FDA-CRCG Workshop on Visionary Standards: Advancing Science and Regulation in Generic Ophthalmic Products

Public Workshop
November 19-20, 2025
Agenda

Day 1 November 19

8:30 AM – 8:35 AM **Welcome and CRCG Opening Remarks**
Anna Schwendeman, PhD Co-Director, CRCG

8:35 AM – 8:50 AM **FDA Opening Remarks**
Markham Luke, MD, PhD Director, DTP I, ORS, OGD, FDA

Session 1: Ophthalmic Product Standards and General Bioequivalence Considerations

This session will explore key regulatory standards, scientific principles, and methodologies that underpin the demonstration of bioequivalence in ophthalmic drug products. Presentations will cover FDA regulatory research shaping the ophthalmic landscape, current and emerging approaches for establishing bioequivalence, and case studies highlighting formulation and manufacturing challenges. Additional topics will address the influence of preservatives on ocular absorption, scientific considerations for non-Q1/Q2 formulations, and strategies for developing robust in vitro release testing methods. Together, these talks will provide a comprehensive perspective on advancing safe, effective, and high-quality ophthalmic generics that meet rigorous regulatory and patient care standards.

8:50 AM – 8:55 AM ***Speaker Introductions***
Bin Qin, PhD Senior Staff Fellow, DTP I, ORS, OGD, FDA

8:55 AM – 9:15 AM ***Impact of FDA Regulatory Research on the Landscape of Ophthalmology Drugs***
Andre O'Reilly Beringhs, PhD Pharmacologist, DTP I, ORS, OGD, FDA

9:15 AM – 9:35 AM ***Bioequivalence Assessment of Topical Ophthalmic Products: Current and Future Thinking***
Bruce Lerman, PhD Lead Pharmacologist, DB I, OB, OGD, FDA

9:35 AM – 9:55 AM ***Challenges and Opportunities of Q1/Q2 Pathway for Biowaiver of Ophthalmic Products***
Nemanja Aničić, PhD Senior Scientist, Pharmaceutical Development, Sandoz Development Center

9:55 AM – 10:15 AM ***Preservative Effects on Ocular Drug Absorption from Topically Instilled Eye Drops***
Arto Urtti, PhD Professor, Biopharmaceutics, Univ. of Eastern Finland

10:15 AM – 10:30 AM ***Coffee Break***

10:30 AM – 10:50 AM ***Scientific Hurdles to Demonstrate Bioequivalence for Non-Q1/Q2 Ophthalmic Solutions in Generic Drug Development***
Yoriko Harigaya, PharmD Senior Staff Fellow, DB II, OB, OGD, FDA

10:50 AM – 11:10 AM ***Seeing the Options: Challenges and Strategies in Developing IVRT Methods for Ophthalmic Products***
Xiaoming Xu, PhD Division Director, DPQRV, OPQR, OPQ, FDA

11:10 AM – 11:40 AM ***Q&A Session with Panel***
Moderator: **Bin Qin, PhD** Senior Staff Fellow, DTP I, ORS, OGD, FDA
Panelists:
Nemanja Aničić, PhD Senior Scientist, Pharmaceutical Development, Sandoz Development Center
Andre O'Reilly Beringhs, PhD Pharmacologist, DTP I, ORS, OGD, FDA
Yoriko Harigaya, PharmD Senior Staff Fellow, DB II, OB, OGD, FDA
Bruce Lerman, PhD Lead Pharmacologist, DB I, OB, OGD, FDA
Arto Urtti, PhD Professor, Biopharmaceutics, Univ. of Eastern Finland
Xiaoming Xu, PhD Division Director, DPQRV, OPQR, OPQ, FDA

11:40 AM – 12:40 PM ***Lunch Break***

Session 2: Regulatory Science Applied to Ophthalmic Dispersion Products

This session will focus on regulatory science strategies for evaluating complex ophthalmic dispersions, including suspensions and ointments. Speakers will discuss pharmacokinetic (PK) and pharmacodynamic (PD) assessments, formulation challenges, and case studies illustrating both in vitro and in vivo evaluation methodologies. Presentations will highlight bioequivalence perspectives, modeling approaches, including Physiologically-Based Pharmacokinetic/Pharmacodynamic (PBPK/PD) and Computational Fluid Dynamics (CFD) frameworks, and the extrapolation of pharmacodynamic effects across species. The session aims to provide practical insights and scientific tools to support the development of high-quality generic ophthalmic dispersion products.

