APAC
Asia Partnership Conference
of Pharmaceutical Associations

The 8th Asia Partnership Conference of Pharmaceutical Associations

PROGRAM

Date: April 9 (Tuesday)

Venue: Keidanren Kaikan

To Expedite the Launch of Innovative

Program

8:30 ▶ 8:40	Opening Remarks	G Nakayama, JPMA
8:40 ▶ 8:55	Congratulatory Speech	T Cueni, IFPMA
8:55 ▶ 10:40	**Value-based Healthcare Session**	
8:55 ▶ 9:40	Keynote Lecture – Healthcare Innovation: New Technologies and Effective Evaluation –	H Miyata, Keio Univ.
9:40 ▶ 10:40	Panel Discussion "How do we approach a sustainable healthcare system?"	H Hirate (Chair), JPMA Y Suzuki, MHLW I Kamae, Univ. of Tokyo T Cueni, IFPMA
10:40 ▶ 11:00	< Break > (Photo Session)	
11:00 ▶ 12:30	**ATIM Session: Stability Data Requirement for Post-Approval Changes**	
11:00 ▶ 12:15	・Suggestion & Request from JPMA ・Presentations "Each Economy's Situation for Stability Data" ・Panel Discussion & Conclusion	F Honda (Chair), PMDA Siti Hidayah, NPRA Suchart C, FDA Thailand Juliati, NADFC T Nakagawa, JPMA
12:15 ▶ 12:30	Overview of PACMP pilot program in Japan	K Hara, PMDA
12:30 ▶ 13:30	< Lunch >	
13:30 ▶ 13:40	PMRE Introduction	T Otsuka, JPMA
13:40 ▶ 15:40	**RA Session: Good Registration Management & Regulatory Convergence**	
13:40 ▶ 13:45	Opening	S Hatakeyama, RA-EWG Leader
13:45 ▶ 14:30	1 Good Registration Management ~Success of "Train the Trainers"~ – GRM Overview – Panel Discussion – Closing Remarks	Y C Lin (Chair), TFDA E Fukuda (Chair), PMDA Suchart C, FDA Thailand Tri Asti, NADFC S Chong, SAPI Y W Tarng, PhAMA
14:30 ▶ 15:40	2 Regulatory Convergence ~Reliance Pathway for approval of innovative medicines in APAC~ – Brief introduction – Presentation WHO's Approach to Promoting Reliance – Panel Discussion with Short Presentation – Summary & Future Direction	J Sato (Chair), PMDA J Lim (Chair), Duke-NUS E Cooke, WHO Noraisyah M S, NPRA Juliati, NADFC SB Lim, Duke-NUS S Chong, SAPI Usanee H, PReMA
15:40 ▶ 16:00	< Break >	

Medicines for the Peoples in Asia

16:00 ▶ 18:00	DA Session: Revitalization of Drug Discovery Using Natural Products by Open Innovation in Asia	
16:00 ▶ 17:30	– Introduction – Progress of DA initiative focusing on natural products – 5 Presentations	WK Chi (Chair), DCB A Hasuoka (Chair), JPMA Nares D, TCELS K Tsukahara, JPMA YC Wu, KMU K Shinya, AIST Suparerk B, ECDD M Kawada, IMC
17:30 ▶ 18:00	Panel Discussion	
18:00 ▶ 18:10	Closing Remarks	K Yasukawa, JPMA
18:20 ▶ 20:20	< Reception >	

Value-based Healthcare Session — VBH Task Force Leader Toshinobu Miwa

APAC has previously discussed issues around healthcare access and health technology assessment in 2014 and 2016. Recently, the situation surrounding the pharmaceutical industry has been drastically changed by the emergence of highly effective innovative drugs but is perceived by some for the rising healthcare expenditure in combination with the shifting structure of diseases faced by a rapidly aging society.
What approaches can the pharmaceutical industry take to continue and enhance our contributions to people's health and to increase broader access to these innovative medicines? APAC would like to resume the discussion of challenges presented by these issues in the context of sustainability of healthcare systems, under the broad title "Value-based Healthcare".
Prof. Miyata, Keio University, will give us a keynote speech titled "Healthcare innovation". We will update our knowledge about the recent advancement of healthcare technology and its evaluation through this lecture.
The panel discussion is moderated by Mr. Hirate, JPMA, and we have invited Dr. Suzuki, MHLW, Prof. Kamae, University of Tokyo, and Mr. Cueni, IFPMA, as panelists. We believe the discussion will help us develop our compass to tackle the challenges of future innovations

