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Ashland Pharmaceutical Technology Symposium on Continuous Processing

September 20th, 2018

500 Hercules Rd, Wilmington DE, 19810

Program

Time	Topic	Presenter	Minutes
8:30 - 9:00 a.m.	Registration		
9:00 - 9:15 a.m.	Welcome, Intro, Meeting Objectives and Safety	John Carney and Dr. Thomas Dürig Ashland	15
9:15 - 10:00 a.m.	Copovidone Designed for Continuous Hot-melt Extrusion	Dr. Thomas Dürig, Ashland	45
10:00 - 10:45 a.m.	Loss-in-Weight Feeding of Pharmaceutical Powders, A Critical Step for Continuous Processing	Kendall Moyer, Merck	45
10:45 - 11:05 a.m.	Communication Break		20
11:05 - 11:50 a.m.	Enabling Continuous Direct Compression of Low Dose Drugs Through Particle Engineering	Dr. Calvin Sun, University of Minnesota	45
11:50 a.m. - 12:00 p.m.	Ashland New Product Highlight for Continuous Processing: Benecel™ HPMC DC	Quyen Schwing, Ashland	10
12:00 - 1:00 p.m.	Lunch		60
1:00 - 1:45 p.m.	Twin-screw Continuous Melt Granulation of Thermally Labile High-dose Drugs –	Dr. Feng Zhang, The University of	45

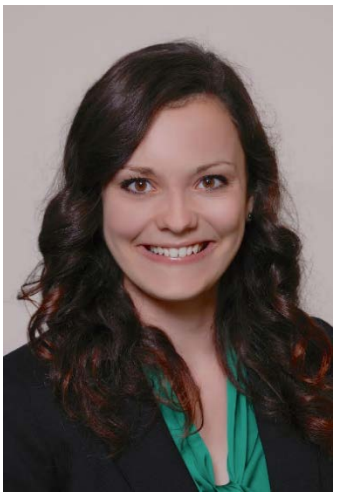
	Formulation and Processing Strategies	Texas at Austin	
1:45 - 2:30 p.m.	Binder Selection for Continuous Granulation	Dr. Vivian Bi, Ashland	45
2:30 – 2:50 p.m.	Communication break		20
2:50-3:35 p.m.	A Novel Continuous Film Coating Process to Support a Flexible Manufacturing Platform	Dr. Andrew Birkmire, GEA	45
3:35-4:20 p.m.	Ashland Excipients for Continuous Processing: Aquarius™ High-solid Coating Systems	Kapish Kiran, Ashland	45
4:20-4:30 p.m.	Wrap-up and Departure	Dr. Thomas Dürig, Ashland	10

Speakers and Bio:

Dr. Thomas Dürig, Ashland

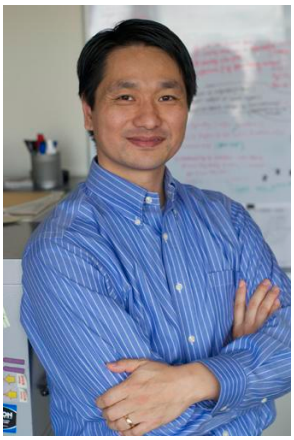
Dr. Tom Dürig is a Senior R&D Director leads global research and development and technical services for Pharmaceutical and Nutrition Specialities. These groups, located in North America, Europe, Middle East, Latin America, and Asia provide technical service and are focused on research and development 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.

Ms. Kendall Moyer, Merck



Ms. Kendall Moyer earned her Bachelor of Science and Master of Science degrees in Chemical Engineering from the University of Michigan. Upon graduating, she entered Merck's Manufacturing Leadership Development Program as part of the technical track. Her first rotation was in Boxmeer, Netherlands where she worked in an improvement team for live vaccines production as part of animal health. In August 2017, she started her second rotation in West Point, PA where she worked in pharmaceutical commercialization technology. In that role, she worked extensively on continuous feeding as part of the continuous manufacturing efforts of oral solid dosage forms. In August 2018, Kendall started her third and final rotation in biologics external manufacturing supporting the operations of an external site.

Dr. Changquan Calvin Sun, University of Minnesota



Dr. Sun is currently Professor of Pharmaceutics and Director of Graduate Studies at the Department of Pharmaceutics, University of Minnesota. After receiving his Ph.D. in Pharmaceutics from the University of Minnesota in 2000, he had worked in the pharmaceutical industry until 2008. Dr. Sun joined the University of Minnesota as Assistant Professor in 2008 and was promoted to Associate Professor in 2013 and Professor in 2017, respectively.

Dr. Sun's research focuses on formulation development of tablet products through appropriate application of materials science and engineering principles, including 1) crystal and particle engineering for superior powder flow and compaction properties; 2) understanding and control of common pharmaceutical unit operations, e.g., blending, granulation, and tableting. Dr. Sun is an expert in the areas of solid-state science, tablet formulation design, and powder technology. As of July 3, 2018, he has published 126 peer-reviewed papers in these areas.

Dr. Sun currently serves on the editorial boards for J. Pharm. Sci., Int. J. Pharm., Crystals, and Tablets and Capsules. He is a member of Expert Committee in Physical Analysis, United States Pharmacopeia. Dr. Sun was elected an AAPS Fellow in recognition of his sustained level of superior and distinguished professional achievement and contributions in Pharmaceutical Sciences. He was also admitted as a Fellow of Royal Society of Chemistry, recognizing his efforts that have made an impact in a field of the chemical sciences.

Dr. Feng Zhang, University of Texas at Austin

Dr. Feng Zhang is an assistant professor at the University of Texas at Austin. He received his Ph.D. in pharmaceutics from the University of Texas at Austin. He has been working in the industry for 14 years prior to joining the department of pharmaceutics at the University of Texas at Austin in 2014. He was the Director of Product Development at PharmaForm from 2007 to 2010 and Senior Scientist in the Formulation and Process development department at Gilead from 2011 to 2013. Zhang has been conducting research and product development using twin-screw extrusion process since 1994.

His principal research interest at UT Austin is in twin-screw extrusion processing for continuous granulation, bioavailability enhancement, abuse deterrent opioid delivery, and controlled release drug delivery. He is the editor of 2nd edition of "Pharmaceutical Extrusion Technology", published in 2018. He has authored four book chapters on twin-screw extrusion process. He has published 40 peer-reviewed papers articles. He is also inventor on 12 issued patents covering a wide range of drug delivery systems. He serves on the editorial board of AAPS PharmSci Tech.

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.

Mr. Andrew P. Birkmire, GEA Process Engineering, Inc

Mr. Andrew P. Birkmire is the Process Development Manager at GEA Process Engineering, Inc. His responsibilities include all internal and on-site process testing and development for North American Pharmaceutical applications.
Mr. Birkmire's background includes extensive experience in coating, drying, and granulation technologies, with a focus on continuous manufacturing processes.