July 26, Japan revision

Draft Agenda for
3rd India -Japan Medical Products Regulation Symposium

Date: Monday & Tuesday, August 27th & 28th, 2018

Venue: India Habitat Centre, New Delhi, India **(Proposed)**

Address: Habitat World at Indian Habitat Centre, Lodhi Road, New Delhi – 110003

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) Pharmexcil, 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):

1st Day 170 (100 (Indian Side) + 70 (Japanese Side))

2nd Day 100 (50 (Indian Side) + 50 (Japanese Side))

Interpreter: English-Japanese simultaneous translation

Program:

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

MC: Outsource

The following is the proposed schedule. The titles and speakers are tentative and indicative only. They will be finalized in consultation between both sides.			
09:00-09:30	Registration		
09:30-10:30	**Opening Remarks**		
	(1) Welcome Address: Dr. S. Eswara Reddy	Drugs Controller General (India), CDSCO	05 min
	(2) Dr. Takao Yamori	Executive Director, PMDA	05 min
	(3) H.E. Mr. Kenji Hiramatsu	Ambassador of Japan to India	05 min

	(4) Dr. Venkatesh	Director General of Health Services (GOI)	05 min
	(5) Mr. Toshihiko Miyajima	Director General, FPMAJ	05 min
	(6) Secretary*	Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers (GOI)	10 min
	(7) Mr. Nobuyoshi Ishii	Executive Director, JFMDA	05 min
	(8) Secretary*	Ministry of Commerce and Industry (GOI)	05 min
	(9) Secretary*	Ministry of Health and Family Welfare	05 min
	(10) Vote of Thanks: Dr. R. K. Vats*	AS & DG (CGHS)	10 min
10:30-10:50	Photo Session & Coffee Break		
10:50-11:30	**Keynote Speeches**		
	(1) "Latest trend of pharmaceutical and medical device regulation, and international cooperation of India"	MHFW/CDSCO	20min
	(2) "Latest trend of pharmaceutical and medical device regulation, and international cooperation of Japan"	Dr. Takao Yamori Executive Director, PMDA	20min
11:30-12:30	**Stem Cells and Products / Regenerative Medicine Products**		
	(1) "Regulatory frameworks of regenerative medicines and products review in Japan"	Mr. Kenji Kuroiwa, Deputy Director, Office of Regenerative Medicine Product Evaluation, MHLW	25min
	(2) "Regulatory Framework on Stem Cells and Products Review in India"	MHFW/CDSCO	25min
	(3) Q&A	All presenters	10min
12:30-13:30	Lunch Time		

13:30-14:40	**Pharmaceuticals** Moderator: MHFW/CDSCO		
	Part A. GMP/Quality		
	(1) "Experience of GMP inspections by PMDA and general advices for manufactures"	Mr. Hiroshi Sakurai GMP Inspector, Office of Manufacturing/Quality and Compliance, PMDA	15 min
	(2) "Enhancement of GMP inspections in India"	CDSCO	15 min
	(3) "Development and utilization of Site Master File"	Mr. Tomonori Nakagawa Otsuka Pharmaceutical Co., Ltd., JPMA	15 min
	(4) "Compliance with the GMP standard in the international level"	CDSCO	15 min
	(5) Q&A	All presenters	10 min
14:40-15:00	Coffee Break		
15:30-16:10	Part B. Pharmacovigilance		
	(1) "Pharmacovigilance system in Japan"	MHLW/PMDA	15 min
	(2) "Pharmacovigilance system in India"	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
16:10-16:30	Pharma clusters/hubs in India A perspective	MHFW/CDSCO	20 min
16:30	End of 1st day		

Day-2, August 28th, 2018

Medical Devices Moderator: MHLW/PMDA			
9:30-10:20	**Medical Device Regulation in India**		
	(1) "Update on the Implementation of Medical Device Rules in India"	CDSCO FICCI / Indian industry	25 min
	(2) "Industry's response and preparation to the medical device regulation in India"		15 min
	Q&A Session		10 min
10:20-10:40	Coffee Break		
10:40-11:50	**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"	Mr. Kensei Tanaka, Inspector, Office of Safety I, PMDA	15 min
	(4) "Post market surveillance/vigilance in Japan: Industry perspective"	Dr. Hideki Watanabe, Terumo, JFMDA	15 min
	(5) Q&A	All presenters	10 min
11:50-12:05	**Closing Remarks**		
	(1) TBD, FICCI, 5 min (2) TBD, Pharmexcil, 5 min (3) TBD, MHLW/PMDA, 5 min		
12:05-13:00	Lunch Break Close out Meeting		