2018.4.9

2018 Joint New Drug-GBO WG Meeting of Taiwan and Japan: Regulatory Update for New Drug Application and Bioequivalence Studies

Agenda

Date： MAY 8, 2018

Venue：CHANG YUNG-FA FOUNDATION International Convention Center Rm801

Interpreter: Japanese-Chinese interpreter

Tuesday, May 8, 2018		
Time	**Topic**	**Speaker**
08:30-09:00	**Registration**	
09:00-09:20	**Opening Remarks**	• **Shou-Mei Wu** *Director General, TFDA* • **Fumi Yamamoto** *Division Director, MHLW* • **Wei-Jen Chen** *President, TPMA*
09:20-09:30	**Memorial photo taking**	
Session 1: Introduction		
09:30-09:50	• **Summary of 2017 Joint Conference of Taiwan and Japan on Medicinal Product: Issues on New Drug WG and GBO WG**	• **Chao-Yi Wang** *Director, Division of Medicinal Product, TFDA*
Session 2: Regulations and Evaluation on Innovative New Drugs and Efforts for patient's faster access to Innovative Drugs Moderator: **Naoyuki Yasuda** *(Office Director, Office of International Programs, PMDA)* and **Chao-Yi Wang** *(Director, Division of Medicinal Product, TFDA)*		
09:50-10:10	• **Recent updates for Sakigake Strategy and regulatory policy for promoting Innovative Drugs in Japan**	• **Fumi Yamamoto** *Division Director, MHLW*
10:10-10:30	• **TFDA's recent regulatory updates for Innovative Drugs**	• **Lien-Cheng Chang** *Section Chief, Division of Medicinal Products, TFDA*
10:30-10:50	**Coffee Break**	
10:50-11:10	• **Role and expectation of pharmaceutical industry for patient's faster access to Innovative Drugs – JPMA Challenge through APAC**	• **Hiroyuki Okuzawa** *Corporate Officer, President of ASCA Company, Daiichi Sankyo*

11:10-11:30	• **Role and expectation of pharmaceutical industry for patient's faster access to Innovative Drugs**	• **Hong-Jen Chang** *Chairman & CEO, YFY Biotech Management Company*
11:30-12:00	**Q & A for Session 2**	• **All Session 2 Speakers**
12:00-13:00	**Lunch**	
Session3: Strategy for promoting Generic Drugs and Regulations on Bioequivalence Studies utilizing Foreign Subjects Moderator: **Naoyuki Yasuda** *(Office Director, Office of International Programs, PMDA)* and **Hui-Ping Chang** *(Section Chief, Section of Clinical Trial Management, TFDA)*		
13:00-13:30	• **Strategy for promoting the use of Generic Drugs and Regulations of Review Processes on Bioequivalence Studies in Japan**	• **Taku Oohara** *Deputy Director, Division of Pharmaceutical Evaluation Division, MHLW*
13:30-14:00	• **Introduction of Consultation System for Bioequivalence Studies and its review consideration in Japan**	• **Toru Yamaguchi** *Reviewer Pharmacist, Office of Generic Drugs, PMDA*
14:00-14:30	**Coffee Break**	
14:30-15:00	• **Bioequivalence Studies in Taiwan: Regulations and Review Processes**	• **Wen-Yi Hung** *Reviewer, Division of Medicinal Products, TFDA*
15:00-15:20	• **Experience Sharing on Submitting Generic Drug Registrations (including BE Studies) in Japan**	• **Meng-Kai Kuo** *Director, Business Development, PeiLi Pharm*
15:20-15:50	**Q & A for session 3**	**All Session 3 Speakers**
15:50-16:00	**Closing Remarks**	• **Naoyuki Yasuda** *Office Director, Office of International Programs, PMDA* • **Chao-Yi Wang** *Director, Division of Medicinal Products, TFDA*