APAC
Asia Partnership Conference
of Pharmaceutical Associations

The 14th Asia Partnership Conference of Pharmaceutical Associations

Theme : Achieving a healthier future for Asia through trust and collaboration

PROGRAM

Date: April 22 (Tuesday), 2025

Venue: Keidanren Kaikan

Greeting

Nobuo Murakami

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.

This is the 14th APAC conference, and we meet both in-person and on-line.

The theme for this year's conference is "Achieving a healthier future for Asia through trust and collaboration."

While there are differences in medical supply systems, including social infrastructure and health insurance systems, improving access to innovative medicines is a common challenge for each country. By fostering strong relationships and partnerships, we strongly believe that APAC activities can leverage the strengths and resources of various stakeholders for realizing APAC mission and this year's theme.

We look forward to your active participation and engaging discussions to deepen our collaboration and achieve our mission.

Thank you for being a part of this important conference. Let us come together to shape the future of pharmaceuticals in Asia.

Chairperson APAC steering committee
& JPMA APAC management committee

Achieving a healthier future for Asia through trust and collaboration

Program

08:30 ▶ 08:45	Come-in		
08:45 ▶ 09:00	Opening Remarks	Hiroaki Ueno	JPMA
09:00 ▶ 09:10	Congratulatory Speech	David Reddy	IFPMA
09:10 ▶ 09:25	Keynote Lecture	Masami Sakoi	MHLW
09:25 ▶ 09:40	Keynote Lecture	Yasuhiro Fujiwara	PMDA
09:40 ▶ 09:55	< Picture taking & Break >		
09:55 ▶ 11:35	RA Session: Efforts to Promote Reliance Practice		
	Chair	Ayumi Endo Shinji Hatakeyama	PMDA JPMA
09:55 ▶ 10:10	Importance of Predictability & Transparency to Facilitate Reliance Scheme	Alireza Khadem	WHO
10:10 ▶ 10:25	Predictability and Transparency to Facilitate Reliance Schemes: APAC Insights	Helene Sou Huyen Do	SAPI PG Vietnam
10:25 ▶ 10:40	Best Practices for Predictability & Transparency to Facilitate Reliance	Siti Noor Haryani Binti Ismail	NPRA
10:40 ▶ 10:55	Best Practice for Predictability & Transparency to Facilitate Reliance Scheme in Thailand	Worasuda Yoongthong	Thai FDA
10:55 ▶ 11:10	Asia Office's Activity to Support to Facilitate Reliance Scheme	Jun Kitahara	PMDA
11:10 ▶ 11:35	Panel Discussion	Alireza Khadem Siti Noor Haryani Binti Ismail Worasuda Yoongthong Jun Kitahara KC Wong	WHO NPRA Thai FDA PMDA SAPI
11:35 ▶ 11:40	< Preparation >		
11:40 ▶ 12:10	DA Session: Progress on Microbiome Therapeutics Drug Development in Asian Countries		
	Chair	Megumi Ikemori	JPMA
11:40 ▶ 11:42	Opening	Megumi Ikemori	JPMA
11:42 ▶ 11:50	Accelerating Microbiome-Based Drug Discovery in Asia: The Power of Public-Private Partnerships	Jun Terauchi	Japan Microbiome Consortium (JMBC)/Metagen Therapeutics Inc.
11:50 ▶ 12:05	Identification of Beneficial Bacteria in the Japanese Population and Its Application to Microbiome Medicines	Jun Kunisawa	National Institutes of Biomedical Innovation, Health and Nutrition
12:05 ▶ 12:10	Regulatory Perspective on Quality Aspects for Microbiome Medicines in Japan	Ryosuke Kuribayashi	PMDA
12:10 ▶ 13:00	< Lunch Break >		
13:00 ▶ 14:40	e-labeling Session: Accelerate e-labeling Initiatives, Interoperability across Digital Health Platforms, as Part of Health Data Ecosystem for Patients		
	Chair	Miki Ota Rie Matsui	PMDA JPMA
13:00 ▶ 13:06	Opening Including Introduction of Speakers	Rie Matsui	JPMA
13:06 ▶ 13:21	FHIR ePI and the Future of Electronic Labeling and Digital Health	Craig Anderson	HL7 VULCAN Electronic Product Information International Labeling, Pfizer Inc.
13:21 ▶ 13:29	e-Labeling Progression - Thailand	Worasuda Yoongthong	Thai FDA

