

Conference Team : Combination Products -Safer, more Effective, and more Convenient-

13-Sep-22				
	Title	Time	Lecturer	Moderator
Opening	Opening remarks	9:00-9:10	Mr. Eiji Watanabe (PDA Japan Chapter)	
Session A Quality assurance for biopharmaceuticals				
A-1	Invited educational lecture: Evaluation of protein aggregates/insoluble particulate matters in prefilled syringe products	9:10-10::10	Dr. Hiroko Shibata (National Institute of Health Sciences)	Ms. Morikawa Michiyo (Terumo)
Session B Risk management of combination products.				
B-1	Risk management of combination products.	10:10-10:50	J-PDA Medical Device Committee.	Ms. Morikawa Michiyo (Terumo)
Exhibition break				
B-2	Case Study "Design for Impulsive Stress Conditions": how could you decrease the risk of failure in spring-actuated auto-injector?	10:50-11:30		
B-2	Case Study "Design for Impulsive Stress Conditions": how could you decrease the risk of failure in spring-actuated auto-injector?	11:30-12:10	Mr. Enrico Barichello (Stevanato Group)	Mr. Tetsuro Odaka(Kyowa Krin)
Lunch & Exhibition				
B-3	Manufacturing process monitoring utilized by crystal piezoelectricsensors.	12:10-13:10		
B-3	Manufacturing process monitoring utilized by crystal piezoelectricsensors.	13:10-13:50	Mr. Yasushi Wakebe(Kistler Japan G.K.)	Mr. Tetsuro Odaka(Kyowa Krin)
Session C: Storage and transport at low temperatures.				
C-1	(Ultra) Low Temperature Performance of COC Polymer Prefillable Syringes	13:50-14:30	Mr. Michael Weber(SCHOTT AG)	Mr. Takuro Kaya(Hirabara engineering Service)
C-2	Thermal packaging solutions for deep frozen shipments	14:30-15:10	Ms. Kristina Kletzel (Va-Q-Tec)	Mr. Takuro Kaya(Hirabara engineering Service)
Exhibition break				
Session D: Examples of pen/autoinjector development				
D-1	Case study: Autoinjector Assembling and Control Processes	15:50-16:30	Ms. Susanne Hall(Vetter Pharma)	Ms. Brigitte Reutter-Haerle(Vetter Pharma)
D-2	Development of customized autoinjector combination products based on platform products – Case study examples	16:30-17:10	Mr.Orfeo Niedermann(Ypsomed AG)	Ms. Brigitte Reutter-Haerle(Vetter Pharma)
Session E: Connected Device systems and sustainability				
E-1	SMART Drug Delivery technologies enables patients safer and more convenient	17:10-17:50	Mr.Koichi Muramoto(Phillips-Medisize / Molex Japan LLC)	Mr. Shuichi Hatano (Shionogi & Co., Ltd.)
14-Sep-22				
	Title	Time	Lecturer	
Session F: Product development for Asia-Pacific region.				
F-1	DMF system in China Application procedures for pre-filled syringes	9:00-9:40	Mr. Katsuaki Kojima(WORLDWIDE INTELLECTUAL PROPERTY CONSULTING JAPAN CO., LTD)	Mr.Kenta Goto (Takeda Pharmaceutical Company Ltd.)
F-2	Comparative insights into the diabetes self-injection therapy in APAC	9:40-10:20	Mr. Chun Chang(SHL Medical)	Mr.Kenta Goto (Takeda Pharmaceutical Company Ltd.)
Exhibition break				
Session G: Cybersecurity regulation and Human Factors Engineering for Combination Products				
G-1	Regulatory trends for the medical device cybersecurity	11:00-11:40	Mr. Gen Murase(UL Japan)	Mr. Tomohiko Tsurumaru (3M Japan)
G-2	Human Factors Engineering in Combination Product Development. -Practical methodologies common to the global market.	11:40-12:20	Dr. Yanoura Nomane (Becton Dickinson)	Mr. Tomohiko Tsurumaru (3M Japan)
Lunch & Exhibition				
Session H: Innovation in combination products				
H-1	Tentative title: A novel design to make prefilled syringes safer, user friendly and compliant	13:20-14:00	Mr. Rajeev Kabbur (Brevetti Angela)	Ms.Yu Kishi(Janssen Pharmaceutical K.K.)
H-2	Powder dosage in double-chamber syringes	14:00-14:40	Mr. Joan Mele Vidal (Dara Pharmaceutical Equipment)	Ms.Yu Kishi(Janssen Pharmaceutical K.K.)
Exhibition break				
Session I: Robot technology in aseptic filling processes.				
I- 1	How pharma robots can make aseptic fill and finish safer more effective and more convenient	15:20-16:00	Mr. Felix Mausolf (groninger & Co. GmbH)	Mr. Shuichi Hatano (Shionogi & Co., Ltd.)
Session J: Syringe and pen development case studies				
J-1	Considerations in Combination Product Development Derived from the Experience in Developing our Adalimumab Biosimilar Products	16:00-16:40	Mr. Akihiro Kumagai(FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.)	Mr. Shuichi Hatano (Shionogi & Co., Ltd.)
Session K : Panel discussion				
K	Panel discussion (answers to pre-questions and discussions)	16:40-17:30		

Closing

17:30