APAC
Asia Partnership Conference
of Pharmaceutical Associations

The 7th Asia Partnership Conference of Pharmaceutical Associations

PROGRAM

Date: April 10 (Tuesday)

Venue: Keidanren Kaikan

To Expedite the Launch of Innovative

Program

MC : A. Matsubara (JPMA)

8:30 ▶ 8:40	Opening Remarks	Y Hatanaka, JPMA
8:40 ▶ 8:55	Congratulatory Speech	G Perry, IFPMA
8:55 ▶ 9:40	Keynote Lecture Regulatory Science and Work together for the global patients –"Rational Medicine Initiative"–	T Kondo, PMDA
9:40 ▶ 10:00	< Break > (Photo Session)	
10:00 ▶ 10:10	Introduction of the Entire Program	H Hirate, JPMA
10:10 ▶ 12:15	RA Session : Regulatory Landscape for "Access to Innovative Medicine" in Asia	
10:10 ▶ 10:50	1 Further dissemination of GRM	J Sato (Chair), PMDA
	・Report 1: GRM CoE Workshop (20 min)	YC Lin, TW-FDA
	・Report 2: Local Training (5 min x 2)	Busakorn L, PReMA KC Wong, SAPI
	・Performance Indicators to evaluate GSubP implementation status (10 min)	H Kawaguchi, JPMA
10:50 ▶ 12:05	2 "Conditional Early Approval (CEA)" Systems in Asia	J Lim (Co-Chair), Duke-NUS CoRE M Shibatsuji (Co-Chair), PMDA
	・Explanation of this part (5 min)	O Inagaki, JPMA
	・Presentation: Introduction of "Japanese CEA" System (15 min)	M Shibatsuji, PMDA
	・Presentation: Introduction of "Malaysian CEA" System (10 min)	Ramli Z, NPRA
	Panel Discussion with Short Presentations (5 min x 3)	
	Short Presentation: View on CEA systems from each economy	SH Kim, NIFDS YC Lin, TW-FDA
	Discussion & Summary: How to secure early access to innovative medicines, which are approved by CEA systems (30 min)	Juliati, NADFC Ramli Z, NPRA
12:05 ▶ 12:15	3 Summary of RA-EWG activities in FY2017 (10 min)	S Hatakeyama, JPMA
12:15 ▶ 13:15	< Lunch >	
13:15 ▶ 15:25	ATIM Session: Promoting Efficiency in GMP Review and Post-approval Variations	
13:15 ▶ 14:05	1 Site Master File (SMF)	S Sakurai (Chair), PMDA
	・Summary of the consensus at 6th APAC session, with inviting reviewers (10 min)	
	・Comments from each reviewer and comments from the industry side (25 min)	M Yabuki, PMDA Ellen C, TW-FDA Rumondang S, NADFC Suchart C, TH-FDA Busakorn L, PReMA T Nakagawa, JPMA
	・Message from Mr. Boon, PIC/S Chairman	
	・Comments & questions from the audience (5 min)	
	・Conclusion (recommendation for convergence in Asia) (10 min)	S Sakurai, PMDA

Medicines for the Peoples in Asia

14:05 ▶ 15:25	**2 Post approval Variations**	F Honda (Co-Chair), PMDA EK Kim (Co-Chair), NIFDS
	・Difference analysis in change control in Asia: from JPMA (10 min)	T Nakagawa, JPMA
	・Presentation: Optimising the management of post-approval changes for patients' timely access to medicines (15 min)	Sannie C, SAPI
	・Key-points of post-approval variation (Regulatory Authorities in Asia) (30 min)	Ellen C, TW-FDA EK Kim, NIFDS Juliati, NAFDC Suchart C, TH-FDA
	Discussion (20 min)	
	Summary of the discussions (5 min)	F Honda, PMDA
15:25 ▶ 15:45	< Break >	
15:45 ▶ 17:45	**DA Session: How to Establish Drug Discovery Ecosystem in Asia**	
15:45 ▶ 17:25	**1 Presentation** (100min)	WK Chi (Co-Chair), DCB A Hasuoka (Co-Chair), JPMA
	・Opening (5 min)	A Hasuoka, JPMA
	・Update on pillar 5 initiative "natural compound-based drug discovery" (15 min)	Nares D, TCELS
	・Presentations by 4 panelists (80 min)	N Kohno, AMED P Wang, Yabao N Nishimura, Mie Univ CH Wu, DCB
17:25 ▶ 17:45	**2 Panel discussion & Summary** (20 min) Possibility of "Drug Discovery Ecosystem in Asia" Challenges to realize "Drug Discovery Ecosystem in Asia", etc.	All presenters
17:45 ▶ 17:55	Closing Remarks	H Naito, JPMA
18:15 ▶ 20:15	< Reception >	

RA Session **Session Leader Osamu Inagaki**

Regulatory Landscape for "Access to Innovative Medicine" in Asia

The Regulation and Approval Expert Working Group (RA-EWG) aims to “Expedite the launch of innovative medicines for the peoples in Asia” through supporting the optimization of the registration processes in Asian economies. For this purpose, the RA-EWG has been advocating the “Good Submission Practice” as a part of Good Registration Management (GRM) to increase the quality of the submission and the review processes. In the 7th APAC RA-EWG session, our dissemination activity for GRM is reported. In addition, this session will cover a new topic related to Conditional Early Approval (CEA) mechanisms in Asia. CEA mechanism may promote an early access to new medicines into an economy, while this development process may have a risk to delay the drug access to some other economies requesting Phase-III confirmatory clinical data during the submission.
In the RA-EWG session we will discuss the potential risks of CEA systems, and how to achieve the early access to innovative medicines in whole Asia through new regulatory pathways.