13:29 ▶ 13:37	The Future of Pharmaceutical Labeling: Updates on Malaysia's e-Labeling Initiative	Maslinda Mahat	NPRA
13:37 ▶ 13:45	Advancing E-Labeling in Taiwan: Implementation Journey and Future Plans	Mei-Chen Huang	Taiwan FDA
13:45 ▶ 14:35	Panel Discussion	All Speakers plus Miki Ota Maria Cecilia Matienzo YeonHae Han Nova Emelda Visala Annam	 PMDA Philippines FDA MFDS BPOM CDSCO
14:35 ▶ 14:40	Closing	Miki Ota	PMDA
14:40 ▶ 14:45	< Preparation >		
14:45 ▶ 16:15	MQS Session: GMP Inspection Reliance		
	Chair	Michihiro Imada Miyako Maruyama	PMDA JPMA
14:45 ▶ 14:55	Introduction	Makoto Ono	JPMA
14:55 ▶ 15:10	GMP Inspection Reliance in Asia	Kentaro Hara	PMDA
15:10 ▶ 15:25	ASEAN MRA for GMP Inspection: Malaysia's Perspective on GMP Inspection Reliance	Kim Mi Hng	NPRA
15:25 ▶ 15:40	Good Manufacturing Practice (GMP) Inspection Reliance in Singapore	Li Lian Lim	HSA
15:40 ▶ 16:10	Panel Discussion	Kentaro Hara Kim Mi Hng Li Lian Lim	PMDA NPRA HSA
16:10 ▶ 16:15	Conclusion	Michihiro Imada Miyako Maruyama	PMDA JPMA
16:15 ▶ 16:35	< Break >		
16:35 ▶ 18:15	aUHC Session: Realize True UHC in Asia		
	Chair	Toshihiko Takeda	Boston Consulting Group
16:35 ▶ 16:50	From Health Reform to Global Vision: Building the Future of Healthcare Together	Keizo Takemi	Member of the House of Councillors, Japan
16:50 ▶ 17:00	New Drug Expenditure by Therapeutic Area in South Korea: International Comparison and Policy Implications	Seung-Rae Yu	Dongduk Women's University
17:00 ▶ 17:10	Utilizing Health Technology Assessment (HTA) to Support the Universal Health Coverage in Thailand	Pattara Leelahavarong	Mahidol University
17:10 ▶ 17:20	The Role of Commercial Health Insurance within the Singapore Health Financing System	Alec Morton	National University of Singapore
17:20 ▶ 17:30	Taiwan's Cancer Drugs Fund (TCDF) Enhancing Access to Innovative Cancer Medicines	Chung-Liang Shih	National Health Insurance Administration (Taiwan)
17:30 ▶ 18:15	Discussion	All speakers	
18:15 ▶ 18:20	< Preparation >		
18:20 ▶ 18:30	Wrap-up for All Program and Session	Nobuo Murakami	JPMA
18:30 ▶ 18:35	Closing Remarks	Sunao Manabe	JPMA

Opening Remarks

Hiroaki Ueno

President
Japan Pharmaceutical Manufacturers Association (JPMA)

Hiroaki Ueno was born in Aichi, Japan, in 1958. He received a Ph.D. in Chemistry at the Graduate School of Bioscience and Biotechnology, Tokyo Institute of Technology. He joined with pharmaceutical division of Mitsubishi Chemical Industries in 1983, and he spent his career for drug discovery research as a medicinal chemist for about twenty years. During this period, he was sent to the Scripps Research Institute in San Diego, California, as a visiting scientist to join the project for total synthesis of Taxol. Mitsubishi Chemical was merged with Tanabe Seiyaku in 2007 to be Mitsubishi Tanabe Pharma corporation. He was promoted to be an executive officer in 2014-2017, a managing executive officer in 2018-2019, and a member of the board in 2019. From 2020 to present, he is a representative director of Mitsubishi Tanabe and he was appointed to a president of JPMA in 2023.

Closing Remarks

Sunao Manabe

Vice President
Japan Pharmaceutical Manufacturers Association (JPMA)

Sunao Manabe is Executive Chairperson of Daiichi Sankyo Co., Ltd.
He previously served as President and COO from 2017 to 2019, as President and CEO from 2019 to 2023 and as Executive Chairperson and CEO from 2023 to March 2025.

Dr. Manabe began his career at Sankyo Co., Ltd as a researcher in 1978. He has been involved in various areas, including R&D, general affairs & human resources, corporate strategy, and global sales & marketing, in Daiichi Sankyo.

Additionally, he has been appointed as Vice President of Japan Pharmaceutical Manufacturers Association since May 2021. He also served as Vice President of International Federation of Pharmaceutical Manufacturers & Association from January 2023 to March 2025.

Dr. Manabe received DVM degree in 1977 and PhD degree in 1988 from Veterinary Science, the University of Tokyo. He also obtained an MS degree in Medical Sciences from the University of Tsukuba in 1982.
Also, he was based in the Ohio State University from 1988 to 1990 as a visiting scientist of College of Veterinary Medicine.

Congratulatory Speech

David Reddy

Director General
The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)

David Reddy joined IFPMA as Director General in April 2024, taking up the post after 13 years as Chief Executive of the Medicines for Malaria Venture (MMV).

At the Medicines for Malaria Venture, David played a pivotal role as the organization established the largest portfolio of malaria drugs ever assembled, bringing forward 15 medicines that have saved more than 15 million lives. David has been a Board Member of the Coalition for Epidemic Preparedness (CEPI) since 2018 and serves on the Board of Malaria No More UK.

