COLLEGE OF PHARMACY
PHARMACEUTICAL SCIENCES
UNIVERSITY OF MICHIGAN

Pharmaceutical Sciences Seminar

Wednesday, April 26, 2023
4:00pm
NCRC Building 10 Research Auditorium or Zoom

"*PBBM applications in drug development and regulatory filings*"

Presented by:

Tycho Heimbach, PhD, FAAPS
Pharmaceutical Sciences
Merck Research Laboratories

Abstract: Physiologically based biopharmaceutics models (PBBM) are evolving tools which can be used throughout drug product development. PBBM focusses on the generation of mechanistic understanding of how drug product quality attributes interact with physiology to influence the in vivo drug performance. The application of PBBM is not only important in the development of drug products but can also be a key component for regulatory approval of e.g. clinically relevant specifications and continued quality assurance throughout the product life cycle.

Topics covered will include:
A. PBBM Background and History
B. PBBM applications during clinical development and marketing application
C. Establishing PBBM Models
D. Challenges and considerations in the development of biorelevant/biopredictive inputs such as solubility, dissolution, permeability etc. for the PBBM model development
E. PBBM/PBPK to inform food effect studies
F. The use of PBPK to anticipate/remediate Drug-Drug Interactions with Acid Reducing Agents (ARA's)

Dr. Heimbach is a Senior Principal Scientist and Director at MSD in the Biologics Development and Biopharmaceutics Group which is part of the Sterile and Specialty Products Group. There he serves as a biopharmaceutics and PBBM/PBPK expert in oral and long-acting injectables drug development, which includes establishing the bioequivalence safe space of new drug candidates. Prior to that Tycho was Director in DMPK at Novartis where he led a global PBPK modeling group and served as PBPK and biopharmaceutics expert and implemented PBPK/PBBM for oncology drugs.

Dr. Heimbach served as cochair on working groups for the PBPK Modeling and the PBPK renal and hepatic impairment WG and the PBBM WG for the Innovation and Quality in Pharmaceutical Development (IQ) consortium. He is currently serving as the MSD representative on the PBBM Innovation & Quality (IQ) Consortium Working Group.

Dr. Heimbach has been a speaker at 50 national and international conferences. He has authored/coauthored ~65 peer-reviewed publications in ADME, PBPK and formulation sciences and was recognized as an AAPS Fellow in 2021.