APAC
Asia Partnership Conference
of Pharmaceutical Associations

"To Expedite the Launch of Innovative Medicines for the Peoples in Asia"
- APAC's continued challenge to create and improve access to innovative medicines -

The Fifth Asia Partnership Conference of Pharmaceutical Associations

PROGRAM

Date: April 7 (Thursday) – 8 (Friday), 2016

Venue: Imperial Hotel, Tokyo

"To Expedite the Launch of Innovative
-APAC's continued challenge to create and

Program

Day 1 Thursday, April 7, 2016

MC : A. Matsubara, JPMA

9:30 ▶ 9:35	Opening Remarks	M. Tada, President, JPMA
9:35 ▶ 9:50	Congratulatory Speech	E. Pisani, Director General, IFPMA
9:50 ▶ 10:30	Keynote Lecture Health Care Vison 2035 & Access Improvement in Asia	K. Shibuya, Univ. of Tokyo
10:30 ▶ 10:50	< Break >	
10:50 ▶ 14:45	ATIM Session : Government Challenges for Access Improvement & Industry Roles	
10:50 ▶ 11:00	Intruduction to the ATIM Session	Chair: H. Hirate, JPMA
	Part 1. (East Asia)	
11:00 ▶ 11:20	1. Implementation of International Regulatory Harmonization Strategy	K. Mori, Councilor, MHLW
11:20 ▶ 11:40	2. Korean Healthcare Strategy for the Improvement of Access to Innovative Medicines	S.B. Kim, Director, MFDS
11:40 ▶ 11:50	3. Healthcare System Reform & Innovative Medicine in China	J. Cho, RDPAC
11:50 ▶ 12:00	4. Introduction of APEC Harmonization Center Activities	S.I. Um, AHC Secretariat, KPMA
12:00 ▶ 12:15	5. Discussion and Q&A	Floor
12:15 ▶ 13:45	< Lunch > (Photo session)	
	Part 2. (ASEAN)	
13:45 ▶ 14:05	1. ASEAN Regulatory Harmonization (Prerecorded)	Dato' Eisah, ASEAN RH Leader
14:05 ▶ 14:25	2. UHC expansion & Innovative Medicine Position	Bahdar Hamid, NADFC
14:25 ▶ 14:35	3. Discussion and Q&A	Floor
14:35 ▶ 14:45	ATIM session Wrap up	H. Hirate, JPMA
14:45 ▶ 15:00	< Break >	

Medicines for the Peoples in Asia"
improve access to innovative medicines-

15:00 ▶ 17:15	**RA Session : Envisioning the Regulatory Convergence in Asia with greater collaborations among Regulatory Agencies, Academia and Industries**	
	1. Keynote Lecture	**Chair: I. Sasaki, JPMA**
15:00 ▶ 15:20	**APEC 2020 Roadmap of the Good Registration Management**	**L. Liu, TFDA**
	2. Presentations	
15:20 ▶ 15:40	**(1) Regulatory Capacity Development and Regulatory Convergence:Perspectives from the Centre of Regulatory Excellence**	**J. Lim, Duke-NUS**
15:40 ▶ 16:00	**(2) Report of APAC RA-EWG activities**	**K. Nagao, JPMA**
	3. Panel discussion	**Co-Chair: J. Lim, Duke-NUS / K. Nagao, JPMA**
16:00 ▶ 17:15	**Future Directions of Regulatory Convergence for New Drug Review (Assessment) and Approval : What further efforts would be needed to facilitate the Regulatory Convergence in Asia?**	**1. J. Sato, PMDA 2. L. Liu, TFDA 3. Rungpetch Sakulbumrungsil, Chula. Univ. 4. Nurma Hidayati, NADFC 5. I. Sasaki, JPMA**
17:15 ▶ 17:30	**< Break >**	
17:30 ▶ 18:30	**Opening Ceremony of Asian Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs Sponsored by PMDA/MHLW**	
18:45 ▶	**< Reception >**	

Program

Day 2 Friday, April 8, 2016

MC : A. Matsubara (JPMA)

