28 March draft

2nd Japan - India Medical Products Regulation Symposium [tentative]

Date: 24th April 2017 (Mon) 9:30-17:20

Venue: Nihonbashi Life Science Building
2-3-11, Nihonbashi-Honcho, Chuo-ku, Tokyo

Host: (Japan) MHLW (Ministry of Health, Labour and Welfare)/PMDA (Pharmaceutical and Medical Device Agency)
(India) MHFW (Ministry of Health, Family and Welfare)/ CDSCO (Central Drugs Standard Control Organization)

Supported by: (Japan) JPMA (Japan Pharmaceutical Manufacturers Association),
JFMDA (Japan Federation of Medical Devices Association),
FPMAJ (Federation of Pharmaceutical Manufacturers' Associations of JAPAN),
OPMA (Osaka Pharmaceutical Manufacturers Association),
(India) Pharmexil,
FICCI (Federation of Indian Chambers of Commerce and Industry)

Number of participants (including audience): 150

Interpreter: English-Japanese simultaneous

Program:

Overall Session (@ 2F 201 Hall)

MC: Mr. Fumihito Takanashi, Deputy Director (MHLW)

09:00-09:30	Registration
09:30-10:30	**1. Opening Remarks** (1) Mr. Toshihiko Takeda, Director General (MHLW) 10 min (2) Sh. K. L. Sharma, Joint Secretary (MHFW) and Sh. Sudhanshu Pandey, Joint Secretary (Department of Commerce) 10 min (3) Tadaharu Goto, Director General (JPMA) 10min (4) ***, Representative of Pharmaceutical Industry (India) 10 min (5) Koji Nakao, Chairman (JFMDA)10 min (6) ***, Representative of Medical Device Industry (India) 10 min
10:30-10:40	Photo Session
10:30-10:50	Coffee Break
10:50-12:00	**2. Keynote Speeches** (1) "Development of the bilateral regulatory cooperation between Japan and India", Mr. Yasuhiro Sensho (MHLW, former Secretary at Embassy of Japan in India), 20 min (2) "Latest trend of pharmaceutical and medical device regulation in Japan", Dr. Nobumasa Nakashima, Office Director (MHLW), 25 min

	(3) “Latest trend of pharmaceutical and medical device regulation in India”, Dr. S. Eswara Reddy, Joints Drug Controller(I), (CDSCO), 25 min
12:00-13:00	Lunch Time

Pharmaceutical Session (@ 2F 201 Hall)

MC: Mr. Fumihito Takanashi, Deputy Director (MHLW)

13:00-14:30	**1. GMP/Quality issues** Moderator: *** (MHFW/CDSCO) (1) “Report back from the discussion in last year’s symposium”, Mr. Fumihito Takanashi, Deputy Director (MHLW) (2) “GMP system in Japan”, Mr. Toshihiko Kudo, Senior Coordinator (MHLW)/ *** (PMDA), 30 min (3) “Quality standards and GMP system in India”, Dr. V. G. Somani, Joints Drug Controller(I) (CDSCO), 30 min (4) “Industry’s activity related to the quality standards and GMP”, Yoshio Urawa, General Manager and Officer, Kashima Plant (Eisai Demand Chain Systems, Eisai Co., Ltd.), 15 min (5) “Industry’s activity related to the quality standards and GMP”, *** (India Industry), 15 min (6) Panel discussion, 20 min
15:00-15:20	Coffee Break
15:20-17:00	**2. GCP/Clinical trials** Moderator: Toshiyoshi Tominaga, Associate Executive Director (PMDA) (1) “Clinical trial system and review in India”, Dr. V. G. Somani, Joints Drug Controller(I) (CDSCO), 20 min (2) “Trend of Multi-Regional Clinical Trials (MRCTs) and Japan’s approach”, *** (PMDA), 20 min (3) “Experience of drug development and clinical trials in India” *** (India Industry), 20 min (4) “Strategies and challenges for global drug development” Satoshi Kunitada, Ph. D., Chairperson, Drug Evaluation Committee (JPMA), 20 min (5) Panel discussion, 20 min
17:00-17:20	**3. Closing Remarks** (1) Tatsuya Kondo, Chief Executive (PMDA) (2) *** (MHFW/CDSCO)

Medical Device Session (@ 10F1004 Room)

MC: Ms. Yumiko Aoyagi, Deputy Director (MHLW)

13:00-14:40	**1. Development of Medical Device Regulation**
	(1) "Overview and way of implementation of Medical Devices Rules 2017 in India", Dr. S. Eswara Reddy, Joints Drug Controller(I) (CDSCO), 30 min (2) "Medical device regulation in Japan", *** (MHLW), 20 min (3) "Industry's response and preparation to the medical device regulation in India", Yoshiaki Nakura (JFMDA, Terumo), 15 min/ *** (India Industry), 15 min (4) Panel discussion, 20 min
14:40-15:40	**2. Classification, Notified bodies and Certification Standards**
	Topic Moderator: Ms. Madoka Murakami, Unit Chief (PMDA) (1) "Risk based inspection in India and experience gain thereof", Dr. S. Eswara Reddy, Joints Drug Controller(I) (CDSCO), 20 min (2) "Third party certification system and Certification standards in Japan", *** (PMDA), 20 min (3) Panel discussion, 20 min
15:40-16:00	Coffee Break
16:00-17:00	**3. GCP/Clinical trials**
	Moderator: *** (MHFW/CDSCO) (1) "Regulations for medical device clinical trial in Japan", Yuka Suzuki, International Coordination Officer (PMDA), 20min (2) "Clinical trial system of medical device in India" Dr. S. Eswara Reddy, Joints Drug Controller(I) (CDSCO), 20 min (3) Panel discussion, 20 min
17:00-17:20	**4. Closing Remarks**
	(1) *** (MHFW/CDSCO) (2) Haruo Akagawa, Senior Executive Director (PMDA)