

17-Sep-25

	Title	Time	Lecturer	Moderator
Opening	Opening remarks	9:20-9:30	Mr. Eiji Watanabe(PDA Japan Chapter)	
SessionA:Educational Lecture :Issues on ICHQ2(R2)/Q14 and Examples of biopharmaceutucals				
A-1	Issues on ICH Q2(R2)/Q14 and examples of biopharmaceutucals	9:30-10:30	Dr.Hiroko Shibata, Dr.Akiko Ishii-Watabe (National Institute of Health Sciences)	Ms. Michiyo Morikawa(CM Plus)
Exhibitors' presentations		10:30-10:45	Half of exhibitors	
Exhibition break		10:45-11:15		
SessionB : Points to consider in combination product development.				
B-1	Next-Generation Autoinjectors - Balancing the needs of Patients, Pharma, Payers, and Planet	11:15-11:55	Mr.Takuya Matsui (Cambridge Consultants)	Mr. Shuichi Hatano (Shionogi & Co., Ltd.)
Lunch (luncheon seminar)		12:00-12:40		
Exhibition break		12:40-13:30		
Session C: Design and development of transpulmonary formulations.				
C-1	Utilization of Simulation in the Development of Inhalation Devices	13:30-14:10	Mr.Masaki Fukushima (zenius)	Mr.Shiuhei Mieda (Daiichi Sankyo Co.Ltd.)
C-2	Key Considerations When Repositioning from Parenteral to Inhaled Drug Administration	14:10-14:50	Dr.Geraldine Venthoye (Phillips Medisize)	Mr.Shiuhei Mieda (Daiichi Sankyo Co.Ltd.)
Exhibitors' presentations		14:50-15:05	Half of exhibitors	
Exhibition break		15:05-15:30		
Session D: Key points related to the design of manufacturing and quality control processes.				
D-1	Approach to developing an efficient tangential flow filtration (TFF) process	15:30-16:10	Taichi Hanada(Merck)	
D-2	Ensuring Sterility: Container Closure Integrity Testing in the Era of EU GMP Annex 1	16:10-16:50	Ms.Leoni Ransmann(Syntegon Technology)	
Session E: Development of combination products				
E-1	Developing Combination Products: Aligning Regulatory Compliance with Business Expectations (Pre-recorded lectures)	16:50-17:30	Mr.Frank Bamberg(CSL Behring)	Ms. Brigitte Reutter-Haerle(Vetter Pharma)
Mixer		17:30-19:30		

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Session F: Risk management of combination products				
F-1	Holistic Control Strategy for Combination Products' Performances and Risks: A Hierarchical Model Based on PDA Technical Report 54-5	9:00-9:40	Dr. Kazuya Iki (Kyowa Kirin)	Mr. Shuichi Hatano (Shionogi & Co., Ltd.)
Session G: Dosing system design.				
G-1	Challenges and solutions in prefilled syringe development of ophthalmic drugs	9:40-10:20	Mr. Katsuyuki Takeuchi (Terumo)	Ms. Michiyo Morikawa(CM Plus)
Exhibition break		10:20-10:50		
G-2	Advancing Drug Delivery: Enhancing Safety and Usability with Innovative Luer Lock Syringe Closure Systems	10:50-11:30	Mr. Tobias Nemeth (Vetter Pharma)	Mr. Hiroaki Suzuki(Vetter Pharma)
G-3	"Supporting the large-volume subcutaneous trend: Development of a large-volume pre-fillable syringe for auto-injector use"	11:30-12:10	Ms. Cristina Schitco (SCHOTT Pharma)	Mr. Hiroaki Suzuki(Vetter Pharma)
Lunch (luncheon seminar)		12:15-12:55		
Exhibition break		12:55-13:40		
G-4	INTEGRATED COMBINATION PRODUCT DEVELOPMENT: HOW TO DERISK YOUR WAY TO MARKET	13:40-14:20	Mr. Stefano Pilati (Stevanato Group)、Additional speakers (currently being selected by medical device	Mr.Tomohiko Tsurumaru (Solventum)
Session H: Manufacturing environmental management, in-process inspections				
H-1	Real-world challenges – and solutions – for the use of biofluorescent particle counters in Grade A aseptic filling applications	14:20-15:00	Mr. Manny Khera (Cytiva)	Mr.Tomohiko Tsurumaru (Solventum)
Exhibition break		15:00-15:30	展示休憩	
Session I: Trends and future developments in self-administration devices				
I-1	From Pipeline to Patient: Strategic Planning and Implementation of Self-Injection Devices	15:30-16:10	Mr. Orfeo Niedermann (YPSOMED)	Mr. Kazuhisa Matsunaga (Astellas Pharma)
I-2	Self-Injection Devices in Europe and the U.S.: Development Trends and Strategic Market Insights	16:10-16:50	Dr. Mitsuru Takahashi (Nippon Becton Dickison)	Mr. Kazuhisa Matsunaga (Astellas Pharma)
Session J: Q&A and panel discussion				
J-1	Q&A and Panel Discussion	17:00-18:00	Mr. Eiji Watanabe(PDA Japan Chapter)	
	Closing	18:00-18:10	Mr. Eiji Watanabe(PDA Japan Chapter)	