Summit of Heads of Medicines Regulatory Agencies Symposium

October 27, 2017 | Kyoto International Conference Center, Japan

Host: Ministry of Health, Labour and Welfare, Pharmaceuticals & Medical Devices Agency, Kyoto Prefecture and DIA Japan

Endorsement: JPMA and JFMDA

Website: http://www.c-linkage.co.jp/12th-summit-symposium/en/

From October 23 through October 26, 2017, the international Summit of Heads of Medicines Regulatory Agencies and meeting of the International Coalition of Medicines Regulatory Authorities (ICMRA) will convene for the first time in Japan, at the Kyoto International Conference Center. This "Kyoto Meeting" will bring together regulatory authorities from more than 30 countries and regions around the world, including the United States, Europe, China, Brazil, and Japan. A main topic will be innovation in pharmaceuticals, medical devices, and regenerative medicine. Participants will exchange viewpoints on a variety of topics including future of relevant regulation, review processes, postmarketing surveillance, stable product supply, and risk management.

The Kyoto Meeting is not open to the public, but following completion of the closed meeting, on October 27, a one-day symposium will be offered to provide an early report of the results of the Summit. This is the first time that a public symposium has been offered in conjunction with this type of regulatory summit conference, and is also the first time for representatives of regulatory authorities from so many countries to convene a summit conference in Japan.

In addition to providing a "flash report" about the results of the Kyoto Meeting, representatives from a variety of countries and industries will discuss innovative technological developments and their practical applications, both current status and future expectations, and will discuss how the various national regulatory authorities address technological development and what challenges can be expected. There will also be a not-to-be missed presentation by Professor Shinya Yamanaka, Nobel laureate. We look forward to seeing broad participation in this truly unique opportunity.

Overview (Featured Speakers)

Morning: *For the Practical Application of Innovative Technology*

Primary speakers:

Shinya Yamanaka, MD, PhD, Director, Center for iPS Cell Research and Application (CiRA), Kyoto University

Guido Rasi, MD, Executive Director, European Medicines Agency (EMA)

Representatives of regulatory agencies and industry

Afternoon: *How the Various National Regulatory Authorities Approach Technological Innovations and What Challenges Can Be Expected - Focusing primarily on results from the 12th Summit of Heads of Medicines Regulatory Agencies and International Coalition of Medicines Regulatory Authorities (ICMRA) Meeting*

Primary speakers:

Tatsuya Kondo, MD, PhD, Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA)

Kazuhiko Mori, MSc, Councilor for Pharmaceutical Affairs, Minister's Secretariat, Ministry of Health, Labour and Welfare (MHLW)

Ian Hudson, MD, FFPM, FRCP, Chief Executive; Medicines and Healthcare products Regulatory Agency (MHRA) / ICMRA Chair

Representatives of the Summit of Heads of Medicines Regulatory Agencies and of the ICMRA authorities

Simultaneous translation will be provided in Japanese and English.

Registration fee: ¥2,000 (Excluding Consumption Tax)/person

* Box lunches are available on request (extra charge)

Online Registration

http://www.c-linkage.co.jp/12th-summit-symposium/en/

Contact: DIA Japan

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厚生労働省 Ministry of Health, Labour and Welfare | Pmda | 京都府 Kyoto Prefecture | DIA

Summit of Heads of Medicines Regulatory Agencies Symposium — October 27th, 2017

9:00-10:00 **REGISTRATION**

10:00-10:30 **WELCOME AND OPENING REMARKS**

OVERALL HOST

Ko Sekiguchi, MBA
Director, DIA Japan

Organizer
Shinji Miyamoto
Director General of Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (MHLW)

Host
Keiji Yamada
Governor, Kyoto Prefecture

Industry Representative
Yoshihiko Hatanaka
President, the Japan Pharmaceutical Manufacturers Association (JPMA)

10:30-13:15 **MORNING SESSION**

Innovative Technology and Its Launch into Market

10:30-11:15

Recent Progress in iPS Cell Research and Application
Shinya Yamanaka, MD, PhD
Director, Center for iPS Cell Research and Application (CiRA), Kyoto University / Professor, Kyoto University

11:15-11:45

EU's Innovative Medical Technology and EMA's Measures
Guido Rasi, MD
Executive Director, European Medicines Agency (EMA)

11:45-12:15

US 21st Century Cures Act - Challenge of FDA - [Video Letter]
Scott Gottlieb, MD
Commissioner, US Food and Drug Administration (FDA)

12:15-12:45

For Early Access of Innovative Medicines to Patients
Yoshihiko Hatanaka
President, the Japan Pharmaceutical Manufacturers Association (JPMA)

Chief Executive Officer and President, Astellas Pharma, Inc.

12:45-13:15

For Early Access of Innovative Medical Devices to Patients
Masaya Watanabe, MSc
Chairman, The Japan Federation of Medical Devices Associations (JFMDA)

13:15-14:30 **LUNCH BREAK**

14:30-16:50 **AFTERNOON SESSION**

Measures and Challenges of Pharmaceutical Regulatory Authorities, Mainly Based on the Results of the 12th Summit and ICMRA Meeting

14:30-14:50

Results of the 12th Summit of Heads of Medicines Regulatory Agencies
Tatsuya Kondo, MD, PhD
Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA)

14:50-15:05

Results of the ICMRA Meeting
Ian Hudson, MD, FFPM, FRCP
Chief Executive; Medicines and Healthcare products Regulatory Agency (MHRA) / ICMRA Chair

15:05-15:20

Report of Workshops of the ICMRA [I]: Supply Chain Integrity
Guido Rasi, MD
Executive Director, European Medicines Agency (EMA)

15:20-15:35

Report of Workshops of the ICMRA [II]: Pharmacovigilance
John Skerritt, PhD
Deputy Secretary, Therapeutic Goods Administration (TGA)

15:35-15:50

Report of Workshops of the ICMRA [III]: Crisis Management
Jarbas Barbosa da Silva Jr, MD, PhD
Director-President of National Health Regulatory Agency (ANVISA)

15:50-16:20

Pharmaceutical Regulatory Activities of WHO
Emer Cooke, MBA
Head of Regulation of Medicines and other Health Technologies, World Health Organization (WHO)

16:20-16:50

Global Cooperation on Regulatory Authorities and Japan's Activities
Kazuhiko Mori, MSc
Councilor for Pharmaceutical Affairs, Minister's Secretariat, Ministry of Health, Labour and Welfare (MHLW)

16:50-17:30 **PANEL DISCUSSION**

International Cooperation on Pharmaceutical Regulatory Authorities

SESSION CO-CHAIRS

Tatsuo Kurokawa, PhD
Former DIA President

Lorraine Nolan, PhD
Chief Executive, the Health Products Regulatory Authority (HPRA)

Panelists

Kazuhiko Mori, MSc
Councilor for Pharmaceutical Affairs, Minister's Secretariat, Ministry of Health, Labour and Welfare (MHLW)

Dara Corrigan, JD
Acting Deputy Commissioner, US Food and Drug Administration (FDA)

Guido Rasi, MD
Executive Director, European Medicines Agency (EMA)

Jürg H. Schnetzer
Executive Director, Swissmedic

Supriya Sharma, MD, MPH, FRCPC
Chief Medical Advisor, Health Canada (HC)

17:30-17:45 **CLOSING REMARKS**

Masaya Watanabe, MSc
Chairman, The Japan Federation of Medical Devices Associations (JFMDA)

Speakers and agenda are tentative and subject to change without notice. Recording or shooting of the symposium in any type of media, is prohibited without prior written consent from organizers.