ATIM Session **Session Leader Kenichi Yamada**

Promoting Efficiency in GMP Review and Post-approval Variations

In the last APAC conference, in order to achieve the APAC mission “To expedite the launch of innovative medicines for the peoples in Asia”, APAC has focused on the GMP fields and suggested to share the SMF draft template for review by Asian authorities and industries. At the 7th APAC meeting we will finalize the SMF template.
For the second topic, we will discuss the differences in the change control systems in Asia to understand the situations for the improvement of steady supply of innovative medicines in the region. Key discussion points are GMP review concept at the PAS stage and details for site change, modify of production change, and about stability data requirements.

DA Session **Session Leader Atsushi Hasuoka**

How to Establish Drug Discovery Ecosystem in Asia

"Drug discovery ecosystem" represents a situation where all the players for drug discovery including academia, bioventures, pharmaceutical companies and the governments fulfil their expected roles in a synergistic way with other players. The concept is critical to generate useful drugs in a sustainable manner.
When we look at Asia from the viewpoint of "drug discovery ecosystem" we can recognize that Asia has developed the key players such as academia, research organizations, bioventures and pharmaceutical companies. In addition, those key players are located within three-hour time difference. On the other hand, Asia as a whole accounts for about 60% of world population and many of Asian countries are on the way of economic development. These features make us believe that the potential of "drug discovery ecosystem in Asia" is greater than the sum of the ecosystem of each Asian country.
At the APAC 2018, we will invite presenters from Asian countries and discuss how to establish the drug discovery ecosystem in Asia.

Keynote Lecture — Tatsuya Kondo

Regulatory Science and Work together for the global patients –"Rational Medicine Initiative"–

Pharmaceutical and Medical Devices Agency (PMDA) is a regulatory agency. The scope of jurisdiction is limited but regulatory agency should consider holistic approach to medicine. I believe the implementation of holistic approach to medicine is a common theme over the countries/regions. Not only to provide innovative medicine to patients as early as we can, but also regulatory agencies has to perform continuing challenges to promote regulatory science for scientific decisions. Based on this concept, I have released 'Rational Medicine' Initiative in February 2017. In order to serve the best overall interests of the patients, I would like to share my vision, experiences and challenge with foreign regulators and other stakeholders.

Present Position
Dr. Tatsuya Kondo has served as the Chief Executive of the Pharmaceuticals and Medical Devices Agency (PMDA) since 2008.

Professional Experience
Before being appointed to his current role, Dr. Kondo spent the majority of his career as a neurosurgeon. Dr. Kondo worked at various medical institutions and as part of the Faculty of Medicine at the University of Tokyo. From 1978 to 2008, he worked in the Department of Neurosurgery at the National Center for Global Health and Medicine (formerly the First Tokyo National Hospital), serving as Hospital Director during the last five years. As Hospital Director, Dr. Kondo was responsible for the management and oversight of the 900-bed hospital. Dr. Kondo was also actively engaged during this period in R&D activities as a surgeon-scientist, inventing a stereotactic radiotherapy system for applications in cancer treatment and discovering the fibroblast growth factor (FGF)-9 using brain tumor tissue.

Education
Dr. Kondo graduated from the Graduate School of Medicine at The University of Tokyo in 1968. He has extensive international experience, including a graduate fellowship at the Max-Planck Institute in Germany to conduct biological research on brain tumors.

Congratulatory Speech — Greg Perry

Greg Perry joined IFPMA on 1st February 2018, and has responsibility for IFPMA's external outreach and stakeholder engagement in global health topics including innovation, access, and the international regulatory environment. Greg Perry brought with him more than 20 years' leadership and advocacy experience in the public healthcare arena.

Prior to joining IFPMA, Greg worked as Executive Director of the Medicines Patent Pool, which he joined in 2013 and as Director General of the European Generic Medicines Association (1999 - 2013) in Brussels. Previously he worked as a partner in a UK public affairs company as a European Union policy advisor to corporate and non-governmental organizations, and before that as a Parliamentary Advisor to Members of the European Parliament. Greg is a Member of the Advisory Council of the Organization for Professionals in Regulatory Affairs (TOPRA) and is a former member of the Standing Advisory Committee before the European Patent Office (SACEPO). Greg also holds the Golden Cross of Merit of the Republic of Poland.

