmidt S, Johnson J, Frye R, Fang L, Zhao L, Binkley P, Schmidt S, and Cavallari L. *A Randomized, Cross-over Trial of Metoprolol Succinate Formulations to Evaluate PK and PD Endpoints for Therapeutic Equivalence*. Clinical and Transitional Science. (2022) 15(7): 1764-1775. <https://doi.org/10.1111/cts.13294>. PMID: 35488487.
56. Naageshwaran V, Ranta V, Toropainen E, Tuomainen M, Gum G, Xie E, Bhoopathy S, Urtti A, and Del Amo E. *Topical Pharmacokinetics of Dexamethasone Suspensions in the Rabbit Eye: Bioavailability Comparison*. International Journal of Pharmaceutics. (2022) 615: 121515. <https://doi.org/10.1016/j.ijpharm.2022.121515>. PMID: 35091006.
57. Newman B, Babiskin A, Bielski E, Boc S, Dhapare S, Fang L, Feibus K, Kaviratna A, Li B, Luke M, Ma T, Walenga R, Wang Z, Zhao L, El-Gendy N, Bertha C, El-Shafy M, and Gaglani D. *Scientific and Regulatory Activities Initiated by the U.S. Food and Drug Administration to Foster Approvals of Generic Dry Powder Inhalers: Bioequivalence Perspective*. Advanced Drug Delivery Reviews. (2022) 190(114526). <https://doi.org/10.1016/j.addr.2022.114526>. PMID: 36067967.
58. Owens K, Argon S, Yu J, Yang X, Wu F, Lee S, Sun W, Ramamoorthy A, Zhang L, and Ragueneau-Majlessi I. *Exploring the Relationship of Drug BCS Classification, Food Effect, and Gastric pH-Dependent Drug Interactions*. The AAPS Journal. (2021) 24(1): 16. <https://doi.org/10.1208/s12248-021-00667-w>. PMID: 34961909.
59. Patel N, Clarke J, Salem F, Abdulla T, Martins F, Arora S, Tsakalozou E, Hodgkinson A, Arjmandi-Tash O, Cristea S, Gosh P, Alam K, Raney S, Jamei M, and Polak S. *Multi-Phase Multi-Layer Mechanistic Dermal Absorption (MPML MechDermA) Model to Predict Local and Systemic Exposure of Drug Products Applied on Skin*. CPT: Pharmacometrics Systems Pharmacology. (2022) 11(8): 1060-1084. <https://doi.org/10.1002/psp4.12814>. PMID: 35670226.
60. Peck C, Campbell G, Yoo I, Feng K, Hu M, and Zhao L. *Comparing a Bayesian Approach (BEST) with the Two One Sided Tests (TOST) for Bioequivalence Studies*. The AAPS Journal. (2022) 24(5): 97. <https://doi.org/10.1208/s12248-022-00746-6>. PMID: 36050426.
61. Raney S, Ghosh P, Ramezanli T, Lehman P, and Franz T. *Cutaneous Pharmacokinetic Approaches to Compare Bioavailability and/or Bioequivalence for Topical Drug Products*. Dermatologic Clinics. (2022) 40(3): 319-332. <https://doi.org/10.1016/j.det.2022.02.007>. PMID: 35750415.
62. Ray S, Boudewyns V, Davis C, Tzeng J, Srivastava I, Oguntiemein O, Conti D, and Feibus K. *Patient Perceptions of Switching to a Generic Dry Powder Inhaler – Increased Understanding Through Journey Mapping*. International Journal of Chronic Obstructive Pulmonary Disease. (2022) 17: 1751-1768. <https://doi.org/10.2147/COPD.S362696>. PMID: 35965841.
63. Roberts M, Cheruvu H, Mangion S, Alinaghi A, Benson H, Mohammed Y, Holmes A, Hoes J, Pastore M, and Grice J. *Topical Drug Delivery: History, Percutaneous Absorption, and Product Development*. Advanced Drug Delivery Reviews. (2021) 177. <https://doi.org/10.1016/j.addr.2021.113929>. PMID: 34403750.

64. Schroeter J, Rose M, Kimbell J, Chopski S, and Walenga R. *A Physiologically-Based Pharmacokinetic Model to Estimate Absorption and Bioavailability of Corticosteroid Nasal Sprays*. Respiratory Drug Delivery (RDD) 2022. (2022) 1: 197-200.
65. Schroeter J, Rose M, Kimbell J, Chopski S, and Walenga R. *A Physiologically-Based Pharmacokinetic Model to Estimate Absorption and Bioavailability of Corticosteroid Nasal Sprays*. Respiratory Drug Delivery (RDD) 2022. 1: 197-200.
66. Sharan S, Choi S, Zou Y, Wang Y, Kim M, Fang L, Choi S, Makhlouf F, Grosser S, Zhang X, and Zhao L. *Application of Modeling and Simulation to Identify a Shortened Study Duration and Novel Bioequivalence Metric for a Long-Acting Intrauterine System*. The AAPS Journal. (2022) 24(3): 63. <https://doi.org/10.1208/s12248-022-00715-z>. PMID: 35501412.
67. Shi Y, ValizadehAslani T, Wang J, Ren P, Zhang Y, Hu M, Zhao L, and Liang H. *Improving Imbalanced Learning by Pre-finetuning with Data Augment*. Proceedings of the Fourth International Workshop on Learning with Imbalanced Domains: Theory and Applications. (2022). PMLR 183:68-82.
