FDA-CRCG Workshop on Long-Acting Injectable (LAI) Generics: Advancing Innovation in Product Development and Regulatory Assessment

Public Workshop
December 1-2, 2026
Agenda

Day 1 Tuesday, December 1

8:00 AM – 8:10 AM	**Welcome by CRCG & FDA**	
	Anna Schwendeman, PhD	Co-Director, CRCG
	Sam Raney, PhD	Associate Director for Science & Chief Scientific Advisor, ORS, OGD, FDA
8:10 AM – 8:20 AM	**FDA Opening Remarks**	
	Darby Kozak, PhD	Deputy Director, OGD, FDA

Session 1: Critical Aspects of LAI Development: Formulation, Excipient Characterization, and Manufacturing Considerations

Session Lead: Dr. Young K. Jhon

This session will explore the scientific and technical challenges in developing long-acting injectable (LAI) products, with an emphasis on establishing formulation sameness from characterizing complex excipients and reverse engineering. Presenters will highlight analytical challenges in excipient identification and quantitation, critical formulation properties affecting drug release, and manufacturing consideration influencing performance and batch consistency. Industry and FDA speakers will provide insight into regulatory experiences, common ANDA deficiencies, and best practices to aid in facilitating successful product development and approval.

8:20 AM – 8:25 AM	***Speaker Introductions***	
	Young K. Jhon, PhD	Senior Chemist, DPQA IV, OPQA I, OPQ, FDA
8:25 AM – 8:40 AM	***Landscape, Progress, and Unresolved Challenges of LAI Generics***	
	Bin Qin, PhD	Senior Staff Fellow, DTP I, ORS, OGD, FDA
8:40 AM – 8:55 AM	***Development Challenges and Manufacturing Hurdles in Long-Acting Injectables (LAI) Products***	
	Nirav Khatri, PhD	VP & Delivery Manager, Dr. Reddy's Laboratories Ltd
8:55 AM – 9:10 AM	***Challenges in Reverse Engineering of Generic LAI Products***	
	Daniel Wehrung, PhD	R&D Formulation Manager, American Regent Inc.
9:10 AM – 9:25 AM	***Common Drug Product Quality Deficiencies of Generic LAI products***	
	Kai Kwok, PhD	Senior Pharmaceutical Quality Assessor, DPQA I, OPQA I, OPQ, FDA
9:25 AM – 9:40 AM	***Excipient Quality Challenges, Standards, and Solutions for LAIs***	
	Peng Zhang, PhD	Senior Principal Scientist, Excipients, USP
9:40 AM – 9:55 AM	***Q1/Q2 Sameness in LAI Generics: Practical Challenges with Legacy Products and Pathways to Q3 Similarity***	
	Richard Rittenschober, MSc	Scientific Advisor, Pharm. Develop., Sandoz Develop. Center Kundl, Austria
9:55 AM – 10:10 AM	***Peptide Stability in Peptide-PLGA Microspheres***	
	Steve Schwendeman, BSE, PhD	Ara G. Paul Prof, Pharm Sci, Prof of Biomedical Engineer, U Michigan
10:10 AM – 10:25 AM	***Coffee Break***	
10:25 AM – 11:10 AM	***Q&A Session with Panel***	
Moderator:	**Young K. Jhon, PhD**	Senior Chemist, DPQA IV, OPQA I, OPQ, FDA
Panelists:	**Nirav Khatri, PhD**	VP & Delivery Manager, Dr. Reddy's Laboratories Ltd
	Kai Kwok, PhD	Senior Pharmaceutical Quality Assessor, DPQA I, OPQA I, OPQ, FDA
	Bin Qin, PhD	Senior Staff Fellow, DTP I, ORS, OGD, FDA
	Richard Rittenschober, MSc	Scientific Advisor, Pharm. Develop., Sandoz Develop Center Kundl, Austria
	Bhasker Sambar, MS	Senior Manager, External R&D and Technical Services, Alvogen Inc.
	Steve Schwendeman, BSE, PhD	Ara G. Paul Prof, Pharm Sci, Prof of Biomedical Engineer, U Michigan

