Agenda for
5th India -Japan Medical Products Regulatory Symposium

Dates :
Tuesday, **21 December 2021** (11.30 - 14.30 IST) (15:00 - 18:00 JST) and
Wednesday, **22 December 2021** (11.30 - 13.40 IST) (15.00 - 17.10 JST)

Venue: Virtual meeting through Webex

Host: (India) MoHFW(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)

Interpreter: English-Japanese simultaneous translation

Day 1 (Tuesday, 21 December 2021)			
OPENING SESSION			
15:00-15:34 JST 11:30-12:04 IST	(1) Representative of Ministry of Health & Family Welfare, Government of India	MOHFW, GOI	04 min
	(2) Minister Economic & Commerce, Embassy of India, Tokyo	Ms. Mona Khandhar	02 min
	(3) Representative of Ministry of Health, Labor and Welfare, Japan	Ms. YAMAMOTO Fumi, Councilor for Pharmaceutical Affairs, MHLW	04 min
	(4) Representative of Central Drugs Standard Control Organization, India	Dr. V. G. Somani, DCG(I), CDSCO	02 min
	(5) Representative of Pharmaceuticals and Medical Devices Agency, Japan	Dr. FUJIWARA Yasuhiro, Chief Executive, PMDA	02 min
	(6) Representative of Indian Pharmaceutical Industry	Mr. Ravi Uday Bhaskar, Director General, Pharmexcil	04 min
	(7) Representative of Indian Medical Device industry	Mr. Himanshu Baid, Managing Director, M/s Poly Medicure Ltd. and Chairman, CII - National Medical Technology Forum, Members' FICCI, PHD and AIMED	04 min

	(8) Representative of Japanese Pharmaceutical Industry	Dr. SHIRAISHI Junichi, Director General, JPMA	04 min
	(9) Representative of Indian JapaneseDevice industry	Dr. MATSUMOTO Kenichi, Vice Chairman, JFMDA	04 min
	Photo & Break		04 min

Keynote Speeches			
15:34-16:00 JST 12:04 - 12:30 IST	Latest trend of pharmaceutical, medical device regulation, and international cooperation of India	Dr. V. G. Somani, DCG(I) ,CDSCO	08 min
	Latest trend of pharmaceutical, medical device regulation, and international cooperation of Japan	Dr. FUJIWARA Yasuhiro, Chief Executive, PMDA	08 min
	Q&A	**All presenters**	**10 min**

1. Pharmaceuticals Session			
Part A	**International Collaboration and Reliance**		
16:00-16:40 JST 12:30-13:10 IST	International Collaboration and Reliance (Indian Perspective)	Dr. S. Eswara Reddy, CDSCO	15 min
	International Collaboration and Reliance (Japan Perspective)	Mr. MATSUKURA Yuji, MHLW	15 min
	Q&A	All presenters	10 min
Part B	**GMP and Quality Management**		
16:40-17:20 JST 13:10-13:50 IST	Updates of GMP and Quality Management (India)	Dr. Rubina Bose, CDSCO	15 min
	Updates of GMP and Quality Management (Japan)	Mr. AKAZAWA Koki, PMDA	15 min
	Q&A	All presenters	10 min
Part C	**Latest trend of clinical trial requirements**		
17:20-18:00 JST 13:50-14:30 IST	Latest trend of clinical trial requirements (India)	Mr. A.K. Pradhan, CDSCO	15 min
	Latest trend of clinical trial requirements (Japan)	Dr. SUGAI Hana, PMDA	15 min
	Q&A	All presenters	10 min

Day 2 (Wednesday, 22 December 2021)			
2. MEDICAL DEVICES SESSION			
Part D	**Implementation of medical device regulations**		
15:00-15:30 JST 11:30 - 12:00 IST	Implementation of medical device regulations (India)	Dr. Ravi Kant Sharma,CDSCO	10 min
	Implementation of medical device regulations (Japan)	Ms. SASAKI Kanako, MHLW	10 min
	Q&A	All Presenters	10 min
Part E	**IVD (clinical investigation requirements)**		
15:30-16:00 JST 12:00-12:30 IST	IVD (clinical investigation requirements) (India)	Dr. Ravi Kant Sharma,CDSCO	10 min
	VD (clinical investigation requirements) (Japan)	Dr. YABANA Naoyuki, PMDA	10 min
	Q&A	All Presenters	10 min

3. REGENERATIVE MEDICINES SESSION			
Part F	**Updates of Regulations & recent trends in Regenerative Medical Products**		
16:00-16:30 JST 12:30 - 13:00 IST	Updates of Regulations & recent trends in Regenerative Medical Products (India)	Sh. Sanjeev Kumar, CDSCO	10 min
	Updates of Regulations & recent trends in Regenerative Medical Products (Japan)	Dr. KASAI Masaki, PMDA	10 min
	Q&A	All Presenters	10 min
Part G	**Post marketing safety requirements.**		
16:30-17:00 JST 13:00 - 13:30 IST	Post marketing safety requirements (India)	Dr. P.B.N. Prasad, CDSCO	10 min
	Post marketing safety requirements (Japan)	Dr. NODA Shinichi, PMDA	10 min
	Q&A	All Presenters	10 min

Closing Remarks			
17:00-17:10 JST	Representative of Central Drugs Standard Control Organization, India	Dr. V. G. Somani, DCG(I), CDSCO	5 min
13:30-13:40 IST	Representative of Pharmaceuticals and Medical Devices Agency, Japan	Dr. FUJIWARA Yasuhiro, Chief Executive,PMDA	5 min