**CURRICULUM VITAE**

## Name: Rodrigo Cristofoletti

**Date of Birth:** 03rd March 1981
**Place of Birth:** Rio Claro, Sao Paulo, Brazil
**Marital status:** Married
**Nationality:** Brazilian
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## Academic Profile

### 2015-2017: PhD, *summa cum laude*, School of Biochemistry, Chemistry and Pharmacy of the Johann Wolfgang Goethe-Universität, Frankfurt am Main, Germany

The qualification was based on a dissertation which aimed at exploring the utilization of *in vitro and in silico* tools to improve the assessment and extrapolation of therapeutic equivalence. In vitro to in vivo extrapolation using PBPK models was the core of the dissertation. The feasibility of extrapolating bioequivalence results from the traditional healthy adults model to special populations as well as an integrative approach combining *in vitro* predictive dissolution, PBPK and PK/PD models for decision making about generic drug BE standards were also addressed.

Committee: Prof. Dr. Jennifer B. Dressman, Prof. Dr. Cristos Reppas, Prof. Dr. Dieter Steinhilber and Prof. Dr. Achim Schmidtko.

### 2010-2013: MSc Applied Toxicology to Health Surveillance, State University of Londrina, PR, Brazil

The qualification was based on a thesis which aimed at analyzing the predictive capacity of BCS and BDDCS on bioequivalence outcome.

Advisor: Prof. Dr. Silvia Storpirtis

**2000-2004: BSc Pharmaceutical Sciences, University of Sao Paulo, FCFRP, Ribeirao Preto, SP, Brazil**

This included four-year experience in a Pharmacology laboratory, working on antipyretic and pain relief models. The final year was dedicated to industrial pharmacy, including a 6-month placement at the CIMED Indústria Farmaceutica Ltda, Brazil (drug product development).

## Employment Profile

**2023-current: Associate Director of the Center for Pharmacometrics and Systems Pharmacology, College of Pharmacy, University of Florida.**

**2020-current: Assistant Professor at the Department of Pharmaceutics, College of Pharmacy, University of Florida.**

On July 1st of 2020 I joined the College of Pharmacy, University of Florida as a tenure-track, Assistant Professor.

**2019-2020: Research Assistant Professor at the Center for Pharmacometrics and Systems Pharmacology in Lake Nona (Orlando), University of Florida.**

In June of 2019 I joined the CPSP in Lake Nona in a full-time position at the Research Assistant Professor level to develop state-of-the-art physiologically-based pharmacokinetic (PBPK) models to anticipate clinically relevant drug-drug interactions as well as to investigate the impact of intrinsic and extrinsic factors on systemic and tissue drug distribution as potential sources of variability in the time course of pharmacological effect. Exploring integrated frameworks combining mechanistic absorption modeling with *in vitro* to *in vivo* extrapolation techniques to reduce regulatory burden will also be part of my research line, with potential to attract external funding from regulatory authorities, pharmaceutical companies, contract research organizations and providers of pharmacometrics software and services.

**2005-2019: Brazilian Health Regulatory Agency (Anvisa), Brasilia, DF, Brazil**

From 2005 on I have been working at the Biopharmaceutics & Clinical Pharmacology Department of Anvisa where I am responsible for carrying out inspections under the scope of GCP and GLP as well as for reviewing biopharmaceutics and clinical pharmacology reports submitted to support

generic and new drug applications as well as biosimilars. I have been a member of the Brazilian Pharmacopoeia since 2010. I was given a leave of absence to work on my Ph.D.

**2004-2005: CIMED Industria Farmaceutica Ltda, Pouso Alegre, MG, Brazil**

Projects included the development of oral drug products and *in vitro* biopharmaceutics analysis.

