FDA-CRCG Workshop on Implementing FDA's IVPT Guidance Recommendations: A Step-By-Step Illustration

Public Workshop

April 29-30, 2025

Agenda

Day 1 April 29, 2025

8:30 AM – 8:40 AM	**Welcome and Opening Remarks**	
	James Polli, PhD	Co-Director, CRCG
8:40 AM – 8:50 AM	**FDA Opening Remarks**	
	Markham Luke, MD, PhD	Director, DTP I, ORS, OGD, FDA
8:50 AM – 8:55 AM	***Workshop Day 1 Overview***	
	Priyanka Ghosh, PhD	Lead Pharmacologist, DTP I, ORS, OGD, FDA

Session 1: IVPT Recommendations: FDA Guidance Development, Implementation Considerations, and Outstanding Challenges

In this session, regulatory and industry scientists will discuss the research that supported the development of the IVPT Guidance for Industry, scenarios where ANDA applicants have encountered difficulties with IVPT studies, and current challenges with the design, conduct, and analysis of IVPT studies as a component of a characterization-based bioequivalence approach.

8:55 AM – 9:00 AM	***Speaker Introductions***	
	Tannaz Ramezanli, PharmD, PhD	Senior Pharmacologist, DTP I, ORS, OGD, FDA
9:00 AM – 9:20 AM	***Development of FDA's Guidance for Industry on IVPT Studies for Topical Drug Products Submitted in ANDAs***	
	Sam Raney, PhD	Associate Director for Science & Chief Scientific Advisor, ORS, OGD, FDA
9:20 AM – 9:35 AM	***Current Status and Outstanding Challenges with IVPT Studies***	
	Priyanka Ghosh, PhD	Lead Pharmacologist, DTP I, ORS, OGD, FDA
9:35 AM – 9:50 AM	***Challenges with the Implementation of IVPT Guidance Recommendations – Industry Perspective***	
	Lakshmi Raghavan, PhD	Founder and CEO, Healios Labs LLC
9:50 AM – 10:05 AM	***Challenges with the Implementation of IVPT Guidance Recommendations – Industry Perspective***	
	Aaditya Bhatt, PhD	Director, Analytical R&D, Amneal Pharmaceuticals
10:05 AM – 10:30 AM	***Q&A Session with Panel Discussion***	
Moderator:	**Tannaz Ramezanli, PharmD, PhD**	Senior Pharmacologist, DTP I, ORS, OGD, FDA
Panelists:	**Aaditya Bhatt, PhD**	Director, Analytical R&D, Amneal Pharmaceuticals
	Priyanka Ghosh, PhD	Lead Pharmacologist, DTP I, ORS, OGD, FDA
	Markham Luke, MD, PhD	Director, DTP I, ORS, OGD, FDA
	S. Narasimha Murthy, PhD	Chief Scientific Officer, Topical Products Testing LLC, MS, USA
	Lakshmi Raghavan, PhD	Founder and CEO, Healios Labs LLC
	Sam Raney, PhD	Associate Director for Science & Chief Scientific Advisor, ORS, OGD, FDA
	Elena Rantou, PhD	Master Mathematical Statistician, DB VIII, OB, OTS, FDA
	Rong Wang, PhamD, PhD	Supervisory Associate Director, DB I, OB, OGD, FDA
10:30 AM – 10:40 AM	***Coffee Break***	

Session 2: How to Develop an IVPT Method – Theoretical Understanding and Hands-On Demonstrations

This session will include a presentation by the FDA laboratory on their approach to IVPT method development, along with recorded demonstrations of suitable IVPT study procedures, and common pitfalls to avoid during IVPT method development, using different diffusion cell equipment from multiple manufacturers.

10:40 AM – 11:00 AM	***Designing IVPT Methods: Practical Insights for Integrating the IVPT Guidance Recommendations***	
	Ahmed Zidan, PhD	Senior Research Pharmacologist, DPQR V, OPQR, OPQ, FDA