12:40 PM – 12:45 PM	***Speaker Introductions***	
	Huzeyfe Yilmaz, PhD	Senior General Physical Scientist, DPQR II, OPQR, OPQ, FDA
	Yan Wang, PhD	Deputy Director, DTP I, ORS, OGD, FDA
12:45 PM – 1:05 PM	***Topical and Intracameral Pharmacokinetics of Complex Ophthalmic Suspensions***	
	Vatsala Naageshwaran PhD	CEO, Franklin Biolabs
1:05 PM – 1:25 PM	***Development and Optimization of Particle Size for Ophthalmic Dispersion Formulations***	
	Romit Jani, MS	Senior Director, Formulation R&D, Solaris Pharma
1:25 PM – 1:45 PM	***In Vitro & In Vivo Assessment of Tobramycin & Dexamethasone Ophthalmic Ointments for Generic Product Equivalence***	
	Xiuling Lu, PhD	Professor, School of Pharmacy, University of Connecticut
1:45 PM – 2:05 PM	***Bioequivalence Perspective for Complex Ophthalmic Products—Common Challenges and Deficiencies***	
	Hee Sun Chung, PhD	Lead Pharmacologist, DB I, OB, OGD, FDA
2:05 PM – 2:25 PM	***Extrapolation of PD Effects Across Species Using Ocular PBPK Modeling***	
	Jessica Spires, PhD	Principal Scientist, Simulations Plus, Inc
2:25 PM – 2:45 PM	***Ocular PBPK/PD Modeling to Explore In Vitro Bioequivalence Approaches for Brinzolamide Ophthalmic Suspensions***	
	Mingliang Tan, PhD	Senior Pharmacokineticist, DQMM, ORS, OGD, FDA
2:45 PM – 3:05 PM	***In Silico Modeling of Ophthalmic Suspensions: From In Vitro to In Vivo***	
	Carrie German, PhD	Director, Experimental and Computational Biology, CFD Research Corp.
3:05 PM – 3:35 PM	***Q&A Session with Panel***	
Moderators:	**Huzeyfe Yilmaz, PhD**	Senior General Physical Scientist, DPQR II, OPQR, OPQ, FDA
	Yan Wang, PhD	Deputy Director, DTP I, ORS, OGD, FDA
Panelists:	**Hee Sun Chung, PhD**	Lead Pharmacologist, DB I, OB, OGD, FDA
	Carrie German, PhD	Director, Experimental and Computational Biology, CFD Research Corp.
	Romit Jani, MS	Senior Director, Formulation R&D, Solaris Pharma
	Xiuling Lu, PhD	Professor, School of Pharmacy, University of Connecticut
	Vatsala Naageshwaran, PhD	CEO, Franklin Biolabs
	Jessica Spires, PhD	Principal Scientist, Simulations Plus, Inc
	Mingliang Tan, PhD	Senior Pharmacokineticist, DQMM, ORS, OGD, FDA
3:35 PM – 3:40 PM	***Closing Remarks for Virtual Audience***	
	Yan Wang, PhD	Deputy Director, DTP I, ORS, OGD, FDA
3:40 PM – 4:00 PM	***Coffee Break***	

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

These interactive, in-person discussions will provide a forum for deeper engagement with FDA speakers and other attendees on session topics from Day 1. Attendees will have the opportunity to exchange perspectives, share experiences, and explore potential regulatory and research pathways for advancing generic ophthalmic products. The small group format will encourage collaboration and practical problem-solving among FDA scientists, industry representatives, and academic experts.