9:00 ▶ 11:30	DA Session : Establishing Open Innovation in Asia for the Golden Age of Innovation Policy – A Focus on Matching and Human Resource Development	
9:00 ▶ 9:30	1. Keynote Lecture SIMM Global Strategies and Human Resource Development Measures	Chair: Y. Ikeura, JPMA Shanghai Institute of Materia Mediaca Chinese Academy of Sciences (SIMM) J. Li, SIMM
9:30 ▶ 9:45	2. Panel discussion (1) Presentation ① Developing Global Researchers in Drug Discovery	Co-Chair: Y. Ikeura, JPMA / W. Chi, DCB H. Isoda, Univ. Tsukuba
9:45 ▶ 10:00	② Strengthening Academic Researchers' Drug Discovery Capabilities through DSANJ Business Meeting	Z. Terashita, Osaka Univ.
10:00 ▶ 10:15	③ Natural Product Sciences in the Open Innovation Model	Nares Damrongchai, TCELS
10:15 ▶ 10:30	④ IP challenge in Open Innovation between Academia and Industry	Y. Okumura, JPMA
10:30 ▶ 10:45	⑤ Collaboration-based New Drug R&D Strategy	P. Wang, Yabao
10:45 ▶ 11:30	(2) Panel discussion Theme: Establishing Open Innovation in Asia for the Golden Age of Innovation Policy – A Focus on Matching and Human Resource Development	Co-Chair: Y. Ikeura, JPMA / W. Chi, DCB All members noted above
11:30 ▶ 11:50	Overall Wrapping	H. Hirate, JPMA
11:50 ▶ 12:05	Closing Remarks	H. Naito, JPMA

Profile

Eduardo Pisani

Director General of the IFPMA

Eduardo Pisani became Director General of the IFPMA in January 2010. An industry leader with over two decades of international pharmaceutical experience in companies like Bristol-Myers Squibb, Baxter, SmithKline Beecham, Immuno, he has seen health policy and patient access discussions evolve from a close vantage point, and is convinced that platforms for constructive policy discussion are essential to effective policy making.
As IFPMA Director General, Eduardo leads the dialogue between research-based pharmaceutical companies and associations with the United Nations and its specialized agencies, and other international organizations. Working on many of IFPMA's key initiatives on non-communicable and neglected tropical diseases, he demonstrated that informed debate and partnerships are important for moving forward global health goals.
Mr. Pisani graduated in Law at the University of Catania, Italy, and was admitted to the Italian Bar in 1991. He studied business administration, as well as International Relations in Belgium and in Italy. He has served in several working groups and Boards of various institutions and trade associations. Mr. Pisani is the author of a number of articles in professional reviews concerning legal and health policy issues.

Profile

Kenji Shibuya, MD, DrPH

Professor and Chair, Department of Global Health Policy, Graduate School of Medicine, University of Tokyo

Dr. Shibuya is Professor and Chair of Global Health Policy at the University of Tokyo's Graduate School of Medicine and President of the Japan Institute for Global Health. He obtained his MD at the University of Tokyo and his doctorate in international health economics at Harvard University. After teaching at Teikyo University in Tokyo, he joined the WHO's Global Programme on Evidence for Health Policy in 2001 and was chief of the Health Statistics and Evidence Unit from 2005 until 2008. He has published widely on mortality, causes of death, burden of disease, risk factors, cost-effectiveness, priority setting, health system performance assessment and health diplomacy. He spearheaded the future strategic directions of the Japanese global health policy agenda after the Hokkaido Toyako G8 Summit in 2008. He led the Lancet Series on Japan, published in 2011 in an effort to jump-start debates on Japanese domestic and global health policy reform. He is currently an advisor to both central and local governments. This year he chaired the landmark Advisory Panel on Health Care 2035 for the Minister of Health, Labour and Welfare. He is currently the Executive Advisor on Global Health for the Ministry of Health, Labour and Welfare.

Profile

Kazuhiko Mori, MSc.

Councilor for Pharmaceutical Affairs, Minister's Secretariat of the Ministry Health, Lobour and Welfare (MHLW).

