

7th APAC Program (Draft)

Our Mission: To expedite the launch of innovative medicines for the peoples in Asia

Tuesday, April 10, 2018

MC : A. Matsubara (JPMA)

Updated 2018.03.13

08:30 ▶ 08:40	Opening Remarks	Y Hatanaka	JPMA
08:40 ▶ 08:55	Congratulatory Speech	T Cueni/ G Perry	IFPMA
08:55 ▶ 9:40	Keynote Lecture Regulatory Science and International Harmonization (<i>tentative</i>)	T Kondo	PMDA
09:40 ▶ 10:00	< Break > (<i>Photo session</i>)		
10:00 ▶ 10:10	Introduction of the entire program	H Hirate	JPMA
10:10 ▶ 12:15	RA Session : Regulatory landscape for "Access to Innovative Medicine" in Asia		
10:10 ▶ 10:50	1 Further dissemination of GRM <ul style="list-style-type: none"> • Report 1: GRM CoE Workshop (20 min) • Report 2: Local Training (5 min x 2) • KPI to evaluate GRM implementation status (10 min) 	J Sato (Chair) YC Lin Busakorn/KC Wong H Kawaguchi	PMDA TW-FDA PRReMA/SAPI RA-EWG
10:50 ▶ 12:00	2 "Conditional Early Approval (CEA)" Systems in Asia <ul style="list-style-type: none"> • Explanation of this part (5 min) • Presentation: Introduction of "Japanese CEA" System (15 min) • Presentation: Introduction of "Malaysian CEA" System (10 min) Panel Discussion with Short Presentations Short Presentation: View on CEA systems from each economy (5 min x 4) Discussion: How to secure early access to innovative medicines, which are approved by CEA systems (20 min)	John Lim (Chair) M Shibatsuji (Co-Chair) O Inagaki M Shibatsuji Ramli SH Kim YC Lin Juliati Ramli	Duke-NUS CoRE PMDA JPMA PMDA NPRA NIFDS TW-FDA NADFC NPRA
12:00 ▶ 12:15	3 Summary (15 min)	S. Hatakeyama	JPMA
12:15 ▶ 13:15	< Lunch >		
13:15 ▶ 15:25	ATIM Session: Promoting Efficiency in GMP Review and Change Control		
13:15 ▶ 14:05	1 Site Master File (SMF) <ul style="list-style-type: none"> • Summary of the consensus at 6th APAC session, with inviting reviewers (10 min) • Comments from each reviewer and comments from the industry side (25 min) 	S Sakurai (Chair) S Sakurai Ellen C xxxxx Rumondang Suchat C Busakorn L	PMDA PMDA TW-FDA MFDS (TBD) NADFC TH-FDA PRReMA/JPMA (TBD)
14:05 ▶ 15:25	2 Post-approval Variations <ul style="list-style-type: none"> • Difference analysis in change control in Asia: from JPMA (10 min) • Presentation: Overview of Challenges in Implementing Post-Approval Variations (15 min) • Key-points of post approval variation (Regulatory Authorities in Asia) (30 min) Discussion (20 min) Summary of the discussions (5 min)	F Honda (Chair) EK Kim (Co-Chair) T Nakagawa Sannie C Ellen C EK Kim Rumondang Suchat C F Honda	PMDA NIFDS JPMA SAPI TW-FDA NIFDS NAFDC TH-FDA PMDA
15:25 ▶ 15:45	< Break >		
15:45 ▶ 17:45	DA Session: How to establish drug discovery ecosystem in Asia		
15:45 ▶ 17:25	1 Presentation (100min) <ul style="list-style-type: none"> • Opening (5 min) • Update on pillar 5 initiative "natural compound-based drug discovery" (15 min) • Presentations by 4 panelists from Asian (80 min) 	WK Chi (Chair) A Hasuoka (Co-Chair) A Hasuoka Nares D N Kohno P Wang N Nishimura CH Wu	DCB (Taiwan) JPMA JPMA TCELS (Thailand) AMED Yabao Mie Univ DCC
17:25 ▶ 17:45	2 Panel discussion & Summary (20 min) Possibility of "Drug Discovery Ecosystem in Asia" Challenges to realize "Drug Discovery Ecosystem in Asia", etc.	all presenters	
17:45 ▶ 17:55	Closing Remarks	H Naito	JPMA
18:15 ▶ 20:15	< Reception >		

TBC: To be confirmed, TBD: To be decided