ATIM Session — ATIM Task Force Leader Kenichi Yamada

Stability Data Requirement for Post-Approval Changes

To achieve the APAC mission "To expedite the launch of innovative medicines for the peoples in Asia", in the last ATIM TF (Access To Innovative Medicines) JPMA picked up a topic on the change control systems in Asia and shared current situation of each region.
After analyzing provided information, the ATIM TF is planning to pick a topic on post-approval change procedure in this 8th APAC, especially focusing on the stability data requirements.
Related to this topic, JPMA ATIM TF made an approach to accomplish APAC mission by proposing "Position paper on efficient CMC/GMP for Access to Innovative Medicine" and invites leading ASEAN regulatory agencies to discuss on the Stability data requirements through the Panel discussion.
The members of ATIM TF believes if the stability data requirements would be handled by science and risk based approaches, it will bring more efficient use of time and resource to review the change proposals and reduce the stock out risk in the patients in Asia.
In the end of this session, PMDA will present a sense of using PACMP (Post-Approval Change Management Protocol), a new tool introduced in Japan for the efficient management of change control.

PMRE Introduction — PMRE Task Force Leader Tomoyuki Otsuka

Staying current with pharmaceutical market & regulatory environment as factual grounds to achieve APAC mission

We proudly announce that we launched a new report"Pharmaceutical Market & Regulatory Environment in Asia" (PMRE) by expanding the scope of the Analysis Report. This report contains information on both the market & regulatory environments. The Analysis report, which APAC published since 2012, provided a factual base of discussion to achieve regulatory convergence for APAC members and government authorities. On the other hand, Asia Committee of JPMA International Affairs has been publishing its own"Regulatory and Market environment report" of Asian economies covering market information such as healthcare system, IP and distribution in addition to the regulatory information for Japanese industry and authorities. APAC mission is"To expedite the launch of innovative medicines for the peoples in Asia." Various solutions to improve access to innovative medicines have been proposed at this APAC platform since its establishment. To further advance Access to Innovative Medicine (ATIM), it is crucial for APAC participants to find solutions from a broader perspective. This report was made possible by extensive efforts of all APAC member associations. We hope it will be helpful for APAC members on the journey to pursue our shared mission.

RA Session **RA EWG Leader Shinji Hatakeyama**

Good Registration Management & Regulatory Convergence

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 Asia economies. For this purpose, the RA-EWG has continuously promoted Good Registration Management (GRM) and Regulatory Convergence in close collaboration with the regulatory authorities and the industries associations of APAC member economies. For promoting GRM, the RA-EWG has collaborated with Taiwan FDA and PMDA to facilitate APEC GRM Regulatory Science Center of Excellence Workshop in Taipei since 2016. In the 8th APAC RA-EWG session, successful "Train the Trainers" will be introduced for further dissemination of GRM within APAC member economies. In addition, this session will cover a new topic related to Reliance Pathway as a part of Regulatory Convergence. Reliance Pathway has been proposed for collaborative procedure in the assessment and accelerated national registration of pharmaceutical product by WHO. The RA-EWG invites WHO representative for introducing a concept of Reliance Pathway and initiates discussions how APAC member economies to utilize Reliance Pathway for achieving the early access to innovative medicines efficiently.

DA Session **DA EWG Leader Atsushi Hasuoka**

Revitalization of Drug Discovery Using Natural Products by Open Innovation in Asia

APAC DA-EWG has been focusing on five initiatives to realize its mission"Promote cross-border open innovation in Asia to deliver innovative drugs to people in Asia". Of the five initiatives, DA-EWG has put the highest priority on the fifth initiative"drug discovery using natural products". DA-EWG believes that collaboration among Asian countries could facilitate use of natural product in drug discovery.

2018 was a big year for DA-EWG because it reached critical milestones and launched APAC Natural Product Drug Discovery Consortium (ANPDC) ; (1) creation of the guideline defining important policies of ANPDC, (2) establishment of the core management structure of ANPDC and (3) enrollment of Japanese pharmaceutical companies in ANPDC.

