

**Asia Partnership Conference of
Pharmaceutical Associations**

To Expedite the Launch of Innovative Medicines for the Peoples in Asia



The Third Asia Partnership Conference of Pharmaceutical Associations

PROGRAM

“To Expedite the Launch of Innovative Medicines for the Peoples in Asia”
– Progressing towards a Strategic Roadmap for a Framework of Drug Discovery and Development in Asia –

Date: April 10 (Thursday) – 11 (Friday), 2014

Venue: Imperial Hotel, Tokyo

“To Expedite the Launch of Innovative Medicines for the Peoples in Asia” – Progressing towards a Strategic Roadmap for a Framework of Drug Discovery and Development in Asia –

Program

Day 1 April 10, 2014 (12:30~17:40)

Facilitator : Akihiko Matsubara (Managing Director, JPMA)

| Expert Working Group / APAC Steering Committee Session | |
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| 12:30 ▶ 12:35 | Session Remarks : Tadaharu Goto (Director General, JPMA) |
| 12:35 ▶ 14:35 | Chair : Yutaka Tsuchiya (Chairperson, International Affairs Committee, JPMA) Regulations and Approvals - Expert Working Group Report, Yoshimasa Shimoto (EWG Leader) Drug Discovery Alliances - Expert Working Group Report, Keisuke Watanabe (EWG Leader) APAC Steering Committee Report, Yoshihiro Takada (Secretariat of APAC SC) |
| 14:35 ▶ 14:45 | Wrap-up : Masafumi Nogimori (Vice President, JPMA) |
| 14:45 ▶ 15:00 | 《Break》 |
| 15:00 ▶ 15:10 | Opening Remarks : Isao Teshirogi (President, JPMA) |
| 15:10 ▶ 15:20 | Guest Speech : Hiroto Izumi (Special Advisor to the Prime Minister, Cabinet Secretariat) |
| Issues and Challenges in Asian Pharmaceutical Market | |
| 15:20 ▶ 16:20 | “Pros and Cons of the Utilization of HTA in Asia and its Future Direction” |
| | Chairs : Yutaka Tsuchiya (Chairperson, International Affairs Committee, JPMA), Ted Padilla (Executive Director, PHAP) Panelists : Mie Azuma (JPMA), Busakorn Lerswatanasivalee (CEO, PReMA) , Sean Kim (Senior Director, KRPIA), Heather Lin (COO, IRPMA) |
| 16:20 ▶ 16:40 | 《Break》 |
| 16:40 ▶ 17:40 | Intellectual Property in Asia : Current Status and Future Responses |
| | Chairs : Yoichi Okumura (Chairperson, Intellectual Property Committee, JPMA), Parulian Simanjuntak (Executive Director, IPMG) Panelists : Kunchithapatham Shivkumar (OPPI) Busakorn Lerswatanasivalee (CEO, PReMA) Kwang-bum Kim (KPMA) Hiroshi Morita (Vice Chairperson, Intellectual Property Committee, JPMA) |

Day 2 April 11, 2014 (9:30~17:30)

Facilitator : Akihiko Matsubara (Managing Director, JPMA)

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| 9:00 ▶ 9:20 | Guest's Speech : Eduardo Pisani (Director General, IFPMA) |
| Keynote Address 1 : | |
| 9:20 ▶ 9:50 | “Global expansion of healthcare sector - Recent progresses and remaining challenges” Speaker : Hidehito Sekino (Director of Office for Global Expansion of Japanese Healthcare) |
| 9:50 ▶ 10:10 | 《Break》 |
| Panel Discussion 1 : Regulations and Approvals | |
| 10:10 ▶ 12:10 | “Collaboration between Regulatory Agencies and Industries to Achieve Regulatory Convergence Smoothly in Asia” Chairs : Shinobu Uzu (Office Director, PMDA), Chih-Ping Yang (President, IRPMA) 1. Proposals based on APAC activities Yoshimasa Shimoto (EWG Leader) Agency's perspectives regarding NDA review 2. Experiences & Challenges for NDA review in Japan Shinobu Uzu (Office Director, PMDA, Japan) 3. Good Review Practice Activity in Korea In-Sook Park (Director, MFDS, Korea) 4. TFDA's perspectives on Good Review Practice Li-Ling Liu (Director, TFDA, Taiwan) 5. Thailand's perspectives regarding NDA review including implementation of Good Review Practice to support Regulatory Convergence in Asia Prapassorn Thanaphollert (Acting Director, FDA, Thailand) 6. Discussion : Including Churn-Shiouh Gau (Executive Director, CDE, Taiwan) |
| | 12:10 ▶ 13:30 |
| Keynote Address 2 : | |
| 13:30 ▶ 14:00 | “Challenges towards iPS cell therapy for Parkinson's disease” Speaker : Jun Takahashi, Professor of Center for iPS Cell Research and Application, Kyoto University |