	Daniel Wehrung, PhD	R&D Formulation Manager, American Regent Inc.
	Peng Zhang, PhD	Senior Principal Scientist, Excipients, USP

11:10 AM – 12:10 PM ***Lunch Break***

Session 2: Drug Release Mechanism Understanding of LAI products: From IVRT to Totality of Evidence Approach

Session Lead: Dr. William (Billy) C. Smith

This session will focus on the mechanistic understanding of drug release from long-acting injectable products and the development of appropriate in vitro release testing (IVRT) methods to support bioequivalence (BE) assessments. Presenters will discuss the scientific principles underlying drug release from various LAI platforms, from crystalline suspensions, polymeric microspheres, in situ forming depots, to non-biodegradable matrix systems, and the challenges in developing IVRT methods designed to be discriminatory and reflective of in vivo performance. The session will also address the totality of evidence approach for establishing BE of complex LAI products, integrating understanding of formulation characterization, IVRT data, and potential in vitro-in vivo correlations (IVIVC) to support regulatory submissions and reduce reliance on clinical endpoint studies.

12:10 PM – 12:15 PM	***Speaker Introductions***	
	William (Billy) C. Smith, PhD	Research Scientist, DPQR V, OPQR, OPQ, FDA
12:15 PM – 12:30 PM	***IVRT Methods for Different Types of Dosages***	
	Jankiben Andhariya, PhD	Senior Scientific Reviewer, DB II, OB, OGD, FDA
12:30 PM – 12:45 PM	***Challenges in the Development of Generic Microsphere Products***	
	Ajay Jaysingh Khopade, PhD	VP & Head, Formulation Develop. Sun Pharmaceuticals Industries Ltd R&D
12:45 PM – 1:00 PM	***Mechanistic Drug Release as a Foundation for Formulation Design and BE in LAI Generics***	
	Naresh Mittapelly, PhD	Senior Research Scientist, Certara Predictive Technologies (Simcyp Division)
1:00 PM – 1:15 PM	***Understanding the Complex Interplay of Formulation Aspects, Processing, and Microstructure on Drug Release Mechanisms from LAI Suspensions***	
	Diane Burgess, PhD	Prof of Pharmaceutics & Pfizer Chair of Pharma Technology, Univ of Conn
1:15 PM – 1:30 PM	***IVRT Method for In Situ Forming System: Best Practice and Method Validation***	
	Haiou Qu, PhD	Staff Fellow, DPQR V, OPQR, OPQ, FDA
1:30 PM – 1:45 PM	***IVR and IVIVC in Preclinical Species of In Situ Depot***	
	Jaymin Shah, PhD	Sr. Research Fellow & Global Head, Biopharmaceutics, Pfizer R&D
1:45 PM – 2:00 PM	***Development of Accelerated IVRT for PDMS-based Drug Delivery Systems: Comparison of Empirical and Semi-Empirical Approaches***	
	Coleman Johnson, PhD	Postdoctoral Research Fellow, OPQR, OPQ, FDA
2:00 PM – 2:15 PM	***Elucidation of Drug Release Mechanisms of Ethylene Vinyl Acetate Based Implant***	
	Feng Zhang, PhD	Associate Professor, Molecular Pharma & Drug Delivery, COP, UT at Austin
2:15 PM – 2:30 PM	***LAI Microstructure and Drug Release Prediction***	
	Andrew Clark, PhD	Senior Director, Research & Strategy, digiM Solution LLC