Considering the above achievements, DA-EWG is going to hold a session entitled"Revitalization of drug discovery using natural products by open innovation in Asia" at the 8th APAC. In the session, presenters from Thailand, Taiwan and Japan will talk about potential of natural product in drug discovery based on their experience in specific research fields. At the panel discussion, they will discuss how to facilitate use of natural product in drug discovery, how to increase the value of ANPDC, etc.

Congratulatory Speech

Thomas Cueni

Thomas B. Cueni is Director General of IFPMA since 1 February 2017. He is Chair of the Business at OECD Health Committee and a member of the Board of Directors of the City Cancer Challenge, an initiative aiming to improve cancer care in major cities in low- and middle-income countries. Thomas Cueni also serves as Chair of the Board of the cross-sectoral AMR Industry Alliance, a group, which includes more than 100 companies and associations representing Rx pharma, generics, biotech, and diagnostics.

Prior to joining IFPMA he was Secretary General of Interpharma, the association of pharmaceutical research companies in Switzerland and served on the Council of IFPMA and Board and committees of EFPIA.

Prior to his appointment with Interpharma, Thomas Cueni had a career as a journalist, inter alia as London correspondent for the "Basler Zeitung" and "Der Bund", and he served as a Swiss career diplomat with postings in Paris (OECD) and Vienna (IAEA, UNIDO). He studied at the University of Basle, the London School of Economics, and the Geneva Graduate Institute for International Studies, and has Master degrees in economics (University of Basel) and politics (London School of Economics, LSE).

Value-based Healthcare Session

Keynote Lecture

Hiroaki Miyata

Dr. Hiroaki Miyata is Professor of Health Policy and Management at the School of Medicine at Keio University, and is Director of Global Health Systems and Innovation at National Center of Global Health and Medicine.
After receiving his doctoral degree in Epidemiology, he has worked as a faculty in the Department of Healthcare Quality Assessment at the Graduate School of Medicine, the University of Tokyo which he currently remains affiliated to as an Adjunct Professor. He has been involved in numerous studies related to the assessment and improvement of healthcare quality in Japan using the national clinical database which is a nationwide clinical registry database that he had actively participated as one of the main leaders in its development.

Profile (Panelist)

Yasuhiro Suzuki

Chief Medical & Global Health Officer Vice-Minister for Health Ministry of Health, Labour and Welfare

Dr. Suzuki was born in 1959. He graduated from School of Medicine, Keio University (MD) in 1984 and trained as neurologist. He received PhD for public health from Keio University in 1996 and two Master's degrees from the Harvard School of Public Health (MPH in 1989 & MSc in 1990).

Dr. Suzuki has a professional career at the Ministry of Health, Labour and Welfare (MHLW), Japan for 30 years covering infectious diseases, mental health, environmental health, food safety, international health, ageing & health, and health research policy. He also worked for the World Health Organization as Executive Director for Social Change & Mental Health, later for Health Technology and Pharmaceuticals (covering vaccines, immunization and biologicals) from 1998 to 2002.

He is currently the Chief Medical & Global Health Officer, Vice-Minister for Health in MHLW from July 2017.

Dr. Suzuki is married and has one daughter.

Profile (Panelist)

Isao Kamae

Isao Kamae is a physician, Project professor of Health Policy and Technology Assessment, Graduate School of Public Policy, The University of Tokyo, Japan, and has been one of the internationally recognized leaders in value-based healthcare. He was the first Japanese to be awarded a Doctor of Public Health in health decision sciences, Harvard University in 1995. He is well known as one of the founders for the ISPOR Asia Consortium; the founding President of ISPOR Japan Chapter in 2005 - 2009; the first Asia-origin member on the ISPOR Board of Directors 2004-2006, and former Chair 2016-2018, ISPOR Asia Consortium. He hosted the HTAi 2016 Tokyo (Board 2017-2019) and the ISPOR Asia-Pacific 2018 Tokyo. He has been invited to an advisory committee on HTA in WHO and OECD. His research interest highlights methodology on economic evaluations and value-based healthcare systems. He is on the editorial board for Journal of Medical Economics.

