5th FDA/PQRI Conference on

Advancing Product Quality: Advancing Quality & Technology of Future Pharmaceuticals

Virtual Event | **December 1-3, 2021**

PQRI
Product Quality Research Institute

FDA U.S. FOOD & DRUG ADMINISTRATION

pqri.org/5th-pqri-fda-conference

Day 1 – Wednesday, December 1, 2021 (All time is in US ET)	
Biopharmaceutics Track – *Biopharmaceutical Considerations for Product Design and Development*	
Development of robust pharmaceutical products requires comprehensive/orthogonal evaluation of the link between critical quality attributes (e.g., dissolution, release) and absorption properties along with the use of computational tools to predict in vivo performance. The judicious use of physiological based pharmacokinetic modelling and simulation (PBPK) along with patient-centric approaches for drug product development is essential to the delivery of transformative therapies.	
9:45 – 10:00 AM ET	Pre Conference – Check Connections
10:00 – 10:15 AM	***Welcome to Conference and Overview of PQRI*** • Ajit Narang, Ph.D., ORIC Pharmaceuticals, Conference Committee Co-Chair ***Introduction to the Conference*** • Lawrence X. Yu, Ph.D., Director, Office of New Drug Products, OPQ/CDER/FDA Conference Committee Co-Chair
10:15 – 10:45 AM	***Keynote: Advancing Pharmaceutical Product Quality*** • Michael Kopcha, Ph.D., R.Ph., Director, Office of Pharmaceutical Quality, CDER/FDA
SESSION 1: Patient-centric Dissolution and International Harmonization	
Moderator: Filippos Kesisoglou, Ph.D., Merck and Co., Inc.	
10:45 AM – 11:10 AM	***How Do We Improve Predictions of Drug Concentration-Time Profiles?*** • Swati Nagar, Ph.D., Temple University
11:10 AM – 11:35 AM	***The Link Between the Human Gastrointestinal Tract and Oral Drug Absorption: Theory and Case Examples*** • Bart Hens, Ph.D., Pfizer
11:35 AM – 12:00 PM	***Risk-based Approach to Establishing Patient-Centric Dissolution Specifications*** • Elsbeth Chikhale, Ph.D., FDA
12:00 – 1:00 PM	Break Including Poster Session
SESSION 2: Biopharmaceutics for Complex Drug Products	
Moderator: Wenlei Jiang, Ph.D., US FDA	
1:00 – 1:25 PM ET	***Biopharmaceutics and Inhaled Drugs - Development of an iBCS*** • Jayne E. Hastedt, Ph.D., JDP Pharma Consulting, LLC; PQRI iBCS WG
1:25 – 1:50 PM ET	***Modeling and Simulation of Long-Acting Injectable Psychiatric Products*** • Hao Zhu, Ph.D., FDA
1:50 – 2:15 PM ET	***Biopharmaceutics of Complex Parenteral Drug Products - IVIVC and Development In Vitro Release Testing*** • Diane J. Burgess, Ph.D., University of Connecticut
Hot Topic: Biopharmaceutics for Nano-Drug Delivery	
Moderator: Mehran Yazdanian, Ph.D., Teva Pharmaceuticals	
2:15 – 2:45 PM ET	***Overlooked Biopharmaceutics of Nanomedicines/NanoVaccines Impacts Clinical Dose/Efficacy/Safety*** • Duxin Sun, Ph.D., University of Michigan
2:45 – 3:00 PM ET	Wrap up of Day 1 • Jennifer D. Ahearn, ESi Conference Committee Co-Chair