Before joining MMV, David was a Vice President at Roche, where he held corporate responsibility for Roche's response to the 2009/2010 influenza pandemic. In this role, he led the work to develop, communicate, and implement the company's strategy for working with governments and the WHO on pandemic preparedness, and establishing a sustainable access program. Prior to this, he led Roche's HIV/AIDS Disease Area Strategy Team, providing strategic leadership for Roche's HIV portfolio.

David holds a PhD in Cellular and Molecular Biology from the University of Auckland, New Zealand and completed a post-doctoral fellowship in molecular neurobiology at the Friedrich-Miescher Institute in Basel, Switzerland. David has more than 30 years of management experience in the healthcare sector, including leadership of drug development teams including working on anti-viral diagnostics, a recombinant vaccine, and novel antiviral strategies; licensing and alliance management; market analytics and business planning; product and disease area management; and interfacing with governments, NGOs, and patient advocacy groups in priority disease areas.

Keynote Lecture

Masami Sakoi

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

Birth: October 1962, Hiroshima Prefecture

Dr. Sakoi, Masami graduated from the University of Tokyo Faculty of Medicine in 1989.
He has served as a surgical clinician at institutions including the University of Tokyo Hospital and Toranomon Hospital.

After joining the Ministry of Health and Welfare in 1992, he visited the U.S. to study at the Harvard School of Public Health and received the Master of Public Health in 1997.

Various roles he has held at the ministry since 2005 include Director, Health Risk Management Office, Minister's Secretariat; Planning Director, Health Insurance Bureau; Director, Division of the Health for the Elderly; Director, Medical Care Planning Division; Director, Medical Economics Division; Deputy Director-General of the ministry, Minister's Secretariat; and Director General of the Health Policy Bureau.

He also has an experience working at the Hiroshima Prefectural Government as Director General of Health and Welfare Department (2006-2009).

He was appointed Director General, Office for COVID-19 and Other Emerging Infectious Disease Control Cabinet Secretariat in October 2021 and the current position in July 2023.

Keynote Lecture

Yasuhiro Fujiwara

Chief Executive
Pharmaceuticals and Medical Devices Agency (PMDA)

Dr. Yasuhiro Fujiwara has taken his position as Chief Executive of the Pharmaceuticals and Medical Devices Agency (PMDA) since April 1, 2019. He is a Vice-chair of the International Coalition of Medicines Regulatory Authorities (ICMRA) since October 1, 2019

Dr. Fujiwara was previously Director-General of, the Strategic Planning Bureau of the National Cancer Center, and the Deputy Director of the Hospital, National Cancer Center Hospital. He is a medical oncologist, specializing in breast cancer. Between Jan 2011 to Feb 2013, he was a Deputy Secretary General of the Office of Medical Innovation, Cabinet Secretariat of Japan, and led health policy issues regarding life science.

Dr. Fujiwara has authored or co-authored over 280 original articles in peer-reviewed journals including Nature Reviews Drug Discovery, Lancet Oncology, Journal of Clinical Oncology, and Annals of Oncology. He is an active member of the American Society of Clinical Oncology (between 2003 and 2006, he was the International Affairs Committee's member). He is on the Editorial Board of Cancer Chemotherapy and Pharmacology; Cancer Science; Japanese Journal of Clinical Oncology.

RA Session

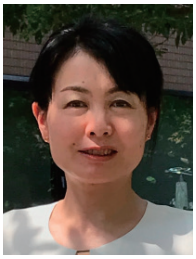
Overview — RA-EWG Shinji Hatakeyama

Efforts to Promote Reliance Practice

The Regulations and Approvals Expert Working Group will feature a focused discussion on the topic of reliance schemes in drug reviews. This session aims to explore how transparency and predictability in the review process can be enhanced, drawing insights from both applicants and regulatory authorities. Expert speakers will share best practices and expectations, fostering mutual understanding and collaboration. Additionally, PMDA will highlights showcasing their reliance initiatives via the Asia Office, established in Thailand.
The session will also include a dynamic panel discussion, inviting applicants and regulators to exchange perspectives on the critical points of transparency and predictability within reliance schemes. This open dialogue will provide valuable insights, strengthen partnerships, and advance the efficiency and trustworthiness of regulatory processes across the region.

Chair

Ayumi Endo



Office Director
Pharmaceuticals and Medical Devices Agency (PMDA)

Ms. Ayumi Endo is the office director of the Asia Training Center (ATC) in PMDA. The ATC organizes many trainings for overseas regulators. Ms. Ayumi Endo also worked as a reviewer or team director in the new drug review office. Another work experience was post-marketing drug safety including reviewing safety reports, updating labeling, establishing a database (MID-NET) to utilize real world data, introducing pharmacoepidemiology and leading ICH E2B(R2). Ms. Ayumi Endo received a Master of Pharmacy degree from the Kyoto University.

