2018 Taiwan-ASEAN Drug Regulatory Symposium

Regulations on Biologics, Biosimilars and Vaccines

Date: September 5th, 2018 (Wednesday)
Venue: GIS NTU Convention Center 台大集思會議中心：國際會議廳

Time	Agenda Item	Speaker
08:10-08:40	Registration	
08:40-08:50	Opening Remarks	• **Shou-Mei Wu** Director-General, Taiwan FDA
08:50-09:00	Memorial Photo Taking	
Session 1: Keynote Moderator: Jo-Feng Chi Deputy Director of Division of Medicinal Products, Taiwan FDA		
09:00-09:50	Back to the Future-from Cowpox to Recombinant DNA Vaccines for Dengue; Are You Ready for the Challenges that Lie Ahead?	• **Michael D. Malison** Adjunct Professor, Department of Global Health, Rollins School of Public Health, Emory University
09:50-10:00	Q&A	
10:00-10:45	***(Video)*** Perspectives on Current Quality Issues for Biologicals	• **Ragini Shivji** Scientific Administrator, Quality and Specialised Scientific Disciplines Department, European Medicines Agency (EMA)
10:45-11:00	Coffee Break	
Session 2: Experience Sharing of Asia Pacific Pharmaceutical Science Regulation Moderator: Po-Wen Yang Associate Researcher of Division of Medical Products, Taiwan FDA		
11:00-11:30	The Biological Products Registration Requirements of Thailand	• **Morakot Papassiripan** Senior Pharmacist, Professional Level Biological Product Sub-division Bureau of Drug Control, Thai FDA

11:30-12:00	Role of NADFC to Ensuring the Quality of Vaccines and Biotechnology Products	• **Desi Eka Putri** Section Head, Biological Product Registration, Directorate of Drug Registration, NADFC
12:00-12:15	Q&A	
12:15-13:15	Lunch	
13:15-13:45	The Malaysian Perspective on Biologics Regulation	• **Noraisyah Mohd Sani** Head of Biologics Section, NPRA
13:45-14:15	Vaccine Registration in Vietnam	• **Le Thi Tuyet Lan** Drug Registration Division Officer, DAV
14:15-14:45	Registration of Vaccine Products in the Philippines	• **Justin Jerome C. De Jesus.** Food-Drug Regulation Officer III, Philippine FDA
14:45-15:05	Coffee Break	
15:05-15:35	Biologics Registration in Thailand in the Era of Biosimilars	• **Wisit Tangkeangsirisin** Assistant Professor, Department of Biopharmacy, Silpakorn University
15:35-16:05	Lot Release System in Malaysia	• **Zarina Rosli** Head of Biopharmaceutical Testing Section, NPRA
16:05-16:35	Regulation – Drugs and Cosmetics Act 1940 and Rule 1945	• **Naresh Sharma** Deputy Drugs Controller (India), Central Drugs Standard Control Organisation, DGHS, MoHFW
16:35-17:00	Q&A	
Session 3: Experience Sharing of Taiwan Pharmaceutical Science Regulation Moderator: Hui-Ping Chang Section Chief, Division of Medical Products, Taiwan FDA		
17:00-17:20	The Regulatory Perspective for Biosimilar in Taiwan	• **Fong-Chun Huang** Reviewer, Center of Consultation CDE, Taiwan

17:20-17:25	Q&A	
17:25-17:30	**Closing Remarks**	• **Jo-Feng Chi** Deputy Director of Division of Medicinal Products, Taiwan FDA