2:30 PM – 2:45 PM ***Coffee Break***

2:45 PM – 3:30 PM	***Q&A Session with Panel***	
Moderator:	**William (Billy) C. Smith, PhD**	Research Scientist, DPQR V, OPQR, OPQ, FDA
Panelists:	**Jankiben Andhariya, PhD**	Senior Scientific Reviewer, DB II, OB, OGD, FDA
	Diane Burgess, PhD	Prof of Pharmaceutics & Pfizer Chair of Pharma Technology, Univ of Conn
	Andrew Clark, PhD	Senior Director, Research & Strategy, digiM Solution LLC
	Coleman Johnson, PhD	Postdoctoral Research Fellow, OPQR, OPQ, FDA
	Ajay Jaysingh Khopade, PhD	VP & Head, Formulation Develop. Sun Pharmaceuticals Industries Ltd R&D
	Naresh Mittapelly, PhD	Senior Research Scientist, Certara Predictive Technologies (Simcyp Division)
	Haiou Qu, PhD	Staff Fellow, DPQR V, OPQA, OPQ, FDA
	Dinesh Satone, MPharm	General Manager, Orbicular Pharmaceutical Technologies, Ltd.
	Jaymin Shah, PhD	Sr. Research Fellow & Global Head, Biopharmaceutics, Pfizer R&D
	Feng Zhang, PhD	Associate Professor, Molecular Pharma & Drug Delivery, COP, UT at Austin
3:30 PM – 3:35 PM	***Closing Remarks for Virtual Audience***	
	Yan Wang, PhD	Deputy Director, DTP I, ORS, OGD, FDA

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

These interactive, in-person discussions will provide a forum for deeper engagement with session topics from Day 1. Attendees will have the chance to exchange perspectives, share experiences, and explore challenges and opportunities to push the field forward. The small group format will encourage collaboration and practical problem-solving among FDA scientists, industry representatives, and academic experts.

3:35 PM – 5:05 PM

Session 3: In Person-Only Discussion

The topics areas will include:

- Demonstrating Bioequivalence with a Totality of Evidence Approach
- Product Characterization and Formulation Sameness
- In Vitro Release Studies for Long-Acting Injectable Products
- Scope and Applicability of MIE
- Model Credibility, Validation and Regulatory Expectations for MIE-Related Submissions

Day 2 Wednesday, December 2

Session 4: Alternative Bioequivalence Approaches and Alternative Pharmacokinetics Study Designs for LAI Products

Session Lead: Dr. Bin Qin

This session will focus on alternative bioequivalence (BE) strategies and innovative pharmacokinetic (PK) study designs for long-acting injectable products. Presenters will discuss the practical challenges faced by industry in conducting traditional PK BE studies for LAI products, including the burden of extended study durations and large sample sizes. The session will explore alternative PK study design approaches that may reduce study duration and sample size requirements while maintaining scientific rigor, as well as innovative methodologies tailored to the unique characteristics of LAI formulations. Participants will also learn about the totality of evidence approach for establishing BE of LAI products, integrating comprehensive formulation characterization and in vitro data.

8:00 AM – 8:10 AM	***Speaker Introductions and Day 1 Summary***	
	Bin Qin, PhD	Senior Staff Fellow, DTP I, ORS, OGD, FDA
8:10 AM – 8:25 AM	***Challenges in Planning and Conducting In Vivo BE Studies for LAI Using Conventional Approaches***	
	Alhan Oraha, MSc	Scientific Leader, Clinical R&D, Apotex Inc.
8:25 AM – 8:40 AM	***Alternative Study Designs for Conducting PK BE Study for LAI Products***	
	Yuqing Gong, PhD	Lead Pharmacologist, DQMM, ORS, OGD, FDA
8:40 AM – 8:55 AM	***Application of Suitable Statistical & Simulation Methods for Two-Stage Design Approach for a Parallel or Replicated (Full/Partial) Crossover Design BE Studies for LAI Products***	
	Hiren Mehta, PhD	Global Biometrics, Veeda Lifesciences Ltd
8:55 AM – 9:10 AM	***In Vitro BE Approach for LAIs: Waiving PK BE Study***	
	Qiangnan Zhang, PhD	Staff Fellow, DTP I, ORS, OGD, FDA
9:10 AM –9:25 AM	***Classification System for Biopharmaceutics of Long-Acting Parenteral Products***	
	Simone Perazzolo, PhD	Sr. Research Scientist, Dept. of Pharmaceutics, University of Washington
9:25 AM – 9:40 AM	***Coffee Break***	
9:40 AM – 10:25 AM	***Q&A Session with Panel***	
Moderator:	**Bin Qin, PhD**	Senior Staff Fellow, DTP I, ORS, OGD, FDA
Panelists:	**Andrew Babiskin, PhD**	Deputy Division Director, DQMM, ORS, OGD, FDA
	Yuqing Gong, PhD	Lead Pharmacologist, DQMM, ORS, OGD, FDA
	Martin Klein, PhD	Senior Mathematical Statistician, DB VIII, OB, OTS, FDA
	Hiren Mehta, PhD	Global Biometrics, Veeda Lifesciences Ltd
	Alhan Oraha, MSc	Scientific Leader, Clinical R&D, Apotex Inc.
	Simone Perazzolo, PhD	Sr. Research Scientist, Dept. of Pharmaceutics, University of Washington
	Andrew Shaw, PhD	Head, Global Clinical Pharmacology, Viatris Inc.
	Qiangnan Zhang, PhD	Staff Fellow, DTP I, ORS, OGD, FDA