Chair

Shinji Hatakeyama

APAC RA-EWG leader
Regulations and Approvals Expert Working Group
Asia Partnership Conference of Pharmaceutical Associations

<Membership>
2014 - Present: Regulations and Approvals Expert Working Group, Asia Partnership Conference of Pharmaceutical Associations (act as Leader since 2018)
<Work Experiences>
2012 - Present: Asia Regulatory Affairs, Eisai Co., Ltd. (act as Director since 2015)
2005 - 2012: Project Management, Planning & Coordination for R&D, Eisai Co., Ltd.
1991 - 2005: Discovery Research in Neuroscience Area, 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

Speaker / Panelist

Alireza Khadem Broojerdi

Team Lead
World Health Organization (WHO)

Dr. Alireza Khadem is a pharmacist by background with extensive experience in pharmaceutical and biopharmaceutical production, quality control, quality assurance, and regulatory affairs. He began his career at the Pasteur Institute of Iran in 1997.
Since 2010 and in his role within the RSS team, he focuses on supporting WHO Member States in strengthening their national regulatory capacity. Throughout his career at WHO, he has played a key role in developing WHO guidelines, policies, methodologies, and benchmarking tools for regulatory systems and has led numerous National Regulatory Authority (NRA) benchmarking activities.
He has contributed to several significant initiatives, including the development of WHO GRP guidelines, the Coalition of Interested Partners, and the WHO Listed Authority. Currently, he leads the Regulatory Systems Strengthening (RSS) team within the Regulation and Safety Unit.

Speaker

Helene Sou

Global Regulatory Policy and Innovation, Growth and Emerging Markets
Takeda

Helene Sou is the Director of Global Regulatory Policy and Innovation at Takeda, specializing in Growth and Emerging Markets and is based in Singapore.

With two decades of experience in international regulatory affairs, Helene has held diverse roles spanning local, regional, and global scopes. Her career began in Paris with Voisin Consulting Life Sciences as an EU Regulatory Consultant, followed by international regulatory work in Boston, USA.
At Shire Pharmaceuticals, she served as Asia-Pacific Regional Regulatory Lead and Head for Southeast Asia. At Takeda, Helene was a Global Regulatory Lead for plasma-derived therapies and a Regulatory Liaison for Emerging Markets before focusing on Regulatory Policy.

Helene earned her Master of Sciences in Biotechnology and Management at ESIEE-Management in Paris.

Speaker

Huyen Thi Thanh Do

Senior Policy Officer
Pharma Group Vietnam

Huyen Do is the Senior Policy Officer (Regulatory and Compliance) of Pharma Group Vietnam. She manages Regulatory advocacy initiatives as well as Ethics & Compliance activities within Pharma Group and is an active representative in regional and international forums such as APAC, APRIA and APEC Business Ethics for SMEs.

Huyen Do holds a Master of Commercial Law from the University of Cambridge and receives her Bachelor of Law from Nagoya University.

Speaker / Panelist

Siti Noor Haryani Binti Ismail

Senior Principal Assistant Director
Centre of Products and Cosmetics Evaluation
National Pharmaceutical Regulatory Agency (NPRA)
Ministry of Health Malaysia

Ms. Haryani is a regulatory pharmacist currently serving at the National Pharmaceutical Regulatory Agency (NPRA) of Malaysia. With 16 years of experience under the Ministry of Health, she began her career as a hospital pharmacist before transitioning to regulatory affairs, specializing in the evaluation of generic medicines and clinical trials. She holds a Master's degree in Clinical Pharmacology from King's College London, where her research focused on drug development and regulatory science. Haryani has extensive experience in Good Manufacturing Practice (GMP) compliance, licensing, and regulatory policy development. At NPRA, she is responsible for the assessments of pharmaceutical products, ensuring compliance with safety, efficacy, and quality standards. Committed to advancing regulatory frameworks, she integrates scientific innovation, reliance practices, and sound policies to support the safe and effective use of emerging therapies.

Speaker / Panelist

Worasuda Yoongthong

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

Ms. Worasuda Yoongthong is the Director of the Medicines Regulation Division at Thai Food and Drug Administration.

Ms. Yoongthong has 30 years' experience in health product regulatory control. She was a former Director of Food Control Division. She has taken significant roles in formulation of National List of Essential Medicines in Thailand. She has participated in many international and regional activities including WHO Expert Committee on Essential Medicines, ASEAN Harmonization and APEC. Currently, she serves as the Thai FDA Head of Delegates (HOD) in Pharmaceutical Product Working Group (PPWG) and Chair of Implementation Working Group (IWG) in ASEAN. She has contributed to establish the abbreviated drug licensing pathway in Thailand since 2018.

Ms. Yoongthong graduated with a Bachelor Degree in Pharmaceutical Sciences from Prince of Songkla University, Thailand. She holds Master of Science in Epidemiology from Harvard University, USA.