RA Session

Profile (Chair)

Junko Sato

Dr. Junko Sato is an Office Director of Office of International Cooperation at Pharmaceuticals and Medical Devices Agency (PMDA). She also works for International Cooperation including coordination of Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC).
She started her job at Jikei University, School of Medicine as an instructor. She was involved in the education and the research. In 1997, she gained her doctoral degree from Jikei University. Next year, she joined Office of New Drug, Pharmaceutical and Medical Devices Evaluation Center (PMDEC), and started to work in regulatory agency. She became a review director and moved to Office of Safety to introduce a new risk management system through life cycle of drugs. During the period, she visited FDA as a guest reviewer from September 2002 to March 2003. From May 2012 to April 2014, she was dispatched to EMA as MHLW/PMDA Liaison. She enhanced collaboration between EMA and MHLW/PMDA and brought a huge success as the liaison.
She contributed to some global harmonization activities, for example, ICH-E2C(R2) as the co-rapporteur, E2E, E2F, M5, and also CIOMS VII and IX. She also contributes many DIA activities. She received DIA Outstanding Service Award 2010.
She now leads the activities of PMDA-ATC including planning/conduct of all the trainings, and contributes to building stronger bilateral relationship with ASEAN countries by playing the role as the contact point. She is also the member of the APEC RHSC (APEC Regulatory Harmonization Steering Committee) which is tasked to achieve regional convergence on regulatory approval procedures for medical products by 2020.

Profile (Speaker / Panelist)

Yi-Chu Lin

Section Chief, Section of New Drugs
Division of Medicinal Products,
Taiwan Food and Drug Administration (TFDA)

Dr. Yi-Chu Lin currently serves as the Section Chief of Section of New Drugs, Division of Medicinal Products, TFDA (Taiwan Food and Drug Administration); responsible for reviewing new drugs application, the post-marketing changes, and involving in the regulatory related issues. Dr. Lin has been working in the Taiwan regulatory authority for administration of medicinal products since 2010 after receiving Ph.D in Pharmacology from National Taiwan University. Dr. Lin has experience in regulatory work; furthermore, took the tasks of setting up the Guideline for Biologics and Cellular Therapy Products.

Profile (Speaker)

Busakorn Lerswatanasivalee

Education

1983-1985 Thammasart University
Master of Business Administration
1971-1976 Chulalongkorn University
Bachelor of Sciences, Faculty of Phmaceutical, Second Class Honor

Experiences

Pharmacuetical Research and Manufacturer Association 2013 - Present :Chief Executive Officer
Takeda (Thailand), 2000 - 2013
Pfizer Inc, 1976 - 2000

Award

- Honors 2015 Outstanding Alumnus of Thammasat University
- First Takeda Global Awards
- 2006 Hall of Fame, Alumni of Faculty of Pharmacy, Chulalongkorn Univerysity
- 2007 Marketing Pharmacist of the Year, 4th Pharmacy Congress, Thai Pharmaceutical Association

Profile (Speaker)

Wong Kum Cheun

Head Asia Pacific
Regulatory & Development Policy
Regulatory Affairs
Novartis Asia Pacific Pharmaceuticals Pte Ltd

Kum Cheun (KC) is Head of Asia Pacific Regulatory & Development Policy for Novartis, leads in the development of regulatory and development policy guidance and regulatory intelligence for Asia Pacific region. He is Co-Chair of the ASEAN Pharmaceutical Research Industry Association (APRIA), Co-Chair of Singapore Association of Pharmaceutical Industries (SAPI) Regulatory Affairs Committee, Chair of EFPIA ASEAN Regulatory Network. Active member of EFPIA International Regulatory Expert Group (IREG), EFPIA regional regulatory networks, ISPE Asia Pacific Focus Group, Steering Committee of Asia Partnership Conference of Pharmaceutical Associations (APAC) and member of APAC RA-EWG.

KC was former Drug Registration Branch's Deputy Head responsible for the 'Quality Evaluation and Submissions Section' of the Centre for Drug Administration at the Singapore Health Sciences Authority (HSA). In HSA he was involved in the development of product registration guidance such as the Variation Guideline and BA/BE Guideline, participated in the ASEAN Harmonization of Pharmaceutical Products guideline discussion and was co-lead developed the ASEAN Process Validation Guideline.

Profile (Speaker)

Hiroko Kawaguchi

I joined MSD.K.K. (Former Banyu) in clinical development department area in 2000. In 2007 I have joined Japan Regulatory Affairs Liaison group and am mainly responsible for infectious disease drugs and Vaccines. In this role, I play a role of interacting with Japan regulatory authorities for registration of new drug application or consulting of Japan development strategy.

Profile (Co-Chair)

John CW Lim

Executive Director
Centre of Regulatory Excellence
Duke-NUS Medical School

Senior Advisor
Ministry of Health, Singapore

Chairman
Singapore Clinical Research Institute

John Lim is Professor of Practice at the Duke-National University of Singapore Medical School (Duke-NUS) and the NUS Saw Swee Hock School of Public Health. He is a medical graduate of NUS, and holds Masters degrees in Public Health from NUS and Health Policy and Management from Harvard University. He is a Specialist in Public Health Medicine and a Fellow of the Singapore Academy of Medicine.
Professor Lim has held senior positions in Singapore's Ministry of Health (MOH) and Ministry of Education. He was Chief Executive Officer of Singapore's Health Sciences Authority from 2006 to 2014.
In 2014, Professor Lim became founding Executive Director of the Centre of Regulatory Excellence (CoRE) at Duke-NUS. He also served concurrently as Deputy Director of Medical Services (Industry & Research Matters) in MOH and was appointed Senior Advisor in 2017. In CoRE, Professor Lim draws on his international experience and networks in health products regulation to enhance regulatory capacity and scientific excellence for national regulatory authorities and industry in the Asia-Pacific and South-East Asia.
Professor Lim is Chairman of the Singapore Clinical Research Institute, the national academic research organisation of MOH Holdings, Singapore. He is also a member of the Executive Board of the APEC Life Sciences Innovation Forum, the Advisory Group of the US Pharmacopoeia's Quality Institute, the Scientific Advisory Council of the UK Centre for Innovation in Regulatory Science, and the Board of St Andrew's Mission Hospital in Singapore.