ATIM Session

Profile (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 (Speaker / Panelist)

Siti Hidayah Kasbon

Ms. Siti Hidayah Kasbon has been working with National Pharmaceutical Regulatory Agency (NPRA) since year 2004. She has extensive knowledge in the regulation of pharmaceutical products having spent many years at the Centre of Product Registration within NPRA evaluating new chemical entity and generic products. She graduated with a degree in Pharmacy from University of Science, Malaysia and holds a Masters in Pharmaceutical Analysis from The National University of Malaysia. She currently serves as the Head of New Drug Unit II, Centre of Product Registration, NPRA.

Profile (Speaker / Panelist)

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 and 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 Thammasat University, Thailand.
He began his career as a pharmacist in the Food and Drug Administration. He has been appointed to be Director, Bureau of Drug Control since 1 October 2017. He has actively engaged in international flora on drug regulation issues, including, for example, GMP inspection, innovative regulatory framework for self-medication, regulatory pathways of biosimilars, Advanced Therapy Medicinal Products (ATMPs). 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 and he looks forward to collaborating with other regulatory authorities having a comparable GMP inspection system to minimize any unnecessary duplication of GMP inspection.

Profile (Speaker / Panelist)

Juliati

Ms. Juliati is the Deputy Director for New Drug and Biological Product Registration. She was graduated as a Pharmacist from University of Indonesia in 2001. She got her 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 registration.

She has experiences in international activities, such as WHO guidelines 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)

Kentaro Hara

Deputy Division Director
Division of Inspection for Drugs
Office of Manufacturing Quality for Drugs
Pharmaceuticals and Medical Devices Agency (PMDA)

Kentaro Hara has 10 years' experience in regulatory authority, including 3 years as a CMC reviewer and 7 years as a GMP inspector. He conducted many on-site GMP inspections in India, China and other countries. He was a member of ICH Q7 IWG, and also is a member of ICH Q12 EWG. He holds a doctor's degree in biosciences from University of Tokyo, and has the experience of lecturing in regulatory GMP conferences.

RA Session

Profile (Chair)

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 (Chair)

Eriko Fukuda

Office of International Cooperation,
Pharmaceuticals and Medical Devices Agency, JAPAN

She spent about 12 years in Biologics Review Office as a reviewer.
During this period, she was responsible for cellular/tissue based products and blood products.
Her international experience includes stay in US FDA CBER, Office of Cellular, Tissue and Gene Therapies, as a visitor reviewer, and United States Pharmacopeia (USP). During this stay in USP, she worked as an International Liaison Officer to US FDA from PMDA.
She joined to Office of international Cooperation in 2018.

Profile (Panelist)

Suchart Chongprasert

Please refer to ATIM session part.

Profile (Panelist)

Tri Asti Isnariani

Education:
- Postgraduated from Master of Pharmacy - Clinical Pharmacy, University of Science Malaysia, 1999
- Graduated from Pharmacist Profession Program, Bandung Institute of Technology, 1994

Recent Title:
Head of Sub Directorate for Drug Safety and Efficacy Standardization,
Directorate for Drug Standardization
National Agency of Drug and Food Control (NADFC) Republic of Indonesia

Areas of interest:
Drug Regulation and Guideline Development; Drug Information to support rational use of medicine; Health professional and public education activity

Conference/Workshop/Organization:
February 2019: Participant of Legislative drafting training
January 2019: Organizing Committee of Pharmaceutical Review Training, collaboration with PMDA
November 2018: Organizing Committee of The 1st Head Meeting of NMRA of OIC
November 2018: Organizing Committee of The 26th ACCSQ Meeting

Profile (Speaker / Panelist)

Sannie SF Chong

As Head of Asia Pacific Tech Regulatory Policy of Roche Singapore Technical Operations,

(1) Actively engages the Health Authorities and Key Opinion Leaders to ensure an optimal and robust regulatory environment that facilitates patients' access.
(2) Drives for regulatory convergence in Asia-Pacific Economic Cooperation (APEC).
Publication "*developing key performance indicators to measure the progress of regional regulatory convergence and cooperation in APEC*" at AAPS Open https://doi.org/10.1186/s41120-018-0024-2

Formerly from Singapore Health Sciences Authority (HSA) as Branch Director, Sannie Chong supervised all the quality reviewers responsible for all decisions relating to chemistry, manufacturing and control (CMC) in both the pre- and post-marketing stages.

