The 7th Thailand - Japan Symposium

DATE: 13th - 14th Jan, 2021

AGENDA:

Day 1 (Wednesday, 13th Jan, 2021)

Bangkok	Tokyo	
OPENING CEREMONY		
12:30-12:40	14:30-14:40	Opening Remarks (Thai FDA, 5min) (PMDA, 5min)
12:40-12:50	14:40-14:50	Keynote Speech (10min)
PLENARY SESSION		
12:50-13:30	14:50-15:30	Regulatory Update* (Thai FDA, 20min) (PMDA, 20min) *Q&A is included in each presentation
13:30-13:45	15:30-15:45	PHOTO Session and BREAK (15min)
PHARMACEUTICAL SESSION		
13:45-14:40	15:45-16:40	Standardization of submission and review process Good Registration Practice and its Practical Action at Thai FDA (Thai FDA, 20min) Good Registration Practice and its Practical Action at PMDA (PMDA, 20min) Q&A (15min)
14:40-15:35	16:40-17:35	Scientific consultation for efficient communication with industry Scientific consultation at Thai FDA (Thai FDA, 20min) Scientific consultation for resolving issues from early stage of pharmaceutical development (PMDA, 20min) Q&A (15min)
15:35-15:45	17:35-17:45	(BREAK, 10min)
15:45-16:40	17:45-18:40	Benefit / Risk management through a product lifecycle How to manage Benefit / Risk balance of pharmaceuticals from approval review to post-marketing including risk management plan and approval condition (Thai FDA, 20min)

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		How to manage Benefit / Risk balance of pharmaceuticals from approval review to post-marketing including risk management plan and approval condition (PMDA, 20min) Q&A (15min)

Day2 (Thursday, 14th Jan, 2021)

Bangkok	Tokyo	
MEDICAL DEVICES SESSION		
9:00-9:55	11:00-11:55	Effective medical device review for fast and proper access to patients (part 1: IVD) IVD medical device review (Thai FDA, 20min) IVD medical device review (PMDA, 20min) Q&A (15min)
9:55-10:50	11:55-12:50	Effective medical device review for fast and proper access to patients (part 2: Non-IVD) Non-IVD medical device review (Thai FDA, 20min) Non-IVD medical device review (PMDA, 20min) Q&A(15min)
10:50-11:00	12:50-13:00	(BREAK, 10min)
11:00-11:55	13:00-13:55	Post-market surveillance/ medical devices vigilance from an international perspective Sharing experiences with reference to international harmonized criteria specified in GHTF/IMDRF documents and AMDD (Thai FDA, 20min) Sharing experiences with reference to international harmonized criteria specified in GHTF/IMDRF documents and AMDD (including Medical Devices vigilance inspection) (PMDA, 20min) Q&A (15min)