

10-Sep-24				
	Title	Time	Lecturer	Moderator
Opening	Opening remarks	9:30-9:40	Mr. Eiji Watanabe(PDA Japan Chapter)	
Session A Product Development (Formulation Design)				
A-1	Comprehensive countermeasures to reduce proteinaceous visible particles (VP) in liquid monoclonal antibody products	9:40-10:20	Mr. Hitoshi Sasaki (CHUGAI PHARMACEUTICAL)	Mr. Hiroaki Suzuki(Vetter Pharma)
Exhibition break		10:20-10:50		
A-2	Autoinjectors, Obesity, and Cardiometabolic Diseases: Development of Human Soft Tissue Simulation and Physical Test Models to Study Autoinjector Activation Performance	10:50-11:30	Dr. Eric Linvill (SHL Medical)	Mr. Hiroaki Suzuki(Vetter Pharma)
Session B: Educational Lectures: Case studies of new medical device development				
B-1	Development of novel cardiovascular surgical patch - New options for surgical operation for congenital heart diseases -	11:30-12:10	Mr. Kentaro Fujinaga(Teijin)	Ms. Michiyo Morikawa(CM Plus)
Lunch & Exhibition		12:10-13:10		
Session C: Human Factors Engineering				
C-1	Human engineering in autoinjectors	13:10-13:50	Mr. Nemoto Hajime(zenius) Dr. Takeshi AKIYAMA(SIGMAXYZ)	Mr.Tomohiko Tsurumaru (Solventum)
C-2	Connecting Usability and Meaningfulness: Enhancing Device Development to Best Serve the End User	13:50-14:30	Ms. Amanda Tilles, Mr. Paul Erik Fabricius (Phillips Medisize)	Mr.Tomohiko Tsurumaru (Solventum)
Exhibition break		14:30-15:00		
Session D: Components of Combination Products				
D-1	Defining Attributes for Optimum Performance of Prefilled Syringe Systems	15:00-15:40	Ms. Ashwini Bhisikar (Datwyler)	Mr.Paolo Golfett (Stevanato Group)
D-2	Development of a pre-fillable syringe for biologics application with focus on the auto-injector use	15:40-16:20	Dr. Cristina Schitco(SCHOTT Pharma)	Mr.Paolo Golfett (Stevanato Group)
D-3	How a CDMO can support Pharma Partners in Primary Packaging components selection:	16:20-17:00	Ms. Vincenza Pironi (Recipharm)	Mr.Paolo Golfett (Stevanato Group)
Mixer		17:10-19:10		

11-Sep-24				
	Title	Time	Lecturer	Moderator
Session E: Regulatory Trends for Combination Products				
E-1	TR 73-2 Application of EU Medical Device Regulation to Prefilled Syringes.	9:00-9:40	Mr. Daniel Martinez (Stevanato Group)	Mr.Kenta Goto (Takeda Pharmaceutical Company Ltd.)
E-2	Digital Health for injectable treatments – success stories – and regulatory environment	9:40-10:20	Mr. Orfeo Niedermann(Ypsomed)	Mr.Kenta Goto (Takeda Pharmaceutical Company Ltd.)
Exhibition break		10:20-10:50		
E-3	Global regulatory policy landscape for combination products impacting pre-filled syringes and advanced injection devices((Pre-recorded Lecture)	10:50-11:30	Mr. Sujith Kallur(Becton Dickinson and Company)	Mr. Shuichi Hatano (Shionogi & Co., Ltd.)
Session F: Sustainability				
F-1	Improving Integration of Sustainable design principles into combination product development	11:30-12:10	Mr. Takuya Matsui(Cambridge Consultants)	Mr. Shuichi Hatano (Shionogi & Co., Ltd.)
Lunch & Exhibition		12:10-13:10		
Session G: Manufacturing environment management, in-process inspection				
G-1	Contamination Control Strategy – A holistic approach to achieve microbial “no growth”	13:10-13:50	Dr. Helen Sauter(Vetter Pharma)	Ms. Brigitte Reutter-Haerle(Vetter Pharma)
G-2	Practical Approaches within Automated Visual Inspection to manage Difficult-to-Inspect Parenterals (DIP) and meet Container Closed Integrity (CCI) Requirements	13:50-14:30	Dr. Takaya Uno(Syntegon Technology)	Mr.Shiuhei Mieda (Daiichi Sankyo Co.Ltd.)
G-3	Approach to developing an efficient redundant filtration process	14:30-15:10	Mr. Taichi Hanada (Merck)	Mr.Shiuhei Mieda (Daiichi Sankyo Co.Ltd.)
Exhibition break		15:10-15:40		
Session H: Patient Medication Adherence				
H-1	Trends in Improving Patient drug adherence.	15:40-16:20	Dr. Hideyasu Fujiwara (Nippon Becton Dickinson)	Ms.Yu Kishi(Janssen Pharmaceutical K.K.)
Session I: Clinical Development of Combination Products (Pre-recorded Lecture)				
I-1	PFS, decentralized clinical trials, and the future of drug development	16:20-17:00	Mr. Timothy Pang (Citeline/Evaluate Pharma)	Ms.Yu Kishi(Janssen Pharmaceutical K.K.)
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	Closing remarks	18:00-18:10	Mr. Eiji Watanabe(PDA Japan Chapter)	