APAC
Asia Partnership Conference
of Pharmaceutical Associations

"To Expedite the Launch of Innovative Medicines for the Peoples in Asia"
- For Accelerating the Review Process of New Drugs and Establishing Open Innovation Platforms for Drug Discovery-

The Fourth Asia Partnership Conference of Pharmaceutical Associations

PROGRAM

Date: April 9 (Thursday) – 10 (Friday), 2015

Venue: Palace Hotel, Tokyo

"To Expedite the Launch of Innovative
-For Accelerating the Review Process of New Drugs and

Program

Day 1 April 9, 2015 (9:00-17:50)

Facilitator: Akihiko Matsubara (JPMA)

9:00 ▶ 9:05	Opening Remarks	Masayo Tada (President, JPMA)
9:05 ▶ 9:20	Guest Speech	Brendan Shaw (Assistant Director General, IFPMA)
Expert Working Group / APAC Steering Committee Session		
9:20 ▶ 10:20	EWG Report APAC Future Plan	Chair: Haruhiko Hirate (JPMA) Atsuko Higuchi (JPMA)
10:20 ▶ 10:30	Wrap-up	Yoshihiko Hatanaka (Vice President, JPMA)
10:30 ▶ 10:50	< Break >	
Keynote Address I		
10:50 ▶ 11:20	"Drug Discovery Alliance - Japan and Korea" Hak-Bae Choi (CEO, C&C Research Laboratories, Korea)	
Establish a Research Alliance Scheme Throughout Asia		
11:20 ▶ 12:20	Drug Discovery Alliances Session ---Concrete Measures for Promoting Research Alliance in Asia---	Chair: Masaaki Hirano (JPMA) Part 1. Presentation 1. APAC Drug Discovery Alliance Strategy: Keisuke Watanabe (JPMA) 2. Introduction of DSANJ System: Tohru Yoshikawa (OCCI, Japan) 3. Feedback for DSANJ Business Meeting: Suh-Hang Hank Juo (Kaohsiung Medical University, Taiwan) 4. Planning for DSANTW System: Phoenix Wang (NRPB, Taiwan)
12:20 ▶ 13:40	< Lunch >	
13:40 ▶ 14:40	Drug Discovery Alliances Session ---Concrete Measures for Promoting Research Alliance in Asia---	Part 2. Panel Discussion: Expectation and Challenges for DSANA 1. Hak-Bae Choi (C&C Research Laboratories, Korea) 2. Chen Changxiong, (SINO-PhIRDA, China) 3. Cindy Tai Lee Ling (BiotechCorp, Malaysia)
14:40 ▶ 15:00	< Break >	

Medicines for the Peoples in Asia"
Establishing Open Innovation Platforms for Drug Discovery-

Keynote Address II		
15:00 ▶ 15:30	"Advocacy of Regulatory Science and International Collaboration" Tatsuya Kondo (Chief Executive, PMDA, Japan)	
Accelerate the Registration Process in Asia		
15:30 ▶ 16:30	Regulations and Approvals Session ---Approach to Good Registration Management in Asia---	Chairs: Kiminori Nagao (JPMA) / Li-Ling Liu (TFDA, Taiwan) Part 1. Presentation 1. Introduction: Current Status of Good Review Practice (GRevP) Guideline: Li-ling Liu (TFDA, Taiwan) 2. APAC Proposals on Good Submission Practice (GSubP) Guideline and Position Paper: Kiminori Nagao (JPMA) 3. Regulator's View 1: Churn-Shiouh Gau (CDE, Taiwan) 4. Regulator's View 2: Tharnkamol Chanprapah (FDA, Thailand) 5. Q&A
16:30 ▶ 16:50	< Break >	
16:50 ▶ 17:50	Regulations and Approvals Session ---Expectations and challenges for APAC GSubP Guideline---	Part 2. Panel Discussion: 1. Daisaku Sato (PMDA, Japan) 2. Churn-Shiouh Gau (CDE, Taiwan) 3. Tharnkamol Chanprapah (FDA, Thailand) 4. Isao Sasaki (JPMA) 5. Kum Cheun Wong (SAPI, Singapore)
18:00 ▶ 20:00	< Reception >	

Program

Day 2 April 10, 2015 (9:00-12:15)

Special Lecture I		
9:00 ▶ 9:15	"Introduction of Japan Agency for Medical Research and Development" Makoto Suematsu (President, AMED, Japan)	
Special Lecture II		
9:15 ▶ 9:45	"Sakigake Package Strategy" Kazuhiko Mori (Director, MHLW, Japan)	
9:45 ▶ 10:00	< Break >	
Issues and Challenges in Asian Pharmaceutical Market		
10:00 ▶ 11:40	Discussion on Counterfeit Medicines in Asia	Chairs: Kunihiko Kokubo (JPMA) /Joseph Cho (RDPAC, China) 1. Keynote Lecture: "Counterfeit Medicines; Situation/Countermeasure in Asia" - Thomas T. Kubic (Pharmaceutical Security Institute, U.S.A) 2. Report from Authorities: - Haruo Akagawa (MHLW, Japan) - Jinhee Oh (MOHW, Korea) 3. Panel Discussion - Theingi Zin (FDA, Myanmar) - Sabrina Chan (HKAPI, Hong Kong) - Parulian Simanjuntak (IPMG, Indonesia) - Kunihiko Kokubo (JPMA) 4. Wrap-up
11:40 ▶ 12:00	Overall Wrap-up	Haruhiko Hirate (JPMA)
12:00 ▶ 12:15	Closing Remarks	Haruo Naito (Vice President, JPMA)
12:20 ▶ 13:00	Press Conference	Relevant person only

