

# MCERSI Co-Processed API and Regulatory Requirements

## Public Workshop

July 13-14, 2022

## Agenda

### Day 1: July 13, 2022

8:20 AM – 8:30 AM  
N103 Pharmacy Hall

**MCERSI Welcome Remarks**  
Stephen Hoag, PhD Professor, University of Maryland, Baltimore

8:30 AM – 8:40 AM

**Conference Introduction and Workshop Intent**  
Ramesh Sood, PhD Senior Scientific Advisor, ONDP, OPQ, CDER, FDA

#### **Session 1: Why Does the Development Pipeline Need Technology Options**

##### **Keynote Presentations**

8:40 AM – 9:20 AM

*The Present and Future of Pharmaceutical Quality*  
Larry Lee, PhD Deputy Super Office Director of Science, OPQ, FDA

9:20 AM – 10:00 AM

*Need for New Paths to Accelerated Technology Implementation*  
Timothy Watson, PhD Executive Director and Team Leader for CMC Advisory Office, Pfizer

10:00 AM – 10:15 AM

*Coffee Break*

##### **Case Studies**

10:15 AM – 10:35 AM

*Emerging Modalities and Compound Developability Assessment in Small Molecule Early Development*  
Ahmad Sheikh, PhD Senior Research Fellow and Head of Solid-State and Computational Chemistry, AbbVie

10:35 AM – 10:55 AM

*Persistent Needle Challenges: A Class of Compounds Preventing Crystallization Routes to Modulate Bulk Powder Properties*  
Patrick McArdle, PhD Professor, National University of Ireland, Galway

10:55 AM – 11:15 AM

*Overview of Particle Engineering Routes and Pipeline Needs*  
Alastair Florence, PhD Distinguished Professor and Director of CMAC, University of Strathclyde

##### **Breakout Sessions**

11:15 AM – 12:00 PM

*1A Discussion Leaders: Room 306*

**Paresma (Pinky) Patel, PhD** Branch Chief of Division of New Drug API, ONDP, OPQ, CDER, FDA  
**Luke Schenck** Principal Scientist, Merck & Co., Inc.

*2A Discussion Leaders: Room 310*

**Timothy Watson, PhD** Executive Director and Team Leader for CMC Advisory Office, Pfizer  
**Ramesh Sood, PhD** Senior Scientific Advisor, ONDP, OPQ, CDER, FDA  
**Jeremy Merritt, PhD** Director in SMDD, Eli Lilly & Co.

*3A Discussion Leaders: Room 314*

**Deniz Erdemir, PhD** Associate Scientific Director, Bristol-Myers Squibb  
**Mohan Sapru, PhD** Branch Chief, New Drug Products Division III, Branch V, ONDP, OPQ, CDER, FDA  
**Steven Ferguson, PhD** Assistant Professor School of Chemical and Bioprocess Engineering, University of College Dublin; Adjunct Assistant Professor School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin; Principal investigator, NIBRT

12:00 PM – 1:00 PM

*Lunch Break*

#### **Session 2: Technical Considerations for Designation of Co-Processed API as Drug Substance or Drug Product Intermediate**

##### **Keynote Presentations**

1:00 PM – 1:30 PM

*Co-Processed APIs-Scientific and Regulatory Considerations for New Drug Development*  
Rapti Madurawe, PhD Division Director, OPMA, OPQ, CDER, FDA

1:30 PM – 2:05 PM

*Cobicistat on Silicon Dioxide: Utilizing a Carrier Particle Technology to Solve an API's Physical Property Limitations*  
Jared Evans, PhD Senior Director, Drug Substance Regulatory Strategy, Gilead Sciences

