

Day 1 Theme : Quality Assurance of Combination Products

1日目		Title	Time	Lecturer	Modelator
		Opening	9:15-9:20	Mr. Eiji Watanabe (terumo)	
Session ThemeA : Latest trends of Endotoxin					
①	A-1	Notes on endotoxin test	9:20-10:10	Dr. Yuji Haishima (Director of Medical devices,Nihs)	J P D A Chairperson Dr. Katsuhide Terada
②	A-2	Low Endotoxin Recovery	10:10-11:00	Dr. Johannes Reich (Microcoat Biotechnologie GmbH)	J P D A Chairperson Dr. Katsuhide Terada
Coffee Break			11:00-11:30		
Session ThemeB : Required Characteristic of Combination Products					
③	B-1	Changing FDA Requirements for Extractables & Leachables Testing on Pharmaceutical Packaging Systems	11:30-12:20	Piet Christiaens(Nelson Labs)	Dr. Georg Roessling(EU-PDA)
		Lunch	12:20-13:20		
④	B-2	Testing of primary packaging and devices	13:20-14:10	Erik Berndt(Zwick)	Dr. Georg Roessling(EU-PDA)
Session ThemeC : Container Materials of Combination Products					
⑤	C-1	Design, Quality and performance considerations of cartridge-based solutions	14:10-15:00	Daniel Martinez(Ompi)	Mr. Gabriele Peron(Ompi)
⑥	C-2	Dymax Pre-filled Syringe Adhesive Solution	15:00-15:50	Michelle Evanoski (Dymax Corporation)	Mr. Gabriele Peron(Ompi)
Coffee Break			15:50-16:20		
Session ThemeD : Temporary: Difference in manufacturing process of glass PFS and plastic PFS					
⑦	D-1	Temporary: Points to note when designing the syringe line as seen from the production equipment manufacturer	16:20-17:10	TAKUETSU OISHI(K.T.MFG.CO.,LTD.)	Mr. Hiromasa Ookawa(Nipro)
Session ThemeE : Usability of Combination Products					
⑧	E-1	Usability standards that Japanese, US and European regulatory agencies require compliance as regulatory requirements	17:10-18:00	Eiji Oshida(TÜV Rheinland Japan Ltd)	Mr. Hiromasa Ookawa(Nipro)

Day 2 Theme : Regulatory Trends and Case Studies of Combination Products

2日目		内容	Time	Lecturer	
Session ThemeF : Regulatory Trends and Responsies of Combination Products					
①	F-1	Regulation of Drugs, Medical Devices and Drug Device Combinations	9:00-10:30	Dr. Manfred Maeder(Novartis)	Ms. Brigitte.Reutter-Haerle (Vetter)
Coffee Break		(Poster Session Start)	10:30-11:00		
②	F-2	" Launching combination products for the global markets: Case studies on several pre-filled dosage forms and injection devices following relevant guidelines"	11:00-11:50	Dr. Tillman Burghardt (Vetter)	Ms. Brigitte.Reutter-Haerle (Vetter)
Lunch & Postar session			11:50-13:00		
Session ThemeG : Case Studies of User Responsies (Patients,user,etc)					
③	G-1	Enabling Hospital to Home care and improving patient adherence in Chronic disease segments with Innovative Solutions.	13:00-13:50	Fabien Dubuc(BD)	Ms. Michiyo Morikawa (Terumo)
④	G-2	About patient-compliant device (accidental card prevention, sticking mechanism etc.)	13:50-14:40	Toshikazu Hirayama (Nipro Corp.)	Ms. Michiyo Morikawa (Terumo)
Coffee Break		ポスター	14:40-15:10		
Session ThemeH : IT Application of Combination Products					
⑤	H-1	Patient-centered development of connected, digital autoinjectors and its potential to improve therapy outcomes	15:10-16:00	Mr. Orfeo Niedermann (Ypsomed)	Mr.Shuichi Hatano(Shionogi) Dr. Hiroaki Nakano (Sumitomo Rubber)
⑥	H-2	Digital medicine relationship (program administration device: Medisafe with)	16:00-16:50	Mr. Jouji Uchiyama (Terumo Corp.)	Mr.Shuichi Hatano(Shionogi) Dr. Hiroaki Nakano (Sumitomo Rubber)
⑦	H-3	Commercial Success of 3rd Generation Digital Auto-Injector :Consideration for Commercialization, Sustainability and Environmental Impact	16:50-17:40	Mr. Takashi Hanada (JCR Corp.) Mr. Takayuki Makise(PHC Corp.)	Mr.Shuichi Hatano(Shionogi) Dr. Hiroaki Nakano (Sumitomo Rubber)
		panel discussion	17:45-18:30		Mr. Eiji Watanabe(Terumo)