Internationally, she represented HSA as:
- the WHO expert for the pre-qualification of Medicines Program
- the Singapore Lead for ASEAN (for technical); and
- the Singapore Lead of the work-sharing initiatives of ACSS (Australia-Canada-Singapore-Switzerland) https://www.tga.gov.au/acss-nce-work-sharing-pilot

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 (USA).

Currently Sannie also serves as visiting expert of the Duke-NUS (Singapore).

Profile (Panelist)

Yew Wei Tarng

Managing Director
Eisai (Malaysia) Sdn. Bhd.

Mr. Yew Wei Tarng holds a Bachelor of Pharmacy Degree from Universiti Sains Malaysia. Presently the Managing Director of Eisai (Malaysia) Sdn. Bhd., he is also the Board Director of the Pharmaceutical Association of Malaysia (PhAMA).

Mr. Yew began his journey within PhAMA as the Chairman of the Human Resource Committee from 2006 to 2008. He then went on to become the Chairman of Regulatory Affairs Committee with the association and continues to hold this position to date. In 2006, Mr. Yew became Vice President of PhAMA, a position he has held until he became the President of the association from September 2012 to March 2015. He has been a regular participant and working closely with APAC since its inception in 2012.

Besides PhAMA, Mr. Yew has also been active in other associations such as the ASEAN Pharmaceutical Research Industry Association (APRIA), where he was chairman of the association for a year. APRIA is a regional association representing the research-based pharmaceutical companies in ASEAN, committed to ensuring optimal regulatory environment for the continued development of the pharmaceutical industry.

Profile (Chair)

Junko Sato

Dr. Junko Sato is an Office Director of Office of International Program at Pharmaceuticals and Medical Devices Agency (PMDA).
She joined Regulatory Agency in 1998. She became a review director of Office of New Drug in 2004 and moved to Office of Safety in 2009 to develop a new risk management system through life cycle of drugs. During the period, she visited U.S.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, CIOMS etc. She also contributes many DIA activities. She received DIA Outstanding Service Award 2010.
She led the activities of PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (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 also works for AMR project like EMA-FDA-PMDA tripartite meeting to discuss convergence on approaches for the evaluation of antibacterial drugs.
She is an Infection Control Doctor certificated by The Japanese Association of Infectious Disease.

Profile (Chair)

John CW Lim

Professor John CW Lim is founding Executive Director of the Centre of Regulatory Excellence (CoRE) at the Duke-National University of Singapore (Duke-NUS) Medical School and Policy Core Lead at the SingHealth Duke-NUS Global Health Institute.

A medical doctor with graduate degrees in Public Health from NUS and Health Policy and Management from Harvard University, Dr Lim is Professor of Practice at Duke-NUS and the NUS Saw Swee Hock School of Public Health, Senior Advisor at Singapore's Ministry of Health (MOH), and Chairman of the Singapore Clinical Research Institute and National Health Innovation Centre.

Formerly Chief Executive Officer of Singapore's Health Sciences Authority and Deputy Director of Medical Services (Industry & Research Matters) in MOH, Professor Lim has also held other senior positions in the health and education ministries. In his current roles, he draws on his international experience and networks to enhance health regulatory and systems capacity and scientific excellence for national authorities, industry and researchers in the Asia-Pacific and South-East Asia.

He is a member of the Executive Board of the APEC Life Sciences Innovation Forum, Advisory Group of the US Pharmacopoeia's Quality Institute, Scientific Advisory Council of the Centre for Innovation in Regulatory Science, ASEAN Diagnostics Development Initiative Strategic Planning Panel, Board of the Singapore Food Agency and Board of St Andrew's Mission Hospital in Singapore.

In 2018, Professor Lim received the Drug Information Association's Global Connector Inspire Award for leadership in promoting global collaboration to advance healthcare products to patients, and the Regulatory Affairs Professional Society's highest Founder's Award recognising substantial sustained impact in shaping regulatory practice and policy over the course of his career.