2:05 PM – 2:25 PM	<b>Case Studies</b> <b>Integrated Processing for Co-Processed API</b> <b>Steven Ferguson, PhD</b>	Assistant Professor School of Chemical and Bioprocess Engineering, University of College Dublin; Adjunct Assistant Professor School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin; Principal investigator, NIBRT
2:25 PM – 2:40 PM	<b>Precipitation Processes to Control Material and Powder Properties of Amorphous Solid Dispersions</b> <b>Derek Frank, PhD</b>	Senior Scientist in Particle Engineering Lab in Process R&D, Merck & Co., Inc.
2:40 PM – 2:55 PM	<b>Atomic Layer Coating Technology for Enhancing Processability &amp; Enabling Continuous Manufacturing for Challenging APIs</b> <b>Shiv Chiruvolu, PhD</b> <b>Suneel Rastogi, PhD</b>	Senior Director-New Business Development, Office of CTO, Applied Materials Product Marketing Director, Applied Materials
2:55 PM – 3:15 PM	<b>Strategic Considerations in Choosing a Co-Processing Approach</b> <b>San Kiang, PhD</b>	Chief Technology Officer Drug Product, J-Star Research/Porton
3:15 PM – 3:30 PM	<b>Dry Coating Approach to Enhance API Physical Properties</b> <b>Raimudo Ho, PhD</b>	Principal Research Scientist, Materials Science Center of Excellence Lead, AbbVie, Inc.
3:30 PM – 3:45 PM	<b>Coffee Break</b>	
3:45 PM – 4:30 PM	<b>Breakout Sessions</b>	
1B Discussion Leaders: Room 306	<b>Ramesh Sood, PhD</b> <b>Deniz Erdemir, PhD</b> <b>Luke Schenck</b>	Senior Scientific Advisor, ONDP, OPQ, CDER, FDA Associate Scientific Director, Bristol-Myers Squibb Principal Scientist, Merck & Co., Inc.
2B Discussion Leaders: Room 310	<b>Rapti Madurawe, PhD</b> <b>Jeremy Merritt, PhD</b> <b>Raimundo Ho, PhD</b>	Divisional Director, OPMA, OPQ, CDER, FDA Director in SMDD, Eli Lilly & Co. Principal Research Scientist, AbbVie, Inc.
3B Discussion Leaders: Room 314	<b>Paresma (Pinky) Patel, PhD</b> <b>Billie Kline, PhD</b> <b>Haitao Zhang, PhD</b>	Branch Chief of Division of New Drug API, ONDP, OPQ, CDER, FDA Chemical Engineering Senior Fellow, Vertex Pharmaceuticals Associate Research Fellow in Chemical Process R&D, Sunovion Pharmaceuticals Inc.
	<b>End of Day 1</b>	

## Day 2: July 14, 2022

8:30 AM – 8:40 AM N103 Pharmacy Hall	<b>Day 2 Overview and Introduction</b> <b>Luke Schenck</b> <b>Stephen Hoag, PhD</b> <b>Ramesh Sood, PhD</b>	Principal Scientist, Merck & Co., Inc. Professor, University of Maryland, Baltimore Senior Scientific Advisor, ONDP, OPQ, CDER, FDA
<b>Session 3:</b>	<b>Regulatory &amp; Scientific Considerations for Designation of Co-Processed API as Drug Substance or Drug Product Intermediate</b>	
	<b>Keynote Presentations</b>	
8:40 AM – 9:10 AM	<b>An FDA Perspective on Regulatory Considerations for Co-Processed APIs</b> <b>Laurie Graham-Eure, PhD</b>	Director, Division of Internal Policies and Programs, OPPQ, OPQ, FDA
9:10 AM – 9:40 AM	<b>Motivation to Define Co-Processed API as a Drug Substance and Overview of Current Regulatory Landscape</b> <b>Sharon Page, BSc (Hons)</b> <b>Lindsey Saunders Gorka, PhD</b>	Director, Global Chemistry, Manufacturing and Controls (GCMC), Pfizer R&D UK Ltd Director and Team Leader, Global Regulatory CMC, Pfizer, Inc.
	<b>Case Studies</b>	
9:40 AM – 10:10 AM	<b>Excellent CU of Low Dose Direct Compression Tablets Achieved Using Co-Processed API</b> <b>Changquan Calvin Sun, PhD</b>	Professor and Associate Department Head, University of Minnesota
10:10 AM – 10:25 AM	<b>Coffee Break</b>	
10:25 AM – 10:45 AM	<b>Treatment of Non-active Components in Co-Processed API: Do Excipients Obscure GMP DS Method Ability to Detect Chemical/Phase Purity</b> <b>Frank Bernardoni, PhD</b>	Principal Scientist, Analytical R&D, Merck & Co.
10:45 AM – 11:15 AM	<b>Considerations in Regard to Designation of Active Substance for mRNA Therapeutics</b> <b>Don Parsons, PhD</b>	Vice President, Early Technical Development and Lipid Nanoparticle Process Development, Moderna