Profile (Co-Chair / Speaker)

Masayoshi Shibatsuji

2017.7-	Coordination Officer for Review of Breakthrough Products / Coordination Officer for the Practical Application of Innovation Advancements, Pharmaceuticals and Medical Devices Agency(PMDA)
2014.4-2017.7	Director, Office of New Drug V (Oncology), PMDA
2012.12-2014.3	Deputy Director, Compliance and Narcotics Div., Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare
1992.4	New Drug Div., Pharmaceutical Affairs Bureau, Ministry of Health and Welfare

Profile (Panelist)

So Hee Kim

PROFESSIONAL TITLE
Deputy Director, Oncologic and Antimicrobial Products Division, Drug Evaluation Department, National Institute of Food and Drug Safety Evaluation, Ministry of Food and Drug Safety

PROFESSIONAL EXPERIENCE

2010 - Present	Deputy Director, Oncologic & Antimicrobial Products Division, MFDS
2011 - 2012	Government Overseas Fellowship Program
2006 - 2010	Deputy Director, Bioequivalence Evaluation Division, etc, MFDS
1997 - 2006	Reviewer, Gastrointestinal, Urinary and Metabolic Drug Division, etc, KFDA

Profile (Panelist)

Juliati

Ms. Juliati is the Head of Sub Directorate of New Drug and Biological Product Evaluation. She was graduated from University of Indonesia in 2001. She got master degree in Biomedical Science from Medical Faculty of University of Indonesia in 2012.
She has been working with National Agency of Drug and Food Control (NADFC), Indonesia since 2001 until now. She started her carrier as an evaluator for new drug evaluation from 2001 to 2007. From 2007 to April 2008, she was in charge with the post market control. From 2008 to July 2017, she had been the Head Section of Biological Product Evaluation. From July 2017 up to February 2018, She was the Head Section of New Drug Product Evaluation. Currently, she is in charge with new drug and biological product evaluation.
She has experiences in international activities, such as WHO guideline development, WHO Global Learning Opportunity (GLO), WHO NRA Joint Assessment, and ASEAN Consultative Committee on Standard and Quality-Pharmaceutical Product Working Group (ACCSQ-PPWG).

Profile (Speaker)

Ramli Zainal

Dr Ramli Zainal is currently the Director of National Pharmaceutical Regulatory Agency (NPRA). Prior to the present appointment, he is the Director of Pharmacy Policy & Strategic Planning Division, Pharmaceutical Services Division (PSD) Ministry of Health Malaysia. He graduated with a degree in Pharmacy from Universiti Sains Malaysia (USM) and completed a Master's degree from University of Bradford. He then pursue a postgraduate degree and was awarded a PhD in Pharmaco-Economics from USM.
Earlier appointment includes, Head of Healthcare Economic Research Division at the Institute for Health Systems Research (IHSR), GMP Auditor, Head of Cosmetic Unit, Head of Secretariat Unit and Head of Organisational Development & IT Division. He has also worked as a Drug Enforcement Officer and as a Hospital Pharmacist.
Dr Ramli Zainal is one of the principle investigators for projects funded by UNDP and the National Institute of Health, Malaysia. He is actively involved in conducting trainings in the field of economics evaluation in healthcare. He is an expert member to the Ministry of Health Malaysia, Pharmaco-Economics Technical Working Group, Health Technology Assessment group and is an appointed member to the Pharmacy Board Malaysia.
He has served the World Health Organisation (WHO) as a consultant for the Training of Trainer in QA/QI in Papua New Guinea, countries within the WHO Western Pacific Regional Office and the training for QA/QI at national level.
He is currently the Honorary Secretary to the Malaysian Society for Pharmaco-Economics and Outcomes Research (MySPOR) and a member of the Malaysian Pharmaceutical Society (MPS).

Profile (Speaker)

Shinji Hatakeyama

Director
Japan/Asia Regulatory & Asia Clinical Operations Department
Medicine Development Center
Eisai Co., Ltd.

Education

2002	Ph.D. of Medical Sciences, University of Tsukuba
1990	Master of Pharmaceutical Sciences, Toyama Medical and Pharmaceutical University
1988	Pharmacist and Bachelor of Pharmaceutical Sciences, Toyama Medical and Pharmaceutical University

Work Experiences

2012 -	Asia Regulatory Affairs, Eisai Co., Ltd.
2005 - 2012	Project Management, Planning & Coordination for Medicine Development, Eisai Co., Ltd.
1991 - 2005	Discovery Research in Neuroscience Area, Eisai Co., Ltd.

