

As on 12th May, 2016

1st India -Japan Medical Products Regulation Symposium

Date: 18-19th May 2016

Venue: Silver Oak, India Habitat Centre / IHC New Delhi

Host: MHFW/CDSCO (India)

: MHLW/PMDA (Japan)

Supported by:

Indian side: Pharmexil,

FICCI (Federation of Indian Chambers of Commerce and Industry)

Japanese side:

FPMAJ (Federation of Pharmaceutical Manufacturers' Associations of JAPAN),

JPMA (Japan Pharmaceutical Manufacturers Association),

OPMA (Osaka Pharmaceutical Manufacturers Association),

JFMDA (Japan Federation of Medical Devices Association)

Number of participants (including audience): 135

Interpreter: English-Japanese simultaneous

- Day 1 (18th May): Pharmaceutical Session (including regenerative medicine products)

: To be assigned by India, : To be assigned by Japan

MCs: Outsource

08:30-09:00	Registration
09:00-10:15	1. Opening Remarks
	(1) Welcome Address: Dr. G. N. Singh, DCGI (GOI) 5 min (2) Dr. Kazuhiro Shigetoh, Executive Director (PMDA) 10 min (3) Mr. Koji Nakao, Chairman (JFMDA) 5 min (4) Mr. K. B. Agarwal, Additional Secretary (F&D), Ministry of Health and Family Welfare (GOI) 5 min (5) Dr. Jagdish Prasad, Director General of Health Services, Ministry of Health and Family Welfare (GOI) 5 min (6) Secretary, Department of Pharmaceutical, Ministry of Chemical

	<p>and Fertilizer (GOI) 10 min</p> <p>(7) Secretary, Ministry of Commerce and Industry (GOI) 10 min</p> <p>(8) Mr. B. P. Sharma, Secretary, Ministry of Health and Family Welfare (GOI) 10 min</p> <p>(9) Ambassador of Japan to India (JP) 5 min</p> <p>(10) Mr. J. P. Nadda, Minister of Health and Family Welfare (GOI) 10 min</p>
10:15-10:20	Photo Taking
10:20-10:40	Tea Break
10:40-13:00	2. Keynote Speeches I [Pharmaceuticals]
	<p>(1) “Latest trend of pharmaceutical regulation in India”, Dr. Eswara Reddy (CDSCO), 30 min</p> <p>(2) “Latest trend of pharmaceutical regulation in Japan”, Dr. Toshiyoshi Tominaga, Associate Executive Director, (PMDA), 30 min</p> <p>(3) “Trend of regulation on regenerative medicine products in Japan”, Dr. Daisaku Sato, Office Director (PMDA), 30 min</p> <p>(4) “Way to regulation on regenerative medicine products in India” Dr. Narinder Mehra, Former Head of Department, Transplant Immunology and Immunogenetics, AIIMS, 15 min</p> <p>(5) “Expectation on India-Japan partnership at the pharmaceutical industries and the bilateral cooperation between the regulatory authorities”, Dr. Gurpreet Sandhu, Honorary Advisor (Pharmexcil), 15 min</p> <p>(6) “Expectation on India-Japan partnership at the pharmaceutical industries and the bilateral cooperation between the regulatory authorities (Tentative)”, Mr. Sudhanshu Pandey, Joint Secretary, Ministry of Commerce and Industry , 20 min</p>
13:00-13:45	Lunch Time
13:45-15:40	3. GMP System and International Cooperation
	<p>Moderator: Mr. Fumihito Takanashi, Deputy Director (MHLW)</p> <p>(1) “GMP inspection system in Japan”, Mr. Toshiaki Kudo, Senior Coordinator (MHLW) / “Practical aspects of GMP inspection”, Mr. Masatoshi Morisue, Director of GMP Inspection (PMDA), 40 min</p> <p>(2) “GMP inspection system in India”, / “Practical aspects of GMP inspection”, Dr. V. G. Somani, Joint Drugs Controller (India) (CDSCO), 40 min</p> <p>(3) Dr. Sanjit Singh Lamba (Eisai India), 15 min</p>

	(4) Panel discussion, 20 min
15:40-15:55	Tea Break
	4. Pharmacopoeias and International Cooperation
15:55-16:55	<p>Moderator: Dr. P. D. Sneth, Fellow, Federation of International Pharmaceutical</p> <p>(1) “Japanese Pharmacopoeia”, Dr. Naoyuki Yabana, Division Director (PMDA), 20 min</p> <p>(2) “Indian Pharmacopoeia”, Dr. P. L. Sahu, Indian Pharmacopoeia commission, 20 min</p> <p>(3) Panel discussion, 20 min</p>
	5. Industries’ Activities related to Pharmaceutical Regulation and Expectation on Bilateral Cooperation
16:55-18:25	<p>Moderators: Dr. Sanjit Singh Lamba (Eisai India)</p> <p>JP (1) Mr. Tetsuya Oishi (Eisai), 10 min</p> <p>JP (2) Mr. Makoto Shigemitsu (Meiji Seika Pharma), 10 min</p> <p>IN (1) Dr. Kiran Mazumdar Shaw (Biocon), 10 min</p> <p>IN (2) Mr. Statish Reddy (Dr. Reddy’s Laboratories)</p> <p>IN (3) “Contract Manufacturing India Prospective”, Mr. Srinivas Lanka (Pharmexcil) 10 min</p> <p>JP/IN (1) Mr. Durgesh Sharma (CBC India) 10 min</p> <p>JP/IN (2) Dr. Tsutomu Une (Daiichi Sankyo) 10 min</p> <p>Panel discussion, 20 min</p>
End of 1 st Day	

● Day 2 (19th May) morning: Medical Devices Session

MCs: Outsource

08:40-09:00	Registration
9:00-10:00	1. Keynote Speeches II [Medical Devices]
	(1) “Latest trend of medical device regulation in India”, Mr. K. L. Sharma, Joint Secretary (Ministry of Health and Family Welfare), 20 min (2) “Latest trend of medical device regulation in Japan”, Dr. Toshiyoshi Tominaga, Associate Executive Director (PMDA), 20 min (3) “Expectation on India-Japan partnership at the medical device industries and the bilateral cooperation between the regulatory authorities”, Mr. Probir Das, Chairman of Medical Devices Forum (FICCI), 20 min
10:00-11:00	2. Medical Devices Regulation and Capacity Building
	Topic Moderator: Mr Taihei Tanaka, Division Director (PMDA) (1) Dr. Katsuhisa Ide (PMDA) 30 min (2) Dr. Eswara Reddy / Mr. Aseem Sahu (CDSCO) 30 min
11:00-11:15	Coffee Break
11:15-12:00	3. Industries’ Activities related to Medical Device Regulation and Expectation on Bilateral Cooperation
	Topic Moderator: Mr. Probir Das, Chairman of Medical Devices Forum (FICCI) (1) Ms. Kuniko Shoji (Terumo) 15 min (2) Mr. Hisao Masuda (Omron Healthcare India) 15 min (3) Mr. Nandakumar S, Chief Executive Officer (Perfint) 15 min
	4. Overall Panel Discussion
12:00-12:30	Topic moderator: (CDSCO) (IN), Dr. Toshiyoshi Tominaga (PMDA) (JP) * Panels consists of the speakers in the topic 2 and 3, and additional regulatory persons (one for each country)
	5. Closing Remarks
12:30-13:00	(1) Mr. Yasuhiro Sensho (Embassy of Japan in India) (2) Dr. P. V. Appaji, Director General (Pharmexcil) (3) Ms. Shoba Ghosh, Senior Director (FICCI)
13:00-14:00	Lunch