Speaker / Panelist

Jun Kitahara

Head
Pharmaceuticals and Medical Devices Agency (PMDA)

Dr. Jun KITAHARA has been a Head of PMDA Asia Office located in Bangkok since July 2024. He was joined to PMDA in 2005. Since then, he was involved in new drug review, medical device review, safety measures and others. Based on such experience, he has more than 10 years of experience in the field of international affairs which include international collaboration such as ICH, IMDRF and liaison between PMDA and Swissmedic. He had his post-doctoral training in the US. He is a pharmacist, graduated Kitasato University and received Ph.D.

Panelist

Kum Cheun Wong

Co-Chair, SAPI
Head Asia Pacific Regulatory & Development Policy,
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. He is Co-Chair of Singapore Association of Pharmaceutical Industries (SAPI) Regulatory Affairs Committee, Chair of EFPIA ASEAN Regulatory Network. KC is actively involved in ASEAN Pharmaceutical Harmonisation and is Chair of the ASEAN Pharmaceutical Research Industry Association (APRIA). He is an active member of EFPIA International Regulatory Expert Group (IREG), EFPIA regional regulatory networks (India, Korea-Taiwan), Steering Committee of DIA Singapore, Steering Committee of Asia Partnership Conference of Pharmaceutical Associations (APAC), member of APAC RA-EWG and APAC E-Labelling WG, member of Asia Partnership Conference of Regenerative Conference (APACRM), and DUKE-NUS Centre of Regulatory Excellence (CoRE) Visiting Expert.

DA Session

Overview — DA-EWG Megumi Ikemori

Progress on Microbiome Therapeutics Drug Development in Asian Countries

Design future drug discoveries and collaboration among Asian countries

Drug Discovery Alliances Expert Working group (DA EWG) 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.

At the previous conference, the 13th APAC Conference, we highlighted microbiome research as a new drug discovery study in Asia, which received positive feedback from many attendees. The microbiome is gaining attention worldwide as a new modality in drug discovery research. and in Japan, activities related to microbiome control are progressing. Since 2016, research to clarify the relationship between various diseases and the microbiome has been initiated within AMED-CREST projects. Particularly regarding FMT, clinical research has been conducted as Advanced Medical Care B, and discussions on regulations have also begun.
This time, we will invite three experts to introduce the current state of microbiome research in Asian countries, the challenges and current activities in Japan, and the plan for creating FMT quality guidelines.

Chair

Megumi Ikemori

APAC 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 is the Vice-chair of the Research and Development Committee and the Chairperson of the Industry-Academia-Government Collaboration Subcommittee of the Japan Pharmaceutical Manufacturers Association (JPMA).

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 based 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

Jun Terauchi

JPMA DA-EWG member
Steering Committee Chair, Japan Microbiome Consortium (JMBC)
Cheif Scientific Officer, Metagen Therapeutics Inc.

EDUCATION
1986-1991 Kyoto University, The Graduate School of Engineering (Kyoto, Japan)

WORK EXPERIENCE
2022 - present Chief Scientific Officer Metagen Therapeutics Inc.
2017 - present Steering Committee Chair, Japan Microbiome Consortium
2014 – 2022 Ono Pharmaceutical Co. Ltd.
1991 – 2013 Takeda Pharmaceutical Company Ltd.

Jun Terauchi, Ph.D. has been a member of DA-EWG since 2014. He contributed to create the Drug Seeds Alliance Network Asia, DSANA in the DA-EWG. He has more than 30 years' experience in drug discovery field. He also serves as the Steering Committee Chair at Japan Microbiome Consortium, since 2017. He was awarded the Dr. Tisser's Medal of The Intestinal Microbiology Society in 2024.

Speaker

Jun Kunisawa

Deputy Director General
National Institutes of Biomedical Innovation, Health and Nutrition

Prof. Jun Kunisawa is Deputy Director General of National Institutes of Biomedical Innovation, Health and Nutrition (NIBIOHN), and serves as Director of Microbial Research Center for Health and Medicine, one of centers in NIBIOHN. He also serves as Adjunct/Visiting Professor at Osaka University, Kobe University, The University of Tokyo, Hiroshima University and Waseda University. He was awarded his Ph.D. from Osaka University at 2001, and received postdoctoral training at University of California, Berkeley. In 2004, he was recruited by The University of Tokyo, where he spent 9 years as Assistant and Associate Professor before moving to NIBIOHN to establish a new laboratory in 2013. In 2019, he was promoted to Director, and subsequently to current position in 2024. His research has been focusing on the immune regulation by gut environment (e.g., diets and commensal bacteria) and its association with immune diseases and health.

