# FDA/PQRI Workshop on the Regulatory Framework for Distributed and Point of Care Pharmaceutical Manufacturing

## An Opportunity for DM/POC Stakeholder Engagement

PQRI
Product Quality Research Institute

FDA U.S. FOOD & DRUG ADMINISTRATION

# Organizers

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- **Tom O'Connor**, FDA CDER
- **Nathan Davis**, FDA CDER
- **Adam Fisher**, FDA CDER
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- **Dede Godstrey**, PQRI Secretariat
- **Doug Kiehl,** Eli Lilly and Company
- **Jennifer Maguire,** FDA CDER
- **Riley Myers,** FDA CDER
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- **Pahala Simamora**, FDA CDER
- **Cat Vicente**, Johnson & Johnson
- **Glenn Wright**, PDA
- **Carolyn Yong,** FDA CBER
- **Maotang Zhou**, FDA CDER

# Speakers and Panelists

- **Ashley Boam**, FDA CDER
- **Celeste Frankenfeld Lamm,** Merck & Co., Inc.
- **Alvaro Goyanes**, FabRx and UCL School of Pharmacy
- **Michael Kopcha**, FDA CDER
- **John Lewin**, On Demand Pharmaceuticals, Inc.
- **J. Christopher Love**, MIT and Sunflower Therapeutics
- **Riley Myers**, FDA CDER
- **Thomas O'Connor**, FDA CDER
- **Richard McFarland**, Advanced Regenerative Manufacturing Institute
- **Christine Moore**, Organon
- **Steven Oh**, FDA CBER
- **Fred Parietti**, Multiply Labs
- **Dennis Powers**, G-Con
- **Laura Ricles**, FDA CBER
- **Thomas Roper**, Virginia Commonwealth University
- **Laura Sands**, Lonza
- **Rakhi Shah**, FDA CDER
- **Paul Smolenski**, DEKA Research and Development
- **Joel Welch**, FDA CDER
- **Carolyn Yong**, FDA CBER

Thank you for your participation!

If you have additional feedback, please submit comments on the DM/POC Discussion Paper under docket number FDA-2022-N-2316 by December 13th, 2022