

Conference Team :What are required to deliver combination products to medical front

14-Sep-21

1 日目	Title	Time	Lecturer	Moderator
Opening	Opening remarks	9:00-9:10	Mr. Eiji Watanabe	
Session A: Latest regulatory status				
A-1	Invited Lecture: Japanese medical device regulations as seen from prefilled syringes	9:10-9:50	Mr. Katsunori Ishiguro (JAAME)	Ms. Michiyo Morikawa(Terumo)
A-2	(Tentative) Update- Regulations in Biosimilar Combination Drug Development-Focusing on US FDA Cases	9:50-10:30	Dr.Alison BASCOU (BECTON DICKINSON)	
Exhibition break		10:30-11:20		
Session B: Aseptic operation & sterilization technology				
B-1	Qualification of X-ray Sterilization for Single-Use Bioprocess Equipment: A Coordinated Industry Approach to Ensure Business Continuity	11:20-12:00	Dr. James Hathcock (Pall Biotech)	
Lunch & Exhibition		12:00-13:00		
B-2	How to Manage the ring of concern of Rapid Transfer Systems.	13:00-13:40	Mr. Thierry GIRARD (ABC TRANSFER)	
B-3	PERFORMANCE OF NEW 5th GENERATION PFS	13:40-14:20	Mr. Rajeev Kabbur (Brevetti Angela)	
Exhibition break		14:20-15:10		
Session C: Freeze-drying technology and its applications				
C-1	Latest developments in the field of pharmaceutical freeze drying	15:10-15:50	Dr. Benjamin Ledermann(GEA Lyophil)	
C-2	"Development of a drug product in a dual chamber 2 system: things to consider and lessons learnt"	15:50-16:30	Dr. Markus Neumeier (Vetter Pharma-Fertigung GmbH & Co. KG)	
Session D: What's New in Europe				
D	Voice From EU	16:30-17:30	Dr.Georg Roesslong (PDA Europe)	Mr. Tomohiko Tsurumaru(3M)

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2 日目	内容	時間	演者	
Session E: What's New in the United States				
E	Voice From US : Recent Trend of Injectable Combination Product Development In US	9:00-9:50	Dr. Amy Wang(Alexion US)	Mr. Kenta Goto(Jhonson & Jhonson)
Session F: Physical test for combination products				
F-1	Reliable test results guarantee high quality of Primary Packaging and Devices	9:50-10:30	Mr. Erik Berndt, Mr. Peter Schmidt (ZwickRoell)	
Exhibition break		10:30-11:20		
Session G: Dosage design				
G-1	Integrated capabilities from Design to final Device Assembly: early considerations for an emergency use auto-injector	11:20-12:00	Mr. Paolo Golfetto (Stevano)	
Lunch & Exhibition		12:00-13:00		
G-2	Bringing a high Volume PFS Immuglobulin Drug Successfully to the Market	13:00-13:40	Frank Bamberg(CSL Behring) & Tom van Ginneken (SCHOTT)	
G-1	Key points in the development of combination products through intradermal injection device (Immucise®) and future development trends	13:40-14:20	Dr. Yoichiro Iwase(Terumo)	Mr. Hiroaki Suzuki(Vette Pharma)
Exhibition break		14:20-15:10		
Session H: Container integrity in ultra cold environments				
H-1	Container closure integrity of syringes stored and shipped at ultra cold temperatures	15:10-15:50	Dr. James Veale (Lighthouse)	
Session I: From development to market response in antibody medicine				
I-1	Development of injection device for antibody drug	15:50-16:30	Mr. Yoshiya Minakami (Chugai pharmaceutical)	Mr. Shuichi Hatano(Shionogi Pharma)
Session J:Panel discussion				
J	Panel discussion (answers to pre-questions and discussions)	16:30-17:30	Mr. Gabrielle Peron(Stevano Group) Ms. Brigitte Reuter-Haurle(Vetter Pharma)	Mr. Eiji Watanabe(PDA Japan Chapter)