Day 2 – Thursday, December 2, 2021 (All Time is in US ET)	
Development Track– *New Horizons for Pharmaceutical Development*	
The future direction of pharmaceutical development for small and large molecule drug products has been profoundly influenced by recent events and technological advances. Prominent on the horizon are emerging modalities for novel therapeutics, and innovative approaches for applying knowledge and data to expedite meaningful decision-making. This track will explore opportunities and challenges represented by these areas, superimposed on a landscape of rapidly evolving industry practice and regulatory expectations.	
9:45 – 10:00 AM ET	Pre Conference – Check Connections
10:00 – 10:15 AM	***Welcome*** • Jennifer D. Ahearn, ESi Conference Committee Co-Chair ***Kick off Day 2*** • Steven Kozlowski, MD, Director, Office of Biotechnology Products, OPQ/CDER/FDA Conference Committee Co-Chair
***SESSION* 1: Accelerating Development: Fast Tracking Critical Treatments, Antibody Platforms, and Quality Standards for Emerging Modalities**	
Moderator: Diane Paskiet, MS, West Pharmaceutical Services	
10:15 – 10:35 AM	***Accelerated Development of Molnupiravir*** • Michael Lowinger, Ph.D., Merck & Co., Inc.
10:35 – 10:55 AM	***Platform and Prior Knowledge in the Development of Neutralizing Monoclonal Antibodies: A Regulatory Perspective*** • Maria-Teresa Gutierrez-Lugo, Ph.D., FDA
10:55 – 11:15 AM	***Cell and Gene Therapy Consensus Standards – A Shared Path Forward*** • Catherine B. Zander, Ph.D., The Standards Coordinating Body
11:15 AM– 11:40 AM	**HOT TOPIC: *Emergency Use Authorizations: COVID-19 Therapeutics*** • Andrew A. LeBoeuf, JD, MS, FDA
11:40 AM – 12:00 PM	**Q&A**
12:00 – 12:30 PM	Break -Including Poster Session
SESSION 2: Modeling and Simulations to Enable Rapid Decision Making	
Moderator: Robert Meyer, Ph.D., Merck & Co. Inc.	
12:30 – 12:55 PM ET	***Navigating Potentials and Pitfalls in using Artificial Intelligence for Expedited Decision Making in Pharmaceutical Problems*** • Rob Smith, Ph.D., Prime Labs, Inc.
12:55 – 1:20 PM ET	***Data Visualization Approaches for Enabling Rapid, Heuristic Interpretation of Highly Complex Mixtures of Structurally and Compositionally Diverse Chemical Entities Associated with Pharmaceutically Relevant Materials*** • Doug Kiehl, Eli Lilly and Company
1:20 – 1:45 PM	***Role of eXtended Reality (XR) in Empowering Knowledge Workers of the Future*** • Suresh Nulu, MS, Merck & Co., Inc.
1:45 – 2:00 PM	**Q&A**
Moderator: Cheryl LM Stults, Ph.D., C & M Technical Consulting LLC	
2:00 – 3:00 PM	***Roundtable: Drug-Device Combination Products*** This roundtable is focused on Drug–Device Combination Products. Discussions with panelists will consider differences in Industry practice and regulators' approaches to various topics of interest to the combination products community. • Susan Neadle, MS, BS, FAAO, Combination Products Consulting Services, LLC • Karthik Balasubramanian, Ph.D., Teva Pharmaceuticals • Prasad Peri, Ph.D., Teva Pharmaceuticals
3:00 PM	Wrap up of Day 2 - Ajit Narang, Ph.D., ORIC Pharmaceuticals, Conference Committee Co-Chair

