## The 18th New Pharmaceutical Technology and Engineering Conference 2021 Program

Kyoto International Conference Center (Japan) / Virtual Conference
Organized by: The New Pharmaceutical Technology and Engineering Institute (NPTE)

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Tue. June 22, 2021		Wed. June 23, 2021			
			< <session chair="">&gt; Yasuyuki Ikematsu (Eisai Co., Ltd.)</session>		
- 09:50~ 10:00	Opening Remarks Hirofumi Takeushi, Chairman, New Pharmaceutical Technology and Engineering Institute (Emeritus Professor, Gifu Pharmaceutical University)	111		Thomas O'Connor  Director of Division of Product Quality Research, CDER/Office of Pharmaceutical Quality  US Food and Drug Administration  [FDA's Advanced Manufacturing Journey.]	
	< <session chair="">&gt; Makoto Miyajima (Daiichi Sankyo Co., Ltd)</session>	П		Remote Session 21:20 (MA/EST)	
1 10:00~ 10:50	Jose E. Tabora Sierra  Research Fellow, Pharmaceutical Development/Chemical Synthetic Development Bristol Myers Squibb  The Evolution of Digital Data and Modeling in Pharmaceutical Development.	2	11:10	Elcin Icten –Gencer Senior Scientist, Drug Product Technologies – Process Development, Amgen Inc.  Virtual Plant for End-to-End Continuous Manufacturing of Synthetic Drug Substance and Development of Advanced Process Control Strategy.	
				<>Session Chair>> Yuji Tokunaga (SAWAI Pharmaceutical Co., Ltd.)	
2 10:50~ 11:40	Masayuki Imagawa Vice President, Head, Japan Vaccine Business Unit, Takeda Pharmaceutical Co., Ltd.  [Adaptive thinking and capacity in Japan against pandemic outbreak of infectious diseases.]		12:00	Yoshinori Nakajima Executive Officer and Deputy General Manager, Formulation Manufacturing Division Daito Pharmaceutical Co., Ltd.  [Daito's strategy for development/ manufacturing of highly potent compounds and introduction of the 8th formulation plant~ The latest case of containment facility~]	
- 11:40~ 12:30	Lunch Time (50 mins)		12:00 <b>~</b> 12:50	Lunch Time (50 mins)	
	<>Session Chair>> Katsuhide Terada (Takasaki University of Health and Welfare)	<u> </u>		<>Session Chair>> Hirofumi Takeuchi (Gihu Pharmaceutical University)	
3 12:30~ 13:20	Kenji Kuramochi Office Director, Office of Manufacturing Quality for Drugs Pharmaceuticals and Medical Devices Agency (PMDA)  [The situation of the recent GMP inspection - mainly on the revised GMP ordinance -]	4	12:50 <b>~</b> 13:40	Yoshihiko Hatanaka Representative Director, Chairman of the Board, Astellas Pharma Inc. 『Society by Future Healthcare』	
	Yasuhide Horiuchi			< <session chair="">&gt; Makoto Fukuta (SPERA PHARMA, Inc.)</session>	
4 13:20~ 14:10	General Manager, CMC Technical Dept., Toray Industies, Inc.   [Development of the OD coating film by use of RADIFIL® technology and the application to  REMITCH® OD TABLET 2.5 $\mu$ g.]	5		Yoshiyuki Yabe Scientist, Drug Metabolism and Pharmacokinetics Research Laboratories Daiichi Sankyo Co., Ltd.  Discovery and Development of Anti-drug Antibody Trastuzumab Deruxtecan (T-DXd, DS-8201a)	
- 14:10~ 14:30	Coffee Break (20 mins)				
- 14:30~ 14:50	Commemoration Ceremony - Adress from the former chairman, Yoshiaki Kawashima The New Pharmaceutical Technology and Engineering Foundation The 8th Particle Design Award Ceremony	-	14:30~ 14:50	Coffee Break (20 mins )	
< <session chair="">&gt; Hirofumi Takeuchi (Gihu Pharmaceutical University)</session>			< <session chair="">&gt; Etsuo Yonemochi (Hoshi University)</session>		
5 14:50~ 15:40	The 8th Particle Design Award Commemorative Lecture  Yu Hoshino  Associate Professor, Department of Chemical Engineering, Kyushu University  [Development of plastic antibodies: synthetic polymer nanoparticles that recognize, bind and neutralie target molecules in vivo.]	6	14:50 <b>~</b> 15:40	Gavin Reynolds Professor, Pharmaceutical Technology & Development, AstraZeneca  [Manufacturing Classification System (MCS): Data Gathering and Analysis from Regulatory Filings.]	
	<>Session Chair>> Shigeo Yanai (Takeda Pharmaceutical Company Limited)	1/1		Kentaro Hayashi	
6 15:40~ 16:30	Goshi Murakami Director, Production Technology, Toyama Technology Center, Astellas Pharma Tech Co., Ltd.  Apprication and Manufacturing process development and quality assurance of SAKIGAKE Designation products, Xospata Tablets 40 mg.			Manager, Formulation Development/Production Technology Department Shionogi Pharma Co., Ltd.  [Adaption of Continuous Manufacturing in Shionogi Pharma]	
	Christoph Wabel Remote Session 09:30 (Germany)	П		Closing Remarks	
7 16:30~ 17:20	Director / Team Leader, Process Management, Product and Process Development Pfizer Manufacturing Deutschland GmbH 『Continuous Manufacturing of Solid Oral Dosage Forms - From Development to Production』	-		Etsuo Yonemochi, Steering Committee & Advisory Committee Members New Pharmaceutical Technology and Engineering Institute (Hoshi University)	
-				*Program may be subject to change	