Profile (Speaker)

Emer Cooke

Ms Emer Cooke obtained her degree in pharmacy from Trinity College, Dublin in Ireland. She has additional Masters degrees in Science and in Business Administration, also from Trinity.
During the period from 1985 to 1988 she worked in a number of positions within the Irish pharmaceutical industry before moving to the Irish drug regulatory authority as a pharmaceutical assessor in 1988. In 1991 she joined EFPIA, the European pharmaceutical industry association as Manager of Scientific and Regulatory Affairs in Brussels. From September 1998 to July 2002, she worked in the Pharmaceuticals unit of the European Commission, following which she was appointed as Head of Sector for Inspection at the European Medicines Agency (EMA) in London. Towards the end of 2008, Emer took on the newly created post of International Liaison Officer. She became Head of International Affairs in the context of EMA's reorganization and remained in this position until November 2016.
In November 2016 Emer Cooke was appointed as Head of Regulation of Medicines and other Health Technologies with the World Health Organization (WHO) in Geneva. In this role, Ms Cooke is responsible for leading WHO's global work on regulation of health technologies (medicines, vaccines, diagnostics, vector control products and devices), coordinating the regulatory teams (Norms and Standards, Prequalification, Regulatory Systems Strengthening, and Safety), and working with member states and international partners to assure the quality, safety and efficacy of appropriate health technologies.

Profile (Speaker / Panelist)

Noraisyah Mohd Sani

Ms. Noraisyah Mohd Sani is a senior officer with NPRA and has been involved with pharmaceutical regulation since 2002. Her area of expertise is in the regulation of pharmaceutical products for both pre and post-marketing having spent many years at the Centre of Product Registration within NPRA evaluating biological and generic products and also at the Centre of Post Product Registration carrying out post-marketing monitoring activities. She holds a Master Degree in Pharmaceutical Analysis and is currently heading the Biologics Section of NPRA. She believes that a good regulatory system will benefit the patients with timely access of medicinal products of safe, efficacious and good quality.

Profile (Panelist)

Juliati

Please refer to ATIM session part.

Profile (Panelist)

Sok Bee Lim

Sok Bee is currently a Senior Associate of the Pharmaceutical Regulatory Science Programme at the Centre of Regulatory Excellence (CoRE), Duke-NUS Medical School. Since joining the Centre in June 2018, she is in-charge of developing workshops related to the regulation of Chemistry, Manufacturing, and Controls (CMC) for pharmaceutical products. Formerly, she was a Senior Regulatory Specialist with the Health Sciences Authority of Singapore, where she performed quality review of marketing authorisation and post-approval applications for medicinal products, and assessed the impact of quality-related product defects reported for approved medicinal products.

Sok Bee graduated with a B.Sc. (Pharmacy) (Honours) from the National University of Singapore and holds a PhD in Biopharmaceutical Sciences from the College of Pharmacy, University of Illinois at Chicago, USA. She is also a Singapore certified pharmacist, with clinical experience as a hospital pharmacist at the National University Hospital of Singapore.

Profile (Speaker / Panelist)

Usanee Harnpramukkul

Regulatory Affairs East ASEAN Cluster Lead and Thailand Country Head Pfizer (Thailand) Limited

EDUCATION

Bachelor Degree in Pharmaceutical Sciences (first class honour), Mahidol University.

CURRENT POSITION

2019 - present Regulatory Affairs East ASEAN Cluster Lead and Thailand Country Head, Pfizer (Thailand) limited

PREVIOUS POSITION

2016 - 2018	Regulatory Affairs ASEAN Cluster Lead -Pfizer Essential Health, Pfizer (Thailand) limited
2015 - 2016	Regulatory Affairs Director - Thailand and Indochina, Pfizer (Thailand) Limited
2010 - 2015	Senior Regulatory Affairs Manager, Pfizer (Thailand) Limited
2008 - 2010	Senior Regulatory Affairs Manager, Wyeth (Thailand) Ltd.
2004 - 2007	Registration Manager, Wyeth (Thailand) Ltd
2002 - 2004	Regulatory Affairs Manager Bristol-Myers Squibb (Thailand) Co., Ltd
1989 - 2002	Thai FDA Officer (C3 - C7), Thai FDA
1988 - 1989	Hospital Pharmacist, National Cancer Institute
1987 - 1988	Hospital Pharmacist, Ramathibodi hospital
1987 - 1987	Sale Representative, East Asiatic Company

