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
11:15 AM – 12:00 PM	**Breakout Sessions**	
1A Discussion Leaders:	**Paresma (Pinky) Patel, PhD**	Branch Chief of Division of New Drug API, ONDP, OPQ, CDER, FDA
Room 306	**Luke Schenck**	Principal Scientist, Merck & Co., Inc.
	Timothy Watson, PhD	Executive Director and Team Leader for CMC Advisory Office, Pfizer
2A Discussion Leaders:	**Ramesh Sood, PhD**	Senior Scientific Advisor, ONDP, OPQ, CDER, FDA
Room 310	**Jeremy Merritt, PhD**	Director in SMDD, Eli Lilly & Co.
	Deniz Erdemir, PhD	Associate Scientific Director, Bristol-Myers Squibb
3A Discussion Leaders:	**Mohan Sapru, PhD**	Branch Chief, New Drug Products Division III, Branch V, ONDP, OPQ, CDER, FDA
Room 314	**Steven Ferguson, PhD**	Assistant Professor School of Chemical and Bioprocess Engineering, University of College Dublin; Adjunct Assistant Professor School of Pharmacy and Pharmaceutical S 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

	Case Studies	
2:05 PM – 2:25 PM	***Integrated Processing for Co-Processed API***	
	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
2:25 PM – 2:40 PM	***Precipitation Processes to Control Material and Powder Properties of Amorphous Solid Dispersions***	
	Derek Frank, PhD	Senior Scientist in Particle Engineering Lab in Process R&D, Merck & Co., Inc.
2:40 PM – 2:55 PM	***Co-Processed API Product and Process Development, Optimization, and Scale-up***	
	Nima Yazdanpanah, PhD	Consultant on Advanced Manufacturing and Modeling and Simulation Applications, Procegence
2:55 PM – 3:15 PM	***Strategic Considerations in Choosing a Co-Processing Approach***	
	San Kiang, PhD	Chief Technology Officer Drug Product, J-Star Research/Porton
3:15 PM – 3:30 PM	***Dry Coating Approach to Enhance API Physical Properties***	
	Raimudo Ho, PhD	Principal Research Scientist, Materials Science Center of Excellence Lead, AbbVie, Inc.
3:30 PM – 3:45 PM	***Coffee Break***	
3:45 PM – 4:30 PM	**Breakout Sessions**	
1B Discussion Leaders:	**Ramesh Sood, PhD**	Senior Scientific Advisor, ONDP, OPQ, CDER, FDA
Room 306	**Deniz Erdemir, PhD**	Associate Scientific Director, Bristol-Myers Squibb
	Luke Schenck	Principal Scientist, Merck & Co., Inc.
2B Discussion Leaders:	**Rapti Madurawe, PhD**	Divisional Director, OPMA, OPQ, CDER, FDA
Room 310	**Jeremy Merritt, PhD**	Director in SMDD, Eli Lilly & Co.
	Raimundo Ho, PhD	Principal Research Scientist, AbbVie, Inc.
3B Discussion Leaders:	**Paresma (Pinky) Patel, PhD**	Branch Chief of Division of New Drug API, ONDP, OPQ, CDER, FDA
Room 314	**Billie Kline, PhD**	Chemical Engineering Senior Fellow, Vertex Pharmaceuticals
	Haitao Zhang, PhD	Associate Research Fellow in Chemical Process R&D, Sunovion Pharmaceuticals Inc.
	End of Day 1	

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**	
	Keynote Presentations	
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, OPPQ, 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

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
Room 306	**Luke Schenck**	Principal Scientist, Merck & Co., Inc.
2C Discussion Leaders:	**Laurie Graham-Eure, PhD**	Director, Division of Internal Policies and Programs, OPPQ, OPQ, FDA
Room 310	**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
Room 314	**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	
1:00 PM – 1:30 PM	***Global Regulatory Harmonization Challenges and Opportunities***	
	Mahesh Ramanadham, PharmD, MBA	Deputy Director, OPPQ, 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
Room 306	**Luke Schenck**	Principal Scientist, Merck & Co., Inc.
	Ben Stevens, PhD, MPH	Director CMC Policy and Advocacy, GSK
2D Discussion Leaders:	**Peter Capella, PhD**	Director, Div. of Immediate and Modified Release Drug Products, OLDP, OPQ, CDER, FDA
Room 310	**Jeremy Merritt, PhD**	Director in SMDD, Eli Lilly & Co.
	Timothy Watson, PhD	Executive Director and Team Leader for CMC Advisory Office, Pfizer
3D Discussion Leaders:	**Mahesh Ramanadham, PharmD, MBA**	Deputy Director, OPPQ, OPQ, CDER, FDA
Room 314	**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)