APAC
Asia Partnership Conference of Pharmaceutical Associations

The 12th Asia Partnership Conference of Pharmaceutical Associations

Theme : We're all together again

PROGRAM

Date: April 18 (Tuesday), 2023

Venue: Muromachi Mitsui Hall & Conference

Greeting

Tatsuya Ito

JPMA

We welcome everyone contributing peoples' health in Asia through the development of innovative medicines and technologies. APAC has been inviting all the stakeholders of the healthcare ecosystem involving members of pharmaceutical manufacturers associations, regulatory authorities and health ministries, academia, and health care professionals to the conference. We could only meet remotely in the last two years and in the 12th APAC this year conference we meet both in-person and on-line. APAC has been well recognized by the achievements of expert working groups and task forces resulted to the publishment of position papers and templates expediting access to innovative medicines. The COVID pandemic enabled to connect instantly with each other by the advancement of online tools, but we also recognized how important the collaboration beyond country/economies or public sectors. We now accelerate our activities by resuming face to face communications. The goal of APAC remains constant, to expedite the launch of innovative medicines to the peoples in Asia, but we flexibly change adopting the expectations to us and becoming more agile partnership.

Chairperson APAC steering committee
& JPMA APAC management committee

We're all together again - Deliver tenacious power for Access

Program

08:45 ▶ 08:55	Come-in		
08:55 ▶ 09:00	Opening Remarks	Yasushi Okada	JPMA
09:00 ▶ 09:10	Congratulatory Speech	Thomas Cueni	IFPMA
09:10 ▶ 09:35	Keynote Lecture	Yasuhiro Fujiwara	PMDA
09:35 ▶ 09:45	< Picture taking & Break >		
09:45 ▶ 11:25	RA Session: Facilitation of efficient application & review for medicine through reliance scheme		
	Opening by Chairs	Junko Sato Janis Bernat	PMDA IFPMA
	Regulatory Agility post pandemic: learning from the strategies during the height of covid-19	Jesusa Joyce N. Cirunay	Philippines FDA
	New Drug Review Cooperation between Japan and Taiwan	Wen-Yi Hung	Taiwan FDA
	Realizing the Objectives of the ICMRA PostapprovalChange Collaborative Assessment Pilot	Sau (Larry) Lee Richard Simon Binos	FDA PHAP
	Sustaining and evolving regulatory agilities with inspiring partnership	Sannie SF Chong Masaaki Kanno Desi Eka Putri	MSD International JPMA BPOM
	Panel Discussion • "Regulatory reliance in Indonesia" by BPOM • Discussion Topic	Jesusa Joyce N. Cirunay Wen-Yi Hung Sau (Larry) Lee Sannie SF Chong	Philippines FDA Taiwan FDA FDA MSD International
	Closing by Chairs	Junko Sato Janis Bernat	PMDA IFPMA
11:25 ▶ 11:35	< Break >		
11:35 ▶ 12:35	MQS Session: Expansion of PACMP utilization in Asia		
	Opening	Shinichi Okudaira Makoto Ono	PMDA JPMA
	Session introduction and objectives	Tomonori Nakagawa	JPMA
	Short presentation from panelists	Wan-Yu Chao Subin Sankarankutty Satomi Yagi	Taiwan FDA HSA PMDA
	Panel discussion	Wan-Yu Chao Subin Sankarankutty Satomi Yagi Tomonori Nakagawa	Taiwan FDA HSA PMDA JPMA
	Closing	Shinichi Okudaira Makoto Ono	PMDA JPMA
12:35 ▶ 13:05	< Lunch Break >		

to Innovative Medicine by reaffirming cooperation in Asia

13:05 ▶ 14:45	**e-labeling Session: Future of digital Health: Moving towards e-labeling for patients**		
	Opening with sharing the progress of e-labeling initiatives for APAC regions including the regulators' workshop	Rie Matsui	JPMA
	Share and agree to the APAC EWG position paper	Paul Marvin Quizon Naomitsu Yamaya	PHAP JPMA
	E-labeling implementation experience and future in Japan	Tomoko Ohsawa	PMDA
	E-labeling initiative and pilot project for pharmaceuticals in the Republic of Korea	Yubin Lee	MFDS
	E-labeling Update in Malaysia	Rosilawati Ahmad	NPRA
	2023 APAC e-labeling summit	All speakers from regulatory authorities, plus Nova Emelda Po-Wen Yang Worasuda Yoongthong Jesusa Joyce N. Cirunay Nguyen Thanh Lam	 BPOM Taiwan FDA Thai FDA Philippines FDA DAV
	Closing	Junko Sato	PMDA
14:45 ▶ 14:55	**< Break >**		
14:55 ▶ 16:15	**DA Session: DESIGN future drug discoveries and collaboration among Asian countries**		
	Opening Presentation	Megumi Ikemori	JPMA
	Developing next generation therapy for Age-related Fibrotic Disorders targeting secreted type pro-fibrotic protein (A-FiD research consortium study).	Ippei Shimizu	National Cerebral and Cardiovascular Center
	Attractiveness of Japan (seeds/market) seen from Asia (Taiwan)	Tsai-Kun Li	DCB
	Industry-Academia-Government Collaboration from an International Perspective	Masato Nakagawa	Denso Corporation / JST / Hiroshima University
	Q&A and Panel Discussion	All speakers and Jun Terauchi	 JPMA
	Closing	Megumi Ikemori	
16:15 ▶ 16:25	**< Break >**		
16:25 ▶ 18:05	**aUHC Session: "Toward the achivement of true UHC in ASIA by focusing Financing"**		
	Facilitator of the session	Toshihiko Takeda	Boston Consulting Group
	Opening Presentation	Keizo Takemi	Member of the House of Councillors
	Experience Sharing Japan	Teruyuki Katori	Future Institute Wolong / Hyogo Prefectural University
	Experience Sharing Thailand	Rungpetch Sakulbumrungsil	Pharmacy Council Bangkok
	Experience Sharing Singapore	Jeremy Lim	National University of Singapore
	Panel Discussion		
18:05 ▶ 18:20	Message from regulatory agencies	Jesusa Joyce N. Cirunay Rosilawati Ahmad Shou-Mei Wu	Philippines FDA NPRA Taiwan FDA
18:20 ▶ 18:30	Closing Remarks	Hiroshi Nomura	JPMA

Opening Remarks

Yasushi Okada

Representative Corporate Officer, COO, Eisai Co., Ltd.