Membership

2014 -	Asia Partnership Conference of Pharmaceutical Associations, Regulations and Approvals Expert Working Group (APAC, RA-EWG)

ATIM Session

Profile (Chair / Speaker)

Shingou Sakurai

1985 Department of Pharmacoscience (master degree program), Graduate School of Pharmaceutical Science
1985 Worked for mainly in the area of Quality Control and Technology Development for biological products at an industrial firm
Product Security Pharmacist, Quality Assurance Manager
2004 Principal Inspector : Office of GMP/QMS Inspection, PMDA
2007 Director for GMP Inspection : Office of GMP/QMS Inspection, PMDA
2010 Office Director : Office of Manufacturing/Quality and Compliance, PMDA
2017 Associate Director of PMDA, Office Director : Office of Manufacturing/Quality and Compliance

Others
Ph. D. (Health Science, Faculty of Medicine, The University of Tokyo)
Visiting Professor, Graduate school of Medicine, Chiba University
Research Evaluation Committee, National Institute of Infectious Diseases

Profile (Speaker)

Mami Yabuki

April, 2007 Inspector, Office of GMP/QMS Inspection, PMDA
July, 2014 Principal Inspector, Office of Manufacturing/Quality and Compliance, PMDA

Profile (Speaker)

Ying-Hua (Ellen) Chen

Ms. Ying-Hua (Ellen) Chen is the Senior Specialist within the Risk Management Division (GXP Inspectorate) of the Taiwan Food and Drug Administration under the Ministry of Health and Welfare, supervising the GMP compliance of manufacturers of medicinal products, Good Tissues Practice compliance of cell/tissue-based products and Tissue/Cells banking, Good Practice compliance of blood establishment, and international cooperation affairs in the field of GMP/GDP for medicinal products. She has been working in the GXP inspectorate over 12 years after receiving M.S. in MBA (Technology & Innovation Management) from National Cheng-Chi University in Taiwan. Before that, she graduated from Pharmacy School of Taipei Medical University in 1999; then, worked as a laboratory specialist in Pharmaceutical Chemistry, National Laboratories of Foods & Drugs, Department of Health, Taiwan for about 3 years. She has been actively participating in international harmonization activities and has extensive experience working with PIC/S included being the Taiwan FDA representative in PIC/S.

Profile (Speaker)

Rumondang Simanjuntak

Dra. Rumondang Simanjuntak, Apt. is a Pharmacist. She graduated from the Faculty of Mathematics and Natural Sciences – University of North Sumatera, Medan in 1988. She started working at Badan POM (National Agency of Drug and Food Control), Republic of Indonesia since 1991 and has held several positions such as Head Section of Administration in Directorate of Control of Narcotic, Psychotropic, and Addictive Substance, Head of Section of Inspection of Therapeutic Product and Household Product Facility, and Head of Sub-Directorate of Inspection & Certification of Production of Therapeutic Product & Household Product.

She is currently the Head of Sub-Directorate of Control of Production of Active Pharmaceutical Ingredients (including API of Narcotics, Psychotropics, and Precursors). She was member of Team of Development of Indonesian GMP Guideline for Pharmaceutical since 2010, as well as experienced Lead GMP Inspector since 2003.

Contact email: inspeksiterapetik@yahoo.com ; rumondangsimanjuntak@yahoo.com

Profile (Speaker)

Suchart Chongprasert

Dr Suchart Chongprasert is a registered pharmacist. After serving shortly as a faculty member of the Faculty of Pharmacy, Prince of Songkla University, since graduation, he was awarded a Royal Thai Government scholarship to pursue an advanced degree abroad.
He earned his doctorate degree from School of Pharmacy, Purdue University, US. Immediately after graduation, he entered a post-doctoral program at the University of Colorado Health Sciences Center, CO, US. He was also graduated a bachelor's degree in law (LLB) from the Faculty of Law, Thammasat University, Thailand.

He began his career as a pharmacist in the Thai Food and Drug Administration since his doctorate graduation in 1998. He was promoted to be the Director, Post marketing Control Division in 2016. He officially represents the Thai FDA as member of the PIC/S Committee since Thai FDA became the 49th Participating Authority of the PIC/S. Dr Chongprasert has been appointed by the Ministry of Public Health to be Director, Bureau of Drug Control since 1 October 2017. He has actively engaged in international fora on drug regulation issues, including, for example, GMP inspection, innovative regulatory framework for self-medication, regulatory pathways of biosimilars.

Dr.Chongprasert has involved more in building up and strengthening the capacities of the GMP Inspectorate and Surveillance Office to keep pace with a rapidly changing demand for GMP inspection of domestic and international drug manufacturers according to the latest PIC/S GMP Guide. He also has the expertise in the health policy related to IPR, in particular access to medicines, in the bilateral or multilateral Free Trade Agreements (FTAs) between Thailand and other trade partners.

Profile (Co-Chair)

Futaba Honda

Dr. Futaba Honda received her PhD in analytical chemistry from Tokyo University of Science. She is Deputy Director in the Office of Cellular and Tissue-based Products of the Japanese regulatory agency, Pharmaceuticals and Medical Devices Agency (PMDA). She have been enrolled since PMDA was inaugurated in 2004. She has been in charge of review of new drugs, regenerative medical products and quality review of chemicals and biopharmaceuticals.