Program

Panel Discussion 2 : Drug Discovery Alliance

“How can open innovation promote drug discovery in Asia”

Chairs : Kentaro Yoshimatsu (Vice Chairperson Biopharmaceuticals Committee, JPMA),
Yew Wei Tarnng (President, PhAMA)

1. APAC's vision of an open innovation platform for Asian drug discovery
Keisuke Watanabe (EWG Leader)
2. Innovation to foster new drug R&D
Youe-Kong Shue (OBI phama, Inc. Taiwan)
3. The role of a university in driving drug discovery
Rajata Rajatanavin (President, Mahidol University, Thailand)
4. The incubator's role in activating open innovation
Dongho Lee (CEO, Korea Drug Development Fund, Korea)
5. New approach for cancer treatment
Nobuyuki Takakura (Professor, Osaka University)
6. Discussion

14:00 ▶ 16:00

16:00 ▶ 16:20

《Break》

Keynote Address 3 :

“GHIT, Challenge and the Possibility”

Speaker : Shiro Konuma (Director, Office of Health and Medical Strategy, Cabinet Secretariat)

16:20 ▶ 16:50

16:50 ▶ 17:10

Overall Wrap-up : Isao Teshirogi (President, JPMA)

17:10 ▶ 17:30

Closing Remarks : Haruo Naito (Vice President, JPMA)

17:40 ▶ 18:20

※ 《Press Conference》

18:30 ▶ 20:30

《Reception》

※ Relevant person only

Profile

Keynote Address 1



Hidehito Sekino

Director of Office for Global Expansion of Japanese Healthcare, and Director of Office of Medical Device Policy of Economic Affairs Division, Health Policy Bureau, and Medical Alliance Coordinator. Japan

February 1989: Joined the Ministry of Health and Welfare. Temporary assigned to the Science and Technology Agency, and the Embassy of Japan in Nigeria.

Held positions in Medical Economics Division, Health Insurance Bureau; Safety Division, and Evaluation and Licensing Division, and General Affairs Division, Pharmaceutical and Food Safety Bureau of MHLW before appointed as Pharmaceutical Affair Planning Officer, followed by Director of Office of Medical Devices Evaluation.

July 2011: Director of Office of Medical Device Policy of Economic Affairs Division, Health Policy Bureau, and concurrently served as Medical Alliance Coordinator.

May 2013~present: being served as Director of Office for Global Expansion of Japanese Healthcare in addition to Director of Office of Medical Device Policy of Economic Affairs Division, Health Policy Bureau, and Medical Alliance Coordinator.



Profile

Keynote Address 2

Jun Takahashi

Professor of Center for iPS Cell Research and Application (CiRA) at Kyoto University, Kyoto, Japan

Jun Takahashi is a professor of Center for iPS Cell Research and Application (CiRA) at Kyoto University, Kyoto, Japan. He graduated from Kyoto University Faculty of Medicine in 1986, and started his carrier as a neurosurgeon at Kyoto University Hospital. After he earned his Ph.D. from Kyoto University Graduate School of Medicine in 1993, he became a postdoctoral fellowship at the Salk Institute (Dr. Fred Gage’s laboratory, 1995 & 1996), CA, U.S.A., where he started a research work on neural stem cells. After getting back to Kyoto University Hospital, he has been engaging functional neurosurgery including deep brain stimulation, and also research works on stem cell therapy using ES/iPS cells for Parkinson’s disease. Jun Takahashi was awarded by the Michael J. Fox Foundation for Parkinson’s Research in 2005. He became an associate professor at Institute for Frontier Medical Sciences, Kyoto University in 2007, and in 2012, he moved to CiRA as a full professor to promote a clinical application of the stem cell therapy for Parkinson’s disease.



Profile

Keynote Address 3

Shiro Konuma

Director, Office of Health and Medical Strategy, Cabinet Secretariat. Japan

2014: Office of Healthcare Policy, Cabinet Secretariat

1992: Graduated from Faculty of Medicine, the University of Tokyo and worked for the University of Tokyo Hospital until joining Japanese diplomatic service in 1994.

1996: Studied at INSEAD (“The Business School for the World”) in France. Deputy Director of Economic Policy Division, Economic Affairs Bureau at the Ministry of Foreign Affairs of Japan (MOFA), Counsellor of Cabinet Office (Assistant to Director General for Economic, Fiscal and Social Structure), Deputy Director, Economic Partnership Division of MOFA, Counsellor of the Permanent Mission of Japan to the United Nations and Other International Organizations in Geneva, Director of Global Health Policy Division of MOFA, prior to the assignment as Director, Office of Health and Medical Strategy, Cabinet Secretariat.