Yasushi Okada joined Eisai in 1981. His experience in Eisai covers broad areas including sales and marketing of pharmaceutical products in Japan, Corporate Planning, Asia, Oceania and Middle East business, Human Resources, General Affairs, China business, Data Integrity and Industry Affairs.

In Eisai, Mr. Okada was appointed as Vice President in 2005, Senior Vice President in 2012, Executive Vice President in 2013 and Representative Corporate Officer in 2017. He has been the representative of Eisai for industry and government affairs since 2017 and engaged in several healthcare policy matters.

Mr. Okada has served as President of Japan Pharmaceutical Manufacturers Association since 2021.

Closing Remarks

Hiroshi Nomura

President and Chief Executive Officer
Sumitomo Pharma Co., Ltd. (“SMP”)

Career

Apr 2018	President and Chief Executive Officer, Representative Director
Apr 2017	Representative Director and Executive Vice President
Apr 2016	Member of the Board of Directors and Executive Vice President
Apr 2014	Board of Directors, Senior Executive Officer and Chief Financial Officer, Global Corporate Management, Global Strategy & Business, External Affairs; Corporate Secretariat & Industry Affairs, Finance & Accounting, Regenerative & Cellular Medicine Office
Jun 2012	Member of the Board of Directors and Executive Officer
Feb 2011	Executive Officer, Sunovion Pharmaceutical Inc. (Vice Chairman, Executive Vice President, Chief Financial Officer)
Jun 2011	Executive Officer, Deputy Executive Director, Sales and Marketing, External Affairs
Sep 2010	Executive Officer, Director, Global Business Planning and Development, Finance & Accounting, Information System Panning, Business, Support Center
Nov 2009	Executive Officer, Director, International Business Strategic Planning and Management, Finance & Accounting, Information System Panning
Jun 2009	Executive Officer, Corporate Planning, Finance & Accounting, Information System Panning
Jun 2008	Executive Officer, Dainippon Sumitomo Pharmaceuticals, Co., Ltd Director, Corporate Planning, Finance & Accounting, Information System Panning
Jun 2007	Director, Corporate Planning, Dainippon Sumitomo Pharmaceuticals Co., Ltd
Oct 2005	Director, Finance & Accounting, Dainippon Sumitomo Pharmaceuticals Co., Ltd
Jun 2004	Director, Sumitomo Pharmaceuticals Co., Ltd
Apr 1981	Joined Sumitomo Chemical as administrative staff

Industry Association Activities
President, Kansai Pharmaceutical Industries Association (KPIA)
Vice President, Japan Pharmaceutical Manufacturers Association (JPMA)

Congratulatory Speech

Thomas Cueni

Thomas Cueni, IFPMA Director General

As Director General, Thomas leads IFPMA's mission to encourage the development of sustainable solutions that enable innovation and improve global health.

Over the past two decades, Thomas has been instrumental in developing collaborative solutions for some of the greatest global health challenges. These include HIV/AIDS and antimicrobial resistance, as well as the industry's response to pandemics.

Since he joined IFPMA, Thomas has pioneered collaborative solutions to tackle antimicrobial resistance (AMR), chairing the AMR Industry Alliance and launching the AMR Action Fund. This is a USD 1 billion venture begun in July 2020 to fund the development of between two and four new antibiotics by 2030.
Thomas represents the innovative pharmaceutical industry in the Access to COVID-19 Tools (ACT) Accelerator initiative, set up in April 2019. In 2022, together with industry CEOs and building on the lessons learned from COVID-19, he led the development of the Berlin Declaration. This is a vision for equitable access in global pandemic response that invites multilateral organizations as well as the G7 and G20 to agree to a social contract for future health security. He is Chair of the Business at OECD Health Committee and serves as Industry Co-Chair of the APEC Biopharmaceutical Working Group on Ethics.

Keynote Lecture

Yasuhiro Fujiwara

Dr. Yasuhiro Fujiwara has taken his position as Chief Executive of Pharmaceuticals and Medical Devices Agency (PMDA) since April 1, 2019.

Dr. Yasuhiro Fujiwara was previously Director General, Strategic Planning Bureau of the National Cancer Center , and the Deputy Director of the Hospital (Research), National Cancer Center Hospital. He is a medical oncologist, specializing in breast cancer. B efo re joining National Cancer Center Hospital (NCCH)), he was a deputy director of the Evaluation Division II of the Pharmaceuticals and Medical Devices Evaluation Center of the National Institute of Health Sciences PMDEC, later merged with other organization to form PMDA) of the Ministry of Health and Welfare and Labor between 1997 2002, making his current position as Chief Executive his second appointment . Between Jan 2011 to Feb 2013, he was a Deputy Secretary General of Office of Medical Innovation, Cabi net Secretariat of Japan , and led health policy issues regarding life science.

RA Session

Overview — RA EWG Shinji Hatakeyama

Facilitation of Efficient Application & Review for Medicine through Reliance Scheme

At the 12th APAC, the main theme of the RA session is “Facilitation of Efficient Application & Review for Medicine through Reliance Scheme”.
At the 8th APAC held in April 2019, we invited WHO for asking to introduce their concept of Good Reliance Practice among the health authorities. At the 10th APAC held in April 2020, we proceeded discussion on Regulatory Agility in the COVID-19 pandemic. Referring the past high-level discussions among the health authority, academia, and pharmaceutical industry on the theme of Reliance Scheme and Regulatory Agility, we have asked the health authorities and the pharmaceutical industry to introduce their experience and knowledge how far Reliance Scheme and Regulatory Agility have progressed. In addition, in the panel discussion, we plan to ask the panelists to discuss and indicate important points to facilitate Reliance Scheme and Regulatory Agility in Asia as landmark.

Progress Report 2023 – The progress of APAC member associations' activities in 2022 along the Position Paper 2022 for GRM is described. The report can be accessed using the QR code below.

Chair

Junko Sato

PMDA

Dr. Junko Sato is an Office Director of Office of International Program at Pharmaceuticals and Medical Devices Agency (PMDA).
She started to work in regulatory agency in 1998. She became a review director in Office of New Drug, anti-infective drug area and moved to Office of Safety to establish a new risk management system through life cycle of drugs. During the period, she worked in 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 the MHLW/PMDA Liaison. She enhanced collaboration between EMA and MHLW/PMDA and brought a huge success as the liaison. She contributes to some global harmonization activities, for example, ICH, CIOMS etc. Currently she is the chair of IPRP. She is also keen for scientific activities. She works for Japanese Society of Clinical Pharmacology and Therapeutics as a board member, and Japanese Society of Chemotherapy as a member of many committees, and for more than 10 Societies. Her specialty is infection control. She is certified as an infection control doctor by Japanese Association on Infectious Disease.