PROFESSIONAL EXPEREINCES

- 16 years experiences of Regulatory Affairs in multi-national companies
  - 2 years experiences in ASEAN cluster including Thailand, Indonesia, Malaysia, Philippines, Singapore, Vietnam, Cambodia, Myanmar, Laos and Brunei
  - 12 years experiences in Thailand
- Deputy Chairperson of Regulatory Affairs Subcommittee, Pharmaceutical Research and Manufacture Association (PReMA)
- Member of PReMA representatives of ASEAN Pharmaceutical Research Industry Association (APRIA)
- Member of PReMA representatives of Thai FDA subcommittee/working group e.g. e-Submission, Registration fee for psychotropic substance and narcotic drug, etc.
- Participant in "2016 APEC Good Registration Management (GRM) Regulatory Science Center of Excellence Pilot Workshop" on 15-17 November 2016 at Taipei

DA Session

Profile (Chair)

Wei-Kuang Chi

Vice President, R&D
Executive Director, Institute of Pharmaceutics
Director, Bioengineering Group, Institute of Biologics
Development Center for Biotechnology, Taipei, Taiwan

Biography

Dr. Wei-Kuang Chi, Vice President Since November 20, 2018 of the Development Center for Biotechnology (DCB), 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. He established DCB's multi-product 500 L mammalian cell culture and 100 L microbial fermentation CGMP Biopharmaceutical Pilot Plant Facility (BPPF) and certified by Taiwan Department of Health (DOH) on December 2005 and received DMF with USA FDA on March 2006. The CGMP BPPF has been spun-off on 2013 into private sector to provide CDMO service on a broader scale. Dr. Chi's new responsibility will focus on new drug R&D, international collaboration, novel bioengineering technology, CAR-T/iPSC development, application of deep learning/AI on drug discover and /biomanufacturing process.

Profile (Speaker / Panelist)

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)

Yang-Chang Wu

Professor/Dr.
Prof. Wu obtained his Ph.D from Kaohsiung Medical University (KMU), Taiwan, in 1986. He joined the groups of Prof. Yoshimasa Hirata at Meijo University, Japan and Prof. Kuo-Hsiung Lee at the University of North Carolina, Chapel Hill, USA as a postdoctoral researcher from 1986 to 1987. In 1990, he became professor at the College of Pharmacy and served as the director of the Graduate Institute of Natural Products (GINP) in 1992, the dean of the Office of Research and Development at KMU, from 2006 to 2009 and the chair professor and vice-president at China Medical University (CMU), Taiwan, from 2010 to 2017. Currently, he served as the Chair Professor of the GINP and Research Center for Natural Products and Drug Development (RCNPDD). So far, Prof. Wu has published *ca*. 600 papers in SCI journals along with the authorship in several book chapters. He has been granted more than 50 patents and is in cooperation with more than 20 industry-academic organizations and has transferred six patent/technologies to industry. He also has served as an editorial board member of 6 journals and as a referee for about 30 journals and received several outstanding medical and pharmaceutical research award from government and industry in Taiwan.

Profile (Speaker / Panelist)

Kazuo Shinya

Education:
1984-1988: Tokyo University of Agriculture and Technology
1988-1990: Master of Agriculture, Faculty of Agriculture, Department of Agricultural Chemistry, The University of Tokyo
1990-1993: Doctor of Agriculture, Faculty of Agriculture, Department of Agricultural Chemistry, The University of Tokyo
1993: Awarded the degree of Doctor of Philosophy in Agriculture (Ph.D.)

Brief Chronology of Employment:
1993-2006: Assistant Professor, Institute of Molecular and Cellular Biosciences, The University of Tokyo
2006-: Group Reader, Biotechnology Research Institute for Drug Discovery, National Institute of Advanced Industrial Science and Technology

Concurrent posts:
The University of Tokyo, Professor
Tokyo Institute of Technology, Visiting Professor
Musashino University, Visiting Professor
National Defense Medica College, Part-time lecturer

Honors and Awards:
2001: Award for Young Scientist of The Japanese Association for Molecular Target Therapy of Cancer
2002: Award for Young Scientist of 43rd Symposium of The Chemistry of Natural Products
2003: Award for Young Scientist of Japan Society for Bioscience, Biotechnology, and Agrochemistry
2006: Sumiki-Umezawa memorial Award