68. Shi Y, Wang J, Ren P, ValizadehAslani T, Zhang Y, Hu M, and Liang H. *Fine-Tuning BERT for Automatic ADME Semantic Labeling in FDA Drug Labeling to Enhance Product-Specific Guidance Assessment*. <https://doi.org/10.48550/arXiv.2207.12376>.
69. Shin S, Yu M, Hammell D, Ghosh P, Raney S, Hassan H, and Stinchcomb A. *Evaluation of In Vitro/In Vivo Correlations for Three Fentanyl Transdermal Delivery Systems Using In Vitro Skin Permeation Testing and Human Pharmacokinetic Studies under the Influence of Transient Heat Application*. Journal of Controlled Release. (2022) 342, 134-147. <https://doi.org/10.1016/j.jconrel.2021.11.030>. PMID: 34838928.
70. Shukla S, Bunge A, Hassan H, and Stinchcomb A. *Investigator Impact on Reproducibility of Drug Bioavailability in Stratum Corneum Sampling by Tape Stripping*. Pharmaceutical Research. (2022) 39: 703–719. <https://doi.org/10.1007/s11095-022-03199-w>. PMID: 35411510.
71. Singh N, Kannan R, Arey R, Walenga R, Babiskin A, and Przekwas A. *Predicting Systemic and Pulmonary Tissue Barrier Concentration of Orally Inhaled Drug Products*. <https://doi.org/10.1101/2022.03.10.483633>.
72. Stern S, Coghlin J, Krishnan V, Raney S, Babiskin A, Jiang W, Lionberger R, Xu X, Schwendeman A, and Polli J. *Research and Education Needs for Complex Generics*. Pharmaceutical Research. (2021) 38: 1991-2001. <https://doi.org/10.1007/s11095-021-03149-y>.
73. Sulaiman M, Liu X, and Sundaresan S. *Effects of Dose Loading Conditions and Device Geometry on the Transport and a Aerosolization in Dry Powder Inhalers: A Simulation Study*. International Journal of Pharmaceutics. (2021) 610: 121219. <https://doi.org/10.1016/j.ijpharm.2021.121219>. PMID: 34699949.
74. Svirkin Y, Lee J, Marx R, Seongkyu Y, Landrau N, Kaisar M, Qin B, Park J, Alam K, Kozak D, Wang Y, Xu X, Zheng J, and Rivnay B. *Amphotericin B Release Rate is the Link between Drug Status in the Liposomal Bilayer and Toxicity*. Asian Journal of Pharmaceutical Sciences. (2022) 17(4): 544-556. <https://doi.org/10.1016/j.ajps.2022.04.007>. PMID: 36105314.

75. Thacker S, Her C, Kelley Baker L, Ireland D, Manangeeswaran M, Pang E, and Verthelyi D. *Detection of Innate Immune Response Modulating Impurities (IIRMI) in Therapeutic Peptides and Proteins: Impact of Excipients*. Frontiers in Immunology. (2022) 13(970499). <https://doi.org/https://doi.org/10.3389/fimmu.2022.970499>. PMID: 36148237.
76. Tiffner K, Kanfer I, Augustin T, Raml R, Raney S, and Sinner F. *Comparative In Vitro Release Testing (IVRT) of Acyclovir Products*. International Journal of Pharmaceutics. (2021) 609: 121186. <https://doi.org/10.1016/j.ijpharm.2021.121186>. PMID: 34655706.
77. Van Duong T, Ni Z, and Taylor L. *Phase Behavior and Crystallization Kinetics of a Poorly Water-Soluble Weakly Basic Drug as a Function of Supersaturation and Media Composition*. Molecular Pharmaceutics. (2022) 19(4): 1146–1159. <https://doi.org/10.1021/acs.molpharmaceut.1c00927>. PMID: 35319221.
78. Wan B, Bao Q, Zou Y, Wang Y, and Burgess D. *Effect of Polymer Source Variation on the Properties and Performance of Risperidone Microspheres*. International Journal of Pharmaceutics. (2021) 610. <https://doi.org/10.1016/j.ijpharm.2021.121265>. PMID: 34748813.
79. Wang D, Park J, Zheng J, Cai B, Keire D, and Chen K. *Multiphase Drug Distribution and Exchange in Oil-in-Water Nanoemulsion Revealed by High-Resolution 19F qNMR*. Molecular Pharmaceutics. (2022) 19(7): 2142–2150. <https://doi.org/10.1021/acs.molpharmaceut.2c00025>. PMID: 35657300.
80. Wang J, Gong X, Hu M, and Zhao L. *Improved GSimp: A Flexible Missing Value Imputation Method to Support Regulatory Bioequivalence Assessment*. Annals of Biomedical Engineering. (2022). Online Ahead of Print. <https://doi.org/10.1007/s10439-022-03070-4>. PMID: 36107365.
81. Wang Z, Ahluwalia S, Newman B, Dhapare S, Zhao L, and Luke M. *Medication Cost-Savings and Utilization of Generic Inhaled Corticosteroid (ICS) and Long-Acting Beta-Agonist (LABA) Drug Products in the USA*. Therapeutic Innovation & Regulatory Science. (2022) 56(2): 346–357. <https://doi.org/10.1007/s43441-021-00372-y>. PMID: 35118630.
82. Zhang L, Liu Q, Huang S, and Lionberger R. *Transporters in Regulatory Science: Notable Contributions from Dr. Giacomini in the Past Two Decades*. Drug Metabolism and Disposition. (2022) 50: 1211–1217. <https://doi.org/10.1124/dmd.121.000706>. PMID: 35768075.