Chair

Janis Bernat

Director, Scientific and Regulatory Affairs
IFPMA

Janis leads cross-functional activities in regulatory science and international health policy for IFPMA, while partnering with policy experts and stakeholders to strengthen the pharmaceutical regulatory environment. She is responsible for guiding the organization’s regulatory team to successfully deliver its policy objectives and advocate for improved regulatory system strengthening. Prior to joining IFPMA, Janis worked in quality assurance and regulatory compliance for a US-based multinational company that specializes in supplying custom value-added food products to a world leading food service and retail food brand. Janis holds a Master of Science in Communication-Public Relations and a Bachelor of Science in Agriculture-Food Science.

Speaker / Panelist

Jesusa Joyce N. Cirunay

Food and Drug Administration, Philippines

JESUSA JOYCE N. CIRUNAY is currently the Director IV of the Center for Drug Regulation and Research at the Food and Drug Administration Philippines. She is a Registered Pharmacist (*cum laude*) with graduate studies on Pharmaceutical Science at the Vrije Universiteit van Brussel in Belgium. Her government service began at the Product Services Division (PSD) covering Marketing Authorizations as Pharmaceutical Researcher then as Senior Drug Evaluator including New Drug Applications and Vaccines. Before her current post, she was assigned to head several key offices of the Agency at various timelines, i.e., Field Cluster Director in various parts of the Philippines, as Head of the GMP Inspectorate; as Head of the Distribution Inspectorate and as Head of the Marketing Authorization. Her repertoire also covers experiences in international collaboration as former OIC–FDA International Affairs Office; media relations as former FDA Spokesperson; Quality Management System as former Quality Manager for the FDA Quality Management System on ISO 9001 initially for 2008 version and then 2015 version; on ASEAN Harmonization in the Healthcare Sector representing FDA PH as Head of Delegation or Delegate; on APEC as Delegate. Her publications include, among others, as lead author in several scientific articles published in peer-reviewed international journals (few accepted without correction) covering pharmaceutical science, chemometrics in drug formulation development (i.e. factorial designs, central composite designs) and liquid chromatography. She is also a part time faculty teaching Pharmacy to undergraduate students.

Speaker / Panelist

Wen-Yi Hung

Senior Reviewer
Section of New Drug, Division of Medicinal Products, Taiwan Food and Drug Administration (TFDA)

Dr. Wen-Yi Hung joined TFDA in 2012 after she acquired her PhD degree in Pharmacology from National Yang Ming University. She worked in the Section of Clinical Trial Management for 6 years, and shifted to the Section of New Drug in 2018. Dr. Hung assisted New Drug Working Group activities under the Framework of the Cooperation on the Medical Products Regulation between Japan and Taiwan, and participated in the development of New Drug Review Cooperation Scheme between Japan and Taiwan.

Speaker / Panelist

Sau (Larry) Lee

Food and Drug Administration

Dr. Sau (Larry) Lee is the Deputy Super Office Director of Science in the Office of Pharmaceutical Quality. He directs the activities of staff members in OPQ sub-offices responsible for the quality assessment of regulatory submissions (Office of Biotechnology Products (OBP), Office of Lifecycle Products (OLDP), Office of New Drug Products (ONDP), and Office of Pharmaceutical Manufacturing Assessment (OPMA)). He represents OPQ in programs and activities that impact quality assessments by coordinating with OPQ, CDER, and ORA. He also serves as the point person for the pharmaceutical industry and scientific/academic groups in developing programs to support science- and risk-based application assessment and approval.

Speaker / Panelist

Richard Simon R. Binos

Pharmaceutical and Healthcare Association of the Philippines

Richard Simon Binos is the Health Systems and Market Access Manager of PHAP. He reviews and prepares recommendations on health, regulatory, and trade policies impacting the pharmaceutical industry. Prior to joining PHAP, he was the policy lead for the Center for Drug Regulation and Research, Food and Drug Administration Philippines, working on pharmaceutical regulatory policies and representing the agency in various collaborative activities. Mr Binos is a board of director (BoD) for the International Society for Pharmacoeconomics and Outcomes Research Philippines, and previously a BoD for the International Society for Pharmaceutical Engineering, Philippines Affiliate. Mr. Binos is a Pharmacy graduate from the University of the Philippines-Manila, and is finishing his Master's thesis on Health Policy Studies from the same university.

Speaker / Panelist

Sannie SF Chong

MSD International

Senior Director, Global Regulatory Policy at MSD: Leader of regulatory affairs, strategic filing, policy and intelligence with nearly 20 years of experience in the pharmaceutical and healthcare industry. Proven 9 years in managerial role; and 7 years in leadership role including APEC Co-Championship on behalf of the Biotechnology Innovation Organization (BIO). Strong government affairs contacts and networks across markets in APEC.

Career Highlights:

- Branch Director at the Singapore's Health Sciences Authority until early 2014. Internationally, Sannie represented Singapore in the WHO prequalification program, the ASEAN Pharmaceutical Products Working Group, and the Australia-Canada-Singapore-Switzerland (ACSS) Consortium for work-sharing initiatives.

- Asia Pacific Lead of F. Hoffmann La-Roche in shaping regulatory policy to expedite regulatory convergence to enable patients' access. As Roche's Global Lead for reliance and work-sharing, Sannie leads initiatives to track convergence in APEC and co-champions the APEC biotherapeutics work areas.

As a key thought leader, Sannie's publications include:

- ✓ Developing *key performance indicators to measure the progress of regional regulatory convergence and cooperation in APEC"*; AAPS Open (2018) https://doi.org/10.1186/s41120-018-0024-2
- ✓ *Measuring progress of regulatory convergence and cooperation among APEC member economies in the context of the COVID-19 pandemic"*; Therapeutic Innovation & Regulatory Science (2021) https://doi.org/10.1007/s43441-021-00285-w
- ✓ *Asia Partnership Conference of Pharmaceutical Associations (APAC) Report on Regulatory Agility Implemented During the COVID-19 Pandemic: Inspiring Partnerships and Recommendations for the Way Forward;* Therapeutic Innovation & Regulatory Science (*2022*) https://doi.org/10.1007/s43441-022-00435-8

Sannie holds a bachelor's degree and a Ph.D. in Chemistry at the University of Hull of the UK and a postdoctoral research fellowship at the University of North Carolina at Chapel Hill of the USA.