Profile (Speaker / Panelist)

Suparerk Borwornplnyo

Profile (Speaker / Panelist)

Manabu Kawada

Current Professional
Laboratory Head, Laboratory of Oncology
Microbial Chemistry Research Foundation
Institute of Microbial Chemistry, Laboratory of Oncology

Professional Summary

1995~1997	Postdoctral Research Fellow, National Institute of Health, Japan
1997~2003	Researcher, Institute for Chemotherapy, Microbial Chemistry Research Foundation, Japan
2003~2010	Leader, Drug Development Unit, Numazu Bio-Medical Research Institute, Microbial Chemistry Research Center, Microbial Chemistry Research Foundation, Japan
2010-2014	Chief Researcher, Institute of Microbial Chemistry, Numazu, Microbial Chemistry Research Foundation, Japan
2014-present	Branch Head, Institute of Microbial Chemistry, Numazu, Microbial Chemistry Research Foundation, Japan
2015-present	Laboratory Head, Laboratory of Oncology, Institute of Microbial Chemistry, Microbial Chemistry Research Foundation, Japan

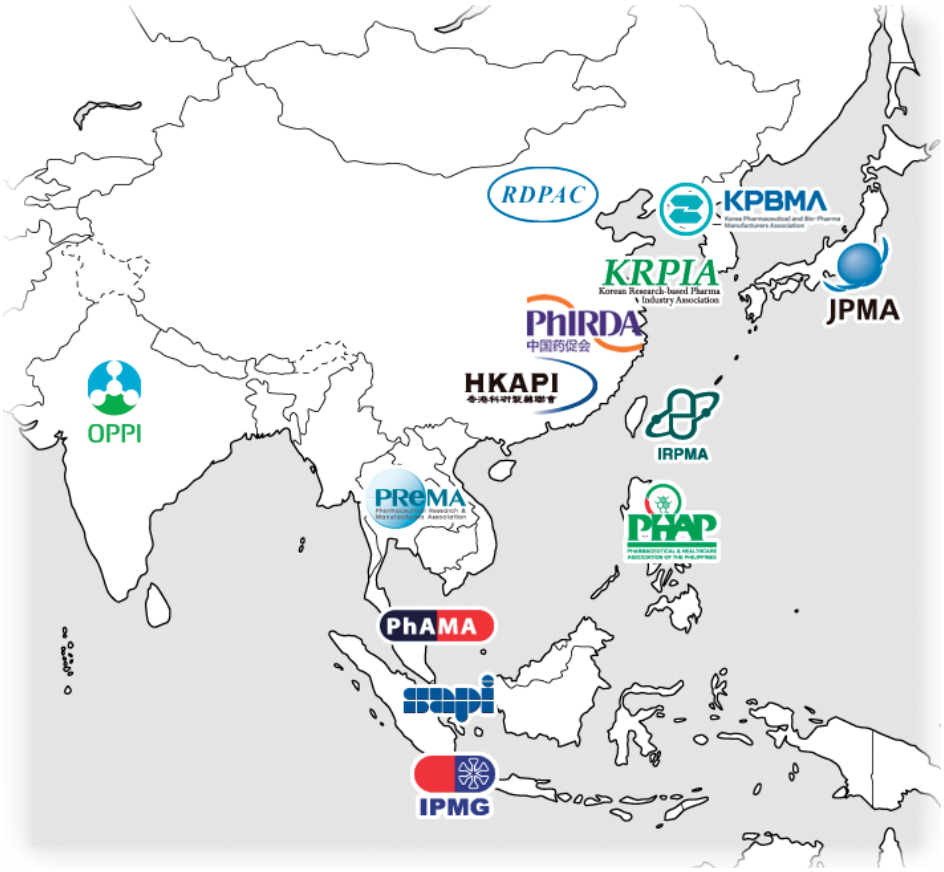
Education

1995	Keio University Graduate School of Science and Technology, Ph.D.

Award

1999	The Incitement Award of the Japanese Association for Molecular Target Therapy of Cancer
2006	The Incitement Award of the Japanese Association for Metastasis Research
2006	The Incitement Award of the Japanese Cancer Association
2015	Sumiki-Umezawa Memorial Award

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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