11:00 AM – 1:25 PM	***Step-by-Step Illustrations and Discussions of IVPT Study Procedures with a Q&A Panel of Experts***	
Moderator:	**Sam Raney, PhD**	Associate Director for Science & Chief Scientific Advisor, ORS, OGD, FDA
Panelists:	**Bryan DeBarr, BS**	Director, Global Pharmacology and Toxicology Lab Operations, Viatris Inc.
	Keith Hamman, BS	President and CEO, Logan Instruments
	John Heaney, BS	General Manager, PermeGear, Inc.
	Theo Kapanadze, PhD, DSc	CSO, Diteba Inc
	Ashvin Patel, PhD	Director of Analytical Research, Teledyne Hanson Research
	Hiren H. Patel, PhD	Senior Staff Fellow, DB II, OB, OGD, FDA
	Audra L. Stinchcomb, PhD, RPh	Professor, School of Pharmacy, University of Maryland Baltimore
	Ahmed Zidan, PhD	Senior Research Pharmacologist, DPQR V, OPQR, OPQ, FDA

1:25 PM – 1:30 PM ***Closing Remarks for the Virtual Session*** **(End of Virtual Session for Day 1)**

1:30 PM – 2:30 PM ***Lunch Break***

Session 3: Small Group Working Sessions (In-Person Only)

Small group working sessions will navigate through scenarios involving the development of IVPT methods for hypothetical products that provide attendees the opportunity for more in-depth discussion and collaboration with experts on IVPT method development, validation, and data analysis.

2:30 PM – 2:40 PM ***An Introduction to the Flight Simulator Exercise on IVPT Method Development***

Tannaz Ramezanli, PharmD, PhD Senior Pharmacologist, DTP I, ORS, OGD, FDA

2:40 PM – 3:50 PM ***Group Activity***

This practical, active-participation group activity will help participants learn how to approach an IVPT method development for a mock drug product and how to engage with the FDA about different types of questions during the development and validation of an IVPT method.

Group 1 Activity Leaders:	**Ying Jiang, PhD**	Chemist, DTP I, ORS, OGD, FDA
	Sam Raney, PhD	Associate Director for Science & Chief Scientific Advisor, ORS, OGD, FDA
Group 2 Activity Leaders:	**Priyanka Ghosh, PhD**	Lead Pharmacologist, DTP I, ORS, OGD, FDA
	TBD	TBD
	Yang Yang, PhD	Research Staff Fellow, DPQR V, OPQR, OPQ, FDA
Group 3 Activity Leaders:	**Nahid Kamal, PhD**	Research Pharmacologist and CMC Assessor, DPQR V, OPQR, OPQ, FDA
	Mengmeng Niu, PhD	Senior Pharmacologist, DTP I, ORS, OGD, FDA
	Tannaz Ramezanli, PharmD, PhD	Senior Pharmacologist, DTP I, ORS, OGD, FDA
Group 4 Activity Leaders:	**Megan Kelchen, PhD**	Senior Pharmacologist, DTP I, ORS, OGD, FDA
	Hiren H. Patel, PhD	Senior Staff Fellow, DB II, OB, OGD, FDA
	Ahmed Zidan, PhD	Senior Research Pharmacologist, DPQR V, OPQR, OPQ, FDA

3:50 PM – 4:00 PM ***Coffee Break***

4:00 PM – 5:20 PM ***Equipment Demonstration (Session 1)***

This hands-on activity will allow participants to familiarize themselves with different diffusion cell and barrier integrity measurement equipment and engage with the subject matter experts on different types of challenges that may arise during the design and conduct an IVPT study.

5:20 PM – 5:30 PM ***Closing Remarks (Day 1)***

James Polli, PhD Co-Director, CRCG

Day 2 April 30, 2025

8:30 AM – 8:35 AM	***Workshop Day 2 Overview***	
	Sam Raney, PhD	Associate Director for Science & Chief Scientific Advisor, ORS, OGD, FDA

Session 1: Considerations Related to the Assessment of IVPT Data

This session will include presentations from FDA on the scientific and regulatory considerations when assessing IVPT method validation and pivotal study data.

