Krina Mehta, PhD

krinaj@gmail.com, 707-416-3252, Cypress, CA, USA

www.linkedin.com/in/krina-mehta-50989210
https://orcid.org/0000-0002-7621-6436

- 15+ years of pharmaceutical industry experience driving quantitative drug development across therapeutic areas and modalities
- Passionate innovator, enthusiastic for supporting integration of new approach methodologies to modernize preclinical development and enhance translational relevance
- Pharmacist by training with proven expertise in strategizing and executing model-informed drug development (MIDD) approaches to support decision-making and regulatory submissions.
- Skilled modeler with hands-on experience in diverse methodologies: population PK (PopPK), population pharmacokinetic/pharmacodynamic (PopPKPD), exposure–response (ER), minimal and whole-body PBPK, semi-mechanistic modeling, and quantitative systems pharmacology (QSP).
- Technology-driven scientist, experienced in a broad range of modeling and simulation platforms, including R, NONMEM/Phoenix NLME, PK-Sim/Mobi, SimBiology, Julia, and Python.
- Collaborative leader and mentor recognized for fostering innovation and applying cutting-edge computational methods to accelerate drug development.
- Excellent verbal and written communication skills

Work Experience

Kyowa Kirin Inc.

Director, Pharmacometrics and Quantitative Pharmacology	Jan 2023 – Present
Associate Director, Pharmacometrics	June 2021 – Dec 2022
Pharmacometrics Scientist (Contractor)	June 2020 – June 2021

- Designed and led execution of MIDD strategies to support preclinical-to-clinical translation, IND submissions, first-in-human study designs, and RP2D selection across a variety of modalities for oncology and rare diseases
- Designed, developed and applied semi-mechanistic and QSP models for decision-making and regulatory interactions from research through Phase 2, in collaboration with project teams and CROs, where applicable:
    - Modality-specific: ADCs, bispecific antibodies, hematopoietic stem cell–based gene therapy
    - Disease-specific: cancer immune cycle QSP, acute myeloid leukemia, bone remodeling QSP,
    - Task-specific: Efficacy predictions, toxicity predictions (including, bone marrow related cytotoxicity, peripheral neuropathy, and drug-induced liver toxicity)
- Supported evidence-based decision-making by incorporating a variety of data, including 2D and 3D in vitro systems, emerging biomarkers, omics and expression data, and patient-reported outcomes into model-based analyses.
- Routinely collaborated with and advised DMPK and toxicology colleagues on relevant experiments

for mechanistic modeling approaches

- Contributed to translational and clinical pharmacology leadership through:
    - Reviewing pharmacometric analysis plans, regulatory briefing books and submissions
    - Driving cross-functional initiatives: talent development, process optimization
    - Mentored and supervised junior team members, including two direct reports.
    - Budgeting, contract management, and resourcing

qPharmetra LLC

Associate Consultant, Pharmacometrics 2018 - 2020

- Performed hands-on pharmacometric analyses to guide drug development, i.e., PopPK, PopPKPD, exposure-response analyses, non-compartmental analysis, and development of R shiny applications and submission ready reports.
- Key projects included:
    - Development of a mechanistic PK/PD model for an anti-FcRn receptor protein
    - Semi-mechanistic PopPK and ER analyses (tumor size, time to disease progression, adverse events) for an ADC
    - PopPK and ER modeling (tumor size, overall response rate, progression-free survival, adverse events) for a small-molecule oncology drug, contributing to BLA submission and regulatory approval

Self – Employed

Pharmacometrician (Contractor) 2016 - 2018

- Halozyme Therapeutics Inc.: Developed an R Shiny application for subcutaneous absorption simulations (with/without ENHANZE®) and conducted modeling projects including PopPK from preclinical data to inform FIH/clinical study design and PK/PD-based QTc risk prediction for a protein therapeutic.
- Center for Translational Medicine, University of Maryland: Delivered PBPK modeling training and conducted PBPK-based DDI simulations to support regulatory filing of a small molecule.
- Alexion Pharmaceuticals Inc.: Performed TMDD PopPK modeling for FIH dose selection of a bispecific antibody and PopPKPD pediatric simulations to inform Phase 3 dose selection of a small molecule.

Genentech Inc.

Regulatory Documentation Scientist (Contractor) 2010 - 2016

- Project managed and wrote a variety of clinical and nonclinical regulatory documents, including study protocols, investigator's brochures, periodic safety update reports, and clinical study reports.
- Collaborated with cross-functional teams to support regulatory submissions to the FDA and EMA.

Lifescan Inc.,

Medical Device Safety Associate 2007 - 2009

- Managed patient and providers complaints regarding blood sugar monitoring devices
- Prepared safety narratives and periodic safety regulatory submissions to the FDA and EMA.