4:00 PM – 5:30 PM	***Session 3: In Person-Only Discussion***

Day 2 November 20

9:00 AM – 9:10 AM	***Day 1 Summary***	
	Yan Wang, PhD	Deputy Director, DTP I, ORS, OGD, FDA

Session 4: Regulatory Science Applied to Ophthalmic Insertable and Implantable Products

This session will examine the regulatory science guiding the development, evaluation, and approval of ophthalmic inserts and implants. Topics will include performance characterization of intracanalicular and intravitreal products, advanced analytical methods for polymer-based delivery systems, and reverse-engineering studies that inform generic development. Presentations will also cover novel ocular delivery platforms, strategies for overcoming development and regulatory challenges, and key quality considerations. Attendees will gain insights into how rigorous evaluation and innovative research ensure safe, effective, and long-acting ophthalmic therapies.

9:10 AM – 9:15 AM	***Speaker Introductions***	
	William Smith, PhD	Research Scientist, DPQR V, OPQR, OPQ, FDA
9:15 AM – 9:35 AM	***Product Evaluation and Performance Characterization of Dexamethasone Intracanalicular Inserts***	
	Michael VandenBerg, PhD	Chemical Engineer, DPQR VI, OPQR, OPQ, FDA
9:35 AM – 9:55 AM	***Analytical Methods for Mini-Size Complex Long-Acting Injectable Formulations***	
	Kinam Park, PhD	Professor, Purdue University; President, Akina Inc.
9:55 AM – 10:15 AM	***Reverse Engineering the OZURDEX® Dexamethasone Intravitreal Implant***	
	Coleman Johnson, PhD	Postdoctoral Research Fellow, OPQR, OPQ, FDA
10:15 AM – 10:30 AM	***Coffee Break***	
10:30 AM – 10:50 AM	***Overcoming Development & Regulatory Challenges of Ophthalmic LA Product with Image-based In Vitro In Silico Release Prediction***	
	Andrew Clark, PhD	Senior Director of Research and Strategy, digiM Solution LLC
10:50 AM – 11:10 AM	***Drug Product Quality Considerations for Dexamethasone Intravitreal Implant***	
	Megha Barot, PhD	Pharmaceutical Scientist, DPQA IV, OPQA I, OPQ, FDA
11:10 AM – 11:40 AM	***Q&A Session with Panel***	
Moderator:	**William Smith, PhD**	Research Scientist, DPQR V, OPQR, OPQ, FDA
Panelists:	**Megha Barot, PhD**	Pharmaceutical Scientist, DPQA IV, OPQA I, OPQ, FDA
	Andrew Clark, PhD	Senior Director of Research and Strategy, digiM Solution LLC
	Young Jhon, PhD	Senior Chemist, DPQA IV, OPQA I, OPQ, FDA
	Coleman Johnson, PhD	Postdoctoral Research Fellow, OPQR, OPQ, FDA
	Kinam Park, PhD	Professor, Purdue University; President, Akina Inc.
	Michael VandenBerg, PhD	Chemical Engineer, DPQR VI, OPQR, OPQ, FDA
11:40 AM – 1:00 PM	***Lunch Break***	

Session 5: Regulatory Science Applied to Drug-Device Combination Products

This session will address the complexities of ophthalmic drug-device combination products (DDCPs), with a focus on regulatory pathways, performance expectations, and common development challenges. Topics will include comparative threshold analysis for devices, industry perspectives on clinical conduct and quality, lessons learned from ANDA submissions, and the unique challenges faced in developing complex generic ophthalmic drug-device combination products. Presentations from both FDA and industry will highlight strategies to facilitate innovation while ensuring patient safety, therapeutic efficacy, and consistent product quality.