Speaker / Panelist

Masaaki Kanno

JPMA

Joined Otsuka Pharmaceutical Co., Ltd. as senior regulatory expert at Regulatory Affairs Department since Oct. 2019. He is a member of RA Expert Working Group of APAC at the JPMA counterpart since Mar. 2020, and has been also assigned as the leader of Indonesia team at Asian Committee in JPMA. Therefore, he is expected to work in collaboration between APAC RA-EWG and JPMA Asian Committee in order to overcome common regulatory challenges and promote new agile regulatory framework in the APAC region. He is also one of the co-authors for the APAC Report on Regulatory Agility implemented during the COVID-19 pandemic.

Speaker / Panelist

Desi Eka Putri

Coordinator for New Drug Registration
Directorate of Drug Registration
Indonesian Food and Drug Administration

Employment History
Lecturer/Researcher
- Sekolah Tinggi Farmasi Indonesia, Padang, West Sumatera (2001 – 2008)
- UHAMKA University (2010 – 2014)

Pharmacist
Utama Dispensary, Padang, West Sumatera (2002 – 2008)

Regulator
Indonesian FDA (Badan POM)
- Senior Evaluator (2007 – now)
- Head of Section for Biological Products, 2018- 2022
- Coordinator for New Drug Registration, 2022 – now
- WHO Pre-Qualification Team for Vaccines, 2020 – now

Education
Pharmacist Bachelor Degree (S.Si)
Department of Pharmacy, Faculty of Mathematics and Natural Sciences Andalas University, Indonesia (1995-1999)

Pharmacist Apothecary Program (Apt)
Department of Pharmacy, Faculty of Mathematics and Natural Sciences Andalas University, Indonesia

Magister of Pharmacy (M.Farm)
Andalas University, Indonesia (2005-2007)

MQS Session

Overview

MQS-TF leader Makoto Ono

To achieve the APAC mission “To expedite the launch of innovative medicines for the Asian Patients”, we have covered the topics related to manufacturing and quality control as ATIM task force. Since last APAC conference, the decision was made to change our team’s name to match the activities, and we have been operating as MQS (Manufacturing, Quality control and Supply) task force.
The MQS session picked a discussion theme on the Expansion of PACMP (Post Approval Change Management Protocol) utilization in Asia in 12th APAC. In Japan, the PACMP system has started operating in accordance with ICH Q12 as a pioneer in Asia. Our presenter introduces summary and benefits of PACMP system, and three panelists introduce the current status of PACMP in their countries and discuss the benefits and challenges to introduce PACMP.
The MQS team members believe that if the PACMP system is employed in many Asian countries, it will bring more unified implementation of post-approval change management and enable faster delivery of innovative medicines to Asian patients.

Chair

Shinichi Okudaira

PMDA

Dr. Shinichi Okudaira is currently Deputy Division Director at the Division of Regulatory Cooperation, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA).

Previously to joining PMDA, he was a researcher and an assistant professor in Graduate School of Pharmaceutical Sciences, Tohoku University.
He joined PMDA in 2013 and previously held the positions of Principal Reviewer in the Office of New Drug V (Oncology Drugs) and Deputy Review Director in the Office of Cellular and Tissue-based Products. He was also involved in the ICH Q12 EWG and IWG as an Expert.

Chair

Makoto Ono

Daiichi Sankyo Co. Ltd.
Quality Assurance Department

After having been in charge of quality evaluation of drug substance at analytical research laboratory in Daiichi Sanky Co., Ltd., I moved to quality assurance department in 2019 and am working on quality control for overseas products. A member of Quality and Technology Committee of Japan Pharmaceutical Manufacturing Association (JPMA) since 2019, a chairman of Quality and Technology Committee in 2020-2021. MQS-TF leader since 2020.

Speaker / Panelist

Tomonori Nakagawa

Otsuka Pharmaceutical Co., Ltd.
CMC Headquarters, Department of Strategic Management

Profile: Joined Otsuka Pharmaceutical Co., Ltd. as an API process chemist and afterwards, have experienced over 10 years in the quality areas, particularly on Pharmaceutical Quality Systems, GMPs and post-approval change managements. Current job include CMO identification and oversights, managing projects to develop CMC and supply strategies for the new and as a part of product lifecycle management. Since 2007, a member of Quality and Technology Committee of Japan Pharmaceutical Manufacturing Association (JPMA), and have participated various ICH Quality topics as an experts and topic leads to representing JPMA.

Speaker / Panelist

Wan-Yu Chao

Specialist
Division of Medicinal Products,
Taiwan Food and Drug Administration (TFDA)

Ms. Wan-Yu Chao graduated with a Bachelor of Pharmacy from Kaohsiung Medical University in 2016. She has been serving in Taiwan Food and Drug Administration (TFDA) for about 6 years. Currently, she is a specialist in the Division of Medicinal Products, who is responsible for new drug application related regulatory issues. During her work in TFDA, she has experiences in several areas, including new drug application, post-marketing variations, orphan drugs, and regenerative medicine. She is also a member of ICH Q12 implementation working group.

Speaker / Panelist

Subin Sankarankutty

HSA

Dr. Subin Sankarankutty is a Regulatory Consultant in the Therapeutic Products Branch of the Health Sciences Authority (HSA). He has 27 years of experience in the field of pharmaceutical regulatory affairs, both as an industry expert and a regulator. He is currently working with HSA as a quality assessor for the past 17 years, leading a team of quality assessors and worked as an expert in numerous international working groups, including the ICH Q3D Implementation Working Group and the ICH CTD-Q IWG. He is currently an expert member of the ICH Q12 IWG, the ACCESS Consortium Generic Medicines Working Group, and the IPRP Quality Working Group. He holds a Bachelor of Pharmacy, Master of Public Health and a Ph.D. in Pharmacy.

