PBPK MODELING FOR THE DEVELOPMENT AND APPROVAL OF LOCALLY ACTING PRODUCTS

WEDNESDAY, MARCH 13, 2019 | 8:00 AM – 5:00 PM

Co-Sponsor: ASCPT and the US Food and Drug Administration

This Pre-Conference will address challenges in developing physiologically-based pharmacokinetic (PBPK) models for locally acting drug products and using them during drug development and demonstration of bioequivalence (BE). The Pre-Conference will update the community with the latest progress in understanding drug distribution and delivery of locally acting drug products by PBPK modeling, stimulate discussion, and foster collaborations, especially with a focus on the following routes of delivery: inhalation, topical, ophthalmic, and other non-oral routes. The recent advancement of PBPK models offers a great opportunity to address the existing scientific challenges and regulatory needs across the product lifecycle. This workshop will be especially valuable to industry developing products that need to demonstrate bioequivalence to a locally acting drug product.

Chairs: Liang Zhao, PhD, and Ping Zhao, PhD

8:00 AM – 8:05 AM
Welcome and Objectives
Liang Zhao, PhD, US Food and Drug Administration, Silver Spring, MD
Ping Zhao, PhD, Bill & Melinda Gates Foundation, Seattle, WA

8:05 AM – 8:20 AM
Opening Remarks: Challenges and Critical Role of PBPK for Locally Acting Drug Products in Regulatory Decisions
Robert Lionberger, PhD, US Food and Drug Administration, Silver Spring, MD

Session 1: Orally Inhaled and Nasal Drug Products
Moderators: Myong-Jin Kim, PharmD, US Food and Drug Administration, Silver Spring, MD, and Donald L. Heald, PhD, Janssen - Johnson and Johnson, Spring House, PA

8:20 AM – 8:40 AM
Using PBPK to Link Systemic PK to Local Delivery in the Lung
Guenther Hochhaus, PhD, University of Florida, Gainesville, FL

8:40 AM – 9:00 AM
CFD Lung Models for Drug Delivery
Ching-Long Lin, PhD, University of Iowa, Iowa City, IA

9:00 AM – 9:20 AM
Application of PBPK Modeling for Inhalativa: Potential and Challenges
Michael Block, PhD, Bayer, Leverkusen, Germany

9:20 AM – 9:40 AM
Impact of Orally Inhaled and Nasal Drug Product PBPK Models on Product Development and Regulatory Decision Making
Ross Walenga, PhD, US Food and Drug Administration, Silver Spring, MD

9:40 AM – 10:05 AM
PANEL DISCUSSION

Guenther Hochhaus, PhD, University of Florida, Gainesville, FL
Ching-Long Lin, PhD, University of Iowa, Iowa City, IA
Michael Block, PhD, Bayer, Leverkusen, Germany
Ross Walenga, PhD, US Food and Drug Administration, Silver Spring, MD

10:05 AM – 10:20 AM
BEVERAGE BREAK

Session 2: Dermal Drug Delivery
Moderators: Min Li, PhD, US Food and Drug Administration, Silver Spring, MD, and Lakshmi Vasist, PharmD, GlaxoSmithKline, Research Triangle Park, NC

10:20 AM – 10:40 AM
Skin Physiology and Clinical Considerations for PBPK Models of the Skin
Howard Maibach, MD, University of California, San Francisco, San Francisco, CA

10:40 AM – 11:00 AM
PBPK Models of the Skin (Considering Dosage Form Properties)
Michael Roberts, PhD, DSc, University of South Australia and The University of Queensland Australia, Queensland, Australia

11:00 AM – 11:20 AM
PBPK Modeling of Dermally Applied Drug Products to Support Clinical Development and Regulatory Assessment
Nikunjkumar Patel, PhD, Simcyp (A Certara Company), Sheffield, United Kingdom

11:20 AM – 11:40 AM
PBPK Modeling for the Development of Dermatological Drug Products and its Regulatory Impact
Eleftheria Tsakalozou, PhD, US Food and Drug Administration, Silver Spring, MD

11:40 AM – 12:05 PM
PANEL DISCUSSION

Howard Maibach, MD, University of California, San Francisco, San Francisco, CA
Michael Roberts, PhD, DSc, University of South Australia and The University of Queensland Australia, Queensland, Australia
Nikunjkumar Patel, PhD, Simcyp (A Certara Company), Sheffield, United Kingdom
Eleftheria Tsakalozou, PhD, US Food and Drug Administration, Silver Spring, MD

