

PD2M Advanced Process Control Workshop Addendum

Below are some changes to the program. For Session I, there is now a short break after the first two keynote talks. For Session II, the panelists are now listed.

Monday, September 30, 2019	
9:00 AM – 11:30 AM	Session I: Keynote Talks
9:00 AM – 10:10 AM	<p>Sau “Larry” Lee, <i>FDA</i>, The Role of APC in Journey to Modernize Pharmaceutical Manufacturing</p> <p>Venkat Venkatasubramanian, <i>Columbia University</i>, Artificial Intelligence in Pharmaceutical Engineering: Challenges and Opportunities</p>
10:10 AM – 10:20 AM	Short Break
10:20 AM – 11:30 AM	<p>Olav Lyngberg, <i>J&J</i>, The Journey of Implementing Advanced Process Control in the Pharmaceutical Industry</p> <p>Cenk Undey, <i>Amgen</i>, Intelligent process monitoring and control in the age of industry and biotech 4.0</p>
1:00 PM - 2:00 PM	<p>Session 2: Panel Discussion to Introduce and Discuss Following Topics</p> <p>Topics:</p> <ul style="list-style-type: none"> • Key terminology • Role and relationship of APC with regards to QbD, PAT, continuous manufacturing and digital manufacturing • Organization and governance for APC implementation • Quality Systems for APC Implementation and CMC challenges <p>Panelists:</p> <ul style="list-style-type: none"> • Paul Collins, <i>Eli Lilly</i> • Jun Huang, <i>Pfizer</i> • Thomas O’Connor, <i>FDA</i> • Cenk Undey, <i>Amgen</i> • Jasdeep Mandur, <i>Merck</i> • Marianthi Ierapetritou, <i>University of Delaware</i> • Saly Romero-Torres, <i>Biogen</i>