

# 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	<b>Welcome and Opening Remarks</b> James Polli, PhD	Co-Director, CRCG
8:40 AM – 8:50 AM	<b>FDA Opening Remarks</b> Markham Luke, MD, PhD	Director, DTP I, ORS, OGD, FDA
8:50 AM – 8:55 AM	<b>Workshop Day 1 Overview</b> 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	<b>Speaker Introductions</b> Tannaz Ramezanli, PharmD, PhD	Senior Pharmacologist, DTP I, ORS, OGD, FDA
9:00 AM – 9:20 AM	<b>Development of FDA's Guidance for Industry on IVPT Studies for Topical Drug Products Submitted in ANDAs</b> Sam Raney, PhD	Associate Director for Science & Chief Scientific Advisor, ORS, OGD, FDA
9:20 AM – 9:35 AM	<b>Current Status and Outstanding Challenges with IVPT Studies</b> Priyanka Ghosh, PhD	Lead Pharmacologist, DTP I, ORS, OGD, FDA
9:35 AM – 9:50 AM	<b>Challenges with the Implementation of IVPT Guidance Recommendations – Industry Perspective</b> Lakshmi Raghavan, PhD	Founder and CEO, Healios Labs LLC
9:50 AM – 10:05 AM	<b>Challenges with the Implementation of IVPT Guidance Recommendations – Industry Perspective</b> Aaditya Bhatt, PhD	Director, Analytical R&D, Amneal Pharmaceuticals
10:05 AM – 10:30 AM	<b>Q&amp;A Session with Panel Discussion</b> Moderator: Panelists:	Senior Pharmacologist, DTP I, ORS, OGD, FDA Director, Analytical R&D, Amneal Pharmaceuticals Lead Pharmacologist, DTP I, ORS, OGD, FDA Director, DTP I, ORS, OGD, FDA Chief Scientific Officer, Topical Products Testing LLC, MS, USA Founder and CEO, Healios Labs LLC Associate Director for Science & Chief Scientific Advisor, ORS, OGD, FDA Master Mathematical Statistician, DB VIII, OB, OTS, FDA Supervisory Associate Director, DB I, OB, OGD, FDA
10:30 AM – 10:40 AM	<b>Coffee Break</b>	

#### 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 – 11:10 AM	<b>Designing IVPT Methods: Practical Insights for Integrating the IVPT Guidance Recommendations</b> Ahmed Zidan, PhD	Senior Research Pharmacologist, DPQR V, OPQR, OPQ, FDA
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11:10 AM – 1:25 PM

*Moderator:*

*Panelists:*

***Step-by-Step Illustrations and Discussions of IVPT Study Procedures with a Q&A Panel of Experts***

**Sam Raney, PhD**

**Bryan DeBarr, BS**

**Keith Hamman, BS**

**John Heaney, BS**

**Theo Kapanadze, PhD, DSc**

**Ashvin Patel, PhD**

**Hiren H. Patel, PhD**

**Audra L. Stinchcomb, PhD, RPh**

**Ahmed Zidan, PhD**

Associate Director for Science & Chief Scientific Advisor, ORS, OGD, FDA  
Director, Global Pharmacology and Toxicology Lab Operations, Viatri Inc.  
President and CEO, Logan Instruments  
General Manager, PermeGear, Inc.  
CSO, Diteba Inc  
Director of Analytical Research, Teledyne Hanson Research  
Senior Staff Fellow, DB II, OB, OGD, FDA  
Professor, School of Pharmacy, University of Maryland Baltimore  
Senior Research Pharmacologist, DPQR V, OPQR, OPQ, FDA

1:25 PM – 1:30 PM

***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 (RM 1032):*

**Ying Jiang, PhD**

**Sam Raney, PhD**

Chemist, DTP I, ORS, OGD, FDA

Associate Director for Science & Chief Scientific Advisor, ORS, OGD, FDA

*Group 2 Activity*

*Leaders (RM 1042):*

**Priyanka Ghosh, PhD**

**Yang Yang, PhD**

Lead Pharmacologist, DTP I, ORS, OGD, FDA

Research Staff Fellow, DPQR V, OPQR, OPQ, FDA

*Group 3 Activity*

*Leaders (RM 1052):*

**Nahid Kamal, PhD**

**Mengmeng Niu, PhD**

**Tannaz Ramezanli, PharmD, PhD**

Research Pharmacologist and CMC Assessor, DPQR V, OPQR, OPQ, FDA

Senior Pharmacologist, DTP I, ORS, OGD, FDA

Senior Pharmacologist, DTP I, ORS, OGD, FDA

*Group 4 Activity*

*Leaders (RM 2052):*

**Megan Kelchen, PhD**

**Hiren H. Patel, PhD**

**Ahmed Zidan, PhD**

Senior Pharmacologist, DTP I, ORS, OGD, FDA

Senior Staff Fellow, DB II, OB, OGD, FDA

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 cells 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 – 9:05 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

9:05 AM – 9:30 AM

**Common Deficiencies for IVPT Studies Submitted in ANDAs**  
**Allison Schafer, PhD**

Senior Interdisciplinary Scientist, DB II, OB, OGD, FDA

9:30 AM – 9:55 AM

**Advances and Challenges in the Statistical Analysis of IVPT Data**  
**Elena Rantou, PhD**

Master Mathematical Statistician, DB VIII, OB, OTS, FDA

9:55 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