1:00 PM – 1:05 PM	***Speaker Introductions***	
	Nathan Reed, PhD	Chemist, DPQR II, OPQR, OPQ, FDA
	Markham Luke, MD, PhD	Director, DTP I, ORS, OGD, FDA
1:05 PM – 1:25 PM	***Challenges with Ophthalmic DDCPs: Clinical Conduct and Quality- An Industry Perspective***	
	Tausif Ahmed, PhD	Senior VP & Head of Clinical and Biopharmaceutics, Mankind Pharma
1:25 PM – 1:45 PM	***Ophthalmic Drug-Device Combination Products – Comparative Analyses***	
	Shinae Kim, PhD	Pharmacokineticist, DTP I, ORS, OGD, FDA
1:45 PM – 2:05 PM	***Ophthalmic Drug-Device Combination Product ANDA Submissions – Lessons Learned***	
	CDR Andrew Fine, PharmD, BCPS	Senior Advisor, DCR, OSCE, OGD, FDA

2:05 PM – 2:25 PM	***Challenges in the Development of Complex Generic Ophthalmic Products***	
	Ajay Khopade, PhD	Vice President R&D, Sun Pharmaceuticals Industries Limited
2:25 PM – 2:55 PM	***Q&A Session with Panel***	
Moderators:	**Nathan Reed, PhD**	Chemist, DPQR II, OPQR, OPQ, FDA
	Markham Luke, MD, PhD	Director, DTP I, ORS, OGD, FDA
Panelists:	**Tausif Ahmed, PhD**	Senior VP & Head of Clinical and Biopharmaceutics, Mankind Pharma
	CDR Andrew Fine, PharmD, BCPS	Senior Advisor, DCR, OSCE, OGD, FDA
	Ajay Khopade, PhD	Vice President R&D, Sun Pharmaceuticals Industries Limited
	Shinae Kim, PhD	Pharmacokineticist, DTP I, ORS, OGD, FDA
2:55 PM – 3:05 PM	***Virtual Workshop Closeout***	
	Robert Lionberger, PhD	Director, ORS, OGD, FDA
3:05 PM – 3:20 PM	***Coffee Break***	

Session 6: Small Working Group Sessions (In-Person Only)

This closing in-person session will provide participants with a collaborative forum to discuss and expand on key themes from Day 2. Attendees will engage in focused discussions on regulatory science, technical challenges, and innovation opportunities for ophthalmic drug-device combination products, inserts, and implants. The interactive format will foster direct dialogue among FDA scientists, industry experts, and academic researchers, encouraging the exchange of practical strategies, regulatory insights, and research priorities to advance the development of safe, effective, and high-quality generic ophthalmic products.

3:20 PM – 4:45 PM	***Session 6: In Person-Only Discussion***	
4:45 PM – 5:00 PM	***In Person-Only Workshop Closeout***	
	Andre O'Reilly Beringhs, PhD	Pharmacologist, DTP I, ORS, OGD, FDA

Appendix of Abbreviations

ANDA	Abbreviated New Drug Application
BCPS	Board Certified Pharmacotherapy Specialist
CDR	Commander
CEO	Chief Executive Officer
CRCG	Center for Research on Complex Generics
DB	Division of Bioequivalence
DCR	Division of Clinical Review
DDCP	Drug Device Combination Products
DPQR	Division of Pharmaceutical Quality Research
DTP	Division of Therapeutic Performance
DQMM	Division of Quantitative Methods and Modeling
FDA	Food and Drug Administration
Inc	Incorporated
IVRT	In Vitro Release Testing
LLC	Limited Liability Company
Ltd	Limited
MD	Doctor of Medicine
OB	Office of Biostatistics
OGD	Office of Generic Drugs
OPQ	Office of Pharmaceutical Quality
OPQR	Office of Pharmaceutical Quality Research
ORS	Office of Regulatory Science
PBPK	Physiologically Based Pharmacokinetic
PD	Pharmacodynamic
PharmD	Doctor of Pharmacy
PhD	Doctor of Philosophy
PK	Pharmacokinetic
Q1	Qualitative 1
Q2	Quantitative 2
R&D	Research and Development
VP	Vice President