Day 3 – Friday, December 3, 2021 (All Time is in US ET)	
Product Quality Track– *Innovation in Quality & Technology Beyond the Pandemic*	
In a post-pandemic world, developing agile and innovative solutions that adapt to the pace of change is critical for all aspects of the pharmaceutical product lifecycle including regulatory, manufacturing, and quality. This Track will explore current developments in modernization of regulatory submissions, in advanced manufacturing, and in remote site evaluations which are each evolving in real-time to address these future challenges.	
9:45 – 10:00 AM ET	Pre Conference – Check Connections
10:00 – 10:15 AM	***Welcome*** • Ajit Narang, Ph.D., ORIC Pharmaceuticals, Conference Committee Co-Chair ***Kick off Day 3*** • Susan M. Rosencrance, Ph.D., Director, Office of Lifecycle Drug Products, OPQ/CDER/FDA Conference Committee Co-Chair
SESSION 1: Knowledge-Aided and Structured Application (KASA) and Pharmaceutical Quality/CMC (PQ/CMC) Update	
Moderator: Nina S. Cauchon, Ph.D., Amgen Inc.	
10:15 AM– 10:35 AM	***An Overview of FDA's KASA System*** • Susan M. Rosencrance, Ph.D., FDA
10:35 AM– 10:55 AM	***KASA for Biologics*** • Steven Kozlowski, MD, FDA
10:55 AM– 11:15 AM	***FDA Pharmaceutical Quality Electronic Standards (aka PQ/CMC)*** • Geoffrey Wu, Ph.D., FDA
11:15 – 11:35 AM	***Accumulus Synergy and Data Exchange: A CMC Application Using Structured Data and a Cloud-Based Eco-system*** • Michael Abernathy, MS, RAC, Accumulus Synergy
11:35 AM– 11:55 AM	***Cloud-based Assessment and M4Q(R2) Revision*** • Lawrence Yu, Ph.D., FDA
11:55 AM – 12:15 PM	Q&A Session
12:15 – 12:45 PM	Break - Including Poster Session
Moderator: Cat Vicente, Johnson & Johnson	
12:45 – 1:30 PM	***HOT TOPIC: Remote Interactive Evaluations (RIEs) to Support FDA's Facility Oversight during the COVID-19 Pandemic and Beyond*** • Stelios Tsinontides, Ph.D., FDA • Lane Christensen, Ph.D., FDA
SESSION 2: Advanced Manufacturing Concepts Beyond Continuous Manufacturing	
Moderators: Robert Meyer, Ph.D., Merck & Co., Inc. and Rajan Jog, Ph.D., FDA	

1:30 – 2:00 PM	• Introduction (5 minutes)
	• ***A Vision for Agile Manufacturing*** (5 minutes)
	  ○ Celeste Frankenfeld Lamm, Ph.D., Merck & Co.
	• ***Pre-Fabricated Solutions for New Facilities*** (5 minutes)
	  ○ Peter Makowenskyj, MEng., G-CON
	• ***Decentralized Pharmaceutical Manufacturing: The Next Big Thing?*** (5 minutes)
	  ○ Christine Moore, Ph.D., Organon
	• ***Regulatory Perspective on Advanced Manufacturing*** (10 minutes)
	  ○ Sau (Larry) Lee, Ph.D., FDA

2:00 – 2:45 PM	Q&A Panel
2:45 PM	Wrap up and End Conference: Jennifer D. Ahearn, ESi Conference Committee Co-Chair