Profile (Co-Chair)

Eunkyung Kim

Deputy Director of Pharmaceutical Standardization Division, Drug Evaluation Department, Ministry of Food and Drug Safety(MFDS), Republic of Korea

Eunkyung Kim is currently the deputy director of Pharmaceutical Standardization Division in the Drug Evaluation Department, Ministry of Food and Drug Safety (MFDS). She received her Ph.D. in Medicinal Chemistry from Yeungnam University in Korea. She has evaluated Chemistry, Manufacturing, and Controls (CMC) of herbal drugs and chemical drugs over 18 years in MFDS. Currently, she evaluates CMC of generic drugs and drug master files (DMFs) for drug substances and is also involved in developing quality-related guidelines in Korea.
Eunkyung Kim participated in the ICH Q3D Expert Working Group which developed ICH Q3D guideline for elemental impurities, and recently is participating in ICH Q12 Expert Working Group.

Profile (Speaker)

Tomonori Nakagawa

Otsuka Pharmaceutical Co., Ltd.
Production Headquarter, Manufacturing Process Development Dept. (API)

Profile: Joined Otsuka Pharmaceutical Co., Ltd. as an API process chemist and afterward, spent about 10 years in the quality area of response to overseas GMP inspections, quality/CMC inquires, and company GMP policies. Currently working on the various projects to develop CMC and supply strategy for sustained supply of the products. A member of Quality and Technology Committee of Japan Pharmaceutical Manufacturing Association (JPMA) since 2007, and participated various ICH Quality topics as an expert. JPMA Topic leader for ICH Q12 since 2014.

Profile (Speaker)

Sannie SF Chong

Sannie SF Chong heads the Roche's Technical Regulatory Policy of Asia Pacific. With her strong participation in the Regulatory Harmonization Steering Committee Meeting, Dr. Chong is active in promoting access to safe medical products, innovation and trade through regulatory convergence and cooperation within the 21 APEC (Asia-Pacific Economic Cooperation) countries. Prior to joining Roche, Dr. Chong worked in the Singapore Health Sciences Authority (HSA) starting as a Regulatory Scientist in 2003, followed by Deputy Head of the Innovative Therapeutic Group, Deputy Head of the Quality Regulatory Unit and then Director of the Generics and Biosimilars Branch. As Director, she took charge of all the CMC reviewers responsible for all decisions relating to CMC in the pre- and post-marketing control.
In HSA, Dr. Chong represented Singapore as Chair of Process Validation, Co-Chair of Biologics, as well as Co-Chair of Post-Approval Variation in the Association of Southeast Asian Nations (ASEAN) harmonization activities. Internationally, Dr. Chong was appointed by WHO as expert for the pre-qualification of Medicines Program. She was also the Lead for Singapore in building a functional global network for joint CMC evaluation with Health Canada, Swiss Medic and Australia Therapeutics Goods Administration.
Sannie holds a Ph.D. in Chemistry from the University of Hull (UK) and a postdoctoral research fellowship from the University of North Carolina at Chapel Hill (US). She is currently based in the Roche regional office in Singapore.

DA Session

Profile (Co-Chair)

Wei-Kuang Chi

Distinguished Scientist
Executive Director, Institute of Pharmaceutics
Director, Bioengineering Group, Institute of Biologics
Development Center for Biotechnology, Taipei, Taiwan

Biography

Dr. Wei-Kuang Chi, Executive Director, Institute of Pharmaceutics since July 2017, Distinguished Scientist and Director of Bioengineering Group in Institute of Biologics since September 2009, Vice President of the Development Center for Biotechnology (DCB) from December 2008 to December 2013, obtained his M.S in Engineering and Ph.D. in Chemical Engineering from the University of Pennsylvania, Philadelphia, USA. Dr. Chi has over 30 years of experience in biotechnology process development, including mammalian cell culture (CHO, NS0, hybridoma, 293 cell, insect cell etc.), recombinant yeast (*Saccharomyces cerevisiae*, and *Pichia pastoris*), recombinant *Escherichia coli*, online mass spectrometric off-gas analysis for fed-batch process control, and cell disruption bioseparation technology. In addition to coordinate new biologics and new drug development activities in DCB, he is also responsible for the establishment of DCB's multi-product 500 L mammalian cell culture and 100 L microbial fermentation CGMP Biopharmaceutical Pilot Plant Facility (BPPF), this facility CGMP was certified by Taiwan Department of Health (DOH) on December 2005 and received DMF with USA FDA on March 2006. The CGMP Biopharmaceutical Pilot Plant Facility has joined Boehringer Ingelheim Biopharmaceuticals Production Alliance Network since May 2007. This CGMP facility has been used to conduct bioprocess scale-up/development and to produce clinical trial material for protein drugs (monoclonal antibodies, recombinant proteins), has received eight IND approvals from US FDA, Canadian health authority, Taiwan FDA and EMA. Recently CGMP BPPF has been spun-off into private sector to provide CDMO service on a broader scale. Dr. Chi's new responsibility will focus more on new drug R&D, international collaboration and novel bioprocess engineering technology development.