## Research Interests

- Integrating *in vitro* systems and quantitative methods and modeling to inform drug discovery and drug product development with focus on:
    - Oral and non-oral mechanistic absorption models
    - Translational DMPK
    - Disease-based models
- Integrating stem cell technology, tissue biopsy, co-culture techniques, microfluidics, and next generation sequencing to develop microphysiological systems to investigate drug- and disease-related mechanisms affecting membrane integrity and predict drug absorption/disposition.
    - Development of a segment-specific intestine-on-a-chip to investigate drug- and disease-related mechanism affecting intestinal membrane integrity (leaky gut) as well as transport-mediated kinetics and drug-drug interactions.
    - Development of a neurovascular unit-on-a-chip model to study drug penetration in the brain parenchyma and cerebrospinal fluid as well as molecular and cellular underlying mechanisms in neurodegenerative diseases.
- Development of microphysiological system to study Down Syndrome pathogenesis downstream the extra copy of the chromosome 21 in different tissues.
- Development of microphysiological system to study host-virus interaction in the CNS.
- Development of techniques for precision dosing of metabolically-cleared drugs, *e.g.* liquid biopsy.
- Quantification of human blood-brain barrier drug transporters and solute carriers in health and disease (e.g., in Allan-Herndon-Dudley syndrome).
- Evaluating protein abundance vs. activity relationships of drug-metabolizing enzymes (CYP and UGT) in the human liver and small intestine, using matched iPSC-derived intestinal organoids and hepatocytes.

## Awards

**ATCC Innovation Challenge 2024 for my research on CAR-T therapies**

**International Society for Stem Cell Research (ISSCR) travel award 2023 (Pineiro-Llanes et al, 2023)**

**Top Student & Trainee Abstracts at the 2022 Annual Meeting of the American College of Clinical Pharmacology (Silva et al, 2022);**

**QSP SIG Poster Highlight at the 2021 ACoP12**

**Student Abstract Award Winner at the 2020 Annual Meeting of the American College of Clinical Pharmacology (Cicali et al, 2021);**

**Simcyp Academic Award for the Most Informative and Scientific Report 2020:**

> Cicali B, Long T, Kim S, Cristofoletti R. 2020. Assessing the impact of cystic fibrosis on the antipyretic response of ibuprofen in children: Physiologically-based modeling as a candle in the dark. *Br J Clin Pharmacol* doi: 10.1111/bcp.14326. Online ahead of print.

In recognition of scientific research which is leading the field of virtual bioequivalence trials.

**Simcyp Academic Award for the Most Informative and Scientific Report 2017:**

> Cristofoletti R, Patel N, Dressman JB. 2017. Assessment of Bioequivalence of Weak Base Formulations Under Various Dosing Conditions Using Physiologically Based Pharmacokinetic Simulations in Virtual Populations. Case Examples: Ketoconazole and Posaconazole. *J Pharm Sci* 106(2):560-569.

In recognition of scientific research which is leading the field of IVIVE, ADME, PBPK, Pharmaceutics, Biologics, Safety Pharmacology, Systems Pharmacology and Modeling and Simulation.

## Other Experience and Professional Memberships

2023- Grant reviewer for NIH - Advancing Therapeutics study section: MCST-M (81) S

2023- Grant reviewer for Maryland Industrial Partnerships Program

2023- Grant reviewer for Austrian Science Fund (FWF)

2023- Member of the International Microphysiological System Society (IMPSS)

2023- Member of the European Organ-on-chip society (EUROoCS).

2023- Editorial Board, AAPS J

2022- Grant reviewer for Austrian Science Fund (FWF)

2022- Editorial Board, Journal of Precision Medicine

2022- Guest Editor, European Journal of Pharmaceutics and Biopharmaceutics – special issue on modeling and artificial intelligence in drug delivery

2022- Editorial Board, Journal of Pharmacy & Pharmacology

2021- Guest Editor, AAPS J – special issue on IVIVE-PBPK modeling

2021- Editorial Board, Biopharmaceutics & Drug Disposition

2021- Associate Editor, Frontiers in Pharmacology – Drug Transport and Metabolism

2021- Member, American Association of Pharmaceutical Scientists (AAPS)

2021- Member of the European Network on Understanding Gastrointestinal Absorption-related Processes (UNGAP)

2019- Member, American Society for Clinical Pharmacology (ASCPT)

2017- Member, Iberoamerican Pharmacometrics Network (RedIF)

2008- Member, Brazilian Pharmacopoeia

2008- Member, BCS and Biowaiver Focus Group, FIP

## Publications (papers and book chapters)


1. Klose M, Cristofoletti R, Silva CM, Mangal N, Turgeon J, Michaud V, Lesko LJ, Schmidt S. 2024. Exploring the impact of CYP2D6 and UGT2B7 gene-drug interactions, and CYP-mediated DDI on oxycodone and oxymorphone pharmacokinetics using physiologically-based pharmacokinetic modeling and simulation. *Eur J Pharm Sci* 194:106689.
2. Plano D, Rudolph N, Saal C, Abrahamsson B, Cristofoletti R, Kambayashi A, Langguth P, Mehta M, Parr A, Polli JE, Shah VP, Charoo N, Dressman J. 2023. Biowaiver Monograph for Immediate-Release Solid Oral Dosage Forms: Isavuconazonium Sulfate. *J Pharm Sci* S0022-3549(23)00479-3.

