

1st India -Japan Medical Products Regulation Symposium (tentative)

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)

MCs: Outsouse

08:30-09:00	Registration
	1. Opening Remarks
09:00-10:15	(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. B. P. Sharma, Secretary, Ministry of Health and Family Welfare (GOI) 10 min (5) Secretary, Ministry of Commerce and Industry (GOI) 10 min (6) Secretary, Department of Pharmaceutical, Ministry of Chemical and Fertilizer (GOI) 10 min (7) Ambassador of Japan to India (JP) 5 min (8) Mr. J. P. Nadda, Minister of Health and Family Welfare (GOI) 10

	min (9) Vote of Thanks: Mr. K. L. Sharma, Joint Secretary, Ministry of Health and Family Welfare
10:15-10:20	Photo Taking
10:20-10:40	Coffee Break
	2. Keynote Speeches I [Pharmaceuticals]
10:40-13:00	(1) "Latest trend of pharmaceutical regulation in India", Dr. Eswara Reddy (CDSCO), 30 min (2) "Latest trend of pharmaceutical regulation in Japan", Dr. Toshiyoshi Tominaga (PMDA), 30 min (3) "Trend of regulation on regenerative medicine products in Japan", Dr. Daisaku Sato (PMDA), 30 min (4) "Way to regulation on regenerative medicine products in India" (.....)(IN), 10 min (5) "Expectation on India-Japan partnership at the pharmaceutical industries and the bilateral cooperation between the regulatory authorities", Dr. Gurpreet Sandhu, Honorary Advisor (Pharmexcil), 20 min (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
13:00-14:00	Lunch Time
	3. GMP System and International Cooperation
14:00-15:55	Moderator: Mr. Fumihito Takanashi (MHLW) (1) "GMP inspection system in Japan", Mr. Toshiaki Kudo (MHLW) / "Practical aspects of GMP inspection", Mr. Masatoshi Morisue (PMDA), 40 min (2) "GMP inspection system in India", / "Practical aspects of GMP inspection", Regulatory personnel (CDSCO), 40 min (3) Dr. Sanjit Singh Lamba (Eisai India), 15 min (4) Panel discussion, 20 min
15:55-16:10	Coffee Break
16:10-17:10	4. Pharmacopoeias and International Cooperation

	<p>Moderator: Regulatory personnel (IN)</p> <p>(1) “Japanese Pharmacopoeia”, Dr. Naoyuki Yabana (PMDA), 20 min</p> <p>(2) “Indian Pharmacopoeia”, Regulatory personnel (CDSCO), 20 min</p> <p>(3) Panel discussion, 20 min</p>
17:10-18:30	<p>5. Industries’ Activities related to Pharmaceutical Regulation and Expectation on Bilateral Cooperation</p>
	<p>Moderators: Industry personnel (IN), 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)(Lupin Pharmaceuticals), 10 min</p> <p>IN (2).....(Reva Pharma), 10 min</p> <p>JP/IN (1) Mr. Durgesh Sharma, CBC India (Former country manager, Dr. Reddy), 10 min</p> <p>JP/IN (2) Dr. Tsutomu Une, Daiichi Sankyo (Former chairman, Ranbaxy) 10 min</p> <p>Panel discussion, 20 min</p>
<p>End of 1st Day</p>	

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

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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 (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
	Moderator: Regulatory personnel (IN), Mr Taihei Tanaka (PMDA) (1) Dr. Madoka Murakami (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 Moderators: Industry personnel (IN), Industry personnel (JP) (1) Ms. Kuniko Shoji (Terumo) 15 min (2) Industry personnel (Omron India) 15 min (3) Industry personnel (Perfint) 15 min
	4. Overall Panel Discussion
12:00-12:30	Topic moderator: Dr. Toshiyoshi Tominaga (PMDA) * 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