Profile (Speaker)

Nares Damrongchai

Dr. Nares Damrongchai is the Chief Executive Officer of Thailand Center of Excellence for Life Sciences (TCELS), Thailand's public organization dedicated to supporting translational research and fostering the life sciences industry. He is on the Editorial Board of *Asian Biotechnology and Development Review*, published by RIS, New Delhi. Currently he is Co-Chair of the APEC Life Science Innovation Forum.

From 2005 to 2012 Dr. Damrongchai was the Executive Director of the APEC Center for Technology Foresight, the time during which he conducted a number of international foresight research and training workshops through works with the Rockefeller Foundation, the Institute of Alternative Futures, and Asian Foresight Institute. He was elected Lead Shepherd of the APEC Industrial Science and Technology Working Group (ISTWG), chairing the group during 2011 - 2012 and led the Group's transformation into APEC Policy Partnership in Science Technology and Innovation.
He was a Senior Director at the National Science Technology and Innovation Policy Office (STI) during 2009 - 2012.
Early in his career he was the manager of the Cell and Biomaterial Laboratory conducting research on cultured human epidermis tissue replacement at the National Center for Genetic Engineering and Biotechnology. The cultured skin tissue technology was well received and before long transferred to hospitals in parts of Thailand. In 1999 he became a policy researcher and played key role in developing the roadmap for Thailand's first National Biotechnology Policy Framework.
Dr. Damrongchai obtained the degree of Master of Philosophy from the University of Cambridge (Technology Management) and Doctor of Engineering from Tokyo Institute of Technology (Bioengineering).

Profile (Speaker / Panelist)

Noriatsu Kohno

Education;
Master of Science, Meiji Pharmaceutical University (March 1992)
License of Pharmacist (May 1989)

Carrier;
April 1992; employed Ministry of Health
April 1995; Science and Technology Agency
May 2000; First secretary, Embassy of Japan in Indonesia, Ministry of Foreign Affairs
After July 2003; Deputy Director, Safety Division, Evaluation and License Division, and Economic Affairs Division, Ministry of Health, Labour and Welfare (MHLW)
July 2011; Office Director, Office of New Drug V (oncology), PMDA
July 2013; Director, Office of Clinical Trial Promotion, Research and Development Division, Health Policy Bureau, MHLW
October 2015; Coordination Officer for Review of Breakthrough Products (Sakigake), PMDA
July 2017; Managing Director, Department of Clinical Research and Trials, and Department of Innovative Drug Discovery and Development, Japan Agency for Medical Research and Development (AMED)

Profile (Speaker / Panelist)

Peng Wang

Dr. Peng Wang currently is CEO and President of Suzhou Yabao Pharmaceutical R&D Company. Since 2008 he has been working in China, focusing on innovative pharmaceutical R&D and international collaborations, as R&D President of Yabao Pharmaceutical Group (2013-2017), CSO of Simcere Pharmaceuticals Group (2009-2013), and Vice President and Head of Discovery Biology of WuXi AppTech (2008-2009). Prior to going to China, Dr. Wang focused on new drug discovery through early clinical development at Schering-Plough (now part of Merck) in New Jersey, USA for 18 years (1990-2008). Dr. Wang has played a leadership role in discovery and development up to completion of clinical phase III of about 25 innovative new drug candidates in US and China, and to establishment of 16 collaboration partnerships between the Chinese companies and Western companies including Lilly, BMS, Merck, OSI Pharmaceuticals, Primary Peptides (Canada) and academic organizations including MRC Technology, Lawson Institute (Canada) and University of South Australia.

Profile (Speaker / Panelist)

Norihiro Nishimura

Professor / Graduate School of Regional Innovation Studies, MIE UNIVERSITY
Director/ Regional Area Strategy Center, MIE UNIVERSITY
Vice President/ MIE UNIVERSITY

Graduated from Tsukuba University with a B.A. in Biochemical engineering in 1987, Conferred Ph.D. in Molecular Biology, Tsukuba University, 1995; Researcher at Biotechnology Research Institute, Kobe Steel Ltd., Japan, 1987-1996; Staff scientist at SLS, Pall Corporation, USA & Japan, 1996-1998; R&D Researcher at Molecular Research Div, GlaxoWellcome, Japan, 1998-1999; R&D and Marketing Manager at GeneticLab, Japan, 1999-2002, CEO & President, 2002-2004; Management Professor at Medical/ Industrial Linkage Office, Mie University School of Medicine, 2004-, Professor, 2007-; Director at Community-University Research Cooperation Office, Community-University Research Cooperation Center, Mie University, 2010-2013; Assistant to the President, Mie University, 2011-; Director at Creative Research & Development Institute, Mie University, 2011-; Director at Regional Area Strategy Center, Mie University, 2013-; Vice President, Mie University, 2016-; current Professor Graduate School of Regional Innovation Studies, Mie University.

