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April 06, tentative

3rd India - Japan Medical Products Regulation Symposium

Date: Monday, May 21st, 2018

Venue: TBD, New Delhi, India

Address: TBD

Host: (India) MHFW (Ministry of Health and Family Welfare)/ CDSCO (Central Drugs Standard Control Organization)

(Japan) MHLW (Ministry of Health, Labour and Welfare)/ PMDA (Pharmaceutical and Medical Device Agency)

Supported by:

(India) Pharmexil, FICCI (Federation of Indian Chambers of Commerce and Industry)

(Japan) JPMA (Japan Pharmaceutical Manufacturers Association),
JFMDA (Japan Federation of Medical Devices Association),
FPMAJ (Federation of Pharmaceutical Manufacturers' Associations of JAPAN),
KPIA (Kansai Pharmaceutical Industries Association),

Number of participants (including audience): 200

Interpreter: English-Japanese simultaneous translation

Program:

MC: Mr. Fumihito Takanashi, Deputy Director,
Office of International Regulatory Affairs, MHLW

09:00-09:30	Registration		
09:30-10:05	**1. Opening Remarks**		
	(1) TBD	MHFW/CDSCO	5 min
	(2) Mr. Seiichi Inoue	Executive Director, PMDA	5 min
	(3) H.E. Mr. Kenji Hiramatsu	Ambassador of Japan to India	5 min
	(4) TBD	Indian Pharmaceutical Industry	5 min
	(5) TBD	FPMAJ	5 min
	(6) TBD	Indian Medical Device Industry	5 min
	(7) TBD	JFMDA	5 min
10:05-10:20	Photo Session & Coffee Break		
10:20-11:10	**2. Keynote Speeches**		

	(1) “Latest trend of pharmaceutical and medical device regulation, and international cooperation of India”	MHFW/CDSCO	25 min
	(2) “Latest trend of pharmaceutical and medical device regulation, and international cooperation of Japan”	Mr. Seiichi Inoue Executive Director, PMDA	25 min
11:10-12:00	**3. Regenerative Medicine**		
	(1) “Regulatory frameworks of regenerative medicines and products review in Japan”	Mr. Kenji Kuroiwa, Deputy Director, Office of Regenerative Medicine Product Evaluation, MHLW	20 min
	(2) “Way to regulation on regenerative medicines and products in India”	MHFW/CDSCO	20 min
	(3) Q&A	All presenters	10 min
12:00-13:00	Lunch Time		
13:00-15:00	**4. Medical Devices** Moderator: Mr Naoyuki Yasuda, Office Director, Office of International Programs, PMDA		
	Part A. Medical Device Regulation in India		
	(1) “Update on the Implementation of Medical Device Rules in India”	MHFW/CDSCO	25 min
	(2) “Industry’s response and preparation to the medical device regulation in India”	Indian industry	15 min
	(3) Q&A	All presenters	10 min
	Part B. Medical Device Regulation in Japan		
	(1) “GCP/Clinical Investigation in Japan”	Mr. Shinwa Shibata, Inspector, Office of Non-clinical and Clinical Compliance, PMDA	15 min

	(2) “GCP/Clinical Investigation in Japan: Industry perspective”	Dr. Kazuaki Sekiguchi, Abbott, JFMDA	15 min
	(3) “Post market surveillance/vigilance in Japan”	Dr. Mari Shirotani, Director, Office of International Programs, PMDA	15 min
	(4) “Post market surveillance/vigilance in Japan: Industry perspective”	Mr. Hideki Watanabe, Terumo, JFMDA	15 min
	(5) Q&A	All presenters	10 min
15:00-15:20	Coffee Break		
15:20-17:40	**5. Pharmaceuticals** Moderator: MHFW/CDSCO		
	Part A. GMP/Quality		
	(1) “Experience of GMP inspections by PMDA and general advices for manufactures”	Mr. Koki Akazawa, GMP Inspector, Office of Manufacturing/Quality and Compliance, PMDA	15 min
	(2) “Enhancement of GMP inspections in India”	MHFW/CDSCO	15 min
	(3) “Topic related to post-approval change” (tentative)	Mr. Tomonori Nakagawa, Otsuka Pharmaceutical Co., Ltd., JPMA	15 min
	(4) “Compliance with the GMP standard in the international level”	Indian Industry	15 min
	(5) Q&A	All presenters	10 min
	Part B. Pharmacovigilance		
	(1) “Pharmacovigilance system in Japan”	Dr. Daisaku Sato Director, Pharmaceutical Safety Division, MHLW	15 min
	(2) “Pharmacovigilance system in India”	MHFW/CDSCO	15 min

	(3) “Pharmacovigilance in Japan: Industry perspective”	Mrs. Ayami Komatsu, Torii Pharmaceutical Co.,LTD, JPMA	15 min
	(4) “Pharmacovigilance in India: Industry perspective”	Indian Industry	15 min
	(5) Q&A	All presenters	10 min
17:40-17:50	**6. Closing Remarks**		
	(1) TBD, MHFW/CDSCO, 5 min (2) Dr. Daisaku Sato, Director, Pharmaceutical Safety Division, 5 min		