FDA/PQRI Workshop - Challenges and Opportunities for Modified Release Oral Drug Product Development

A Forum for Stakeholder Engagement

Thursday, April 18, 2024 (In-Person Event)
United States Pharmacopeia (USP) Meeting Center
12601 Twinbrook Pkwy, Rockville, MD 20852

Workshop Objectives:

This FDA/PQRI Workshop will bring together leaders and subject matter experts from regulatory agencies, industry, and academia to discuss critical topics related to solid modified release (MR) drug products for oral administration.

This workshop aims to facilitate interaction among stakeholders to:

1. Review recent advances in pharmaceutical science and technology for MR drug products.
2. Discuss special topics related to demonstrating BE for generic MR products.
3. Discuss current state modeling approaches for BE assessment for MR drug products to support regulatory approval.
4. Identify factors constituting alternative in vitro approaches to support BE for additional strengths of MR products

Thursday, April 18, 2024, 8:00 AM – 5:00 PM US ET All Times are in US Eastern Daylight Savings Time	
Introductions and Opening Remarks	
8:00 - 8:30 AM	Breakfast and Check in
8:30 - 8:35 AM	***Workshop Opening*** Wenlei Jiang, PhD, FDA
8:35 - 8:45 AM	***Welcome and Introductory Remarks*** Iilun Murphy, MD, FDA
SESSION 1: A New Era on Modified Release Oral Drug Products Development and Assessment – Where are we now and where are we heading?	
Moderators:	Wenlei Jiang, PhD, FDA Josephine Aimiuwu, PhD, FDA
8:45 - 9:15 AM	***Scientific Foundations for Development of Generic MR Oral Products*** Robert Lionberger, PhD, FDA
9:15 - 9:35 AM	***Overview of Solid Oral MR Technologies and Recent Advancements*** Yihong Qiu, PhD, QPD Solutions LLC
9:35 - 9:55 AM	***Rethinking Dissolution Testing in the USP Monograph for MR Products*** Shankari Shivaprasad, PhD, United States Pharmacopeia (USP)

9:55 - 10:25 AM	***Panel Discussion*** Robert Lionberger, PhD, FDA Yihong Qiu, QPD Solutions LLC Shankari Shivaprasad, USP Partha Roy, PhD, FDA Myong-Jin Kim, PharmD, FDA Bhagwant Rege, PhD, FDA
10:25 - 10:40 AM	**BREAK**
SESSION 2: Current Tools Available to Leverage for Bioequivalence Determination for Additional Strengths of MR Products	
Moderators:	Heather Boyce, PhD, FDA Fang Wu, PhD, FDA
10:40 - 10:50 AM	***Summary about GBHI Discussion on the BE Demonstration of Additional Strength for Solid Oral MR Products*** Barbara Schug, PhD, SocraTec R&D GmbH
10:50 - 11:05 AM	***Measuring Glipizide Release from Two Different ER Formulations vs. Oral Solution Using In Situ GI Intubation in Humans*** Duxin Sun, PhD, University of Michigan
11:05 - 11:20 AM	***Unlocking the Potential: Gastrointestinal Simulation (TIM Systems) for Predicting Performance*** Robert Schwabe, Boehringer Ingelheim
11:20 - 11:35 AM	***Application of Oral Biopharmaceutics Tools*** James E. Polli, PhD, University of Maryland
11:35 - 11:50 AM	***Industry Perspective: Gaps in the BE Guidance for Additional Strengths and Proposals for Consideration*** Rama Yarasani, PhD, Alvogen
11:50 AM - 12:00 PM	***FDA Summary Talk of Session 2*** Wei-Jhe Sun, PhD, FDA
12:00 - 12:30 PM	***Panel Discussion*** Barbara Schug, PhD, SocraTec R&D GmbH, Duxin Sun, PhD, University of Michigan Robert Schwabe, Boehringer Ingelheim James E. Polli, PhD, University of Maryland Rama Yarasani, PhD, Alvogen Wei-Jhe Sun, PhD, FDA Hongling Zhang, PhD, FDA
12:30 - 1:30 PM	**LUNCH BREAK**
SESSION 3: Special Considerations in the Evaluation of Modified Release Products – Addressing Challenges, Bridging Gaps and Upholding Quality Aspects	
Moderators:	Jyothy John, PhD, RPh, FDA Jason Mao, PhD, FDA
1:30 - 1:45 PM	**Assessing Bioequivalence: A Focus on Tmax, Tlag, and pAUC in ANDA Submissions** Zhen Zhang, PhD, FDA

