Ms. Joyce Macwan

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Title: Physiologically Based Biopharmaceutics Modeling and Virtual Bioequivalence Assessment to Support Formulation Development

Abstract : Physiologically based biopharmaceutics modeling has been increasingly used over the last decade to support innovator and generic drug product development and regulatory interactions. The ability of modern software packages to accurately depict the gastrointestinal tract and other tissue physiologies, combined with basic physicochemical, formulation, and pharmacokinetic properties, allow for the simulation of *in vivo* dissolution, absorption, and systemic exposure, and offers insight about the drug's behavior *in vivo* to guide formulation design, establish clinically relevant specifications, and predict the impact of physiological conditions (e.g., PPI and food effect) on dosage form performance. The applications specific to formulation design include identifying optimal formulation strategies and critical API attributes which result in predicted plasma profiles meeting the drug's therapeutic window criteria, assessing feasibility of an extended release product for prodrugs and compounds with a narrow absorption window, building mechanistic *in vitro-in vivo* correlations to guide generic drugs development, defining dissolution safe space that would result in product bioequivalence, and virtual bioequivalence simulations between reference and test products based on their *in vitro* dissolution profiles. The examples of these applications and their regulatory impact will be provided and discussed.

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Professional Biography

Joyce Macwan is a Senior Scientist II in Simulations Studies group at Simulations Plus, Inc., where she performs primarily PBPK/PD modeling and simulation consulting services for pharmaceutical industry. She has an extensive experience in mechanistic absorption and PBPK modeling to support model-based drug development. She earned Ph.D. in Clinical Pharmacokinetics from the University of Rhode Island, RI, USA and B.S. and M.S. degrees in Pharmaceutical sciences from Sardar Patel University, India.

Her expertise in PBPK modeling and simulations facilitates the decision-making process during drug discovery and through various stages of the drug development by integrating the knowledge of drug metabolism, pharmacokinetics, pharmacodynamics, formulation and pathophysiological factors. She has worked on numerous studies including formulation optimization, bioequivalence studies, first-in-human dose predictions, drug-drug interactions, disease states modeling, and pediatric drug development across different therapeutics areas and routes of administrations. She has been involved in many studies that informed regulatory decisions. She continues to contribute in scientific community by her peer reviewed publications and presentations at the various conferences.