# 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)

MCs: Outsource

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| 08:30-09:00 | **Registration** |
| 09:00-10:15 | **1. Opening Remarks**<br>(1) Welcome Address: Dr. G. N. Singh, DCGI (GOI) 5 min<br>(2) Dr.Kazuhiro Shigetoh, Executive Director (PMDA) 10 min<br>(3) Mr. Koji Nakao, Chairman (JFMDA) 5 min<br>(4) Mr. K. B. Agarwal, Additional Secretary (F&D), Ministry of Health and Family Welfare (GOI) 5 min<br>(5) Dr. Jagdish Prasad, Director General of Health Services, Ministry of Health and Family Welfare (GOI) 5 min<br>(6) Secretary, Department of Pharmaceutical, Ministry of Chemical and Fertilizer (GOI) 10 min<br>(7) Secretary, Ministry of Commerce and Industry (GOI) 10 min<br>(8) Mr. B. P. Sharma, Secretary, Ministry of Health and Family Welfare (GOI) 10 min<br>(9) Ambassador of Japan to India (JP) 5 min<br>(10) Mr. J. P. Nadda, Minister of Health and Family Welfare (GOI) 10 min |

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| 10:15-10:20 | Photo Taking |
| 10:20-10:40 | Tea Break |
| 10:40-13:00 | **2. Keynote Speeches I [Pharmaceuticals]**<br>(1) "Latest trend of pharmaceutical regulation in India", Dr. Eswara Reddy (CDSCO), 30 min<br>(2) "Latest trend of pharmaceutical regulation in Japan", Dr. Toshiyoshi Tominaga, Associate Executive Director, (PMDA), 30 min<br>(3) "Trend of regulation on regenerative medicine products in Japan", Dr. Daisaku Sato, Office Director (PMDA), 30 min<br>(4) "Way to regulation on regenerative medicine products in India" Dr. Narinder Mehra, Former Head of Department, Transplant Immunology and Immunogenetics, AIIMS, 15 min<br>(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<br>(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 |
| 13:00-13:45 | Lunch Time |
| 13:45-15:40 | **3. GMP System and International Cooperation**<br>Moderator: Mr. Fumihito Takanashi, Deputy Director (MHLW)<br>(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<br>(2) "GMP inspection system in India", / "Practical aspects of GMP inspection", Dr. V. G. Somani, Joint Drugs Controller (India) (CDSCO), 40 min<br>(3) Dr. Sanjit Singh Lamba (Eisai India), 15 min<br>(4) Panel discussion, 20 min |
| 15:40-15:55 | Tea Break |

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

- 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]**<br>(1) "Latest trend of medical device regulation in India", Mr. K. L. Sharma, Joint Secretary (Ministry of Health and Family Welfare), 20 min<br>(2) "Latest trend of medical device regulation in Japan", Dr. Toshiyoshi Tominaga, Associate Executive Director (PMDA), 20 min<br>(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)<br>(1) Dr. Katsuhisa Ide (PMDA) 30 min<br>(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)<br>(1) Ms. Kuniko Shoji (Terumo) 15 min<br>(2) Mr. Hisao Masuda (Omron Healthcare India) 15 min<br>(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)<br>* 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)<br>(2) Dr. P. V. Appaji, Director General (Pharmexcil)<br>(3) Ms. Shoba Ghosh, Senior Director (FICCI) |
| 13:00-14:00 | Lunch |