

## The 17th New Pharmaceutical Technology and Engineering Conference 2019

Shinagawa Intercity Hall (Tokyo, Japan)

Organized by: New Pharmaceutical Technology and Engineering Institute (NPTE)

Wed. July 17, 2019		Thur. July 18, 2019					
-	09:50~ 10:00		Opening Remarks	1	9:30~ 10:20	<b><u>Christian Woelbeling</u></b> Senior Director Global Accounts, Werum IT Solutions GmbH 『From Industry 4.0 to the PHARMA 4.0 Operating Model – The Holistic ICH Control Strategy』	
1	10:00~ 10:50	<b><u>Fumi Yamamoto</u></b> Director, Pharmaceutical Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau Ministry of Health, Labour and Welfare (MHLW) 『Recent updates for conditional early approval system etc, and regulatory policy and promoting innovative drags』		2	10:20~ 11:10	<b><u>Osamu Nagayama</u></b> Chairman, Chugai Pharmaceutical Co., Ltd. 『Challenges and Trends for Japanese Pharmaceutical Industry』	
2	10:50~ 11:40	<b><u>Daniel Borginis</u></b> Senior Engineer, Solid Dosage Pilot Plant, Pharmaceutical Sciences Merck & Co., Inc., West Point, PA, USA 『MSD continuous manufacturing strategy and the development of a custom continuous blending system』		3	11:10~ 12:00	<b><u>Carla Luciani</u></b> Assoc Sr Engineer Advisor, Leader of Future Manufacturing Platforms Small Molecule Design and Development – Eli Lilly & Co 『The Future of Drug Substance Continuous Manufacturing』	
-	11:40~ 12:30	<i>Lunch Time (50 mins)</i>		-	12:00~ 12:50	<i>Lunch Time (50 mins)</i>	
3	12:30~ 13:20	<b><u>Youhei Takagi</u></b> Manager, API R&D Center, Process Technology Department, CMC R&D Division Shionogi & Co., Ltd. 『Designing for Peptide API Manufacturing~The process development for scale-up with high quality~』		4	12:50~ 13:40	<b><u>Bertil St. Abrahamsson</u></b> Senior Principal Scientist, Pharmaceutical Technology & Development, Astrazeneca 『Six years of progress in the oral biopharmaceutics area – the OrBiTo project』	
4	13:20~ 14:10	<b><u>Goldi Kaul</u></b> Director, Pharmaceutical Technology, Technical Operations Otsuka Pharmaceutical Development & Commercialization (OPDC), Princeton, NJ, USA 『Abilify MyCite®- The world's first approved digital medicine system with a tablet containing an ingestible event marker (IEM) to track medication ingestion』		5	13:40~ 14:30	<b><u>Satoshi Morino</u></b> Senior Manager, Kashima Quality Assurance, Japan Regional Quality, Global Quality HQs, Eisai Co., Ltd. 『The Latest Global Regulatory Trends on Data Integrity and Issues to be Addressed by the Pharmaceutical Industries』	
-	14:10~ 14:30	<i>Coffee Break (20 mins)</i>		-	14:30~ 14:50	<i>Coffee Break (20 mins)</i>	
-	14:30~ 14:45	The New Pharmaceutical Technology and Engineering Foundation Particle Design & Research Abroad Grant Awards Ceremony		-			
5	14:45~ 15:35	<b><u>PD Award 2019 Commemorative Lecture</u></b> <b><u>Hirokazu Sugiyama</u></b> Associate Professor, Department of Chemical System Engineering, The University of Tokyo 『Development of multiobjective and practical process design methodology for drug product manufacturing』		6	14:50~ 15:40	<b><u>Kikuko Harasawa</u></b> CMC sciences Dept. Regulatory Affairs Division, R&D Division, Janssen 『Janssen's Experience to Introduce Innovative Continuous Manufacturing (CM)』	
6	15:35~ 16:25	<b><u>Masaru Yoshida</u></b> Researcher, Formulation Research & Development Laboratories Technology Research & Development, Sumitomo Dainippon Pharma Co., Ltd 『Introduction of a method for managing the granulation end point of spherical particles using a new PAT tool』		7	15:40~ 16:30	<b><u>Kenji Tsuchiya</u></b> Project Manager, Project Management Department, Shionogi Co., Ltd. 『Global Development of Sakigake Product Xofluza』	
7	16:25~ 17:15	<b><u>Don Wetherhold</u></b> Advisor to the Chairman and Senior Vice President, Aprelia Pharmaceuticals, LLC 『3D Printing in Pharmaceutical Development and Manufacturing: Technological Requirements, Critical Elements, and Process Controls in the Development of Novel Dosage Forms』		-	16:30~ 16:40	Closing Remarks	