Speaker / Panelist

Satomi Yagi

PMDA

Satomi Yagi is reviewer in Office of New Drug III, Pharmaceuticals and Medical Devices Agency (PMDA). She is involved in the review of CMC of small molecules.
She is MHLW/PMDA Topic Lead for ICH Q12 Implementation Working Group and is the lead of PMDA ICH Q12 Working Group.

e-labeling Session

Overview — e-labeling EWG Rie Matsui

Future of digital Health: Moving towards e-labeling for patients

Various electronic labeling (e-labeling) initiatives have been accelerated worldwide in healthcare and pharmaceutical fields. The APAC e-labeling Expert Working Group (APAC e-labeling EWG) was established in July 2021 consisting of 13 member associations with more than 35 participants. We, the APAC e-labeling EWG, are super excited to organise the APAC 2023 e-labeling summit. In this session, we will have 3 regulator speakers from Japan PMDA, S.Korea MFDS, and Malaysia NPRA. They will be giving presentation on the experience following the e-labeling implementation in Japan, e-labeling pilot plans in Korea and Malaysia. Followed with a panel session with all speakers from HAs and 5 panelists from Indonesia BPOM, Philippines FDA, Taiwan FDA, Thai FDA, and Vietnam DAV providing update on their respective e-labeling initiatives. The panelists will also discuss the e-labeling pilot for eliminating paper labeling, how to move towards e-labeling for patients embracing digital health and on which e-labeling areas would be focused more in order to move forward in 3-5 years. Lastly, it is a great pleasure to share our achievements - the publication on the APAC e-labeling survey result, organizing the regulators' e-labeling workshop which 65 regulators from 10 health authorities participated, and the e-labeling position paper at upcoming 12th APAC event.

Chair

Junko Sato

Please refer to RA Session part.

Chair

Rie Matsui

Pfizer R&D Japan

Rie Matsui is Senior Director, Regional Labeling Head for APAC within International Labeling Group (ILG) at Pfizer as well as the Head for External Engagements for ILG. She is the founder of Asia Labeling Hub at Pfizer that has created various local label updates for more than 25 countries in Asia. Her team members are located in Tokyo, Shanghai, Beijing, Seoul, Bangkok, Hanoi, Taipei, Singapore, and Bangalore. She has been with Pfizer for over 25 years in labeling and pharmacovigilance including risk management roles. She has been actively involved in a number of conferences in Japan, China, Singapore, and the U.S., both as a session chair and speaker. Her papers were published in scientific journals such as Therapeutic Innovation & Regulatory Science. The title of her recent publication is "Survey Result for E-labeling Initiatives in Asia". She received the DIA Japan regional award in 2015 and was a member of the Advisory Council of DIA Japan until 2020. She was also the vice chair of the 2021 DIA Japan Annual Meeting Program Committee. She is the chair of the DIA Asia labeling community and the leader of the APAC e-labeling expert working group. Very recently, she received DIA Global Inspire Award Connector in 2022. Furthermore, she is teaching at Keio University and Chiba University. She is a pharmacist.

Speaker

Paul Marvin T. Quizon

Pharmaceutical and Healthcare Association of the Philippines (PHAP)

Paul Marvin Quizon is the Head of Regulatory Sciences for Philippines and East ASEAN Cluster (Philippines, Vietnam and Indonesia) of Pfizer. He is currently the Lead of the Regulatory Affairs Committee and the Chair of the e-labeling workstream of the Pharmaceutical and Healthcare Association of the Philippines (PHAP) and the Vice President for External Affairs of the Philippine Association of Pharmacists in the Pharmaceutical Industry (PAPPI). He is a member of the APAC e-labeling Expert Working Group and one of the leaders of the APAC e-labeling position paper subcommittees. Prior to his role at Pfizer, Paul had quality and regulatory affairs roles in the local pharmaceutical industry and teaching experience in academia. He is a pharmacist and has master's degree in Pharmacy from the University of the Philippines Manila.

Speaker

Naomitsu Yamaya

Otsuka Pharmaceutical Co., Ltd. Regulatory Affairs Department

Naomitsu Yamaya is working in Regulatory Affairs (RA) in Otsuka Pharmaceutical Co., Ltd. He has been working for Global labeling team with responsible for the preparation and maintenance of company core data sheet (CCDS), and management of local labeling creation and updates in Asian countries since he moved to RA in 2019. Previously, he had worked as a researcher of non-clinical pharmacokinetics for 12 years. He is a member of the APAC e-labeling Expert Working Group since its establishment. He has master's degree in Pharmacy from Tokyo University of Science.

Speaker / Panelist

Tomoko Ohsawa

PMDA

Director of Office of Informatics and Management for Safety
Dr. Tomoko Ohsawa is Director of Office of Informatics and Management of Safety at Pharmaceuticals and Medical Devices Agency (PMDA). Dr. Ohsawa majored in Biochemistry and got a PhD in Pharmacy from the University of Tokyo. Dr. Ohsawa joined PMDA in 2005 and engaged in business related to review for new drug approvals, GCP and GLP inspections, personnel affairs and human resources development, and standards and guidelines development. Dr. Ohsawa has been in the current position since 2021.

Speaker / Panelist

Lee Yubin

Deputy Director,
Pharmaceutical Management Division, Pharmaceutical Safety Bureau, MFDS

I have been working at the Ministry of Food and Drug Safety in Korea since 2006.
I've been working on drug approval and IND approval, and now I'm in charge of e-labeling medicine.
MFDS has been conducting an e-labeling pilot project for prescription drugs for two years since 2023, and is in the process of revising related laws.

Speaker / Panelist

Rosilawati Ahmad

Director
National Pharmaceutical Regulatory Agency (NPRA)
Ministry of Health Malaysia

Madam Rosilawati is the recently appointed Director of National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health Malaysia. She has more than 30 years of vast experiences within the Ministry of Health Malaysia specialising in regulatory pharmacy.

Madam Rosilawati holds a Bachelor of Pharmacy from University of Science Malaysia. She also received a Master of Science in Analytical Chemistry & Instrumental Analysis from University of Malaya, Malaysia.

Madam Rosilawati is active in many international working groups aiming towards harmonization of regulatory requirements of medicinal products. Previously, while serving as the Deputy Director of Product and Cosmetic Evaluation Centre, Madam Rosilawati was appointed by the Minister of Health as the secretary of the Drug Control Authority which is responsible to ensure the registered pharmaceutical, traditional and health supplements products are safe, efficacious and of quality.

She also held the position of Chairperson of ASEAN Joint Assessment Coordinating Group (ASEAN JACG) which aims to intensify cooperation among National Regulatory Authorities in ASEAN and improve access of essential medicines for the public.