Speaker

Ryosuke Kuribayashi

Office of Cellular and Tissue-based Products, Review Director
Pharmaceuticals and Medical Devices Agency (PMDA)

Ryosuke Kuribayashi is a Review Director, Office of Cellular and Tissue based Products at PMDA since 2022. Currently, he is responsible for the review of biosimilars and the quality review of new biologics such as monoclonal antibodies, antibody-drug conjugates, and also bispecific antibodies. Also, he is responsible for quality of new modalities such as extracellular vesicles and microbiome of live biotherapeutic products and fecal microbial transplantation. Before that, he was in charge of the review of generics in the Office of Generic Drugs at PMDA. Before that, he served as a researcher, Division of Biological Chemistry and Biologicals at National Institute of Health Sciences, to engage in analytical research on biopharmaceuticals. Before that, he served as a Reviewer within the Office of New Drugs II at PMDA.

e-labeling Session

Overview — e-labeling-EWG Rie Matsui

Accelerate e-labeling Initiatives, Interoperability across Digital Health Platforms, as Part of Health Data Ecosystem for Patients

The acceleration of e-labeling initiatives and the interoperability across digital health platforms are crucial components of the health data ecosystem for patients. Since 2021, the APAC e-labeling EWG and the APAC regulatory authorities have significantly advanced e-labeling initiatives, including issuing an e-labeling guidance. Recent discussions have focused on the structured contents of labeling based on international electronic common standards for digital health across regions. The adoption of HL7FHIR for healthcare systems has been progressing in many Asian markets and is being considered for e-labeling in more markets. Currently, only around 30 % of the markets prepare and provide patient labeling for prescription drugs in APAC region, with the primary adoption of e-labeling being for healthcare professionals rather than patients. Discussions have also begun on the important introduction of patient-centric e-labeling.
In this session, co-chaired by PMDA and JPMA, there are four speakers representing regulatory authorities and industry. Thai FDA, NPRA, and Taiwan FDA will share the progress of e-labeling in respective market. A co-lead for HL7 Vulcan e-pi project will share the progress of FHIR e-labeling in US and EU. In addition, four panelists from MFDS, CDSCO, BPOM and Philippines FDA as well as all speakers will discuss how to accelerate e-labeling initiatives for more products and markets, move forward with structured contents of labeling based on international electronic common standards, and utilize e-labeling for digital health for patients. The session will also explore the interoperability of e-labeling platforms with other digital health platforms.

Chair / Panelist

Miki Ota

Director, Office of Informatic and Management for Safety
Pharmaceuticals and Medical Devices Agency (PMDA)

Ms.Ota joined the Ministry of Health, Labour and Welfare (MHLW) in 2000.
After joining the ministry, She has been involved in wide range of experience in public health field especially pharmaceutical administration, including pharmacovigilance.
She worked in several organizations including the Ministry of the Environment, PMDA, National Personnel Authority,
This is her second assignment to PMDA. During her previous assignment, She gained experience in the review of pharmaceuticals and medical devices.
Since April 2024, She has been working as the current position.

Chair

Rie Matsui

APAC e-labeling-EWG leader
Senior Director, Regional Labeling Head for APAC
International Labeling, Pfizer R&D Japan

Rie Matsui is Senior Director, Regional Labeling Head for APAC, International Labeling Group, Global Regulatory Science, Pfizer Japan. She is also the Head, External Engagements for ILG and the co-chair for Pfizer E-labeling Centre of Excellence (ELCOE). She is the founder of Asia Labeling Hub at Pfizer that has created various local label updates for more than 25 countries in Asia. She is the lead for the APAC e-labeling Expert Working Group and the program chairperson for DIA Global Labeling Conference in 2025. She received the DIA Japan Regional Award in 2015. Her papers were published in scientific journals such as Therapeutic Innovation & Regulatory Science. She was the vice chair of the 2021 DIA Japan Annual Meeting Program Committee and is the vice chairperson for the DIA Advisory Council of Japan since July 2024. She received DIA Global Inspire Award Connector in 2022. She teaches at Keio University and Chiba University and is a pharmacist.

Speaker / Panelist

Craig Anderson

Co-lead HL7 VULCAN Electronic Product Information Project
Director, R&D Labeling Lead
International Labeling Group
Pfizer

As Director, R&D Lead at Pfizer, Craig Anderson is responsible for research, development, and business projects across the International Labeling organization. This includes topics such as electronic labelling, medicinal product information, digital health, and data standards.

In addition to having industry experience, Craig also has regulator experience from Health Canada where he led informatics projects related to Structured Product Labelling, IDMP, and AE reporting.

Craig is Co-lead of HL7's Vulcan accelerator project for electronic Product Information (ePI) and co-lead for HL7 BR&R's Pharmaceutical Quality (Industry Use Case) project.

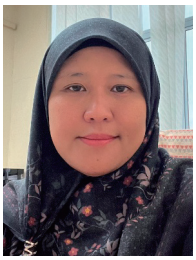
Speaker / Panelist

Worasuda Yoongthong

Please refer to RA Session part.

Speaker / Panelist

Maslinda Mahat



Senior Principal Assistant Director
National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health Malaysia

Maslinda Mahat is a pharmacist with 19 years of experience working in the National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health Malaysia.