Education

Doctor of Philosophy (PhD), Quantitative Pharmacology	2021 –2024
Leiden University, The Netherlands	
Master of Science (MS), Pharmacometrics	2015 – 2017
University of Maryland, USA	
Bachelor of Pharmacy (BPharm)	2001 – 2004
Saurashtra University, India	

Professional Development Courses and Workshops

AI-driven Drug Development Certificate, Pumas AI and SOPHAS	Expected May 2026
Python for Machine Learning Certificate, Deep Learning AI through Coursera	2025
Parameter Estimation with Simbiology, Mathworks	2024
PK/PD Modeling in Pumas Workshop, Pumas AI	2022
Protein Therapeutics PK/PD Modeling Workshop, University of Buffalo	2019
Systems Biology Certificate, Icahn School of Medicine through Coursera	2018
PK/PD Modeling Workshop, University of Buffalo	2018
Advanced methods for NONMEM Workshop, Uppsala Pharmacometrics	2017
PBPK Modeling Using Gastroplus, Simulations Plus	2016
American Medical Writers Association Certificate	2011
Regulatory Affairs Professional Certificate	2009

Volunteer Positions

Communications Director on International Society of Pharmacometrics QSP special interest group leadership team	2024 – Present
American conference of pharmacometrics planning – alumni committee	2019 – 2021
Peer reviewer on several occasions for various journals and conferences	2020 – Present

Journal Publications

1. Mehta, K, Maass, Christian 2, Cucurull-Sanchez, L, Pichardo, C, Subramanian, K, Androulakis, IP, Gobburu, J, Schaller, S, Sherwin, CM. Modernizing Preclinical Drug Development: The Role of New Approach Methodologies. June 2025. ACS Pharmacol. Transl. Sci. https://doi.org/10.1021/acsptsci.5c00162
2. Androulakis, IP, Cucurull-Sanchez, L, Kondic, A, Mehta, K, Pichardo, C, Pryor, M, Renardy, M. The dawn of a new era: Can Machine Learning and Large Language Models reshape QSP modeling? J Pharmacokinet Pharmacodyn. 2025 Jun 16;52(4):36. doi: 10.1007/s10928-025-09984-5.
3. Hruska, M.W., Sid-Otmane, L., Gosselin, N.H., Quattrocchi, E., Lee, S.K., Mascelli, M.A., Mehta, K, Jan de Beur, S.M. and Marsteller, D. (2024), Model-Informed Approach to Recommend Burosumab Dosing Regimens for Pediatric and Adult Patients With the

Ultrarare Disease Tumor-Induced Osteomalacia. Clin Pharmacol Ther. https://doi.org/10.1002/cpt.3468

4. Mehta K, Storopoli J, Ramwani N, Quattrocchi E, Gobburu J, Weber T, Hruska M, Marsteller D, Pharmacodynamic Exposure–Response Analysis of Fracture Count Data Following Treatment with Burosumab in Patients with XLH. (2024) J Clin Pharm. https://doi.org/10.1002/jcph.6140
5. Mehta, K., Gosselin, N.H., Insogna, K., Barriere, O., Quattrocchi, E., Hruska, M.W. and Marsteller, D. (2024), Item Response Theory Quantifies the Relationship Between Improvements in Serum Phosphate and Patient-Reported Outcomes in Adults With X-Linked Hypophosphatemia. (2024) Clin Pharmacol Ther. https://doi.org/10.1002/cpt.3406
6. Mehta, K, Balazki P, van der Graaf, PH, Guo, T,van Hasselt, JGC. Predictions of bedaquiline central nervous system exposure in tuberculosis meningitis patients using physiologically-based pharmacokinetic modeling. Clin Pharmacokinet (2024). https://doi.org/10.1007/s40262-024-01363-6
7. Mehta, K, Guo, T, van der Graaf, PH, van Hasselt, JGC. Model-based dose optimization framework for bedaquiline, pretomanid and linezolid for the treatment of drug-resistant tuberculosis. Br J Clin Pharmacol. 2023; 1-12. doi:10.1111/bcp.15925
8. Mehta, K., Guo, T., van der Graaf, P.H. et al. Predictions of Bedaquiline and Pretomanid Target Attainment in Lung Lesions of Tuberculosis Patients using Translational Minimal Physiologically Based Pharmacokinetic Modeling. Clin Pharmacokinet 62, 519–532 (2023). https://doi.org/10.1007/s40262-023-01217-7.
9. Mehta K, Narayanan N, Heysell SK, Bisson GP, Subbian S, Kurepina N, Kreiswirth BN, Vinnard C. Pharmacogenetic variability and the probability of site of action target attainment during tuberculosis meningitis treatment: A physiologically based pharmacokinetic modeling and simulations study. Tuberculosis (Edinb). 2022 Dec;137:102271. doi: 0.1016/j.tube.2022.102271.
10. Mehta K, Guo T, Wallis RS, van der Graaf PH, van Hasselt JGC. Quantitative Systems Pharmacology Modeling Framework of Autophagy in Tuberculosis: Application to Adjunctive Metformin Host-Directed Therapy. Antimicrob Agents Chemother. 2022 Aug 16;66(8):e0036622. doi: 10.1128/aac.00366-22.
11. Mehta K, Spaink HP, Ottenhoff THM, van der Graaf PH, van Hasselt JGC. Host-directed therapies for tuberculosis: quantitative systems pharmacology approaches. Trends Pharmacol Sci. 2022 Apr;43(4):293-304. doi: 10.1016/j.tips.2021.11.016.
12. Oni-Orisan, A., Srinivas, N., Mehta, K., Das, J.L., Nguyen, T.T., Tison, G.H., Bauer, S.R., Burian, M., Funk, R.S., Graham, R.A. and (2021), Leveraging innovative technology to generate drug response phenotypes for the advancement of biomarker-driven precision dosing. Clin Transl Sci, 14: 784-790. https://doi.org/10.1111/cts.12973
13. Mehta K, Ravimohan S, Pasipanodya J, et al. (2019). Optimizing ethambutol dosing among HIV/tuberculosis co-infected patients: a population pharmacokinetic modelling and