Besides, Madam Rosilawati also actively participates as a member of Malaysia Medicine Advertisements Board, Malaysian Adverse Drug Reactions Advisory Committee (MADRAC), Malaysia Pesticide Board and Panel Member of JAKIM Halal Certification Malaysia. In addition, Madam Rosilawati is diligently involved in initiating new policies related to pharmaceutical regulatory in Malaysia.

Panelist

Nova Emelda

Acting Director for Directorate of Safety, Quality, and Export, Import of Drugs, Psychotropics, Narcotics, Precursor and Addictive Substances

Educational Detail
- MS, June 2008, Organic/ Medicinal Chemistry, Ohio University at Athens, U.S.A
- Pharmacist, 1999, Pancasila University at Jakarta, Indonesia
- B.Sc, 1998, Pharmacy, Pancasila University at Jakarta, Indonesia

Professional experiences
- February 2023 – present: acting Director for Directorate of Safety, Quality, and Export, Import of Drugs, Psychotropics, Narcotics, Precursor and Addictive Substances.
- June 2022 – February 2023 : Deputy Director for Clinical Trial Oversight and Investigational New Drug
- March 2022 – June 2022 : Deputy Director for Clinical Trial Evaluation and Special Access Scheme
- Oct 2018 – March 2022 : Deputy Director for Generic Registration, Directorate of Drug Registration, Indonesian FDA
- Feb – Oct 2018 : Head of section of Standardization of Generic Drugs and addictive subtances, Directorate of Drug Standardization, Indonesian FDA
- 2010 – 2018 : Head of Section of Copy Drug Evaluation, Directorate of Drug and Biological Product Evaluation, Indonesian FDA
- 2000 – 2010 : Staff at Copy Drug Evaluation, Directorate of Drug and Biological Product Evaluation, Indonesian FDA

Panelist

Po-Wen Yang

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

Mr. Yang, Po-Wen graduated with a Bachelor of Pharmacy and a Master of Pharmacology. He served at the Taiwan Food and Drug Administration for 12 years. He is currently the section chief at the Division of Medicinal Product. His experience includes pharmacovigilance, drug analysis, and pharmaceutical services.

Panelist

Worasuda Yoongthong

Director of Medicines Regulation Division, Food and Drug Administration
Ministry of Public Health, Thailand

Education Background
1988 B.Sc. (Pharmacy) 2nd Class Honour, Prince of Songkla University, Thailand
1993 Master of Science in Epidemiology, Harvard University, USA
2011 Board of Pharmaceutical and Health Consumer Protection of Thailand, The Pharmacy Council, Thailand

Experience
- Director, Medicines Regulation Division (26 October 2022 – present)
- Director, Food Division (Jan 2022 - 25 Oct 2022)
- Acting Director, Division of Innovative Health Products and services (January 2020 - September 2020)
- Director, Division of Regional and Local Consumer Health Product Protection and Promotion (Feb 2017- Jan 2022)
- Director of the Health Products Entrepreneurship Promotion Division (October 2017- January 2020)
- Director, Institute of health products innovation (2016- 2017)
- Director, Pilot Office for Herbal and Medicinal Products Assessment and registration (2016- 2017)
- Chief of National Drug Policy Division, Bureau of Drug Control (2015- Feb 2017)
- Head of Policy and foreign affairs, Drug system Development Group, Bureau of Drug control (2014-2015)
- Head of National list of essential drug Group, Drug Control Division (2003-2013)
- Senior pharmacist, Post Marketing Control Group, Drug Control Division (2002-2003)
- Secretary, Subcommittee for National List of Essential Drugs (1998-99, 2003- 2013)
- Pharmacist, Standard group, Drug Control Division (1993-2002)
- Technical Officer, Drug registration group, Drug Control Division (1989-1991)

Panelist

Jesusa Joyce N. Cirunay

Please refer to RA Session part.

Panelist

Nguyen Thanh Lam

Deputy Director General
Vietnam Drug Administration (DAV)
Ministry of Health

Mr. Nguyen Thanh Lam currently serves as the Deputy Director General of the Vietnam Drug Administration ("DAV"), Ministry of Health; directly overseeing all medicine, vaccines registration and circulation aspects in Vietnam. He has been working at the DAV since its establishment in 1996 after graduating from the Hanoi University of Pharmacy. Mr. Lam is a Pharmacist and holds an MBA degree.

DA Session

Overview — DA EWG Megumi Ikemori

Design future drug discoveries and collaboration among Asian countries

Background "Our Mission and Strategy"
APAC Drug Discovery Alliances Expert Working group (DAEWG) was established in 2013 to promote open innovation in Asia in order to realize "drug discovery that originates in Asia". DA-EWG aims to promote an Industry Driven Open Innovation that can take both the merits of government-driven and company-driven open innovation. We have been focusing on (1) information sharing about drug seeds, (2) collaboration platform and (3) capacity building of young researcher as a critical factor for successful open innovation in Asia. To address those factors, DAEWG launched and has been promoting two projects, Drug Seeds Alliance Network in Asia (DSANA) and APAC Natural Product Drug Discovery Consortium (ANPDC).

DSANA
The goal of DSANA is to create an Asian-wide information sharing platform by which academic researchers, bio-ventures and pharmaceutical companies can find the best partners to develop innovative medicines from Asia. We start the information sharing between Taiwan and Japan from 2018 with great support from Osaka Chamber of Commerce and Industry. We have confirmed feasibility of the information sharing between Taiwan venture companies and Japanese pharmaceutical companies even under the COVID19 outbreak.

In this session, we will focus on the DSANA project and consider future collaboration between Japan and Asian countries.

Speaker / Panelist

Megumi Ikemori

JPMA DA-EWG leader,
Senior Manager,
Deep Human Biology Learning, Eisai Co Ltd.

Megumi Ikemori, Ph.D. has been a member of DA-EWG from 2018 and serves as the leader of APAC DA-EWG since 2022.
She currently belongs to DHBL Integrity & Site Management in Eisai Co., Ltd. as senior manager. In 2014, she received a doctorate in pharmacy from Gifu Pharmaceutical University. She has over 30 years of experience in the structure base d drug design (SBDD/CADD) and X-ray crystal structure analysis. She has the experience in drug discovery research using natural products, so she contributed to the activities of the Natural Product Drug Discovery Consortium (ANPDC).

