FDA-CRCG Workshop on Advancing Bioequivalence Frameworks for Inhalation Drug Products: Optimizing In Vitro, In Vivo, and In Silico Methods

Public Workshop
October 14-15, 2026
Agenda

Day 1 Wednesday, October 14

8:00 AM – 8:05 AM **Welcome and Opening Remarks**
James Polli, PhD Co-Director, CRCG
Sam Raney, PhD Associate Director for Science & Chief Scientific Advisor, ORS, OGD, FDA

8:05 AM – 8:20 AM **FDA Opening Remarks**
Darby Kozak, PhD Deputy Director, OGD, FDA

Session 1: Current Bioequivalence Approaches for Inhalation Drug Products
Session Lead: Dr. Bryan Newman
Scope: This session details the Agency's latest advancements in bioequivalence strategies recommended for inhalation products, their associated challenges, and opportunities for clarity and efficiency. Topics include the current option-based framework, recommended bioequivalence (BE) studies, method considerations, industry experiences and challenges, and future directions for research initiatives and additional guidance.

8:20 AM – 8:25 AM ***Speaker Introductions***
Bryan Newman, PhD Lead Pharmacologist, Team Lead, Inhal/Nasal Drug Prod, DTP I, ORS, OGD, FDA

8:25 AM – 8:40 AM ***Navigating Bioequivalence for Inhalation Drug Products: An FDA Perspective on Opportunities and Challenges***
Bryan Newman, PhD Lead Pharmacologist, Team Lead, Inhal/Nasal Drug Prod, DTP I, ORS, OGD, FDA

8:40 AM – 8:55 AM ***An Industry Perspective on FDA's Updated Bioequivalence Framework for Generic Inhalation Drugs***
Xian-Ming Zeng, MS, PhD CEO, Transpire Bio Inc.

8:55 AM – 9:05 AM ***Coffee Break***

Session 2: Revisiting Realistic Particle Size Distribution Study Designs and Analyses
Session Lead: Dr. Elizabeth Bielski
Scope: This session examines the FDA expectations and industry experience with conducting conventional and realistic aerodynamic particle size distribution (APSD) studies. Speakers will cover topics such as selection and use of anatomical mouth-throat models and breathing profiles, approaches for statistical analyses, study size, capturing clinically relevant variability, bracketing approaches, and potential opportunities for addressing common challenges.

9:05 AM – 9:10 AM ***Speaker Introductions***
Elizabeth Bielski, PhD Senior Pharmacologist, DTP I, ORS, OGD, FDA

9:10 AM – 9:30 AM ***Current FDA Perspective on Realistic Aerodynamic Particle Size Distribution (rAPSD) Testing***
Elizabeth Bielski, PhD Senior Pharmacologist, DTP I, ORS, OGD, FDA

9:30 AM – 9:50 AM ***Model Matters-Evaluating VCU & OPC Mouth-Throat Models in Terms of Particle Dynamics & Total Lung Dose (TLD)***
Marie Solcher, PhD Technical Lead, Pharmaceutical Development, Sandoz

9:50 AM – 10:10 AM ***Alternative Approaches to Realistic APSD Experiment Design and Data Analysis***
Mark Berry, MSc Director, CMC/Nonclinical Statistics, Respiratory R&D, Viatris
Andrew Cooper, PhD Sr. Director, Respiratory Bioequivalence Strategy Lead, Respiratory R&D, Viatris

10:10 AM – 10:30 AM ***A Novel Approach to rAPSD Testing to Address Current Challenges***
James Jamieson, BEng, BCompSc Senior Design Engineer, Product Development, Prior PLM Medical

10:30 AM – 11:00 AM ***Q&A Session with Panel***
Moderator: **Elizabeth Bielski, PhD** Senior Pharmacologist, DTP I, ORS, OGD, FDA
Panelists: **Mark Berry, MSc** Director, CMC/Nonclinical Statistics, Respiratory R&D, Viatris

	Jamie Clayton, BEng	Chief Executive Officer, Copley Scientific Ltd.
	Andrew Cooper, PhD	Sr. Director, Respiratory Bioequivalence Strategy Lead, Respiratory R&D, Viatris
	James Jamieson, BEng, BCompSc	Senior Design Engineer, Product Development, Prior PLM Medical
	Lucas W.S. Silva, BS	Technical Specialist Manager, Nanopharm, An Aptar Pharma Company
	Marie Solcher, PhD	Technical Lead, Pharmaceutical Development, Sandoz
	Stephen Stein, MS, MEng	President, CGT Pharma Consulting LLC

11:00 AM – 11:50 AM ***Lunch Break***

Session 3: Expectations for Designing Sensitive Dissolution Methods

Session Lead: Dr. Susan Boc

Scope: This session examines the FDA expectations and industry experience with dissolution studies. Speakers will cover topics on the rationale and utility of dissolution for inhalation products, method development and sample collection, validation, demonstrating sensitivity, approaches for statistical analysis, and applicability of biopredictive and/or biorelevant approaches.