Session 5: Small Working Group Sessions (In-Person Only)

This in-person session will provide participants with a collaborative forum to discuss and expand on key themes from Day 2.

10:25 AM – 11:10 AM ***Session 5: In Person-Only Discussion***

The topics areas will include:

- Model-Integrated Evidence and PK BE Design

11:10 AM – 12:00 PM ***Lunch Break***

Session 6: Meet & Learn (In-Person Only)

FDA reviewers from multiple FDA Offices involved with assessing different aspects of information submitted in ANDAs for LAI generic 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 LAI generic drugs.

12:00 PM – 12:10 PM	***Orientation to Meet and Learn Session***	
	Sam Raney, PhD	Assoc. Director for Science & Chief Scientific Advisor, ORS, OGD, FDA

12:10 PM – 1:40 PM ***Meet and Learn Session (In-Person Only)***

Specific topics will include:

- Bioequivalence Evaluation Including a Totality of Evidence Approach
- Product Characterization and Formulation Sameness
- Model-Integrated Evidence and PK Bioequivalence Study Design
- In Vitro Release Studies for Long-Acting Injectable Products

Session 7: Accelerating LAI Generic Development Using Model-Integrated Evidence

Session Lead: Dr. Yuqing Gong

This session will focus on the application of model-integrated evidence approaches to accelerate generic development of long-acting injectable products. Presenters will discuss how industry is leveraging modeling approaches to streamline LAI generic development programs. The session will address regulatory expectations for model-integrated evidence submissions, including successful case examples that demonstrate acceptable approaches for incorporating modeling data into regulatory packages. Participants will explore modeling strategies specific to LAI formulations, including population PK and mechanistic physiologically-based pharmacokinetic (PBPK) models and how model-integrated evidence can be used to support bioequivalence assessments for generic LAI development.

