## MCERSI Co-Processed API and Regulatory Requirements
### Public Workshop
**July 13-14, 2022**

### Agenda

**Day 1:**
**July 13, 2022**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Speaker</th>
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<tbody>
<tr>
<td>8:20 AM – 8:30 AM</td>
<td><strong>MCERSI Welcome Remarks</strong></td>
<td>Stephen Hoag, PhD, Professor, University of Maryland, Baltimore</td>
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<tr>
<td>8:30 AM – 8:40 AM</td>
<td><strong>Conference Introduction and Workshop Intent</strong></td>
<td>Ramesh Sood, PhD, Senior Scientific Advisor, ONDP, OPQ, CDER, FDA</td>
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### Session 1:
*Why Does the Development Pipeline Need Technology Options*

#### Keynote Presentations

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<thead>
<tr>
<th>Time</th>
<th>Keynote Presentation</th>
<th>Speaker</th>
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<tbody>
<tr>
<td>8:40 AM – 9:20 AM</td>
<td><em>The Present and Future of Pharmaceutical Quality</em></td>
<td>Larry Lee, PhD, Deputy Super Office Director of Science, OPQ, FDA</td>
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<td>9:20 AM – 10:00 AM</td>
<td><em>Need for New Paths to Accelerated Technology Implementation</em></td>
<td>Timothy Watson, PhD, Executive Director and Team Leader for CMC Advisory Office, Pfizer</td>
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#### Coffee Break

**10:00 AM – 10:15 AM**

### Case Studies

<table>
<thead>
<tr>
<th>Time</th>
<th>Title</th>
<th>Speaker</th>
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<tr>
<td>10:15 AM – 10:35 AM</td>
<td><em>Emerging Modalities and Compound Developability Assessment in Small Molecule Early Development</em></td>
<td>Ahmad Sheik, PhD, Senior Research Fellow and Head of Solid-State and Computational Chemistry, AbbVie</td>
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<td>10:35 AM – 10:55 AM</td>
<td><em>Persistent Needle Challenges: A Class of Compounds Preventing Crystallization Routes to Modulate Bulk Powder Properties</em></td>
<td>Patrick McArdle, PhD, Professor, National University of Ireland, Galway</td>
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<td>10:55 AM – 11:15 AM</td>
<td><em>Overview of Particle Engineering Routes and Pipeline Needs</em></td>
<td>Alastair Florence, PhD, Distinguished Professor and Director of CMAC, University of Strathclyde</td>
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#### Breakout Sessions

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<thead>
<tr>
<th>Time</th>
<th>Discussion Leaders</th>
<th>Room</th>
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<tbody>
<tr>
<td>11:15 AM – 12:00 PM</td>
<td>1A Paresma (Pinky) Patel, PhD, Branch Chief of Division of New Drug API, ONDP, OPQ, CDER, FDA</td>
<td>306</td>
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<td>Luke Schenck, Principal Scientist, Merck &amp; Co., Inc.</td>
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<td>Timothy Watson, PhD, Executive Director and Team Leader for CMC Advisory Office, Pfizer</td>
<td>310</td>
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<td></td>
<td>2A Ramesh Sood, PhD, Senior Scientific Advisor, ONDP, OPQ, CDER, FDA</td>
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<td>Jeremy Merritt, PhD, Director in SMDD, Eli Lilly &amp; Co.</td>
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<td>Deniz Erdemir, PhD, Associate Scientific Director, Bristol-Myers Squibb</td>
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<td>Mohan Sapru, PhD, Branch Chief, New Drug Products Division III, Branch V, ONDP, OPQ, CDER, FDA</td>
<td>314</td>
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<td></td>
<td>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</td>
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**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

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<thead>
<tr>
<th>Time</th>
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<tr>
<td>1:00 PM – 1:30 PM</td>
<td><em>Co-Processed APIs-Scientific and Regulatory Considerations for New Drug Development</em></td>
<td>Rapti Madurawe, PhD, Division Director, OPMA, OPQ, CDER, FDA</td>
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<tr>
<td>1:30 PM – 2:05 PM</td>
<td><em>Cobicistat on Silicon Dioxide: Utilizing a Carrier Particle Technology to Solve an API’s Physical Property Limitations</em></td>
<td>Jared Evans, PhD, Senior Director, Drug Substance Regulatory Strategy, Gilead Sciences</td>
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**Day 2:**  
July 14, 2022

8:30 AM – 8:40 AM  
**Day 2 Overview and Introduction**

N103 Pharmacy Hall  
Luke Schenck  Principal Scientist, Merck & Co., Inc.

Stephen Hoag, PhD  Professor, University of Maryland, Baltimore

Ramesh Sood, PhD  Senior Scientific Advisor, ONDP, OPQ, CDER, FDA

**Session 3:**  
**Regulatory & Scientific Considerations for Designation of Co-Processed API as Drug Substance or Drug Product Intermediate**

8:40 AM – 9:10 AM  
**An FDA Perspective on Regulatory Considerations for Co-Processed APIs**

Laurie Graham-Eure, PhD  Director, Division of Internal Policies and Programs, OPPO, OPQ, FDA

9:10 AM – 9:40 AM  
**Motivation to Define Co-Processed API as a Drug Substance and Overview of Current Regulatory Landscape**

Sharon Page, BSc (Hons)  Director, Global Chemistry, Manufacturing and Controls (GCMC), Pfizer R&D UK Ltd

Lindsey Saunders Gorka, PhD  Director and Team Leader, Global Regulatory CMC, Pfizer, Inc.