3. Caleffi-Marchesini ER, Herling AA, Macente J, Bonan RH, de Freitas Lima P, Moreno R, Alexandre V, Charbe NB, Borghi-Pangoni FB, Cristofoletti R, Diniz A. 2023. Adult and pediatric physiologically-based biopharmaceutics modeling to explain lamotrigine immediate release absorption process. *CPT Pharmacometrics Syst Pharmacol.* doi: 10.1002/psp4.13071. Online ahead of print.
4. Rodriguez-Vera L, Yin X, Almoslem M, Romahn K, Cicali B, Lukacova V, Cristofoletti R, Schmidt S. 2023. Comprehensive Physiologically Based Pharmacokinetic Model to Assess Drug-Drug Interactions of Phenytoin. *Pharmaceutics* 15(10):2486
5. Koziolek M, Augustijns P, Berger C, Cristofoletti R, Dahlgren D, Keemink J, Matsson P, McCartney F, Metzger M, Mezler M, Niessen J, Polli JE, Vertzoni M, Weitschies W, Dressman J. 2023. Challenges in Permeability Assessment for Oral Drug Product Development. *Pharmaceutics* 15(10):2397.
6. Cristofoletti R, Rostami-Hodjegan A. 2023. Linking in vitro-in vivo extrapolations with physiologically based modeling to inform drug and formulation development. *Biopharm Drug Dispos* 44(4):289-291.
7. Coutinho AL, Cristofoletti R, Wu F, Shoyaib AA, Dressman J, Polli JE. 2023. A robust, viable, and resource sparing HPLC-based logP method applied to common drugs. *Int J Pharm* 644:123325.
8. Schmidt S, Vozmediano V, Cristofoletti R, Kim S, Lin Z, de Moraes N, Azeredo F, Cicali B, Leuenberger H, Brown JD, Jin JY, Musante CJ, Tannenbaum S, Wang Y. 2023. Requirements, expectations, challenges and opportunities associated with training the next generation of pharmacometricians. *CPT Pharmacometrics Syst Pharmacol* 12(7):883-888.
9. Kim S, Cicali B, Pressly M, Da Silva L, Wendl T, Vozmediano V, Schmidt S, Cristofoletti R. 2023. Model-Based Analysis of In Vivo Release Data of Levonorgestrel Implants: Projecting Long-Term Systemic Exposure. *Pharmaceutics* 15(5):1393.
10. Piñeiro-Llanes J, Stec DE, Cristofoletti R. 2023. Insights in drug metabolism and transport. *Front Pharmacol* 14:1198598.
11. Caleffi-Marchesini ER, Borghi-Pangoni FB, Macente J, Chiamulera-Mantovani P, Mazucheli J, Cristofoletti R, Diniz A. 2023. Exploring in vitro solubility of lamotrigine in physiologically mimetic conditions to prospect the in vivo dissolution in pediatric population. *Biopharm Drug Dispos* 44(2):147-156.
12. Yamamoto PA, Cristofoletti R, Vozmediano V, de Gaitani CM, da Silva RM, Kemp R, Sankarankutty AK, Salgado Junior W, Santos JSD, de Moraes NV. 2023. Effect of Roux-En-Y Gastric Bypass in the Pharmacokinetics of (R)-Carvedilol and (S)-Carvedilol. *J Clin Pharmacol* 63(7):838-847.