Throughout her career, Maslinda has been instrumental in leading regulatory initiatives and managing international public relations for NPRA.

She has extensive experience in laboratory testing for pharmaceuticals, traditional medicines, and cosmetics. She was appointed as a laboratory signatory for MS ISO/IEC 17025 and has served as a GMP inspector specialising in quality control. Her expertise in Lot Release has had a significant impact on ensuring the quality, safety, and efficacy of COVID-19 vaccines during the pandemic.

With a strong background in regulatory compliance, Maslinda continues to drive excellence in her field. She is recognised for her contributions to policy development in the implementation of e-labelling, patent linkage, medicine shortage monitoring, and Halal pharmaceuticals.

Speaker / Panelist

Mei-Chen Huang

Senior Technical Specialist
Taiwan Food and Drug Administration

Ms. Mei-Chen Huang received her Bachelor Science degree from Department of Pharmacy, College of Medicine, National Taiwan University in 2004, and Master Science degree from Biochemistry and Molecular Biology, College of Medicine, National Taiwan University in 2006.

She joined Taiwan Food and Drug Administration (TFDA) in 2010. During her work in TFDA, she had experiences in several areas, including new drug registrations, clinical trial applications, regulatory science, drug supply management, and APEC, ICH related international affairs.

Since July 2020, she served as the Section Chief in the Section of New Drug, and responsible for new drugs, biological products, and regenerative medicine registrations.

Since June 2023, she serves as the Senior Technical Specialist, and she is currently responsible for supervising clinical trial management, the development of e-labeling system, pharmaceutical services and drug supply management.

Panelist

Maria Cecilia Credo Matienzo

Director IV
Center for Drug Regulation and Research
Food and Drug Administration

An Electronics and Communications Engineer by profession, and a holder of a degree on Masters of Arts major in Public Administration.
Started her government career at the Hospital Maintenance Service of the Department of Health as a Senior Electronic Technician and gradually rose from the ranks as an Engineer and then as the Division Chief whose expertise is on Hospital Equipment Management.
She headed the Licensing and Registration Division of the Center for Device Regulation, Radiation Health, and Research (CDRRHR) of the Food and Drug Administration (FDA). Aside from being the Division Chief at the CDRRHR, she was also designated on concurrent capacity as the Chief of Staff of the Office of the Director General and the OIC-Director of the Policy and Planning Service (PPS) from 2017-2019. She also served concurrently on special assignment under the Office of the Director General from 2019 – 2020 before she became a full-pledged Director of the CDRRHR in 2020. Currently, she was re-assigned as the Director of the Center of Drug Regulation and Research.

Panelist

YeonHae Han

Deputy Director
Ministry of Food and Drug Safety (MFDS)

YeonHae HAN is a pharmaceutical regulator at MFDS, Korea, with nearly 20 years of experience specializing in pharmaceutical policy and regulatory compliance. She currently oversees pharmaceutical import regulations and foreign manufacturing site inspections while also coordinating policy development for e-labeling in pharmaceuticals. She contributed to COVID-19 response efforts, such as vaccine introduction and national mask supply management. She holds a degree in pharmacy from Seoul National University. In addition to her regulatory work, she has participated in medical volunteer activities, supporting public health initiatives both domestically and internationally.

Panelist

Nova Emelda

Director
Directorate of Safety, Quality, and Export-Import Control of Drugs, Narcotics, Psychotropics, Precursors, and Addictive Substances
The Indonesian Food and Drug Authority

Nova Emelda, S.Si, MS, Apt., a Pharmacist graduated from Pancasila University, Jakarta in 1999. She continued her education in Ohio University, USA and earned Master of Science degree in 2008. Started her career as a civil servant in Indonesian FDA since 2000, she has assigned for many positions that is related to drug and biological product evaluation, standardization of generic drugs and addictive substance, generic registration, clinical trial, and currently on duty as Director of Safety, Quality, and Export, Import Control of Drugs, Psychotropics, Narcotics, Precursor and Addictive Substances.
She has actively participated in international training and workshop including Pharmaceutical Technology by APGI in 2010 (Republic of Malta), Prequalification of Medicine Program by WHO in 2010 (China); in 2012 (Jakarta); in 2015 (Denmark), Pharmaceutical Management and Quality Assurance for TB by USP in 2011 (Laos), the 14th Meeting of the South-East Asia Regional Immunization Technical Advisory Group (SEAR-ITAG) in August 2023, she participated as Speakers at APAC e-labelling Regulator's Workshop Virtually in October 2023. And also Participated in 13th APAC conference in Tokyo on April 2024. She shared about E-labelling overview in Indonesia, legal drafting process of The Decree about E-Labelling Pilot Projects and the implementation.