**Case Studies**

9:40 AM – 10:10 AM  
**Excellent CU of Low Dose Direct Compression Tablets Achieved Using Co-Processed API**

Changquan Calvin Sun, PhD  Professor and Associate Department Head, University of Minnesota

10:10 AM – 10:25 AM  
**Coffee Break**

10:25 AM – 10:45 AM  
**Treatment of Non-active Components in Co-Processed API: Do Excipients Obscure GMP DS Method Ability to Detect Chemical/Phase Purity**

Frank Bernardoni, PhD  Principal Scientist, Analytical R&D, Merck & Co.

10:45 AM – 11:15 AM  
**Considerations in Regard to Designation of Active Substance for mRNA Therapeutics**

Don Parsons, PhD  Vice President, Early Technical Development and Lipid Nanoparticle Process Development, Moderna

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**Breakout Sessions**

18 Discussion Leaders:  
Ramesh Sood, PhD  Senior Scientific Advisor, ONDP, OPQ, CDER, FDA

Deniz Erdemir, PhD  Associate Scientific Director, Bristol-Myers Squibb

Luke Schenck  Principal Scientist, Merck & Co., Inc.

Rapti Madurawe, PhD  Divisional Director, OPMA, OPQ, CDER, FDA

Jeremy Merritt, PhD  Director in SMDD, Eli Lilly & Co.

Raimundo Ho, PhD  Principal Research Scientist, AbbVie, Inc.

Paresma (Pinkie) Patel, PhD  Branch Chief of Division of New Drug API, ONDP, OPQ, CDER, FDA

Billie Kline, PhD  Chemical Engineering Senior Fellow, Vertex Pharmaceuticals

Haitao Zhang, PhD  Associate Research Fellow in Chemical Process R&D, Sunovion Pharmaceuticals Inc.

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**Coffee Break**
11:15 AM – 12:00 PM  **Breakout Sessions**

**1C Discussion Leaders:**
- Peter Capella, PhD  
  Director, Div. of Immediate and Modified Release Drug Products, OLDP, OPQ, CDER, FDA
- Luke Schenck  
  Principal Scientist, Merck & Co., Inc.

**Room 306**
- Laurie Graham-Eure, PhD  
  Director, Division of Internal Policies and Programs, OPPO, OPQ, FDA
- Jeremy Merritt, PhD  
  Director in SMDD, Eli Lilly & Co.
- Deniz Erdemir, PhD  
  Associate Scientific Director, Bristol-Myers Squibb

**3C Discussion Leaders:**
- Mohan Sapru, PhD  
  Branch Chief, New Drug Products Division III, Branch V, ONDP, OPQ, CDER, FDA
- Ben Stevens, PhD, MPH  
  Director CMC Policy and Advocacy, GSK
- Llorente Bonaga, PhD  
  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**
**Global Regulatory Harmonization Challenges and Opportunities**

**Mahesh Ramanadham, PharmD, MBA**  
Deputy Director, OPPO, OPQ, CDER, FDA

1:30 PM – 2:00 PM  **The Zelboraf Story: Sharing Experience with Different Drug Substance Designations**

**Cinzia Gazziola, PhD**  
Pharma Technical Drug Regulatory Affairs Manager, F. Hoffman-La Roche, Switzerland

**Case Studies**

2:00 PM – 2:20 PM  **A Strategy for Co-Processed API as Drug Substance in Early Clinical Studies to Rapidly Inform Tech Feasibility with Critical In Vivo Data**

**Llorente Bonaga, PhD**  
Director, Regulatory Affairs, CMC, Global Regulatory Affairs and Clinical Safety, Merck & Co. USA

2:20 PM – 2:40 PM  **Metformin Premix: Challenges Encountered During Reclassification from Co-Processed API Use to Resolve Severe Metformin Agglomeration to Pharmaceutical Intermediate**

**Dirk Wandscheider, PhD**  
Laboratory Manager Particle Characterization, EMD Serono/Central Analytical Services Merck KGaA, Darmstadt, Germany

**Sandra Masanes Marza**  
CMC Leader Diabetes, Manufacturing Science & Technology, EMD Serono/Merck KGaA, Darmstadt, Germany

2:40 PM – 3:00 PM  **Opportunities and Challenges to Innovation and Harmonization for Pharmaceutical Quality Manufacturing from Industry Perspective**

**Timothy Watson, PhD**  
Executive Director and Team Leader for CMC Advisory Office, Pfizer

3:00 PM – 3:15 PM  **Coffee Break**

3:15 PM – 3:45 PM  **Breakout Sessions**

**1D Discussion Leaders:**
- Mohan Sapru, PhD  
  Branch Chief, New Drug Products Division III, Branch V, ONDP, OPQ, CDER, FDA
- Luke Schenck  
  Principal Scientist, Merck & Co., Inc.
- Ben Stevens, PhD, MPH  
  Director CMC Policy and Advocacy, GSK

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- Peter Capella, PhD  
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- Mahesh Ramanadham, PharmD, MBA  
  Deputy Director, OPPO, OPQ, CDER, FDA
- Llorente Bonaga, PhD  
  Director, Regulatory Affairs, CMC, Global Regulatory Affairs and Clinical Safety, Merck & Co., Inc.
- Cinzia Gazziola, PhD  
  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**

**Luke Schenck**  
Principal Scientist, Merck & Co., Inc.

**Stephen Hoag, PhD**  
Professor, University of Maryland, Baltimore

**Ramesh Sood, PhD**  
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)