Speaker / Panelist

Ippei Shimizu

Department of Cardiovascular Aging, National Cerebral and Cardiovascular Center (NCVC)

EDUCATION
2006-2010 Doctoral coarse, Chiba university graduate school of medicine (Chiba, Japan)
1996-2002 Chiba University faculty of medicine (Chiba, Japan)

WORK EXPERIENCE
2023 - present Director, National Cerebral and Cardiovascular Center (NCVC), Osaka, Japan
2021 - 2023 Associate Professor, Department of Cardiovascular Biology and Medicine Juntendo University Graduate School of Medicine
2014-2021 Associate Professor, Department of Cardiovascular Biology and Medicine, Division of Molecular Aging and Cell Biology, Niigata University Graduate School of Medical and Dental Sciences, Japan
2012-2014 Boston University School of Medicine
2010-2012 Chiba University Hospital Department of Cardiology, postdoctoral fellow
2004-2006 Sakakibara Heart Institute, Cardiovascular Internal Medicine, specialist trainee
2002-2004 National Center for Global Health and Medicine, foundation house officer

Speaker / Panelist

Tsai-Kun Li

Development Center for Biotechnology/National Taiwan University

Current Position
Vice President, Development Center for Biotechnology
Professor, Dept. & Graduate Institute of Microbiology, National Taiwan University

Education
Ph.D. in Pharmacology from the Rutgers University and University of Medicine and Dentistry of New Jersey, U.S.A.

Experience
Deputy Vice President, Academic Affairs, National Taiwan University
CEO, NTU Centers for Genome and Precision Medicine, National Taiwan University
Distinguished Expert, Development Center for Biotechnology
Advisory Committee Member, National Sun Yat-sen University
Dean, International College Provisional Office, National Taiwan University
Associate Dean, College of Medicine, National Taiwan University
Director, Office for International Affairs, College of Medicine, National Taiwan University
Board Member, VSENCE Co., Ltd.
Professor, School of Integrative and Global Majors, University of Tsukuba

Speaker / Panelist

Masato (Max) Nakagawa

DENSO CORPORATION/Japan Science and Technology Agency (JST) /Hiroshima University

Education:
Hiroshima University, Mechanical Engineering

Employment:
DENSO CORPORATION: Fellow (1980 to present)
Japan Science and Technology Agency (JST) :
Senior Fellow (2020 to present)
Hiroshima University: Guest Professor (2018 to present)

Biography:
During the service at DENSO CORPORATION, Masato Nakagawa worked for DENSO European organization consecutive 14 years in the area of Automotive Engineering Field. He was a President and CEO of DENSO Europe in 2015.
Since 2020, he also has been in charge of JST Moonshot Program and COI-NEXT Program (Center of Innovation-NEXT) which are one of the Japanese Government programs.

Panelist

Jun Terauchi

JPMA DA-EWG member
Chair at Japan Microbiome Consortium (JMBC)

Jun Terauchi, Ph.D. has been a member of JPMA DA-EWG since 2014. One of his major contributions at DA-EWG is to create the Drug Seeds Alliance Network Asia, DSANA by collaborating between various organizations in Asian regions and JPMA. DSANA has been operating to promote open innovation among Asian regions from 2018.
He has more than 30 years' experience in drug discovery field as a scientist, a research manager, and a research director in various disease area, such as Central Nervous System, Metabolic Diseases, Inflammatory Diseases and Oncology at Takeda, Ono or Metagen Therapeutics Inc. He also serves as the Steering Committee Chair at Japan Microbiome Consortium, JMBC, precompetitive industry consortium in Japan since the foundation of the JMBC in 2017.

aUHC Session

Overview — aUHC Task Force Osamu Kagawa

Toward the achievement of true UHC in Asia

Japan's journey toward Universal Health Coverage (UHC) began in 1927 with the introduction of a public insurance system for limited population groups. Subsequently, the scope of the insured was gradually expanded, and in April 1961, the National Health Insurance Law was fully revised, establishing a public health insurance system for all citizens. In addition to the Universal Health Insurance System, improved access to health care and the early achievement of UHC have contributed to Japan's world-class healthy life expectancy.

Starting with the 11th APAC, we have launched a new session “the aUHC session” to discuss UHC in Asia. This session is to discuss the current status and issues of UHC in Asian countries, and find out what is necessary for them in the future, in a series of three sessions started from last year.

In the first year of the series of aUHC, we discussed the current status and challenges of UHC in Asian countries under the COVID-19 pandemic and the lessons learned with the perspective of "Resilience" and "Sustainability". And we concluded the “Financing” is the important key role, so for the second year which is this year, we will go over the idea of the construction of UHC in Asia from a medium- to long-term perspective under the theme of "Financing" of UHC in Asian countries.

Facilitator of the Session

Toshihiko Takeda

Senior Advisor, Boston Consulting Group

Former Director-General, Health Policy Bureau.
The Ministry of Health, Labour and Welfare (MHLW), Japan

Current Position
Senior Advisor, Boston Consulting Group
Visiting Professor, Iwate Medical University
Advisor, Nishimura & Asahi

Toshihiko Takeda joined the Ministry of Health and Welfare (MHW) in 1983, immediately after his graduation from the Tokyo University. His experience in the Ministry covers health policy, health insurance policy, industrial policy for health industries, and overall social security policy. He also served as a director with JETRO New York Center, working for health care industry.

He worked as the Deputy Director-General of Health Insurance Bureau in 2014-15, the Director-General of Policy Planning for Social Security System in 2015-16 and the Director-General of Pharmaceutical Safety and Environmental Health in 2016-2017, he was appointed as the Director-General of Health Policy Bureau in July 2017,then retired in 2018.

He joined the Boston Consulting Group in 2019.

