



25th PDA Japan Annual Meeting 2018

Continued Developments in GxP

November 27-28, 2018

Tower Hall Finabori

[1st day] November 27 9:55-17:10

	Room 1 5F Main Hall	Room 2 2F Zuiunn	Room 3 2F Heiann	Room 4 2F Fukuju	Room 5 2F Tougenn
9:55 – 10:00	Opening Remarks : Main Hall				
10:00 - 10:30	PDA Japan Chapter Presidential Address: Main Hall Quality Assurance of Drug Substances and Selection of Starting Materials:Q11Q&A				
10:30 - 11:30	Invited Lecture 1 : Main Hall Continuous manufacturing (working title) Pharmaceuticals and Medical Devices Agency				
11:30 - 11:40	intermission				
11:40 - 12:40	-	Luncheon A	Luncheon B	Luncheon C	Luncheon D
12:40 - 14:00	Exhibition (Refreshment service)				
14:00 - 15:20	Committee session 1 <u>Sterile Product GMP Committee</u>	Committee session 2 <u>Biovirus Committee</u>	Committee session 3 <u>Technology & Education Committee</u>	Committee session 4 <u>ER-ES Committee</u>	Committee session 5 <u>Development QA Committee</u>
	The Consideration for the Current Regulatory Requirements	Current task of manufacturing and quality control for biopharmaceuticals	The Case study of the risk assessments based on QbD approach for Sakuramiru drug substance	Investigation for the new technology factors which contribute to maintain the data integrity	Opportunities for CMC/ GMP throughout product lifecycle following the latest trends
15:20 - 15:50	Coffee break (5F Lobby)				
15:50 - 17:10	Committee session 6 <u>QAQC Committee</u>	N/A	Committee session 7 <u>Medical Device Committee</u>	Committee session 8 <u>API GMP Committee</u>	
	Remaining issues for implementation of Japanese GDP guideline and its solutions		The progress of standard, quality culture and distribution of Medical Products	The Approaches of Cleaning Validation (API) at Each Stage of Product Life Cycle	
17:10 - 17:30	intermission				
17:30 – 19:00	-	reception party	-	-	-

Reception party 17:30-19:00 2F Zuiunn

Luncheon Seminar A:
Luncheon Seminar B:
Luncheon Seminar C:
Luncheon Seminar D:



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[2nd day] November 28 9:00-16:20

	Room 1 5F Main Hall	Room 2 2F Zuiunn	Room 3 2F Heiann	Room 4 2F Fukuju	Room 5 2F Tougenn
9:00 - 9:30	Special Lecture 1 : Main Hall Current Issues in Pharmaceutical Manufacturing - A Global PDA Perspective - Richard M. Johnson (PDA President/CEO)				
9:30 - 10:30	Special Lecture 2 : Main Hall Emerging technology: A key enabler for modernizing pharmaceutical manufacturing and advancing product quality Thomas O'Connor (US Food and Drug Administration Senior Chemical Engineer, Division of Product Quality Research, Office of Testing and Research Member of Emerging Technology Team)				
10:30 - 10:40	intermission				
10:40 - 12:00	Committee session 6 <u>QAQC Committee</u> Remaining issues for implementation of Japanese GDP guideline and its solutions	Committee session 3 <u>Technology & Education Committee</u> The Case study of the risk assessments based on QbD approach for Sakuramiru drug substance	Committee session 7 <u>Medical Device Committee</u> The progress of standard, quality culture and distribution of Medical Products	Committee session 2 <u>Biovirus Committee</u> Current task of manufacturing and quality control for biopharmaceuticals	Committee session 4 <u>ER-ES Committee</u> Investigation for the new technology factors which contribute to maintain the data integrity
12:00 - 12:10	intermission				
12:10 - 13:10	-	Luncheon E	Luncheon F	Luncheon G	Luncheon H
13:10 - 13:20	intermission				
13:20 - 14:40	Committee session 1 <u>Sterile Product GMP Committee</u> The Consideration for the Current Regulatory Requirements	Committee session 8 <u>API GMP Committee</u> The Approaches of Cleaning Validation (API) at Each Stage of Product Life Cycle	Committee session 9 <u>PDA Training Committee</u>	Committee session 5 <u>Development QA Committee</u> Opportunities for CMC/ GMP throughout product lifecycle following the latest trends	
14:40 - 15:10	Coffee break (5F Lobby)				
15:10 - 16:10	Invited Lecture 2 : Main Hall GMP amendment (Ministry of health, Labor and Welfare)				
16:10 - 16:20	Closing Remarks	-	-	-	-

Luncheon Seminar E:

Luncheon Seminar F:

Luncheon Seminar G:

Luncheon Seminar H: