7th APAC Program

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

Tuesday, April 10, 2018

MC : A. Matsubara (JPMA)

08:30 ▶ 08:40	Opening Remarks	10 min	Y Hatanaka	JPMA
08:40 ▶ 08:55	Congratulatory Speech	15 min	G Perry	IFPMA
08:55 ▶ 9:40	**Keynote Lecture** *Regulatory Science and Work together for the global patients –"Rational Medicine Initiative"–*	45 min	T Kondo	PMDA
09:40 ▶ 10:00	< Break > (Photo session)	20 min		
10:00 ▶ 10:10	Introduction of the entire program	10 min	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**	**40 min**	J Sato (Chair)	PMDA
	・Report 1: GRM CoE Workshop	(20 min)	YC Lin	TW-FDA
	・Report 2: Local Training	(5 min x 2)	Busakorn L	PReMA
			KC Wong	SAPI
	・Performance Indicators to evaluate GSubP implementation status	(10 min)	H Kawaguchi	JPMA
10:50 ▶ 12:05	**2 "Conditional Early Approval (CEA)" Systems in Asia**	**75 min**	J Lim (Co-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 Z	NPRA
	・Panel Discussion with Short Presentations			
	Short Presentation: View on CEA systems from each economy	(5 min x 3)	SH Kim	NIFDS
			YC Lin	TW-FDA
	Discussion & Summary: How to secure early access to innovative medicines, which are approved by CEA systems	(30 min)	Juliati	NADFC
			Ramli Z	NPRA
12:05 ▶ 12:15	**3 Summary of RA-EWG activities in FY2017**	**10 min**	S Hatakeyama	JPMA
12:15 ▶ 13:15	< Lunch >	60 min		
13:15 ▶ 15:25	**ATIM Session: Promoting Efficiency in GMP Review and Post-approval Variations**			
13:15 ▶ 14:05	**1 Site Master File (SMF)**	**50 min**	S Sakurai (Chair)	PMDA
	・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)	M Yabuki	PMDA
			Ellen C	TW-FDA
			Rumondang S	NADFC
			Suchart C	TH-FDA
			Busakorn L	PReMA
			T Nakagawa	JPMA
	・Message from Mr. Boon, PIC/S Chairman			
	・Comments & questions from the audience	(5 min)		
	・Conclusion (recommendation for convergence in Asia)	(10 min)	S Sakurai	PMDA
14:05 ▶ 15:25	**2 Post-approval Variations**	**80 min**	F Honda (Co-Chair)	PMDA
			EK Kim (Co-Chair)	NIFDS
	・Difference analysis in change control in Asia: from JPMA	(10 min)	T Nakagawa	JPMA
	・Presentation: Optimising the management of post-approval changes for patients' timely access to medicines	(15 min)	Sannie C	SAPI
			Ellen C	TW-FDA
	・Key-points of post-approval variation (Regulatory Authorities in Asia)	(30 min)	EK Kim	NIFDS
			Juliati	NAFDC
			Suchart C	TH-FDA
	Discussion	(20 min)		
	Summary of the discussions	(5 min)	F Honda	PMDA
15:25 ▶ 15:45	< Break >	20 min		
15:45 ▶ 17:45	**DA Session: How to establish drug discovery ecosystem in Asia**			
15:45 ▶ 17:25	**1 Presentation**	**100 min**	WK Chi (Co-Chair)	DCB
			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
	・Presentations by 4 panelists	(80 min)	N Kohno	AMED
			P Wang	Yabao
			N Nishimura	Mie Univ
			CH Wu	DCB
17:25 ▶ 17:45	**2 Panel discussion & Summary**	**20 min**		
	Possibility of "Drug Discovery Ecosystem in Asia"		all presenters	
	Challenges to realize "Drug Discovery Ecosystem in Asia", etc.			
17:45 ▶ 17:55	Closing Remarks	10 min	H Naito	JPMA
18:15 ▶ 20:15	< Reception >			