13. Subhani S, Lukacova V, Kim C, Rodriguez-Vera L, Muniz P, Rodriguez M, Cristofoletti R, Van Os S, Suarez E, Schmidt S, Vozmediano V. 2023. Leveraging Physiologically Based Modelling to Provide Insights on the Absorption of Paliperidone Extended-Release Formulation under Fed and Fasting Conditions. *Pharmaceutics* 15(2):629.
14. Franco YL, Da Silva L, Charbe N, Kinvig H, Kim S, Cristofoletti R. 2023. Integrating Forward and Reverse Translation in PBPK Modeling to Predict Food Effect on Oral Absorption of Weakly Basic Drugs. *Pharm Res* 40(2):405-418.
15. Sarayani A, Winterstein A, Cristofoletti R, Vozmediano V, Schmidt S, Brown J. 2023. Real-world effect of a potential drug-drug interaction between topiramate and oral contraceptives on unintended pregnancy outcomes. *Contraception* 120:109953.
16. Charoo NA, Abdallah DB, Ahmed DT, Abrahamsson B, Cristofoletti R, Langguth P, Mehta M, Parr A, Polli JE, Shah VP, Kambayashi A, Dressman J. 2023. Biowaiver Monograph for Immediate-Release Solid Oral Dosage Forms: Levocetirizine Dihydrochloride. *J Pharm Sci* 112(4):893-903.
17. Kambayashi A, de Meijer M, Wegman K, van Veldhuizen C, Abrahamsson B, Cristofoletti R, Langguth P, Mehta M, Parr A, Polli JE, Shah VP, Dressman J. 2023. Biowaiver Monograph for Immediate-Release Dosage Forms: Levamisole Hydrochloride. *J Pharm Sci* 112(3):634-639.
18. Wu F, Mousa Y, Raines K, Bode C, Tsang YC, Cristofoletti R, Zhang H, Heimbach T, Fang L, Kesisoglou F, Mitra A, Polli J, Kim MJ, Fan J, Zolnik BS, Sun D, Zhang Y, Zhao L. 2023. Regulatory utility of physiologically-based pharmacokinetic modeling to support alternative bioequivalence approaches and risk assessment: A workshop summary report. *CPT Pharmacometrics Syst Pharmacol* 12(5):585-597.
19. Cicali B, Silva L, Sarayani A, Kim S, Pressley M, Wendl T, Hoechel J, Vozmediano V, Winterstein A, Brown JD, Schmidt S Cristofoletti R. 2022. Development of a Translational Exposure-Bracketing Approach to Streamline the Development of Contraceptive Products. *Clin Pharmacol Ther*. doi: 10.1002/cpt.2690. Online ahead of print.
20. Subhani S, Kim C, Muniz P, Rodriguez M, van Os S, Suarez E, Cristofoletti R, Schmidt S, Vozmediano V. 2022. Application of physiologically based absorption and pharmacokinetic modeling in the development process of oral modified release generic products. *Eur J Pharm Biopharm* 176:87-94.
21. Lingineni K, Chaturvedula A, Cicali B, Cristofoletti R, Wendl T, Hoechel J, Brown JD, Vozmediano V, Schmidt S. 2022. Determining the Exposure Threshold for Levonorgestrel Efficacy Using an Integrated Model Based Meta-Analysis Approach. *Clin Pharmacol Ther* 111(2):509-518.
22. Franco Y, Silva L, Cristofoletti R. 2022. Navigating through cell-based in vitro models available for prediction of intestinal permeability and metabolism. *AAPS J* 24(1):2.