Mr. Mori has led many of MHLW/PMDA's drug initiatives. He contributed to introduce new approaches to drug safety regulation including the concept of Japanese risk management plan (J-RMP) and he also initiate SAKIGAKE designation system for promoting innovative new drug development and review. He served as director of Evaluation and Licensing division, Pharmaceutical and Food Safety Bureau of the MHLW from 2014-2015, and 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 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

Sang Bong Kim

Office address	Pharmaceutical Policy Division, Pharmaceutical Safety Bureau Ministry of Food and Drug Administration (Tel : #82-43-719-2610)
email	sbkim805@korea.kr
Present Position	Director

Education

B.S.	Manufacturing Pharmacy, College of Pharmacy, Seoul National University March, 1990 - February, 1994
M.S.	Medicinal Chemistry, Lab. of Medicinal Chemistry, Seoul National University March, 1994 - February, 1996

Professional Experiences

Feb. 1. 2016 - Present	Director, Pharmaceutical Policy Division, Pharmaceutical Safety Bureau
Feb. 6, 2012 - Jan. 31, 2016	Director, Pharmaceutical Quality Division Pharmaceutical Safety Bureau Korea Food and Drug Administration
Oct. 11. 2011 - Feb. 5, 2012	Director, Medical Products Safety Division, Daejeon regional KFDA
Jan. 24. 2006 - Oct. 10, 2011	Deputy Director, Medical Device Quality Division, Medical Device Safety Bureau, Pharmaceutical Management Division, Pharmaceutical Safety Bureau
Jun. 18. 1996 - Jan. 23. 2006	Assistant Director, Pharmaceutical Safety Policy Division, Pharmaceutical Safety Bureau, Pharmaceutical Management Division, Pharmaceutical Safety Bureau etc.

Profile

Drs. T.Bahdar J.hamid, Apt, M.Pharm

T. Bahdar Johan Hamid obtained his degree in Pharmacy from the Institute of Bandung Technology and his master degree from Master of Pharmacy, Curtin University Australia. Currently his post is Deputy for Therapeutic Product, Narcotics, Psychotropic and Addictive Substance Control, The National Agency of Drug and Food Control (NADFC), The Republic of Indonesia. He used to be Deputy for Traditional Medicine, Cosmetics and Complementary Products, NADFC.
His professional activities include many public health programs, such as Expert Committee for Eradication Polio (2015- now), Member of Food and Snacks for School Children (Year 2011 – now) and Member of Drug Eradication and Food Illegal Task Force Team (2011-now).

Profile

Liling Liu M. S.

Director Liling Liu has been working in the Taiwanese regulatory authority for administration of medical products over 27 years after receiving M.S. in Pharmaceutical Sciences from Wayne State University. Before that, she graduated from Pharmacy School of National Taiwan University in 1980; then, worked as a pharmacist in hospitals for about 5 years. She has broad experience in regulatory work along product life cycles, including pharmaceuticals, biologics, medical devices, and cosmetics. After the establishment of TFDA in 2010, she served as the Division Director of Medical Devices and Cosmetics for 4 years and then the Division Director of Pharmaceuticals for 2 years. Now she is the Office Director of International Pharmaceutical Affairs. Her leadership in TFDA has been acknowledged to facilitate biotechnology development in Chinese Taipei.
In recent years, she involves much in the regulatory convergence. She has been the APEC Regulatory Harmonization Steering Committee (RHSC) member and championing the Good Review Practice roadmap since 2010. She also promotes Good Submission Practice project in APEC RHSC in 2013. Those two projects were merged into 2020 Good Registration Management Roadmap endorsed by APEC RHSC this year. She has been actively participating in international harmonization initiatives, which include being the Chinese Taipei representative in ICH, IPRF and IGDRP. She was elected as Vice Chair of AHWP and the Chair of AHWP WG1a in 2011, and has been the planning committee member of RAPS since 2011. Under her leadership, she successfully organized the 17th AHWP Annual Conference in 2012. She also organized APEC basic and advanced Good Review Practice workshops in 2011 and 2012, respectively. In 2015, the 8th Asia Regulatory Conference (ARC) was successfully organized in cooperation with important regulatory harmonization initiatives and industry associations.

Profile

Associate Professor John LIM MBBS, MSc, MPM, FAMS

Executive Director, Centre of Regulatory Excellence Duke-NUS Medical School, Singapore
Deputy Director of Medical Services (Industry & Research Matters) Ministry of Health, Singapore
Chairman,Singapore Clinical Research Institute

Dr John Lim is a medical graduate of the National University of Singapore (NUS), and holds Masters degrees in Public Health from NUS and in Health Policy and Management from Harvard University. He is a Specialist in Public Health Medicine, a Fellow of the Singapore Academy of Medicine, and Adjunct Associate Professor at the Duke-NUS Medical School and NUS Saw Swee Hock School of Public Health.

