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2nd Korea-Japan Joint Symposium on Medical Products

[April 12th Draft]

· Date and time: 09:10 ~ 17:00 May 11, 2017 (Thu)

· Venue: Overall and Pharmaceutical session: Conference Room (South) 402, Coex, Seoul
Medical Device session: Conference Room (South) 403, Coex, Seoul

· Host: Ministry of Food and Drug Safety (MFDS)
National Institute of Food and Drug Safety Evaluation (NIFDS)
Ministry of Health, Labour and Welfare (MHLW)
Pharmaceuticals and Medical Devices Agency (PMDA)
Korea Pharmaceutical Manufacturers Association (KPMA)
Japan Pharmaceutical Manufacturers Association (JPMA)
Korea Medical Devices Industry Association (KMDIA)
Japan Federation of Medical Devices Association (JFMDA)

· Number of participants: 230 (estimation)

· Interpreter: Korean- Japanese simultaneous

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■ AM: Overall Session - Pharmaceutical and Medical Device
(Venue: Conference Room (South) 402, Coex)
* Master of Ceremony: KPMA

Time	Agenda items	Remarks
09:10 - 09:30	Registration	20 min
09:30 - 10:20	**Opening Remarks**	
	(1) [Korea] MFDS: Dr. Won Sik Lee, Director General, Pharmaceutical Safety Bureau	7 min
	(2) [Japan] PMDA: Mr. Seiichi Inoue, Executive Director	7 min
	(3) [Korea] KPMA: TBD	7 min
	(4) [Japan] JPMA: Tadaharu Goto, Director General	7 min
	(5) [Korea] KMDIA: TBD	7 min
	(6) [Japan] JFMDA: Mr. Koji Nakao, Chairman	7 min
10:20 - 10:40	Photo taking	20 min
10:40 - 11:40	**Keynote Speeches**	
	(1) Latest Trend of Pharmaceutical and Medical Device Regulation in Korea [Korea] MFDS: Dr. Jeong Yeon Kim, Deputy Director, Pharmaceutical Policy Division, Pharmaceutical Safety Bureau	25 min
	(2) Latest Trend of Pharmaceutical and Medical Device Regulation in Japan [Japan] MHLW: Mr. Yoshihiko Sano, Deputy Director	25 min
	(3) Q&A Session	10 min
11:40 - 13:00	Lunch	

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■ PM (1): Pharmaceutical Session (Venue: Conference Room (South) 402, Coex)
* Master of Ceremony: KPMA

Time	Topic	Remarks
▶ Pharmaceutical Regulatory Session		
13:00 - 14:30	**Part I. Pharmacovigilance**	
	* Moderator: [Korea] MFDS	
	(1) PV system in Korea [Korea] MFDS: Dr. Su-jung Lee, Director, Pharmaceutical Safety Evaluation Division, Pharmaceutical Safety Bureau	20 min
	(2) Regulations on PV in Japan [Japan] PMDA: Ms. Yuka Iida, Senior Reviewer, Office of Safety II	20 min
	(3) Topic [Korea] KPMA: TBD	20 min
	(4) Topic [Japan] JPMA: TBD	20min
	(5) Panel Discussion	10 min
14:30 - 14:50	Tea/Coffee Break	20 min
▶ Pharmaceutical Industry Session		
14:50 - 16:50	* Moderator: [Korea] KPMA	
	Part II. Trend of Japanese Bio-pharmaceuticals and Collaborative Opportunity	
	(1) Recent Change of Biologicals/Biosimilars in Korea [KPMA] (2) Recent Trends of Biologicals/Biosimilars in Global and Japanese Market [JPMA] Mr. Hirotomo Akabane	
	Part III. Trend of Drug Pricing System	
	(1) Update of Drug Pricing System in Korea [KPMA] (2) Update of Drug Pricing System in Japan [Japan] MHLW: Mr. Hiroaki Mamiya, Deputy Director, Health Policy Bureau	
16:50 - 17:00	**Closing Remarks**	
	(1) [Korea] MFDS: Dr. Won Sik Lee, Director General,	5 min

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	Pharmaceutical Safety Bureau (2) [Japan]] PMDA: Mr. Naoyuki Yasuda, Office Director	5 min

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■ PM (2): Medical Device Session (Venue: Conference Room (South) 403, Coex)
* Master of Ceremony: KMDIA

Time	Topic	Remarks
▶ Medical device Regulatory Session		
13:30 - 14:30	**Part IV. QMS/GMP**	
	* Moderator: [Korea] KMDIA	
	(1) Introduction of KGMP system [Korea] MFDS: Dr. Jang-Yong Choi, Deputy Director, Medical Device Safety Evaluation Division, Medical Device Safety Bureau	20 min
	(2) Japanese QMS system/Overview of MDSAP [Japan] PMDA: Mr. Junich Ohishi, QMS Inspector, Division of Medical Devices, Office of Manufacturing/Quality and Compliance	20 min
	(3) QMS application strategy of ISO 13485:2016 [Korea] KMDIA: Mr. Young-Soo Seol, Executive Director, Working group member of Legal Committee	20 min
	(4) ISO 13485 and Japanese QMS Ordinance [Japan] JFMDA: Mr.Hideki Asai, Vice-chairman of ISO/TC 210 Japanese National Committee	20 min
	(5) Panel Discussion	10 min
14:30 - 14:50	Tea/Coffee Break	20 min
▶ Medical Device Industry Session		
14:50 - 16:50	**Part V*. Business Trend of Medical Device Industry**	
	(1) UDI introduction plan of Korea [Korea] KMDIA: Ms. Young Kim, CEO, Working group member of International Exchange Committee	30 min
	(2) UDI and Traceability (Temp.) [Japan] JFMDA: Mr. Eishi Harasawa, Executive Director	30 min
	(3) Regulatory requirement for medical device software in Korea [Korea] Mr. Min-Yong Choi, Head of Healthcare (BSI group Korea)	30 min
	(4) Software validation	30 min

	[Japan] Mr. Keiichiro Ozawa (FUJIFILM Corporation)	
16:50 - 17:00	**Closing Remarks**	
	(1) [Korea] MFDS: Mr. Shin Joon-su, Director, Medical Device Policy Division	5 min
	(2) [Japan] MHLW: Ms. Yumiko Aoyagi, Deputy Director	5 min

* In an each time of presentation in Part V, there is Q&A time for 10 minutes.