23. Bego M, Patel N, Cristofoletti R, Rostami-Hodjegan A. 2022. Proof of Concept in Assignment of Within-Subject Variability During Virtual Bioequivalence Studies: Propagation of Intra-Subject Variation in Gastrointestinal Physiology Using Physiologically Based Pharmacokinetic Modeling. *AAPS J* 24(1):21
24. Abrahamsson B, Butler J, Cristofoletti R, Kostewicz E, Saal C, Reppas C. 2022. Jennifer Dressman - 40 years of Oral Drug Absorption. *J Pharm Sci* 111(1):14-17.
25. Charoo NA, Abdallah DB, Bakheit AA, Haque KU, Hassan HA, Abrahamsson B, Cristofoletti R, Langguth P, Mehta M, Parr A, Polli JE, Shah VP, Tajiri T, Dressman J. 2022. Biowaiver Monograph for Immediate-Release Solid Oral Dosage Forms: Sitagliptin Phosphate Monohydrate. *J Pharm Sci* 111(1):2-13.
26. Mohammed A, Zimmerman E, Derendorf H, Schmidt S, Cristofoletti R. 2021. Kinetics of Drug Action: a PKPD approach. In Talevi A (ed). 1 ed. ADME Encyclopedia. Springer.
27. Long T, Cristofoletti R, Cicali B, Michaud V, Dow P, Turgeon J, Schmidt S. 2021. Physiologically-based Pharmacokinetic Modeling to Assess the Impact of CYP2D6-Mediated Drug-Drug Interactions on Tramadol and O-Desmethyltramadol Exposures via Allosteric and Competitive Inhibition. *J Clin Pharmacol* 62(1):76-86.
28. Tatipalli M, Siripuram VK, Long T, Shuster D, Bernstein G, Martineau P, Cook KA, Cristofoletti R, Schmidt S, Vozmediano V. 2021. Model-Informed Optimization of a Pediatric Clinical Pharmacokinetic Trial of a New Spironolactone Liquid Formulation. *Pharmaceutics* 13(6):849.
29. Wu F, Cristofoletti R, Zhao L, Rostami-Hodjegan A. 2021. Scientific considerations to move towards biowaiver for biopharmaceutical classification system class III drugs: How modeling and simulation can help. *Biopharm Drug Dispos.* doi: 10.1002/bdd.2274. Online ahead of print.
30. García MA, Cristofoletti R, Abrahamsson B, Groot DW, Parr A, Polli JE, Mehta M, Shah VP, Tomakazu T, Dressman JB, Langguth P. 2021. Biowaiver Monograph for Immediate-Release Solid Oral Dosage Forms: Carbamazepine. *J Pharm Sci* 110(5):1935-1947.
31. Metry M, Shu Y, Abrahamsson B, Cristofoletti R, Dressman JB, Groot DW, Parr A, Langguth P, Shah VP, Tajiri T, Mehta MU, Polli JE. 2021. Biowaiver Monographs for Immediate Release Solid Oral Dosage Forms: Metformin Hydrochloride. *J Pharm Sci* 110(4):1513-1526.
32. Farhan N, Cristofoletti R, Basu S, Fang L, Lesko L, Schmidt S. 2021. Physiologically Based Pharmacokinetics Modeling to Investigate Formulation Factors Influencing the Generic Substitution of Dabigatran Etexilate. *CPT Pharmacometrics Syst Pharmacol* 10(3):199-210.
33. Cicali B, Lingineni K, Cristofoletti R, Wendl T, Hoechel J, Wiesinger H, Chaturvedula A, Vozmediano V, Schmidt S. 2021. Quantitative assessment of levonorgestrel binding partner

interplay and drug-drug interactions using physiologically based pharmacokinetic modeling. *CPT Pharmacometrics Syst Pharmacol* 10(1):48-58.

34. Pinto L, Jesus S, Cristofoletti R, Perin L, Fonseca K, Barbêdo P, Bandeira L, Carneiro C. 2021. Pharmacokinetics of benznidazole in experimental chronic Chagas disease using the *Swiss* mouse-Berenice-78 *Trypanosoma cruzi* strain model. *Antimicrobial Agents and Chemotherapy* 20;65(2):e01383-20.
35. Loisios-Konstantinidis I, Cristofoletti R, Jamei M, Turner D, Dressman J. 2020. Physiologically based pharmacokinetic/ pharmacodynamic modeling to predict the impact of CYP2C9 genetic polymorphisms, co-medication and formulation on the pharmacokinetics and pharmacodynamics of flurbiprofen. *Pharmaceutics* 12(11):1049.
36. Loisios-Konstantinidis I, Hens B, Mitra A, Kim S, Chiann C, Cristofoletti R. 2020. Using Physiologically Based Pharmacokinetic Modeling to Assess the Risks of Failing Bioequivalence Criteria: a Tale of Two Ibuprofen Products. *AAPS J* 22(5):113.
37. Hens B, Bermejo M, Cristofoletti R, Amidon GE, Amidon GL. 2020. Application of the Gastrointestinal Simulator (GIS) Coupled with In Silico Modeling to Measure the Impact of Coca-Cola® on the Luminal and Systemic Behavior of Loratadine (BCS Class 2b). *Pharmaceutics* 12(6):566.
38. Charoo NA, Abdallah DB, Parveen T, Abrahamsson B, Cristofoletti R, Groot DW, Langguth P, Parr A, Polli JE, Mehta M, Shah VP, Tajiri T, Dressman J. 2020. Biowaiver Monograph for Immediate-Release Solid Oral Dosage Forms: Moxifloxacin Hydrochloride. *J Pharm Sci* 109(9):2654-2675.
39. Cicali B, Long T, Kim S, Cristofoletti R. 2020. Assessing the impact of cystic fibrosis on the antipyretic response of ibuprofen in children: Physiologically-based modeling as a candle in the dark. *Br J Clin Pharmacol* 86(11):2247-2255.
40. Plöger GF, Quizon PM, Abrahamsson B, Cristofoletti R, Groot DW, Parr A, Langguth P, Polli JE, Shah VP, Tajiri T, Mehta MU, Dressman J. 2020. Biowaiver Monographs for Immediate Release Solid Oral Dosage Forms: Cephalexin Monohydrate. *J Pharm Sci* 109(6):1846-1862
41. Loisios-Konstantinidis I, Cristofoletti R, Fotaki N, Turner DB, Dressman J. 2020. Establishing virtual bioequivalence and clinically relevant specifications using in vitro biorelevant dissolution testing and physiologically-based population pharmacokinetic modeling. case example: Naproxen. *Eur J Pharm Sci.* doi: 10.1016/j.ejps.2019.105170.
42. Cristofoletti R, Hens B, Patel N, Esteban VV, Schmidt S, Dressman J. 2019. Integrating Drug- and Formulation-Related Properties With Gastrointestinal Tract Variability Using a Product-Specific Particle Size Approach: Case Example Ibuprofen. *J Pharm Sci* 108(12):3842-3847.

