# Agenda for
# 7th India - Japan Medical Products Regulatory Symposium

**Dates:** **Wednesday, 10 July 2024** (9:30-16:50 IST) (13:00-20:20 JST)
**Venue:** FICCI House, New Delhi
**Style:** In-person
**Host: (India)** MoHFW (Ministry of Health and Family Welfare)
CDSCO (Central Drugs Standard Control Organization)
**(Japan)** MHLW (Ministry of Health, Labour and Welfare)
PMDA (Pharmaceuticals and Medical Devices Agency)
**Interpreter:** English-Japanese simultaneous translation
**MC:** CDSCO

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| 9:00-9:30 | **Registration** | |
| **Opening Ceremony** | | |
| 9:30-10:00 | (1) Representative of Ministry of Health & Family Welfare, Government of India | Sh. Rajiv Wadhawan, Joint Secretary, MoHFW / Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India), CDSCO |
| | (2) Representative of Pharmaceuticals and Medical Devices Agency, Japan | Mr. YADA Shinji Executive Director, PMDA |
| | (3) Representative of Indian Pharmaceutical Industry | Dr. Rajeev Mathur, Senior Vice President and Head of Regulatory at Sun Pharma |
| | (4) Representative of Japanese Pharmaceutical Industry | Dr. NAKAGAWA Sachiko Managing Director, JPMA |
| | (5) Representative of Indian Medical Device industry | Mr. Gurmit Singh Chugh, Chairman, Translumina Therapeutics |
| | (6) Representative of Japanese Medical Device industry | Mr. SAKAGUCHI Yuji, JFMDA (On behalf of Mr. YAMAMOTO Akio, Chairman), JFMDA |
| 10:00-10:30 | **Photo & Tea Break** | |
| **Regulatory updates** | | |
| 10:30-11:30 | (1) Regulatory updates including recent amendments (or keynote) | Dr. Ranga Chandrasekhar, Joint Drugs Controller (India), CDSCO |

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| | (2) Regulatory updates in Japan | Dr. TANAKA Daisuke<br>Director, Office of International Programs, PMDA |
| | (3) Q&A | All presenters |
| **1. Pharmaceuticals Session** | | |
| 11:30-12:15 | (1) Quality Control about APIs | Dr. MIKAMI Kenichi<br>Director, Office of Manufacturing Quality for Drugs, PMDA |
| | (2) Revised GMP requirements for API | Sh. Arvind Kukrety,<br>Deputy Drugs Controller (India), CDSCO |
| | (3) Q&A | All presenters |
| 12:15-13:00 | (4) E-Labeling Implementation in Japan and Asia - from industries perspective - | Ms. MATSUI Rie<br>Pfizer R&D Japan, JPMA |
| | (5) Revised GMP requirements (Schedule –M) | Sh. A K Pradhan,<br>Advisor, CDSCO |
| | (6) Q&A | All presenters |
| 13:00-14:00 | **Lunch Time** | |
| **2. Medical Devices Session** | | |
| 14:00-15:20 | (1) Updates on Requirement for grant of import/manufacturing license / permissions | Sh. Aseem Sahu,<br>Deputy Drugs Controller (India), CDSCO |
| | (2) Regulations for QMS and SaMD in Japan | Dr. MURAKAMI Madoka<br>Principal Reviewer, Office of SaMD, PMDA |
| | (3) Q&A | All Presenters |
| 15:20-15:40 | **Hi Tea Break** | |
| **3. Regenerative Medicines Session** | | |
| 15:40-16:40 | (1) Updates of recent approvals in India (CAR-T cell products) | Dr. Annam Visala,<br>Joint Drugs Controller (India), CDSCO |
| | (2) Regulatory Update of Regenerative Medicine in Japan | Dr. MARUYAMA Yoshiaki<br>Director, Office of Cellular and Tissue-based Products, PMDA |
| | (3) Q&A | All Presenters |
| **Closing Remarks** | | |
| 16:40-16:50 | (1) Representative of Ministry of Health, Labor and Welfare, Japan | Dr. HIROTA Mitsue<br>Deputy Director, Office of International Regulatory Affairs |

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| | | Pharmaceutical Safety Bureau, MHLW |
| | (2) Representative of Central Drugs Standard Control Organization, India | Dr. Ranga Chandrasekhar, Joint Drugs Controller (India), CDSCO |