12:05 PM – 1:00 PM
NETWORKING LUNCH
Vouchers for hotel food outlets, include Harry's, Stone's Throw, Lobby Lounge & Woodley Pantry

12:45 – 1:30 PM
POSTER PRESENTATIONS (Poster authors will be available to discuss their work)

Session 3: Ophthalmic Drug Products
Moderators: Xinyuan Zhang, PhD, US Food and Drug Administration, Silver Spring, MD, and David Wesche, MD, PhD, Certara Strategic Consulting, Princeton, NJ

1:30 PM – 1:50 PM
An Integrated Multiscale-Multiphysics Modeling of Ocular Drug Delivery and Pharmacokinetics
Andrzej Przekwas, PhD, CFD Research Corporation, Huntsville, AL

1:50 PM – 2:10 PM
Developing PBPK for Ocular Delivery
Michael B. Bolger, PhD, Simulations Plus, Lancaster, CA

2:10 PM – 2:30 PM
Use PBPK Model to Evaluate Impact of Ophthalmic Drug Product's Critical Quality Attributes on BA/BE Assessment
Andrew Babiskin, PhD, US Food and Drug Administration, Silver Spring, MD

2:30 PM – 2:55 PM
PANEL DISCUSSION

Andrzej Przekwas, PhD, CFD Research Corporation, Huntsville, AL
Michael B. Bolger, PhD, Simulations Plus, Lancaster, CA
Andrew H. Babiskin, PhD, US Food and Drug Administration, Silver Spring, MD

2:55PM – 3:15 PM
BEVERAGE BREAK AND POSTER VIEWING

Session 4: Methods and Implementation Challenges
Moderators: Ping Zhao, PhD, Bill & Melinda Gates Foundation, Seattle, WA, and Lei Zhang, PhD, Silver Spring, MD

3:15 PM – 3:30 PM
European Experience of Biopharmaceutical Applications of PBPK Models
Susan Cole, BSc, Medicines & Healthcare Products Regulatory Agency, London, United Kingdom

3:30 PM – 3:50 PM
Challenges in Using PBPK Models for Locally Acting Drug Products to Inform Regulatory Decision Makings
Liang Zhao, PhD, US Food and Drug Administration, Silver Spring, MD

3:50 PM – 4:50 PM
PANEL DISCUSSION

3:50-4:20 PM
Session 1: Model verification for regulatory use
1. Guenther Hochhaus, PhD, University of Florida, Gainesville, FL
2. Ching-Long Lin, PhD, University of Iowa, Iowa City, IA

3. Michael Roberts, PhD, DSc, University of South Australia and The University of Queensland
4. Andrzej Przekwas, PhD, CFD Research Corporation, Huntsville, AL
5. Nikunjkumar Patel, PhD, Simcyp (A Certara Company), Sheffield, United Kingdom
6. Michael B. Bolger, PhD, Simulations Plus, Lancaster, CA
7. Michael Block, PhD, Bayer, Leverkusen, Germany
8. Liang Zhao, PhD, US Food and Drug Administration, Silver Spring, MD

4:20-4:50 PM
Session 2: Model application to support regulatory submission
1. Howard Maibach, MD, University of California, San Francisco, San Francisco, CA
2. Lakshmi Vasist, PharmD, GlaxoSmithKline, Research Triangle Park, NC
3. Gary D. Novack, PhD, PharmaLogic, San Rafael, CA
4. Susan Cole, BSc, Medicines & Healthcare Products Regulatory Agency, London, United Kingdom
5. Shinichi Kijima, PhD, Pharmaceuticals and Medical Devices Agency, Tokyo, Japan
6. Xinyuan Zhang, PhD, US Food and Drug Administration, Silver Spring, MD
7. Paul Seo, PhD, US Food and Drug Administration, Silver Spring, MD
8. Robert Lionberger, PhD, US Food and Drug Administration, Silver Spring, MD

4:50 PM – 5:00 PM
Concluding Remarks
Liang Zhao, PhD, US Food and Drug Administration, Silver Spring, MD
Ping Zhao, PhD, Bill & Melinda Gates Foundation, Seattle, WA