Speaker / Panelist

Keizo Takemi

Member of the House of Councillors

Keizo Takemi is a Liberal Democratic Party (LDP) Member of the House of Councillors. Prof. Takemi has been involved in various global initiatives including the Commission on Information and Accountability for Women's and Children's Health, Global Health Workforce Alliance (GHWA), WHO expert working group on R&D Financing, and the international organizing committee of the Prince Mahidol Award Conference (PMAC). He has also been serving as Chair of the parliamentary caucus on Stop TB Partnership and the Asian Forum of Parliamentarians on Population and Development (AFPPD). In 2016, he was appointed to the UN High Level Commission on Health Employment and Economic Growth, and in 2018, to the UHC Financing Advisory Committee for the G20 2019. He has served as Senior Vice Minister for Health, Labour and Welfare, and State Secretary for Foreign Affairs, where he led the initiative to establish the UN Trust Fund for Human Security. Within the LDP, he is Chairperson of the Special Committee on Global Health Strategy, Acting Chairperson of Headquarters for Novel Coronavirus Measures of the LDP Policy Research Council. . In recognition of his contributions to the field over the past decade, he was appointed WHO Goodwill Ambassador for Universal Health Coverage (UHC) from 2019-2022. He was also appointed as Co-Chair of the UNDP's High-Level Advisory Panel for the Special Report on Human Security in May 2021. Prof. Takemi is co-Chairman of the UK-Japan 21st Century Group. He has been a senior fellow with the Japan Center for International Exchange (JCIE), since 2007, where is Chair of the Executive Committee of the Global Health and Human Security Program. Professor Takemi is a visiting professor at a number of universities around Japan, and is the co-author of Global Action for Health System Strengthening: Policy Recommendations to the G8 (2009), and has contributed numerous articles in English and Japanese to journals such as The Lancet, Asia-Pacific Review, and Gaiko [Diplomacy].

Speaker / Panelist

Teruyuki Katori

Representative Director, Future Institute Wolong / Specially Appointed Professor, Graduate School of Social Sciences, Hyogo Prefectural University

Specially Appointed Professor, Department of Management Professions, Graduate School of Social Sciences, University of Hyogo/ President, Future Institute Wolong.

Born in Tokyo, Japan. Joined the Ministry of Health and Welfare in 1980. served as a researcher at the OECD Secretariat (France), Deputy Director General of the Headquarters for Elderly Affairs, Counselor to the Cabinet (Prime Minister Junichiro Koizumi's official residence), Policy Chief of the Cabinet Secretariat, and Director of the Pension Bureau.

After retirement, Ambassador Extraordinary and Plenipotentiary of Japan to the Republic of Azerbaijan in 2017, Professor at Sophia University Faculty of Integrated Human Sciences from 2020, current position from 2023.

Speaker / Panelist

Rungpetch Sakulbumrungsil

College of Pharmacy Administration,
Pharmacy Council
Bangkok, Thailand

Education:
Ph.D. Pharmaceuticalsocioeconomics, University of Iowa, USA
B.S. Pharmaceutical Sciences, Chulalongkorn University

Rungpetch Sakulbumrungsil is a pharmacist by training with area of specialization in Social and Administrative Pharmacy. She was former Dean of the Faculty of Pharmaceutical Sciences, Chulalongkorn University during October 2013-September 2021. She is now the President of FAPA College of Pharmacy and advisory committee of College of Pharmacy Administration under Pharmacy Council of Thailand.

Her current research areas include model development for pharmaceutical fee schedule to support Universal Health Coverage in Thailand, pharmaceutical industry development, regulatory science curriculum development, impact assessment on health system and policy decision. She also serves as the advisory committee for the Community Pharmacy Association of Thailand, particularly on the design of pharmacy benefit package for Universal Health Coverage.

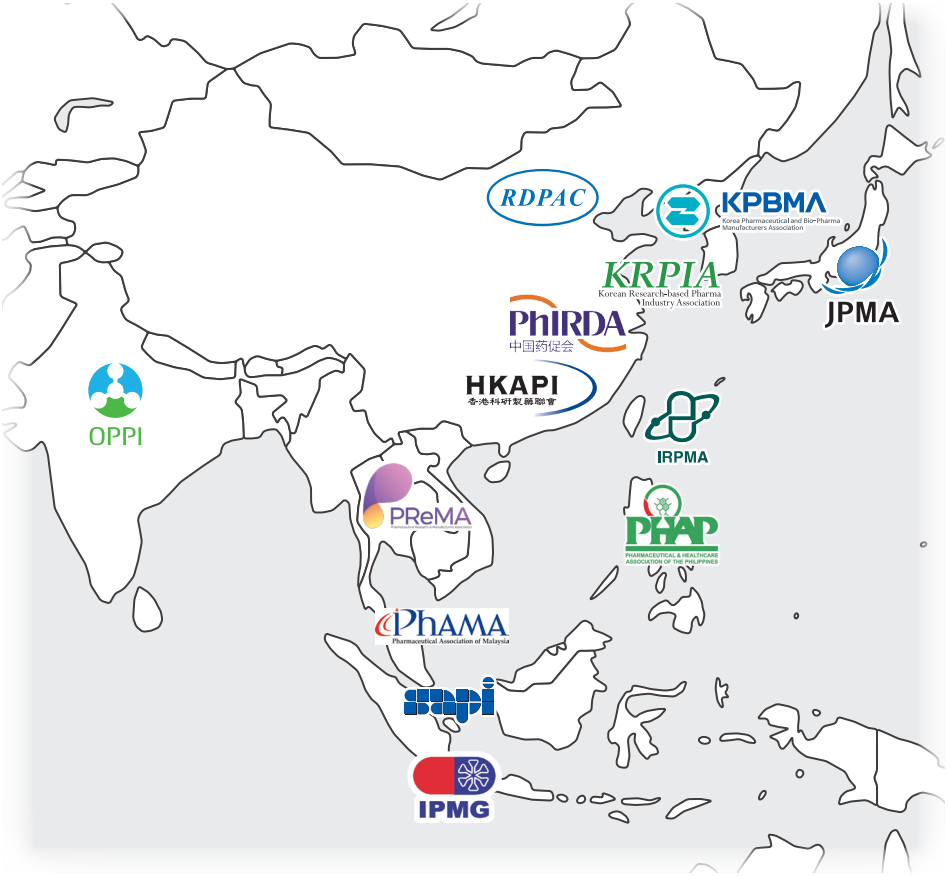
Speaker / Panelist

Jeremy Lim

National University of Singapore

Assoc Prof Jeremy Lim is director for global health in the Saw Swee Hock School of Public Health, National University of Singapore and leads the initiatives in health systems strengthening and universal health coverage. He brings diverse and unique perspectives having spent substantial time in public and private healthcare across Asia as well as in policy advisory with Singapore's Ministry of Health, the World Bank and the World Health Organization. Outside academia, Jeremy serves on the boards of various for-profit and not-for-profit organizations in different aspects of healthcare including migrant worker health, end of life care and digital health interventions. He trained in surgery and public health, attaining post-graduate qualifications in both from the UK and US.

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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