11:15 AM – 12:00 PM	<b><u>Breakout Sessions</u></b>	
<i>1C Discussion Leaders:</i>	<b>Peter Capella, PhD</b>	Director, Div. of Immediate and Modified Release Drug Products, OLD, OPQ, CDER, FDA
<b>Room 306</b>	<b>Luke Schenck</b>	Principal Scientist, Merck & Co., Inc.
<i>2C Discussion Leaders:</i>	<b>Laurie Graham-Eure, PhD</b>	Director, Division of Internal Policies and Programs, OPPQ, OPQ, FDA
<b>Room 310</b>	<b>Jeremy Merritt, PhD</b>	Director in SMDD, Eli Lilly & Co.
	<b>Deniz Erdemir, PhD</b>	Associate Scientific Director, Bristol-Myers Squibb
<i>3C Discussion Leaders:</i>	<b>Mohan Sapru, PhD</b>	Branch Chief, New Drug Products Division III, Branch V, ONDP, OPQ, CDER, FDA
<b>Room 314</b>	<b>Ben Stevens, PhD, MPH</b>	Director CMC Policy and Advocacy, GSK
	<b>Llorente Bonaga, PhD</b>	Director, Regulatory Affairs, CMC, Global Regulatory Affairs and Clinical Safety, Merck & Co. USA

12:00 PM – 1:00 PM **Lunch Break**

**Session 4: How Might We Advance Global Harmonization**

**Keynote Presentations**

1:00 PM – 1:30 PM	<b><i>Global Regulatory Harmonization Challenges and Opportunities</i></b>	
	<b>Mahesh Ramanadham, PharmD, MBA</b>	Deputy Director, OPPQ, OPQ, CDER, FDA
1:30 PM – 2:00 PM	<b><i>The Zelboraf Story: Sharing Experience with Different Drug Substance Designations</i></b>	
	<b>Cinzia Gazzola, PhD</b>	Pharma Technical Drug Regulatory Affairs Manager, F. Hoffman-La Roche, Switzerland

**Case Studies**

2:00 PM – 2:20 PM	<b><i>A Strategy for Co-Processed API as Drug Substance in Early Clinical Studies to Rapidly Inform Tech Feasibility with Critical In Vivo Data</i></b>	
	<b>Llorente Bonaga, PhD</b>	Director, Regulatory Affairs, CMC, Global Regulatory Affairs and Clinical Safety, Merck & Co. USA
2:20 PM – 2:40 PM	<b><i>Metformin Premix: Challenges Encountered During Reclassification from Co-Processed API Use to Resolve Severe Metformin Agglomeration to Pharmaceutical Intermediate</i></b>	
	<b>Dirk Wandscheider, PhD</b>	Laboratory Manager Particle Characterization, EMD Serono/Central Analytical Services Merck KGaA, Darmstadt, Germany
	<b>Sandra Masanes Marza</b>	CMC Leader Diabetes, Manufacturing Science & Technology, EMD Serono/Merck KGaA, Darmstadt, Germany
2:40 PM – 3:00 PM	<b><i>Opportunities and Challenges to Innovation and Harmonization for Pharmaceutical Quality Manufacturing from Industry Perspective</i></b>	
	<b>Timothy Watson, PhD</b>	Executive Director and Team Leader for CMC Advisory Office, Pfizer

3:00 PM – 3:15 PM **Coffee Break**

**Breakout Sessions**

3:15 PM – 3:45 PM	<b><u>Breakout Sessions</u></b>	
<i>1D Discussion Leaders:</i>	<b>Mohan Sapru, PhD</b>	Branch Chief, New Drug Products Division III, Branch V, ONDP, OPQ, CDER, FDA
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	<b>Ben Stevens, PhD, MPH</b>	Director CMC Policy and Advocacy, GSK
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<b>Room 314</b>	<b>Llorente Bonaga, PhD</b>	Director, Regulatory Affairs, CMC, Global Regulatory Affairs and Clinical Safety, Merck & Co., Inc.
	<b>Cinzia Gazzola, PhD</b>	Pharma Technical Drug Regulatory Affairs Manager, F. Hoffman-La Roche Switzerland

3:45 PM – 4:30 PM **Workshop Summation, Review of Breakout Sessions 1-4 for Draft Workshop Proceedings Publication**

	<b>Luke Schenck</b>	Principal Scientist, Merck & Co., Inc.
	<b>Stephen Hoag, PhD</b>	Professor, University of Maryland, Baltimore
	<b>Ramesh Sood, PhD</b>	Senior Scientific Advisor, ONDP, OPQ, CDER, FDA

**Main session presentations will be held in Room N103 Pharmacy Hall**

**Breakout Sessions will be held in:**

- Room 306 Pharmacy Hall (Session 1A, 1B, 1C, 1D Breakout Sessions)**
- Room 310 Pharmacy Hall (Session 2A, 2B, 3C, 2D Breakout Sessions)**
- Room 314 Pharmacy Hall (Session 3A, 3B, 3C, 3D Breakout Sessions)**