8:35 AM – 8:40 AM	***Speaker Introductions***	
	Priyanka Ghosh, PhD	Lead Pharmacologist, DTP I, ORS, OGD, FDA
8:40 AM – 9:00 AM	***Navigating FDA Guidance During the Assessment of IVPT Method Validation for ANDAs***	
	Hiren H. Patel, PhD	Senior Staff Fellow, DB II, OB, OGD, FDA
9:00 AM – 9:20 AM	***Common Deficiencies for IVPT Studies Submitted in ANDAs***	
	Allison Schafer, PhD	Senior Interdisciplinary Scientist, DB II, OB, OGD, FDA
9:20 AM – 9:40 AM	***Power Calculation and Analysis of Pivotal IVPT Study Data***	
	Elena Rantou, PhD	Master Mathematical Statistician, DB VIII, OB, OTS, FDA
9:40 AM – 10:30 AM	***Q&A Session with Panel Discussion***	
Moderator:	**Priyanka Ghosh, PhD**	Lead Pharmacologist, DTP I, ORS, OGD, FDA
Panelists:	**Abhishek Juluri, PhD**	Reviewer, DB III, OB, OGD, FDA
	Theo Kapanadze, PhD, DSc	CSO, Diteba Inc
	Hiren H. Patel, PhD	Senior Staff Fellow, DB II, OB, OGD, FDA
	Lakshmi Raghavan, PhD	Founder and CEO, Healios Labs LLC
	Sam Raney, PhD	Associate Director for Science & Chief Scientific Advisor, ORS, OGD, FDA
	Elena Rantou, PhD	Master Mathematical Statistician, DB VIII, OB, OTS, FDA
	Allison Schafer, PhD	Senior Interdisciplinary Scientist, DB II, OB, OGD, FDA
	Rong Wang, PharmD, PhD	Supervisory Associate Director, DB I, OB, OGD, FDA
10:30 AM – 10:40 AM	***Coffee Break***	
10:40 AM – 11:30 AM	***Summary of Flight Simulator Discussions***	
11:30 AM – 1:00 PM	***Lunch Break***	

Session 2: Lessons Learned and Closing Remarks

Considering the issues and topics discussed across both days of the workshop, this session will focus on developing a synopsis of the insights gleaned and the actions that can be taken to help implement best practices for IVPT method development, validation and pivotal bioequivalence study conduct and data analysis using suitable equipment and techniques. This session will also aim to identify areas where further research may be needed to address ongoing challenges with IVPT studies submitted in ANDAs.

1:00 PM – 1:50 PM	***Q&A Session with Panel Discussion***	
Moderator:	**Priyanka Ghosh, PhD**	Lead Pharmacologist, DTP I, ORS, OGD, FDA
Panelists:	**Haydar Abdalghafor, PhD**	Senior Research Investigator, Pharmaceutical Development Topical, Incyte Corporation
	Aaditya Bhatt, PhD	Director, Analytical R&D, Amneal Pharmaceuticals
	Bryan DeBarr, BS	Director, Global Pharmacology and Toxicology Lab Operations, Viatris Inc.
	Markham Luke, MD, PhD	Director, DTP I, ORS, OGD, FDA
	Hiren H. Patel, PhD	Senior Staff Fellow, DB II, OB, OGD, FDA
	Sam Raney, PhD	Associate Director for Science & Chief Scientific Advisor, ORS, OGD, FDA
	Eleftheria Tsakalozou, PhD	Senior Pharmacologist, DQMM, ORS, OGD, FDA
	Rong Wang, PharmD, PhD	Supervisory Associate Director, DB I, OB, OGD, FDA
1:50 PM – 2:00 PM	***Closing Remarks (Day 2)***	
	Robert Lionberger, PhD	Director, ORS, OGD, FDA
2:00 PM – 2:10 PM	***Coffee Break***	

Session 3: Small Group Working Sessions (In-Person Only)

2:10 PM – 3.30 PM	***Equipment Demonstration (Session 2)***

Appendix of Abbreviations

ANDA	Abbreviated New Drug Application
BS or BSc	Bachelor of Science
CEO	Chief Executive Officer
CMC	Chemistry, Manufacturing, and Controls
CSO	Chief Scientific Officer
CRCG	Center for Research on Complex Generics
DB	Division of Bioequivalence
DB VIII, OB	Division of Biostatistics VIII (Office of Biostatistics)
DSc	Doctor of Science
DTP	Division of Therapeutic Performance
DQMM	Division of Quantitative Methods and Modeling
DPQR	Division of Product Quality Research
FDA	United States Food and Drug Administration
Inc.	Incorporated
IVPT	In Vitro Permeation Test
LLC	Limited Liability Company
MD	Doctor of Medicine
OB	Office of Bioequivalence
OGD	Office of Generic Drugs
OPQ	Office of Pharmaceutical Quality
OPQR	Office of Product Quality Research
ORS	Office of Research and Standards
OTS	Office of Translational Sciences
PhD	Doctor of Philosophy
Q&A	Question and Answer
R&D	Research and Development