simulation study. The Journal of antimicrobial chemotherapy. https://doi.org/10.1093/jac/dkz265

Conference Presentations/Posters

1. Debir B, Kierzek AM, Nishizawa K, Vuppugalla R, Rose R, Matsuura T, Hruska M, Van der Graaf PH, Marsteller D, Mehta K. Application of Quantitative Systems Pharmacology (QSP) Approach to Guide Development of a Bispecific CD40-EpCAM Antibody, KK2269. Poster presented at Population Approach group Europe Conference PAGE 33. Thessaloniki, Greece. (2025) Abstr 11399 [www.page-meeting.org/?abstract=11399]. Jun 3, 2025.
2. Takaichi D, Gewitz A, Okada H, Mehta K, Hosogi J, Nagata Y, Utsey K, Riggs M. Quantitative Systems Pharmacology Modeling of X-linked Hypophosphatemia Disease Pathway. Poster presented at ACoP. 2024. https://acop2024.eventscribe.net/fsPopup.asp?PosterID=690782&mode=posterInfo.
3. Mehta K, et al. Leveraging QSP to Shape the Strategy for Early Phase Clinical Development in Immuno-Oncology. Invited oral presentation at QSP Summit May 2024, Boston, USA.
4. Vupugalla R, Mehta K, Debir B, Kierzek A, Takada H, Adachi M, Ishida H, Ando M, Kierzek A, Debir B, Marsteller D, Hruska M. Development of a Pharmacokinetic-Tumor Target Engagement Model Using Nonclinical Data to Inform Phase 1 Dosing Scheme for a Novel Bispecific CD40-EpCAM Antibody, KK2269. Poster Number: 087, Presented at American College of Clinical Pharmacology Annual Meeting. September 2024. Poster Number 087. https://accp1.onlinelibrary.wiley.com/doi/10.1002/cpdd.1459?
5. Mehta K, Storopoli J, Ramwani N, Quattrocchi E, Gobburu J, Weber T, Hruska M, Marsteller D, Pharmacodynamic Exposure–Response Analysis of Fracture Count Data Following Treatment with Burosumab in Patients with XLH. Poster presented at ACoP. 2023
6. Mehta K, Barriere O, Gosselin NH, et al., Burosumab treatment-induced increases in serum phosphate provide improvements in patient reported outcomes in adults with x-linked hypophosphatemia as assessed with graded item response analysis. Poster presented at ACoP. 2022
7. Mehta K, Patel D, Vupugalla R, et al., Rationale for the clinical use of less frequent dosing of mogamulizumab for T-cell lymphomas using population pharmacokinetic and exposure response analysis. Poster presentation at American Society of Hematology 2021 Conference. Abstract 2475 Dec 12, 2021. https://doi.org/10.1182/blood-2021-148099
8. Mehta K, Koshiba S, Hasegawa M, et al., Population pharmacokinetic-pharmacodynamic analysis of KHK2455 in patients with locally advanced or metastatic solid tumors. Abstract 1368. Poster presented at AACR 2021, July 01, 2021. https://doi.org/10.1158/1538-7445.AM2021-1368
9. Mehta K and Vinnard C. Impact of SLCO1B1 genotype and single nucleotide polymorphism on rifampin pharmacokinetics using linkage analysis and physiologically based pharmacokinetic (PBPK) modeling approach. Poster presented at ACoP10, October 2019.