Profile (Speaker / Panelist)

Chung-Hsiun Herbert Wu

Education

1993	Ph.D., Department of Biological Chemistry, University of Maryland at Baltimore, Baltimore, Maryland, USA
1984	B.S., Department of Botany, National Taiwan University, Taipei, Taiwan
2002~2004	EMBA unfinished, Graduate Institute of Technology, Innovation & Intellectual Property Management, National Chenchi University, Taipei, Taiwan

Professional Experience:

2018~ present	President, Development Center for Biotechnology, New Taipei City, Taiwan
2017~ 2018	Acting President, Development Center for Biotechnology, New Taipei City, Taiwan
2017~ present	Vice President, Development Center for Biotechnology, New Taipei City, Taiwan
2014~2017	Executive Director, Institute of Biologics, Development Center for Biotechnology, New Taipei City, Taiwan
2013~2014	Director/Senior Research Fellow, Department of Protein Engineering, Development Center for Biotechnology, New Taipei City, Taiwan
2008~2009	Founder/Chairman/CEO, Geniusway Biotech.
2006~2008	Founder/Chairman/CEO, Geniusway Technology
2000~2004	Cofounder/Chief Scientific Officer/Vice President of Business Development, AbGenomics Inc.
1996~2000	Associate Professor, Institute of Molecular Medicine, College of Medicine, National Taiwan University
1995~1996	Lecturer, Institute of Molecular Medicine, College of Medicine, National Taiwan University
1992~1995	Jane-Coffin-Childs Memorial Fund Fellow, Department of Embryology, Carnegie Institution of Washington, Baltimore, Maryland, USA

Summary of Experience

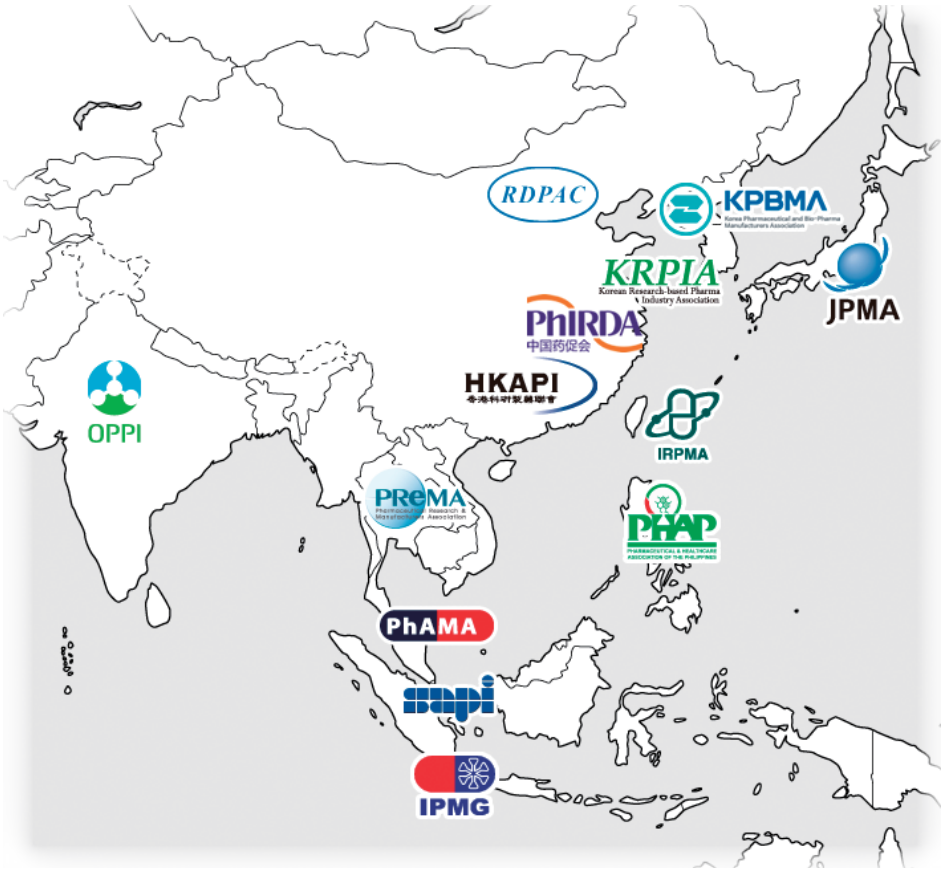
Dr. Wu has over 20 years of experience in the research and development of biologics including antibodies, recombinant proteins and immunotherapy. He has generated over 30 publications in scientific journals and 6 patents. Currently, he is the Executive Director of Institute of Biologics, Development Center for Biotechnology, with responsibility for the development of its research direction and pipeline.

Dr. Wu quitted tenure Associate Professorship in the Institute of Molecular Medicine, National Taiwan University to found AbGenomics Inc., a biotech company specialized in developing therapeutic antibody, with Dr. RH Lin in 2000. The series A fund was 24.2m USD. With several subsequent rounds of fund raising, the cumulative fund thus far is approximately 52m USD. The Company is planning for IPO in USA.

While he was the Chief Technology Officer, he led the RD team to discover several pipeline products, among them several candidates are currently in clinical development. He also helped to out-license ABGN168 to Boehringer Ingelheim while he was the VP of Business Development. This licensing deal is the first case for a Taiwan biotech company licensing its biotech product to major international pharma.

ABGN168 is a monoclonal antibody that can specifically induce apoptosis of activated T cells while sparing other cell bearing the same cell surface antigen CD162. This feature can be applied to eliminate pathogenic T cells in the patients of autoimmune diseases.

APAC is an industry-driven initiative led by R&D-based pharmaceutical associations from Asian economies, aiming to fulfill its mission.



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