

Symposium on "PIC/S Annex 1 and Relevant GMP Inspections"

Saturday, November 16, 2019

@ Iino Hall

MC: Dr. Kotoe Ota

Clock Time	Time Required	Session Title	Chair/Speaker/Panelist
13:00 ▶ 13:05	5	Opening Remarks	Mr. Toru Tanaka (JPN-MHLW)
13:05 ▶ 14:50	105	Presentations	
13:05 ▶ 13:45	45	- Summary of Revising PIC/S GMP Annex 1 - (from UK and France regulators)	1. Ms. Tracy Moore (UK-MHRA) 2. Mr. Abdelaali Sarakha (FR-ANSM)
13:50 ▶ 14:50	60	- Example of observation and inspection points for sterile products - (from US, Europe, and Japan regulators)	1. Ms. Ileana Barretto-Pettit (US-FDA) 2. Mr. Abdelaali Sarakha (FR-ANSM) 3. Ms. Tracy Moore (UK-MHRA) 4. Mr. Tetsuhito Takarada (JPN-PMDA)
14:50 ▶ 15:05	15	< Break (Photo) >	
15:05 ▶ 16:55	110	Panel Discussion	Chairs: Dr. Kevin O'Donnell (IRL-HPRA) Mr. Yuji Moriyama (JPN-JPMA)
15:05 ▶ 16:15	70	GMP Inspection Overview of Each Country From; UK/France/ US/ Russia/ Brasil/ Japan/ Saudi Arabia	1. Ms. Tracy Moore (UK-MHRA) 2. Mr. Abdelaali Sarakha (FR-ANSM) 3. Ms. Ileana Barretto-Pettit (US-FDA) 4. Ms. Elena Denisova (RUS-MIT) 5. Ms. Tatiana Nikolko (RUS-SID&GP) 6. Ms. Andrea Geyer (BRA-ANVISA) 7. Mr. Tetsuhito Takarada (JPN-PMDA) 8. Mr. Mohammed Ali Dahhas (SAU-SFDA)
16:15 ▶ 16:55	40	Questions & Answers	With all participants and floor
16:55 ▶ 17:00	5	Closing Remarks	Mr. Ryutaro Suzuki (JPN-JPMA)