43. Rajawat GS, Belubbi T, Nagarsenker MS, Abrahamsson B, Cristofoletti R, Groot DW, Langguth P, Parr A, Polli JE, Mehta M, Shah VP, Tajiri T, Dressman J. 2019. Biowaiver Monograph for Immediate-Release Solid Oral Dosage Forms: Ondansetron. *J Pharm Sci* 108(10):3157-3168.
44. Schmidt S, Kim S, Vozmediano V, Cristofoletti R, Winterstein AG, Brown JD. 2019. Pharmacometrics, Physiologically Based Pharmacokinetics, Quantitative Systems Pharmacology-What's Next?-Joining Mechanistic and Epidemiological Approaches. *CPT Pharmacometrics Syst Pharmacol* 8(6):352-355.
45. Kim S, Sharma VD, Lingineni K, Farhan N, Fang L, Zhao L, Brown JD, Cristofoletti R, Vozmediano V, Ait-Oudhia S, Lesko LJ, Trame MN, Schmidt S. 2019. Evaluating the Clinical Impact of Formulation Variability: A Metoprolol Extended-Release Case Study. *J Clin Pharmacol* 59(9):1266-1274.
46. Loisios-Konstantinidis I, Paraiso RLM, Fotaki N, McAllister M, Cristofoletti R, Dressman J. 2019. Application of the relationship between pharmacokinetics and pharmacodynamics in drug development and therapeutic equivalence: a PEARRL review. *J Pharm Pharmacol* 71(4):699-723.
47. Ibarra M, Dalla Costa T, Schaiquevich P, Cristofoletti R, Hernández González I, Fajardo-Robledo NS, Aragón Novoa M, Pecchio M, Cortinez I, Trocóniz IF, Romero-Tejeda EM. 2019. Iberoamerican Pharmacometrics Network Congress 2018 Report: Fostering Modeling and Simulation Approaches for Drug Development and Regulatory and Clinical Applications in Latin America. *CPT Pharmacometrics Syst Pharmacol*. doi: 10.1002/psp4.12387.
48. Cristofoletti R, Schmidt S, Diniz A. 2018. Non-Procrustean pathways for complex generic drugs development. *Ther Deliv* 9(9):605-607.
49. Cristofoletti R, Rowland M, Lesko LJ, Blume H, Rostami-Hodjegan A, Dressman JB. 2018. Past, Present, and Future of Bioequivalence: Improving Assessment and Extrapolation of Therapeutic Equivalence for Oral Drug Products. *J Pharm Sci* 107(10):2519-2530.
50. Plöger GF, Abrahamsson B, Cristofoletti R, Groot DW, Langguth P, Mehta MU, Parr A, Polli JE, Shah VP, Tajiri T, Dressman JB. 2018. Biowaiver Monographs for Immediate Release Solid Oral Dosage Forms: Proguanil Hydrochloride. *J Pharm Sci* 107(7):1761-1772.
51. Cristofoletti R, Marques M, Storpirtis S. 2017. Brazil. In: Bioequivalence Requirements in Various Global Jurisdictions (p.1-20). Springer International Publishing. doi. 10.1007/978-3-319-68078-1.
52. Hofsäss MA, Souza J, Silva-Barcellos NM, Bellavinha KR, Abrahamsson B, Cristofoletti R, Groot DW, Parr A, Langguth P, Polli JE, Shah VP, Tajiri T, Mehta MU, Dressman JB. 2017. Biowaiver Monographs for Immediate Release Solid Oral Dosage Forms: Folic acid. *J Pharm Sci* 106(12):3421-3430.