11:50 AM – 11:55 AM	***Speaker Introductions***	
	Susan Boc, PhD	Pharmacokineticist, DTP I, ORS, OGD, FDA
11:55 AM – 12:15 PM	***Current Agency Perspective on Dissolution Testing***	
	Susan Boc, PhD	Pharmacokineticist, DTP I, ORS, OGD, FDA
12:15 PM –12:35 PM	***A Practical Framework for Identifying and Testing Dissolution-Limited OIDPs***	
	Jayne E. Hastedt, PhD	Managing Director, JDP Pharma Consulting, LLC
12:35 PM – 12:55 PM	***Considerations for the Development of a Discriminatory Dissolution Method for Complex Dry Powder Inhalers***	
	Irene Rossi, PhD	Respiratory Science Expert, Harro Höfliger
12:55 PM – 1:15 PM	***Utility of Biopredictive/Biorelevant Dissolution Testing for OIDPs***	
	Tilen Huzjak, MPharm	Leading Scientist, IVIVC Group, Pharmaceutical Research, Sandoz Dev. Center
1:15 PM – 1:45 PM	***Q&A Session with Panel***	
Moderator:	**Susan Boc, PhD**	Pharmacokineticist, DTP I, ORS, OGD, FDA
Panelists:	**Dino Farina, MS, EME**	Founder and CEO, Proveris Scientific
	Dipeshkumar Gohil, MS	Director, Analytical Research & Development, Amneal Pharmaceuticals
	Abhishek Gupta, PhD, PMP	Chief Scientific Officer, Transpire Bio
	Jayne E. Hastedt, PhD	Managing Director, JDP Pharma Consulting, LLC
	Tilen Huzjak, MPharm	Leading Scientist, IVIVC Group, Pharmaceutical Research, Sandoz Dev. Center
	Mark Parry, MSci	Senior Scientific Director, Intertek
	Irene Rossi, PhD	Respiratory Science Expert, Harro Höfliger
	Yan Wang, PhD	Deputy Director, DTP I, ORS, OGD, FDA

Session 4: Expectations and Opportunities with Particle Morphology Testing

Session Lead: Dr. Yang Yang

Scope: This session examines the FDA expectations and industry experience with particle morphology characterization studies. Speakers will cover topics on purpose of utility of particle morphology characterization across inhalation products, current and alternative methods for morphology characterization, and considerations and challenges with multi-component formulations.

1:45 PM – 1:50 PM	***Speaker Introductions***	
	Yang Yang, PhD	Research Staff Fellow, DPQR V, OPQR, OPQ, FDA
1:50 PM – 2:10 PM	***Utilizing Advanced Imaging Technology for Particle Morphology Analysis***	
	Yang Yang, PhD	Research Staff Fellow, DPQR V, OPQR, OPQ, FDA
2:10 PM – 2:30 PM	***The Influence of DPI Sample Collection Technique on MDRS Characterization***	
	James Tibbatts, MEng	Inhalation Product Development Specialist, Sandoz
2:30 PM – 2:45 PM	***Coffee Break***	
2:45 PM – 3:05 PM	***Particle Level Assessment of Morphology and Composition as a Function of Aerosol Particle Size Using Optical Photothermal Infrared Microscopy***	
	Mark Banaszak Holl, PhD	Professor & Associate Dean, University of Alabama at Birmingham

3:05 PM – 3:25 PM	***Chemical Identification and Imaging for Multicomponent Systems***	
	Mark Parry, MS	Senior Scientific Director, Intertek
3:25 PM – 3:55 PM	***Q&A Session with Panel***	
Moderator:	**Yang Yang, PhD**	Research Staff Fellow, DPQR V, OPQR, OPQ, FDA
Panelists:	**Mark Banaszak Holl, PhD**	Professor & Associate Dean, University of Alabama at Birmingham
	Mridul Majumder, PhD, FRSC, FAPS	Founder and Director, M2M Pharmaceuticals Ltd.
	Mark Parry, MS	Senior Scientific Director, Intertek
	Chirag Shah, MPharm	Director, R&D, Formulation Development, Transpire Bio Inc.
	Maria Smith, MS	Director of Applications and Business Development, Proveris Scientific LLC
	Ryan Swart, BS	Associate Director Analytical Research, RNSSL, Hikma Pharmaceuticals
	James Tibbatts, MEng	Inhalation Product Development Specialist, Sandoz
	Vivek Viswanathan, PhD	Senior Manager, R&D, Rubicon Research Canada Limited
3:55 PM – 4:00 PM	***Closing Remarks for Virtual Audience***	
	Sam Raney, PhD	Associate Director for Science & Chief Scientific Advisor, ORS, OGD, FDA

