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		G Perry IFPMA
08:55 ▶ 9:40	**Keynote Lecture** Regulatory Science and International Harmonization *(tentative)*		T Kondo PMDA
09:40 ▶ 10:00	< Break > *(Photo session)*		
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**		J Sato (Chair) PMDA
	・Report 1: GRM CoE Workshop	(20 min)	YC Lin TW-FDA
	・Report 2: Local Training	(5 min x 2)	Busakorn/KC Wong PReMA/SAPI
	・KPI to evaluate GRM implementation status	(10 min)	H Kawaguchi RA-EWG
10:50 ▶ 12:00	**2 "Conditional Early Approval (CEA)" Systems in Asia**		John Lim (Chair) Duke-NUS CoRE M Shibatsuji (Co-Chair) PMDA
	・Explanation of this part	(5 min)	O Inagaki JPMA
	・Presentation: Introduction of "Japanese CEA" System	(15 min)	M Shibatsuji PMDA
	・Presentation: Introduction of "Malaysian CEA" System	(10 min)	Ramli NPRA
	Panel Discussion with Short Presentations	(5 min x 4)	
	Short Presentation: View on CEA systems from each economy		SH Kim NIFDS YC Lin TW-FDA
	Discussion: How to secure early access to innovative medicines, which are approved by CEA systems	(20 min)	Juliati NADFC Ramli 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)**		S Sakurai (Chair) PMDA
	・Summary of the consensus at 6th APAC session, with inviting reviewers	(10 min)	S Sakurai PMDA
	・Comments from each reviewer and comments from the industry side	(25 min)	Ellen C TW-FDA xxxxx MFDS (TBD) Rumondang NADFC Suchat C TH-FDA
	・Comments & questions from the audience	(5 min)	Busakorn L PReMA/JPMA (TBD)
	・Conclusion (recommendation for convergence in Asia)	(10 min)	S Sakurai PMDA
14:05 ▶ 15:25	**2 Post-approval Variations**		F Honda (Chair) PMDA EK Kim (Co-Chair) NIFDS
	・Difference analysis in change control in Asia: from JPMA	(10 min)	T Nakagawa JPMA
	・Presentation: Overview of Challenges in Implementing Post-Approval Variations	(15 min)	Sannie C SAPI Ellen C TW-FDA EK Kim NIFDS Rumondang NAFDC Suchat C TH-FDA
	・Key-points of post approval variation (Regulatory Authorities in Asia)	(30 min)	
	Discussion	(20 min)	
	Summary of the discussions	(5 min)	F Honda 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)	WK Chi (Chair) DCB (Taiwan) A Hasuoka (Co-Chair) JPMA
	・Opening	(5 min)	A Hasuoka JPMA
	・Update on pillar 5 initiative "natural compound-based drug discovery"	(15 min)	Nares D TCELS (Thailand)
	・Presentations by 4 panelists from Asian	(80 min)	N Kohno AMED P Wang Yabao N Nishimura Mie Univ CH Wu 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