

1<sup>st</sup> Japan-Korea Joint Symposium on Medical Products  
[Tentative]

Date: 23<sup>rd</sup> June, 2016 (Thu)

Venue: Overall and Pharmaceutical session: Nihonbashi Life Science Hub.

8 F Muromachi Chibagin Mitsui Building, 1-5-5 Nihonbashi-Muromachi,, Tokyo

Medical Device session: Nihonbashi Life Science B/D 8F Conference  
Hall, 2-3-11 Nihonbashi-Honcho, Tokyo

Host: Ministry of Health, Labour and Welfare (MHLW)

Pharmaceuticals and Medical Devices Agency (PMDA)

Ministry of Food and Drug Safety (MFDS)

Japan Pharmaceutical Manufacturers Association (JPMA)

Korea Pharmaceutical Manufacturers Association (KPMA)

Support: Japan Federation of Medical Devices Association (JFMDA)

Korea Medical Devices Industry Association (KMDIA)

Number of participants: 150

Interpreter: Japanese-Korean simultaneous

■ AM: Overall Session (Pharmaceutical and Medical Device)

MCs: JP: (MHLW) Mr. Yoshihiko Sano , KR:

09:10-09:30	<b>Registration</b>
09:30-10:10	<b>1. Opening Remarks</b>
	(1) MHLW: Mr. Hideaki Nakagaki, Director General 10min
	(2) MFDS: Mr. Kwan Sung Kim, Director General, 10min
	(3) JPMA: Mr. Tadaharu Goto, Director General 5min
	(4) KPMA: Mr. Hang-Myung Lee, Chairman 5min
	(5) JFMDA: Mr. Koji Nakao, Chairman 5min
	(6) KMDIA: Mr Soon-Wook Hong, Vice Chairman 5min
10:10-10:20	Photo Taking
10:20-12:00	<b>2. Keynote Speeches</b>
	(1) “Latest trend of pharmaceutical and medical device regulation in Japan”, Dr. Nobumasa Nakashima, Office Director (MHLW), 25min
	(2) “Latest trend of pharmaceutical regulation in Korea”, Secretary of Pharmaceutical Policy Division (MFDS), 25min
	(3) “Overview of pharmaceutical industry in Japan and its recent trend”, Mr. Hitoshi Okuda, President (Office of Pharmaceutical Industry Research), 25min
	(4) “Expectation on Japan-Korea partnership at the pharmaceutical industries and the bilateral cooperation between the regulatory authorities” (KPMA), 25min
12:00-13:00	Lunch Time (For Medical Device session: 12:00-13:30)

■ PM(1): Pharmaceutical Session

Pharmaceutical Regulatory Session	
13:00-14:40	<b>3. GMP System and International Cooperation</b>
	Moderator: Mr. Naoyuki Yasuda, Office Director (PMDA) (1) “System and practical aspects of GMP inspection”, Mr. Toshiaki Kudo, Senior Coordinator (MHLW), 25min (2) “GMP system and International Cooperation on Korea”, Director (MFDS), 25min (3) “Activity of Quality & Technology Committee in JPMA”, Dr. Tamiki Nishimura, Sr. Qualified GMP Auditor (Sumitomo Dainippon Pharma), 20min (4) (KPMA), 20min (5) Panel discussion, 10min
14:40-15:00	Break
Pharmaceutical Industry Session	
15:00-16:00	<b>4. Business Trend of New Drug Development</b>
	Moderator: Mr. Matsutaro Fujii, Director (JPMA) and (KPMA) (1) “OPDIVO – Its Making Story and International Development”, Dr. Toichi Takino, Corporate Officer, Corporate Development & Strategy (Ono Pharm), 25min (2) “New drug development in Korea”, (Hanmi or Celltrion), 25min (3) Panel discussion, 10min
16:00-17:00	<b>5. Drug Pricing and Innovation</b>
	Moderator: Mr. Matsutaro Fujii, Director (JPMA) and (KPMA) (1) “Evaluation of innovation in the drug pricing system in Japan”, Mr. Mimei Takahashi, Deputy Director (MHLW), 25min (2) “Evaluation of innovation in the health care policy in Korea”, (HIRA –Health Insurance Review Agency), 25min (3) Panel discussion, 10min
17:00-17:10	<b>6. Closing Remarks</b>
	- PMDA: Dr. Toshiyoshi Tominaga, Associate Executive Director, 5min - MFDS: Mr. Kwan Sung Kim, Director General, 5min

■ PM(2): Medical Device Session

Medical Device Regulatory Session	
13:30-15:00	<b>7. Trend of Medical Device Regulation</b>
	<p>Moderator: Dr. Kentaro Azuma, Deputy Director, (MHLW)</p> <p>(1) “Overview of Japanese QMS System” (PMDA), 20min</p> <p>(2) “Overview of Korea MFDS Approval Process for Medical Devices” Dr. Lee Sung-Hee, Deputy Director (MFDS/NIFDS), 20min</p> <p>(3) Biological evaluation framework for medical devices, Mr. Keisuke Sakaguchi, General Manager (Terumo) (JFMDA), 20 min</p> <p>(4) “Korea GMP Regulation”, Ms. Ju-Young Kim (KMDIA), 20min</p> <p>(5) Panel discussion 10 min</p>
15:00-15:20	Break
Medical Device Industry Session	
15:20-17:00	<b>8. Business Trend of Medical Device Industry</b>
	<p>Moderators: Mr. Norio Yoda, Chairman of International Policy &amp; Strategy Committee (JFMDA)</p> <p>[Reimbursement]</p> <p>(1) “The Summary of Medical Device Reimbursement (2016 Japan)”, Mr. Toshiei Mizutani, Chairman of Medical Material Reimbursement Committee (JFMDA) 20min</p> <p>(2) “Introduction of Medical Device Reimbursement”, Mr. Sang-Soo Lee (KMDIA) 20min</p> <p>(3) Panel Discussion 10min</p> <p>[Promotion code]</p> <p>(1) “Activities of JFMDA Corporate Business Ethics Committee”, Mr. Shinichiro Nakashima, Chairman of Corporate Business Ethics Committee (JFMDA), 20min</p> <p>(2) “Promotion Code of KMDIA &amp; Anti-bribery Law”, Mr. Baek Kyeong Yun (KMDIA) 20min</p> <p>(3) Panel Discussion 10min</p>
17:00-17:10	<b>9. Closing Remarks</b>
	<p>- PMDA: Ms. Tomiko Tawaragi, Chief Safety Officer, 5min</p> <p>- MFDS: Director, 5min</p>