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Ashland Pharmaceutical Technology Symposium on Formulation and Process Development

Oct. 3rd, 2018

Residence Inn Cambridge,
120 Broadway, Cambridge, Massachusetts 02142

Program

Time	Topic	Presenter	Minutes
8:35 - 9:00 a.m.	Registration		
9:00 - 9:15 a.m.	Welcome, Intro, Meeting Objectives and Safety	Bruce Kinsey and Dr. Thomas Dürig, Ashland	15
9:15 - 10:00 a.m.	Reducing Formulation Risk with Science-based Excipient Selection	Dr. Thomas Dürig, Ashland	45
10:00 - 10:10 a.m.	Ashland New Product high-light: Aquarius™ Film Coating System	Dr. Thomas Dürig, Ashland	10
10:10 - 10:30 a.m.	Communication Break		20
10:30 – 11:15 a.m.	Understanding Supersaturation of Insoluble Molecules to Improve Bioavailability	Dr. Sudhakar Garad, Novartis	45
11:15 – 12:00 p.m.	Rational Polymer and Process Selection for Amorphous Solid Dispersions	Vivian Bi, Ashland	45
12:00 - 12:10 p.m.	Ashland New Product high-light: New Copovidone Designed for HME	Vivian Bi, Ashland	10
12:10 a.m. - 1:10 p.m.	Lunch		60

1:10 -1:55 p.m.	Continuous Pharmaceutical Processing: from Formulation and Process Development to Production	Dr. Marcus O'Mahony, Vertex	45
1:55 – 2:40 p.m.	Binder Selection: What to Consider for Direct Compression, Wet Granulation and Dry Granulation	Thomas Dürig, Ashland	45
2:40-3:00 p.m.	Communication break		20
3:00-3:45 p.m.	Bioresorbable Polymer Design for Medical and Pharmaceutical Applications	Dr. Sean McMahon, Vornia	45
3:45-3:55 p.m.	Ashland New Product high-light: NaCMC Aqualon™ BET	Dean Ross, Ashland	10
3:55-4:25 p.m.	Panel Discussion	All speakers	30
4:25-4:35 p.m.	Wrap up and Departure	Dr. Thomas Dürig and Eimear O'Connell Ashland	10

Speakers and Bio:

Dr. Thomas Dürig, Ashland Specialty Ingredient (ASI)

Dr. Tom Dürig is a Senior R&D Director leads global research and development and technical services for Pharmaceutical and Nutrition Specialities. These groups, located in North America, Europe, Middle East, Latin America, and Asia provide technical service and are focused on research and development of highly functional materials that enable overcoming drug delivery challenges such as bioavailability enhancement, drug stabilization and controlled drug delivery as well as process technologies to achieve advanced drug delivery and continuous manufacturing.

Dr. Sudhakar Garad, Novartis

Sudhakar Garad received his Ph.D. from the Bombay College of Pharmacy, University of Mumbai, India in 1998 in Pharmaceutical Drug Delivery Technology with Dr, M.S Nagarsenker. Soon after completion of his Ph.D., he worked with Pfizer, India for less than a year in clinical research. Taking into consideration his excellent credentials during his Ph.D, he was selected as a post-doctoral fellow at the University of Connecticut to understand micro-environmental properties above dissolving surface of the polymers. After his post-doctoral fellowship, he worked with Vertex pharmaceutical for a period of three years as Senior Investigator in formulation development group. After Vertex, he joined Novartis as a Group Head. He worked with Novartis for 9 years and joined as a Director of formulation development at Cubist Pharmaceuticals/Merck for 2.5 years. Currently Sudhakar is working as a Global head of Chemical and Pharmaceutical profiling (Discovery Pharmaceutics) and Disease Area Head (New Indications) at Novartis. His primary role is collaborate with research colleagues and build the right biopharmaceutical properties into new chemical entities, if not enable them via solubility/dissolution enhancement technologies to expedite molecules into tox and clinical studies. He is also responsible for enabling research, clinical and commercial molecules via novel delivery technologies (Brain targeting, permeability enhancement, TI improvement etc). He has many publications, book chapters and patents. In last 20 years of his career he has taken more than 200 new chemical entities in clinical studies across dozen disease areas (CVM, Oncology, ATI, MS, Respiratory, NS, GI, Antibacterial, Tropical diseases, HCV etc), via oral, parenteral, inhalation and transdermal route of administration.

Dr. Vivian Bi, Ashland Specialty Ingredient (ASI)

Dr. Vivian Bi is a Director of Pharmaceutical Technology at Ashland Specialty Ingredient (ASI). She has held various positions in Pfizer Global R&D, Vertex Pharmaceuticals and AstraZeneca Pharmaceuticals before joining ASI. Her research interests are oral and parenteral drug delivery systems. Dr. Bi has authored and co-authored over 50 research papers, abstracts and patents. She also serves as a reviewer for research journals such as Pharmaceutical Research and Journal of Pharmaceutical Sciences. Dr. Bi obtained her B.S. degree from Shenyang Pharmaceutical University in China and completed her Ph.D. in Pharmaceutical Science from Meijo University in Japan in March 2000.

Dr. Marcus O'Mahony, Vertex Pharmaceuticals Inc.

Dr. Marcus O'Mahony is a Continuous Processing Scientist dedicated to designing, developing and implementing continuous pharmaceutical processing methodologies at Vertex Pharmaceuticals. Marcus received his PhD in Chemistry from the University of Limerick in Ireland working within the Synthesis and Solid State Pharmaceutical Centre and later joined the Department of Chemical Engineering at MIT as a postdoctoral researcher with the Novartis-MIT Centre for Continuous Manufacturing. While working at Vertex, Marcus has contributed to the fundamental understanding of continuous unit operations and their integration within Vertex's continuous manufacturing platform. He current leads the continuous manufacturing data science initiative at Vertex. In the last 4 years he has published 7 papers, a book chapter and submitted 4 patent applications in the areas of pharmaceutical particle engineering and continuous manufacturing.

Dr. Seán McMahon, Vornia, a subsidiary organization of Ashland

Dr. Seán McMahon is the Business Development Manager and a technical lead for the bioresorbable polymers business at Ashland Specialty Ingredients (ASI). He has previously worked in various technical and managerial positions delivering improved polymer technologies for medical applications and driving business growth. Seán joined the Ashland team as part of the Vornia Limited acquisition in 2018 where he previously held responsibility for the company's major business functions in his role as CEO. He has published several research papers on polymer design and application for both parenteral controlled release and medical device applications. He is deeply passionate about translating

improved medical technologies that can deliver better clinical outcomes. Dr. McMahon obtained his B.Eng. and M.Sc. from the National University of Ireland, Galway (NUIG) and his Ph.D. from the School of Medicine and Medical Sciences at the University College Dublin (UCD), Ireland.