Session 5: Meet & Learn (In-Person Only)

4:00 PM – 5:30 PM ***Meet & Learn***

FDA reviewers from multiple FDA Offices involved with assessing different aspects of information submitted in ANDAs for generic orally inhaled drug products will interact in an informal setting with in-person attendees to discuss and clarify FDA's review process, as well as scientific and regulatory considerations. Experts from Industry, Academia, and the FDA who are subject matter experts in their respective disciplines will share each other's real-world challenges and discuss viable approaches to facilitate the successful development and assessment of generic orally inhaled drugs. Specific topics will include:

- In Vitro Bioequivalence Studies: From Eligibility to Analytical Methods
- In Vivo Bioequivalence Studies: Study Design, Population, & Modeling
- Drug Product Quality Assessment and Manufacturing Considerations
- Human Factors and Comparative Analyses: Showing Substitutability

Day 2 Thursday, October 15

Session 6: Waivers for In Vitro and In Vivo Studies – Challenges and Opportunities

Session Lead: Dr. Ross Walenga

Scope: This session explores the considerations and challenges with the recommended in vivo pharmacokinetics (PK) bioequivalence studies, including more complex designs like charcoal-block studies. Speakers will cover topics related to the rationales for current recommendations, implications and experiences from industry, and where alternative methods like in silico modeling may have potential for improving efficiency.

8:00 AM – 8:05 AM	***Speaker Introductions***	
	Ross Walenga, PhD	Senior Pharmacokineticist, DQMM, ORS, OGD, FDA
8:05 AM – 8:25 AM	***Current FDA Expectations for In Silico Models that Support OIDP Development and Approval***	
	Steven Chopski, PhD	Pharmacokineticist, DQMM, ORS, OGD, FDA
8:25 AM – 8:45 AM	***Integrating CFD-PBBM with In Vitro and In Vivo Evidence to Support BE Assessment for Orally Inhaled Drug Products***	
	Markus Fridén, PhD	Senior Director, Biopharmaceutics, Global Product Development, AstraZeneca
8:45 AM – 9:05 AM	***Enabling Biowaiver Strategies for Locally Acting Products Through a Model-Informed Integration of Population PK and PBPK Models***	
	Massimiliano Germani, PhD	Head of Pharmacometrics, Chiesi
9:05 PM – 9:25 AM	***Current Agency Perspective on Charcoal Block Pharmacokinetics Bioequivalence Studies***	
	Ross Walenga, PhD	Senior Pharmacokineticist, DQMM, ORS, OGD, FDA
9:25 AM – 9:55 AM	***Q&A Session with Panel***	
Moderator:	**Ross Walenga, PhD**	Senior Pharmacokineticist, DQMM, ORS, OGD, FDA
Panelists:	**Jonas Biehler, PhD**	Co-Founder and CTO, Ebenbuild GmbH
	Steven Chopski, PhD	Pharmacokineticist, DQMM, ORS, OGD, FDA
	Markus Fridén, PhD	Senior Director, Biopharmaceutics, Global Product Development, AstraZeneca
	Massimiliano Germani, PhD	Head of Pharmacometrics, Chiesi
	Mark Lepore, MD	Chief Medical Officer, Transpire Bio
	Nuno Silva, MPharm	Associate Director Product Development, RNSSL, Hikma Pharmaceuticals
	Siva Vaithiyalingam, PhD	Senior Vice President, Regulatory Affairs, Cipla Ltd.
	Brandon Wood, BS	Sr. Director, Reg Affairs I & Comb Prod Liaison, Teva Pharmaceuticals USA, Inc.
9:55 AM – 10:10 AM	***Coffee Break***	

Session 7: Small Group Working Session (In-Person Only)

10:10 AM – 12:10 PM	***Rotating Discussions: Realistic APSD, Dissolution, Morphology, General Topics on In Vitro Bioequivalence, In Vivo Studies, In Silico Studies***	
12:10 PM – 1:00 PM	***Lunch Break***	
1:00 PM – 2:00 PM	***Mock Submission Scenario***	
2:00 PM – 3:00 PM	***Small Group Working Sessions Summary***	
3:00 PM – 3:15 PM	***Coffee Break***	

Session 8: Moving Beyond Formulation Sameness – Expanding BE Options for Non-Q1 and/or Non-Q2 Inhalation Products

Session Lead: Dr. Tian Ma

Scope: The final hybrid session focuses on the implications of formulation sameness recommendations for inhalation products. Speakers will cover topics on the role of formulation sameness with inhalation products based on current scientific understanding, along with potential opportunities for moving beyond these recommendations through improved understanding of the critical factors governing product performance.