Profile

Tatsuya Kondo, M.D., Ph.D

Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA)

Dr. Tatsuya Kondo is Chief Executive of Pharmaceuticals and Medical Devices Agency. He has been in this position since 2008. He is responsible for all the operations of PMDA, i.e. relief for adverse health effects of drugs, drug/medical devices reviews, and postmarketing safety measures.

Before taking the current position, he spent most of his career as a neurosurgeon after he graduated from Medical Department of the University of Tokyo in 1968. He worked at various medical institutions, including the First National Hospital and Faculty of Medicine, the University of Tokyo.

He also has wide-ranging experience overseas, such as fellowship in Max-Planck Institute in Germany for biological research on brain tumor in 1977, and visiting staff surgeon in China-Japan Friendship Hospital in Beijing in 1987 to establish its Department of Neurosurgery under JICA project.

Currently, he is also serving as the Advisor on Health and Medical Strategy for Cabinet Secretariat of Japanese Government, and as the Vice President of Medical Excellence JAPAN, a general incorporated association.

Profile

Makoto Suematsu, M.D., Ph.D.

President, Japan Agency for Medical Research and Development (AMED)

Dr. Suematsu graduated from Keio University School of Medicine in 1983. After serving as an assistant professor at Keio University, he studied at the Institute for Biomedical Engineering, University of California San Diego in 1991. He then worked as the professor in the School of Medicine (2001) and in the Faculty of Environment and Information Studies at Keio University (2003).

Dr. Suematsu has been recognized for his leadership and support in the several scientific committees and research projects. Specifically, he was the research representative of the “National Leading Project for Biosimulation” by the Ministry of Education, Culture, Sports, Science and Technology Japan (2003), the member of the Life Sciences Committee of the Council for Science and Technology by the Ministry of Education, Culture, Sports, Science and Technology Japan (2005), the member of the Steering Committee, Research and Development of the Next-Generation Integrated Simulation of Living Matter, RIKEN (2007), the Leader of Global Center of Excellence for Life Sciences, Human Metabolomic Systems Biology, Ministry of Education, Culture, Sports, Science and Technology Japan (2007) and the Director of the Center for Human Metabolomic Systems Biology at Keio University (2007). He has also served as the Dean of Keio University School of Medicine since 2007.

Since 2010, Dr. Suematsu has been the research director of the SUEMATSU Gas Biology Project for the Exploratory Research for Advanced Technology (ERATO), Japan Science Technology Agency (JST). He also serves as the chairman of the Meeting of the President and the Dean of Medical School at the Japanese Association of Private Medical Schools from 2011. He has been the member of the Science Council of Japan in 2014. He was appointed as the president of the Japan Agency for Medical Research and Development (AMED).

Profile

Kazuhiko Mori, MSc.

Director of Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau of the Ministry of Health, Labour and Welfare (MHLW).

He has led many of MHLW/PMDA's drug initiatives. He contributed to introduce new approaches to drug safety regulation including the concept of risk management. He previously served as Chief Safety Officer of Pharmaceuticals and Medical Devices Agency (PMDA) from 2010-2013. He also served as director of Safety division, Pharmaceutical and Food Safety Bureau of the Ministry of Health, Labour and Welfare (MHLW) from 2008-2010. He also led NDA reviews as associate director of Center for Product Evaluation of PMDA from September 2006-2008 and as director of Office of New Drug I, PMDA from 2004-2006. He joined the Pharmaceutical and Medical Devices Evaluation Center (PMDEC) in April and conducted NDA reviews and scientific advices for Anti-cancer drugs and Anti-infective drugs. In July 1998, he joined the Organization for Pharmaceutical Safety and Research (OPSR) and appointed as director of Consultation Division. He joined the pharmaceutical affairs bureau, the Ministry of Health and Welfare (MHW) in 1983 and started his carrier as a technical official, taking charge of NDA review.

Profile

Hak Bae Choi

CEO, C&C Research Laboratories

Graduated from the College of Pharmacy, Seoul National University.
Joined JW Pharmaceutical in 1981.
Started works at development division including product planning, licensing, regulatory affairs as well as clinical development.
Experienced other fields such as marketing, global business and research at JW Pharmaceutical.
Became CEO of C&C Research Laboratories in 2011.
C&C Research Laboratories is a joint venture company established in 1992 between Chugai Pharmaceutical Co. Ltd and JW Pharmaceutical for research of innovative medicine in Korea.
Try to secure global competitiveness in research of oncology & immunology, focus on very specific fields.

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