53. Thambavita D, Galappatthy P, Mannapperuma U, Jayakody L, Cristofoletti R, Abrahamsson B, Groot DW, Langguth P, Mehta M, Parr A, Polli JE, Shah VP, Dressman J. 2017. Biowaiver Monograph for Immediate-Release Solid Oral Dosage Forms: Amoxicillin Trihydrate. J Pharm Sci. DOI: 10.1016/j.xphs.2017.04.068. [Epub ahead of print]
54. Verbeeck RK, Kanfer I, Löbenberg R, Abrahamsson B, Cristofoletti R, Groot DW, Langguth P, Polli JE, Parr A, Shah VP, Mehta M, Dressman JB. 2017. Biowaiver Monographs for Immediate-Release Solid Oral Dosage Forms: Enalapril. J Pharm Sci 106(8):1933-1943.
55. Charoo NA, Cristofoletti R, Kim SK. 2017. Integrating biopharmaceutics risk assessment and in vivo absorption model in formulation development of BCS class I drug using the QbD approach. Drug Dev Ind Pharm 43(4):668-677.
56. Cristofoletti R, Patel N, Dressman JB. 2017. Assessment of Bioequivalence of Weak Base Formulations Under Various Dosing Conditions Using Physiologically Based Pharmacokinetic Simulations in Virtual Populations. Case Examples: Ketoconazole and Posaconazole. J Pharm Sci 106(2):560-569.
57. Cristofoletti R, Dressman JB. 2016. Bridging the gap between in vitro dissolution and the time course of ibuprofen-mediating pain relief. J Pharm Sci 105(12):3658-3667.
58. Cristofoletti R, Dressman JB. 2016. Dissolution Methods to Increasing Discriminatory Power of In Vitro Dissolution Testing for Ibuprofen Free Acid and Its Salts. J Pharm Sci 106(1):92-99.
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60. Cristofoletti R, Dressman JB. 2016. Matching phosphate and maleate buffer systems for dissolution of weak acids: Equivalence in terms of buffer capacity of bulk solution or surface pH? Eur J Pharm Biopharm 103:104-108.
61. Cristofoletti R, Charoo NA, Dressman JB. 2016. Exploratory Investigation of the Limiting Steps of Oral Absorption of Fluconazole and Ketoconazole in Children Using an In Silico Pediatric Absorption Model. J Pharm Sci 105(9):2794-2803.
62. Goodarzi N, Barazesh Morgani A, Abrahamsson B, Cristofoletti R, Groot DW, Langguth P, Mehta MU, Polli JE, Shah VP, Dressman JB. 2016. Biowaiver Monographs for Immediate Release Solid Oral Dosage Forms: Ribavirin. J Pharm Sci 105(4):1362-1369.
63. Cristofoletti R, Patel N, Dressman JB. 2016. Differences in Food Effects for 2 Weak Bases With Similar BCS Drug-Related Properties: What Is Happening in the Intestinal Lumen? J Pharm Sci 105(9):2712-2722.

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65. Cristofoletti R, et al. 2015. Meeting Report: International Workshop on Implementation of Biowaivers Based on the Biopharmaceutics Classification System (BCS). *Dissolution Technologies* 22(2):77-81
66. Charoo NA, Cristofoletti R, Dressman JB. 2015. Risk assessment for extending the Biopharmaceutics Classification System-based biowaiver of immediate release dosage forms of fluconazole in adults to the paediatric population. *J Pharm Pharmacol* 67(8):1156-1169.
67. Petruševska M, Berglez S, Krisch I, Legen I, Megušar K, Peternel L, Abrahamsson B, Cristofoletti R, Groot DW, Kopp S, Langguth P, Mehta M, Polli JE, Shah VP, Dressman J. 2015. Biowaiver Monographs for Immediate Release Solid Oral Dosage Forms: Levetiracetam. *J Pharm Sci* 104(9):2676-2687.
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## Ad hoc reviewer for

JoVE Review

Molecular Pharmaceutics
Journal of Pharmacy and Pharmacology
Pharmaceutical Research
Journal Pharmaceutical Sciences
British Journal of Clinical Pharmacology
Journal of Controlled Release
Pharmaceutics
American Association of Pharmaceutical Scientists Journal (AAPS J)
Clinical Therapeutics
Molecules
Alzheimer's & Dementia
International Journal of Pharmaceutics
Biopharmaceutics & Drug Disposition
Expert Opinion on Drug Metabolism and Toxicology
Scientific Reports (Nature)
European Journal Pharmaceutics and Biopharmaceutics
European Journal of Pharmaceutical Sciences