1:45 - 2:00 PM	***A Review of Internal Data on Bioequivalence Studies Conducted with Soft Food Administration*** Heather Boyce, PhD, FDA
2:00 - 2:15 PM	***Formulation and Bioequivalence Study Considerations for ANDA Products Administered as a Sprinkle*** John Kirsch, PhD, RPh., Viatris
2:15 - 2:30 PM	***In Vitro Alcohol Dose Dumping (ADD) - Data to Support Testing of ADD on All Strengths of MR Products*** Yoriko Harigaya, PharmD, FDA
2:30 - 2:45 PM	***Risk Mitigation for Alcohol Dose Dumping: A Formulation Approach*** Nitin K. Swarnakar, PhD, BASF Corporation
2:45 - 3:15 PM	***Panel Discussion*** Zhen Zhang, PhD, FDA Heather Boyce, PhD, FDA John Kirsch, PhD, RPh, Viatris Nitin K. Swarnakar, PhD, Pharma Solution Yoriko Harigaya, PharmD, FDA Hongfei Zhou, PhD, FDA
3:15 - 3:30 PM	**BREAK**
SESSION 4: IVIVC & PBPK Approaches for MR Products	
Moderators:	Liang Zhao, PhD, FDA Yuqing Gong, PhD, FDA
3:30 - 3:45 PM	***Role of IVIVC or PBBM in Setting Dissolution Specifications for Oral Modified Release Products*** Patrick Marroum, PhD, AbbVie
3:45 - 4:00 PM	***PBPK Absorption Modeling to Support BE Assessment for MR Products: Industry Perspective*** Tausif Ahmed, PhD, Dr. Reddy's Laboratories Ltd.
4:00 - 4:15 PM	***Regulatory Perspective: PBPK Absorption Modeling to Support BE Assessment for MR Products*** Fang Wu, PhD, FDA
4:15 - 4:45 PM	***Panel Discussion*** Patrick Marroum, PhD, AbbVie Tausif Ahmed, PhD, Dr. Reddy's Laboratories Ltd. Fang Wu, PhD, FDA Zhen Zhang, PhD, FDA Rebeka Jereb, PhD; Lek, Sandoz Haritha Mandula, Ph.D.
4:45 - 5:00 PM	***Closing Remarks*** Partha Roy, PhD, FDA

Workshop Faculty

Tausif Ahmed, PhD, Vice President & Head, Biopharmaceutics and Bioequivalence, Dr. Reddy's Laboratories Ltd.
Josephine Aimiuwu, PhD, Lead Pharmacologist, DB II | OB | OGD | CDER | US FDA
Heather Boyce, PhD, Lead Pharmacokineticist, DTP II | ORS | OGD | CDER | US FDA
Yuqing Gong, PhD, Pharmacologist, DQMM | ORS | OGD | CDER | US FDA
Yoriko Harigaya, PharmD, Senior Staff Fellow, DB II | OB | OGD | CDER | US FDA
Rebeka Jereb, Ph.D., Senior Scientist; Lek, Sandoz
Wenlei Jiang, PhD, Senior Advisor for Innovation and Strategic Outreach, ORS | OGD | CDER | US FDA
Jyothy John, PhD, RPh, Senior Staff Fellow, DB I | OB | OGD | CDER | US FDA
Myong-Jin Kim, PharmD, Division Director, DTP II | ORS | OGD | CDER | US FDA
John Kirsch, PhD, RPh, Head of Product Development, Viatris
Robert Lionberger, PhD, Director, Office of Research and Standards | OGD | CDER | US FDA
Haritha Mandula, PhD, Senior Pharmaceutical Quality Assessor, DPQA VI | OPQA I | OPQ | CDER | US FDA
Jason Mao, PhD, Senior Pharmacologist, DB III | OB | OGD | CDER | US FDA
Patrick Marroum, PhD, Distinguished Research Fellow, AbbVie
Iilun Murphy, MD, Director, Office of Generic Drugs
James E. Polli, PhD, Professor and Ralph F. Shangraw/Noxell Endowed Professor in Industrial Pharmacy and Pharmaceutics, University of Maryland
Yihong Qiu, PhD, Founder, QPD Solutions LLC
Bhagwant Rege, PhD, Division Director, Biopharmaceutics | OPQA I | OPQ | CDER | US FDA
Partha Roy, PhD, Director, OB | OGD | CDER | US FDA
Barbara Schug, PhD, Managing Director, SocraTec R&D GmbH
Robert Schwabe, BS, Senior Scientist, Boehringer Ingelheim Pharmaceuticals, Inc.
Shankari Shivaprasad, PhD, Principal Scientist, United States Pharmacopeia (USP)
Duxin Sun, PhD, Associate Dean for Research, Charles Walgreen Jr. Professor of Pharmacy, University of Michigan
Wei-Jhe Sun, PhD, Senior Staff Fellow, DTP II | ORS | OGD | CDER | US FDA
Nitin K. Swarnakar, PhD, NA Applications Lab Manager, BASF Corporation
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Hongling Zhang, PhD, Division Director, DB II | OB | OGD | CDER | US FDA
Zhen Zhang, PhD, Master Pharmacologist, DB I | OB | OGD | CDER | US FDA
Liang Zhao, PhD, Division Director, DQMM | ORS | OGD | CDER | US FDA
Hongfei Zhou, PhD, Senior Pharmacologist, DB III | OB | OGD | CDER | US FDA

Workshop Planning Committee

Heather Boyce, PhD - US FDA (Co-chair)
Wenlei Jiang, PhD - US FDA (Co-chair)
Jyothy John, PhD - US FDA (Co-chair)
Josephine Aimiuwu, PhD - US FDA
Jason (Jinzhe) Mao, PhD - US FDA
Ta-Chen Wu, PhD - US FDA
Lei Zhang, PhD - US FDA
Myong-Jin Kim, PharmD - US FDA
Fang Wu, PhD - US FDA
Yuqing Gong, PhD - US FDA
Shapali Bagde, PhD - US FDA
Fallon Smalls - US FDA
Dede Godstrey - PQRI
Maria Monroy-Osorio - US FDA
Kristin Holbrook, PharmD - US FDA
Irfan Memon, PharmD - US FDA