3:15 PM – 3:20 PM	***Speaker Introductions***	
	Tian Ma, PhD	Lead Pharmacologist, DB I, OB, OGD, FDA
3:20 PM – 3:40 PM	***Current Agency Perspective on Bioequivalence for non-Q1/Q2 Locally-Acting Inhalation Products***	
	Zhen Xu, PhD	Senior Staff Fellow, DB III, OB, OGD, FDA

3:40 PM – 4:00 PM	***Does it have to be the same? The Irrelevance of 'Formulation Sameness' for Generic pMDI!***	
	Nick Smalley, BS	Vice President, Regulatory Affairs, Kindeva
4:00 PM – 4:20 PM	***A Risk Assessment Approach to Evaluate the Suitability of the Option 1 BE Pathway for Non-Q1 and/or Q2 Equivalent DPI's and pMDIs***	
	David Pole, PhD	Sr. Director, Respiratory Drug Product Development, Respiratory R&D, Viatris
4:20 PM – 5:20 PM	***Q&A Session with Panel***	
Moderator:	**Tian Ma, PhD**	Lead Pharmacologist, DB I, OB, OGD, FDA
Panelists:	**Andrew Babiskin, PhD**	Deputy Division Director, DQMM, ORS, OGD, FDA
	Loy Britto, PhD	CEO, Healthy Airways LLC
	Agnes Colombani, PhD	Director Formulation Development, RNSSL, Hikma Pharmaceuticals
	Markham Luke, MD, PhD	Director, DTP I, ORS, OGD, FDA
	David Pole, PhD	Sr. Director, Respiratory Drug Product Development, Respiratory R&D, Viatris
	Gur Jai Pal Singh, PhD	Chief Scientific Advisor, BBSG Pharm Associates, LLC
	Nick Smalley, BS	Vice President, Regulatory Affairs, Kindeva
	Zhen Xu, PhD	Senior Staff Fellow, DB III, OB, OGD, FDA
5:20 PM – 5:30 PM	***Closing Remarks***	
	Bing V. Li, PhD	Associate Director for Science, OB, OGD, FDA

Appendix of Abbreviations

APSD	Aerodynamic Particle Size Distribution
BCompSc	Bachelor of Computer Science
BE	Bioequivalence
BEng	Bachelor of Engineering
BS	Bachelor of Science
CEO	Chief Executive Officer
CMC	Chemistry, Manufacturing, and Controls
Comb	Combination
CRCG	Center for Research on Complex Generics
CTO	Chief Technical Officer
DB	Division of Bioequivalence
Dev	Development
DPI	Dry Powder Inhaler
DPQR	Division of Pharmaceutical Quality Research
DQMM	Division of Quantitative Methods and Modeling
DTP I	Division of Therapeutic Performance I
EME	Engineer, Mechanical Engineering
FAPS	Fellow of the Academy of Pharmaceutical Sciences
FDA	Food and Drug Administration
FRSC	Fellow of the Royal Society of Chemistry
Inc	Incorporated
Inhal	Inhalation
IVIVC	In Vivo In Vitro Correlation
LLC	Limited Liability Company
Ltd	Limited
MD	Doctor of Medicine
MDRS	Morphologically Directed Raman Spectroscopy
MEng	Master of Engineering
MPharm	Master of Pharmacy
MS	Master of Science
OB	Office of Bioequivalence
OGD	Office of Generic Drugs
OIDP	Orally Inhaled Drug Product
OPC	Oropharyngeal Consortium
OPQ	Office of Pharmaceutical Quality
OPQR	Office of Pharmaceutical Quality Research
ORS	Office of Research and Standards
PBPK	Physiologically Based Pharmacokinetic
PBBM	Physiologically Based Biopharmaceutics
PhD	Doctor of Philosophy
PK	Pharmacokinetics
pMDI	Pressurized Metered Dose Inhaler
PMP	Project Management Professional
Prod	Products
Q&A	Questions and Answers
Q1	Qualitative
Q2	Quantitative
R&D	Research and Development
rAPSD	Realistic Aerodynamic Particle Size Distribution
Reg	Regulatory
RNSSL	Respiratory, Nasal, Semi-Solids & Liquids
Sr.	Senior
TLD	Total Lung Dose
VCU	Virginia Commonwealth University