Conference Faculty

- **Michael Abernathy**, MS, RAC, Data Exchange Product Owner, Accumulus Synergy; Executive Director, Global Regulatory Affairs CMC, Amgen Inc.
- **Jennifer D. Ahearn,** Director of Regulatory and Compliance, Pharmaceutical and Medical Devices, ESi
- **Karthik Balasubramanian**, Ph.D., Director, Generic Combination Products and Semisolds R&D, Teva Pharmaceuticals
- **Diane J. Burgess**, Ph.D., Distinguished Professor, University of Connecticut
- **Nina S. Cauchon**, Ph.D., Director Regulatory Affairs, Amgen Inc.
- **Elsbeth Chikhale**, Ph.D., Biopharmaceutics Team Leaders, Division of Biopharmaceutics, ONDP/OPQ/CDER/FDA
- **Lane Christensen**, Ph.D., Branch Chief, Office of Pharmaceutical Manufacturing Assessment (OPMA), OPQ/CDER/FDA
- **Celeste Frankenfeld Lamm**, Ph.D., Director, Merck & Co., Inc.
- **Maria-Teresa Gutierrez-Lugo**, Ph.D., Review Chief, Office of Biotechnology Products/OPQ/CDER/FDA
- **Jayne E. Hastedt**, Ph.D., Managing Director, JDP Pharma Consulting, LLC; PQRI iBCS WG
- **Bart Hens**, Ph.D., Biopharmaceutics Scientist and Drug Product Design Biomodeler, Pfizer, Sandwich, UK
- **Wenlei Jiang**, Ph.D., Senior Science Advisor, Office of Research & Standards, Office of Generic Drugs, CDER/FDA
- **Rajan Jog,** Ph.D., Scientific Reviewer, US Food and Drug Administration
- **Filippos Kesisoglou**, Ph.D., Distinguished Scientist, Merck & Co., Inc.
- **Doug Kiehl**, Research Advisor, Eli Lilly and Company
- **Michael Kopcha,** Ph.D., R.Ph., Director, Office of Pharmaceutical Quality, CDER/FDA
- **Steven Kozlowski,** M.D., Director, Office of Biotechnology Products, OPQ/CDER/FDA
- **Andrew A. LeBoeuf,** JD, MS, Associate Director for Policy (Acting), Office of New Drug Policy, OND/CDER/FDA
- **Sau (Larry) Lee**, Ph.D., Deputy Director of Science, Office of Pharmaceutical Quality, CDER/FDA
- **Michael Lowinger,** Ph.D., Director of Oral Formulation Sciences, Merck & Co., Inc.
- **Peter Makowenskyj,** MEng., Director of Design Consulting, G-CON
- **Robert Meyer**, Ph.D., Principal Scientist, Merck & Co., Inc.
- **Christine M. V. Moore**, Ph.D., Executive Director, Organon
- **Swati Nagar,** Ph.D., Professor and Director of Graduate Studies, Temple University
- **Ajit Narang,** Ph.D., VP, Head of CMC, ORIC Pharmaceuticals
- **Susan Neadle**, MS, BS, FAAO, Principal Consultant/Owner, Combination Products Consulting Services, LLC
- **Suresh Nulu,** MS, Director, Merck & Co., Inc.
- **Diane Paskiet,** MS, Director of Scientific Affairs, West Pharmaceutical Services
- **Prasad Peri**, Ph.D., Senior Director, Teva Pharmaceuticals
- **Susan M. Rosencrance**, Ph.D., Director, Office of Lifecycle Drug Products, OPQ/CDER/FDA
- **Rob Smith**, Ph.D., CEO and Founder, Prime Labs, Inc.
- **Cheryl LM Stults**, Ph.D., Principal, C & M Technical Consulting LLC; PQRI Combination Products Focus Group
- **Duxin Sun**, Ph.D., Charles Walgreen Jr. Professor of Pharmacy and Pharmaceutical Sciences, University of Michigan
- **Stelios C. Tsinontides**, Ph.D., Director, Office of Pharmaceutical Manufacturing Assessment (OPMA)/OPQ/CDER/FDA
- **Catherine (Cat) Vicente**, Manager, Enterprise Regulatory Outreach, Johnson & Johnson
- **Geoffrey Wu**, Ph.D., Deputy Office Director, Office of Lifecycle Drug Products, OPQ/CDER/FDA
- **Mehran Yazdanian**, Ph.D., Vice President, R&D Operations, Teva Pharmaceuticals
- **Lawrence X. Yu**, Ph.D., Director, Office of New Drug Products, OPQ/CDER/FDA
- **Catherine B. Zander**, Ph.D., Scientific Program Manager, The Standards Coordinating Body
- **Hao Zhu**, Ph.D., Deputy Division Director, Division of Pharmacometrics, OCP/OTS/CDER/FDA

PQRI Members

- U.S. Food and Drug Administration (FDA)
- Health Canada (HC)
- Consumer Healthcare Products Association (CHPA)
- International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS)
- International Pharmaceutical Excipients Council of the Americas (IPEC-Americas)
- Parenteral Drug Association (PDA)
- United States Pharmacopeia (USP)

Conference Organizing Committee Members

- Ajit Narang, ORIC Pharmaceuticals — Co-Chair
- Jen Ahearn, ESi — Co-Chair
- Steven Kozlowski, FDA — Co-Chair
- Susan Rosencrance, FDA — Co-Chair
- Lawrence Yu, FDA — Co-Chair

- Nina Cauchon, Amgen
- Dede Godstrey, PQRI Secretariat
- Tere Gutierrez, FDA
- Wenlei Jiang, FDA
- Rajan Jog, FDA
- Filippos Kesisoglou, Merck
- Doug Kiehl, Eli Lilly and Company
- Bob Meyer, Merck
- Diane Paskiet, West
- Dave Schoneker, IPEC-Americas
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- Cat Vicente, Johnson & Johnson
- Mehran Yazdanian, Teva

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The Product Quality Research Institute (PQRI) is a non-profit consortium of organizations working together to generate and share timely, relevant, and impactful information that advances drug product quality, manufacturing, and regulation. To learn more or to join, contact us at **PQRISecretariat@pqri.org**, call, **+1 (202) 230-5607** or visit **www.PQRI.org**.