## Journal Editor

Associate Editor: Frontiers in Pharmacology (Drug Transport and Metabolism)
Guest Editor: AAPS J (special issue on MIDD)
Guest Editor: European Journal of Pharmaceutics and Biopharmaceutics (special issue on MIDD)
Guest Editor: Pharmaceutics (special issue on organotypic models and microphysiological systems)

## Editorial Advisory Boards

AAPS Journal
Journal of Pharmacy & Pharmacology
Biopharmaceutics & Drug Disposition
Journal of Personalized Medicine

## Research Support

| Grant # | Agency | Role | Title | Annual Award Proposed | Dates |
|---|---|---|---|---|---|
| AWD08034 | Simulations Plus | Principal Investigator | Assessing the impact of highly prevalent chronic comorbidities on antifungal treatment in elderly patients: disease-based modeling as a candle in the dark | $180,000.00 | 04/22/2020 11/30/2022 |
| AWD09937 | Simulations Plus | Co-Principal Investigator | Using Physiologically-Based Pharmacokinetic (PBPK) Simulation Approaches to Evaluate Drug-Drug-Interactions (DDIs) | $100,000.00 | 03/22/2021 09/30/2022 |
| AWD14172 | ETECTRX | Principal Investigator | Assessing the in vitro performance of solid dosage forms overencapsulated with the ID-Cap System for improved compliance | $38,125.00 | 03/02/2023 07/01/2023 |
| AWD10586 | US FOOD AND DRUG ADMN | Principal Investigator | Development and validation of a best practices framework for PBPK analysis for biopharmaceutic applications in support of model-informed biowaivers of fed state BE studies | $599,959.00 | 07/20/2021 07/31/2024 |

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| | | | for BCS class II drugs | | |
| AWD12464 | Roche | Principal Investigator | Development of a biopharmaceutics roadmap for integrating in vitro data with gastrointestinal physiology in PBPK models | $750,000.00 | 05/30/2022 05/29/2025 |
| AWD13300 | US FOOD AND DRUG ADMN | Principal Investigator | Development and verification of in vitro integrated mechanistic population-based PBPK model framework towards virtual bioequivalence assessment of locally acting drug products in the GI tract | $599,977.00 | 09/03/2022 08/31/2024 |
| AWD14638 | TEVA | Co-Principal Investigator | Physiologically-based Pharmacokinetic (PBPK) Modeling of Drug-drug interactions (DDI) for TEV-56268 | $60,678.00 | 05/16/2023 05/03/2024 |
| AWD14241 | Janssen | Principal Investigator | Model Integrated Evidence Approach for Intravesical Drug Delivery for Localized Bladder Disease | $166,173.15 | 03/01/2023 03/01/2025 |
| AWD13577 | Gates Foundation | Co-Principal Investigator | Application of physiologically-based pharmacokinetic models to inform | $2,594,622.00 | 11/14/2022 11/30/2024 |

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| | | | dosing recommendations for hormonal contraceptives co-administered with other medications | | |
| AWD03083 | Gates Foundation | Co-Principal Investigator | Application of physiologically-based pharmacokinetic models to inform dosing recommendations for hormonal contraceptives co-administered with other medications | $2,594,622.00 | 11/02/2017 01/31/2024 |
| AWD09338 | Libbs | Principal Investigator | Integrating Dissolution and Translational Modeling Strategies to Establish In Vitro-In Vivo Links | $182,588.00 | 11/17/2020 11/05/2024 |
| AWD13333 | US FOOD AND DRUG ADMN | Principal Investigator | Advancing In Vitro and (patho) Physiology-Based Pharmacokinetics Models to Understand and Predict Pulmonary Absorption and Tissue Retention of Inhaled Drugs | $1,844,289.00 | 09/28/2022 09/29/2025 |
| AWD15776 | US FOOD AND DRUG ADMN | Principal Investigator | State of the Art Virtual Bioequivalence Platform Integrated with a Bayesian Frame | $110,739.00 | 07/03/2023 07/02/2025 |

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| AWD15122 | US FOOD AND DRUG ADMN | Co-Investigator | Feasibility of predicting regional lung exposure from systemic pharmacokinetic da | $499,996.00 | 07/01/2023 06/30/2025 |

## Language competencies

Fluent in Portuguese (native) and English (oral and written). Advanced skills in Spanish (oral and written). Basic skills in German.