He has held senior positions in the Singapore Ministry of Health (MOH) and Ministry of Education. Following the establishment of the Health Sciences Authority (HSA), Dr Lim became Director of its Centre for Drug Administration in 2001. He was appointed HSA's Chief Executive Officer in 2006 and led the organisation for eight years during a period of major development and growth.

In July 2014, Dr Lim assumed the concurrent appointments of Deputy Director of Medical Services (Industry & Research Matters) in MOH and Executive Director of the Centre of Regulatory Excellence (CoRE) at the Duke-NUS Medical School. The MOH role is that of a deputy chief medical officer coordinating research initiatives, policies and industry engagement. In CoRE, Dr Lim draws on his long-standing international experience and networks in health products regulation to enhance regulatory capacity and scientific excellence in Asia-Pacific.

Dr Lim is also Chairman of the Singapore Clinical Research Institute, a national Academic Research Organisation under MOH Holdings, Singapore.

Profile

Jia Li

Deputy director of the Shanghai Institute of Materia Medica Chinese Academy of Sciences, Professor, group leader, Doctoral supervisor and Deputy director of State Key Laboratory of drug research.

Professor Jia Li graduated from the Department of Pharmacy, Zhejiang Medical University in 1992. He entered Shanghai Institute of Materia Medica Chinese Academy of Sciences in 1994 and obtained the doctorate of science in 2000. In the same year he joined Shanghai Institute of Materia Medica, and was responsible for the establishment of high-throughput screening models for drug discovery in the National Center for Drug Screening. From February 2003 till August 2003, he was invited to visit the Department of pathology at University of Cambridge in the United Kingdom, focusing on the study of cell apoptosis and angiogenesis. From August 2004 to February 2005, he was invited to Garvan Institute of Medical Research in Australia for the collaborative research of diabetes as a visiting scholar. He is now Deputy director of the Shanghai Institute of Materia Medica Chinese Academy of Sciences, Professor, group leader, Doctoral supervisor and Deputy director of State Key Laboratory of drug research. Professor Li and his Group have established multi-targets screening, multi-function confirmation, and multi-index efficacy evaluation system for diabetes and cancer drug discovery, built up enzyme family based multi-target integrated high throughput screening platform, in line with international standards. Up to now, his team has completed over million data points in drug screening and discovered hundreds of bioactive compounds. As one of the major inventors, Professor Li led four drug candidates targeting metabolic diseases and two drug candidates targeting tumor with independent intellectual property rights, of which pre-clinical studies are under way. Among this, one of the drug candidates has been successfully transferred to a local pharmaceutical company and move forward cooperatively. As a corresponding author or co-corresponding author, Dr Li has published 112 papers, and as other authors, 85 papers, in e.g. Advanced Materials, Diabetes, Diabetologia, JBC, JMC and other international periodicals with >1500 total citations. The total impact factor is over 500 and the H-index is 21. In recent years, 41 patents have been authorized and other 54 patents were filed. He acquired the funding of National Outstanding Youth and won the twelfth session "Science & Technology Award for Chinese Youth" in 2011. In 2012 he acquired Ten Outstanding Youth of Chinese Academy of Sciences. Besides, he was awarded the second prize of National Science and Technology Progress, the first prize of Shanghai Science and Technology Progress, the second prize of China Pharmaceutical Association Science and Technology Progress and the first prize of Shanghai Pharmaceutical Science and Technology. Dr Li has chaired and participated in a number of national projects, including National Major Scientific and Technological Special Project for "Significant New Drugs Development", National Key Basic Research program of China (973 Program), National High-Tech R&D Program of China (863 Program), the Ministry of Science and Technology international cooperation key projects, the State Natural Science Fund projects for Creative Research Groups, general program of the National Natural Science Foundation of China. In addition, he has undertaken many projects of the Chinese Academy of Sciences, including Priority Program, Main Direction Program. He also takes charge for numbers of major and key programs of Science Foundation of Shanghai.

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