1:40 PM – 1:45 PM	***Speaker Introductions***	
	Yuqing Gong, PhD	Lead Pharmacologist, DQMM, ORS, OGD, FDA
1:45 PM – 2:00 PM	***The Emerging Role of Model-Integrated Evidence (MIE) in Generic LAI Development: Industry Perspectives & Case Studies***	
	Sivacharan Kollipara, PhD	Vice President & Head, Biopharmaceutics, Dr. Reddy's Laboratories Ltd.
2:00 PM – 2:15 PM	***Integrating Mechanistic Modeling into Successful Development Programs of LAIs: Industry Insights***	
	Sunil Iyer, PhD	VP & Head, Biopharmaceutics & Clinical Development, Zydus Lifesciences Ltd
2:15 PM – 2:30 PM	***Integrating In Vitro and In Vivo Evidence Using PBPK Modeling for PLGA LAI Product BE Demonstration***	
	Khondoker Alam, PhD	Senior Pharmacologist, DQMM, ORS, OGD, FDA
2:30 PM – 2:45 PM	***Mechanistic PBPK Modeling Strategies to Accelerate Generic Long-Acting Injectable Development***	
	James M. Mullin, MS	Sr. Principal Scientist, R&D, Simulation Plus, Inc**.**
2:45 PM – 3:00 PM	***Coffee Break***	
3:00 PM – 3:15 PM	***PBPK Model-Based Virtual Bioequivalence Assessment of LAI Suspensions: A Simcyp-Pirana Workflow***	
	Natalie Morris, PhD	Research Scientist, MID 3, Certara
3:15 PM – 3:30 PM	***Modeling to Accelerate LAI Generic Development: Extrapolate Pre-clinical to Clinical/Pilot to Pivotal***	
	Allison Dunn, PharmD, MS	Research Assistant Professor, University of Maryland, Baltimore
3:30 PM – 4:15 PM	***Q&A Session with Panel***	
Moderator:	**Yuqing Gong, PhD**	Lead Pharmacologist, DQMM, ORS, OGD, FDA
Panelists:	**Tausif Ahmed, PhD**	Senior Vice President & Head, Mankind Research Centre
	Khondoker Alam, PhD	Senior Pharmacologist, DQMM, ORS, OGD, FDA
	Allison Dunn, PharmD, MS	Research Assistant Professor, University of Maryland, Baltimore
	Sunil Iyer, PhD	VP & Head, Biopharmaceutics & Clinical Development, Zydus Lifesciences Ltd
	Sivacharan Kollipara, PhD	Vice President & Head, Biopharmaceutics, Dr. Reddy's Laboratories Ltd.
	Natalie Morris, PhD	Research Scientist, MID 3, Certara
	James M. Mullin, MS	Sr. Principal Scientist, R&D, Simulation Plus, Inc**.**
	Prasad N.V. Tata, PhD	Senior Director, Pharmacokinetics and Bioequivalence, American Regent Inc.
	Eleftheria Tsakalozou, PhD	Lead Pharmacologist, DQMM, ORS, OGD, FDA
4:15 PM – 4:30 PM	***Workshop Closeout***	
	Lanyan (Lucy) Fang, PhD	Director, DQMM, ORS, OGD, FDA

Appendix of Abbreviations

ANDA	Abbreviated New Drug Application
Assoc.	Associate
BE	Bioequivalence
BSE	Bachelor of Science in Engineering
COP	College of Pharmacy
CRCG	Center for Research on Complex Generics
DB	Division of Bioequivalence
Dept.	Department
Develop	Development
DPQA	Division of Product Quality Assessment
DPQR	Division of Pharmaceutical Quality Research
DQMM	Division of Quantitative Methods and Modeling
DTP	Division of Therapeutic Performance
FDA	Food and Drug Administration
Inc.	Incorporated (as in a corporation)
IVR	In Vitro Release
IVRT	In Vitro Release Testing
IVIVC	In Vitro-In Vivo Correlation
LAI	Long-Acting Injectable
LLC	Limited Liability Company
Ltd.	Limited (as in a limited liability company)
MIE	Model-Integrated Evidence
MPharm	Master of Pharmacy
MSc	Master of Science
OB	Office of Bioequivalence
OGD	Office of Generic Drugs
OPQ	Office of Pharmaceutical Quality
OPQA	Office of Product Quality Assessment
OPQR	Office of Pharmaceutical Quality Research
ORS	Office of Research and Standards
OTS	Office of Translational Sciences
PBPK	Physiologically-Based Pharmacokinetic
PDMS	Polydimethylsiloxane
PhD	Doctor of Philosophy
Pharm	Pharmaceutical
PharmD	Doctor of Pharmacy
Pharm Sci	Pharmaceutical Sciences
PK	Pharmacokinetics
PLGA	Poly(lactic-co-glycolic acid)
Prof.	Professor
Q1	Quantitative
Q2	Qualitative
Q3	Physicochemical & Structural
Q&A	Questions and Answers
R&D	Research and Development
Sr.	Senior
Univ of Conn	University of Connecticut
U Michigan	University of Michigan
UT	University of Texas
USP	United States Pharmacopeia
VP	Vice President