2nd Japan - India Medical Products Regulation Symposium

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 and Family Welfare)/ CDSCO (Central Drugs Standard Control Organization)

Supported by:
Japanese side:
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),
Indian side: Pharmexil,
FICCI (Federation of Indian Chambers of Commerce and Industry)

Number of participants (including audience): 200

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) 10 min (3) Mr. Tadaharu Goto, Director General (JPMA) 10min (4) Dr. Gurpreet Sandhu, Honorary Advisor (Pharmexcil) 10 min (5) Mr. Koji Nakao, Chairman (JFMDA)10 min (6) Mr. Probir Das, Chairman of Medical Devices Forum (FICCI) 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 (3-1) “Latest trend of medical device regulation in India”, Sh. K. L. Sharma, Joint Secretary (MHFW), 15 min (3-2) “Latest trend of pharmaceutical regulation in India”, Dr. G. N. Singh, Drugs Controller General (I) (CDSCO), 10 min
12:00-13:00	Lunch Time

Pharmaceutical Session (@ 2F 201 Hall)

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

13:00-15:00	**1. GMP/Quality issues** Moderator: Mr. Fumihito Takanashi, Deputy Director (MHLW) (1) “Report back from the discussion in last year’s symposium”, Mr. Fumihito Takanashi, Deputy Director (MHLW) (2) “GMP system in Japan”, Mr. Toshiaki Kudo, Senior Coordinator (MHLW) / Dr. Kentaro Hara, Principal GMP Inspector (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”, Mr. 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”, DVS Reddy, Managing Director (Nosch Laboratories Ltd) / Dr. Satyanarayan, CEO (Laurus Labs Ltd), 15 min (6) Panel discussion, 20 min
15:00-15:20	Coffee Break
15:20-17:00	**2. GCP/Clinical trials** Moderator: Dr. Toshiyoshi Tominaga, Associate Executive Director (PMDA) (1) “Trend of Multi-Regional Clinical Trials (MRCTs) and Japan’s approach”, Dr. Yu Kagami, Reviewer (PMDA) / Mr. Atsushi Kawashima, Inspector (PMDA), 25 min (2) “Clinical trial system and review in India”, Dr. V. G. Somani, Joints Drug Controller(I) (CDSCO), 25 min (3) “Strategies and challenges for global drug development” Dr.

	Satoshi Kunitada, Chairperson, Drug Evaluation Committee (JPMA), 25 min (4) Panel discussion, 25 min
17:00-17:20	**3. Closing Remarks**
	(1) Dr. Tatsuya Kondo, Chief Executive (PMDA) (2) Dr. G. N. Singh, Drugs Controller General (I) (CDSCO)

Medical Device Session (@ 10F1004 Room)

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

13:00-14:40	**1. Development of Medical Device Regulation**
	Topic Moderator: Dr. Madoka Murakami, Unit Chief (PMDA) (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", Ms. Yumiko Aoyagi, Deputy Director (MHLW), 20 min (3) "Industry's response and preparation to the medical device regulation in India", Mr. Yoshiaki Nagura (JFMDA, Terumo), 15 min / Rajiv Nath, Forum Coordinator (Association of Indian Medical Device Industry), 15 min (4) Panel discussion, 20 min
14:40-15:20	**2. Classification, Notified bodies and Certification Standards**
	Topic Moderator: Dr. Madoka Murakami, Unit Chief (PMDA) (1) "Third party certification system and Certification standards in Japan", Dr. Katsuhisa Ide, Director (PMDA), 20 min (2) Panel discussion, 20 min
15:20-15:40	Coffee Break
15:40-16:40	**3. GCP/Clinical trials**
	Moderator: Dr. Madoka Murakami, Unit Chief (PMDA) (1) "Regulations for medical device clinical trial in Japan", Dr. Yuka Suzuki, International Coordination Officer (PMDA), 20min (2) "Clinical trial system of medical device in India", Mr. Sashi Kumar, Managing Director (Phoenix Medical Systems), 20 min (3) Panel discussion, 20 min
16:40-16:55	AOB: "Facilitating regulatory promotion in Industry promotion", Dr. Jitendar Sharma, CEO (Andhra Pradesh Med Tech Zone Ltd.)
16:55-17:15	**4. Closing Remarks**
	(1) Sh. K. L. Sharma, Joint Secretary (MHFW) (2) Mr. Haruo Akagawa, Senior Executive Director (PMDA)