Panelist

Visala Annam

Joint Drugs Controller (India)
Central Drugs Standard Control Organization, MoH&FW, Govt. of India

ACADEMIC BACKGROUND

- Doctorate in Pharmaceutical Sciences
- Master in Pharmaceutical Sciences (Pharmaceutics)
- Bachelor in Pharmacy

WORKING EXPERIENCE

- 21 years regulatory experience with the State Drugs Control Administration, Andhra Pradesh: Assessor of quality, implementation and enforcement of GMP and various provisions of D&C Act & Rules.
- 13 years Regulatory experience in CDSCO (National Regulatory Authority), Ministry of Health &Family welfare, Govt. of India:

- Global Clinical Trials
  - Registration of Ethics Committees, GCP Inspections
- Medicines Safety evaluation & Compensation
- Investigational New Drugs, Cell and Gene therapy Products
- Assisting the Licensing Authority , DCGI, CDSCO in matters relating to approval of New Drug products including CGTPs, their import and Registration &Policy matters arising out the implementation under the Drug &Cosmetics Act & Rules

MQS Session

Overview — MQS-Task Force Miyako Maruyama

GMP Inspection Reliance

To achieve the APAC mission “To expedite the launch of innovative medicines for the Asian Patients”, we have addressed topics related to manufacturing, quality control and supply.
In the context of the increasing complexity of global supply chains and rapidly changing technologies, the importance of GMP Inspection Reliance is gaining recognition. GMP Inspection Reliance contributes to streamlining quality control in the pharmaceutical industry, allocating more resources for innovation and continuous improvement for both regulatory authorities and companies. Ultimately this enables faster delivery of innovative high quality medicines to patients. When building the framework of GMP Inspection Reliance, Communication, Training, and Evaluation are key factors that provide the rationale for reliance and facilitate cooperation among regulatory authorities. The successful implementation of GMP Inspection Reliance in Asia is expected to improve the GMP standards across relevant countries and facilitate the establishment of additional frameworks of GMP inspection reliance.
In the session, we aim to share the vision and benefits of GMP Inspection Reliance, and deepen our understanding through real-world examples, including the processes of building and maintaining such frameworks. Furthermore, we would like to discuss the future benefits of GMP Inspection Reliance by identifying the key points and challenges for its promotion, referring to specific mechanism.

Chair

Michihiro Imada

Inspector
Office of Manufacturing Quality for Drugs
Pharmaceuticals and Medical Devices Agency (PMDA)

Mr. Michihiro IMADA has 6 years of experience in PMDA and his current position is a “Lead inspector” for Biological products. Currently, he engages in operation of annual report and global communications as well as inspection. He has participated in EMA GMDP IWG Meeting (114th and 116th) as a representative of PMDA in a position of MRA partner.

Chair

Miyako Maruyama

APAC MQS-TF leader
Associate Director
Tokyo District Department, Japan Regional Quality, Product Quality HQs
Eisai Co., Ltd.

After serving as the GMP managers at a trading company which is an importer of pharmaceutical ingredients, she joined Eisai Co., Ltd. in March 2019, engaging in quality assurance operations. Currently, she oversees GMP/GDP audit duties of the department. Since April 2021, she has been the Deputy Chair of the GMP Subcommittee of the Quality and Technology Committee of the Japan Pharmaceutical Manufacturing Association. In January 2024, she joined the APAC MQS-TF, and since May 2024, she has been the MQS-TF leader.

Speaker

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

Kentaro Hara

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

Dr. Kentaro HARA has 17 years of experience in PMDA Japan, including 3 years as a CMC reviewer and 14 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 ICH Q12 EWG.

Currently, he manages GMP regulations and global communications by PMDA. He is also a member of the PIC/S Executive Bureau (2022-2025). Technical background is bioscience.

Speaker / Panelist

Kim Mi Hng

Senior Principal Assistant Director
Good Manufacturing Practice Section
Centre for Compliance and Quality Control
National Pharmaceutical Regulatory Agency (NPRA)
Ministry of Health Malaysia

Kim Mi is a Bachelor of Pharmacy graduate from Universiti Sains Malaysia. She has been a GMP Inspector with the National Pharmaceutical Regulatory Agency (NPRA) since 2008, and was appointed to the role of GMP Lead Inspector since 2012. In addition to her portfolio of GMP inspection for both local and foreign manufacturing facilities, she also actively participates and contributes to international collaborations.

Some of these collaborations include:

- A member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) Working Group on Remote Assessments.
- An audit team member on the PIC/S Joint Reassessment Program.
- Invited by the Ministry of Food and Drug Safety (MFDS), Republic of Korea, as a guest speaker at the Korean-ASEAN GMP Conference 2023.
- Moderator at the PIC/S Virtual Seminar 2021, organised by MFDS Korea.

Speaker / Panelist

Li Lian Lim

Senior Regulatory Specialist (Senior GMP Inspector)
Health Sciences Authority (HSA)/Singapore
Audit and Licensing Division
Overseas Audit Unit

Ms. Lim holds a B.Eng. in Chemical and Biomolecular Engineering from Nanyang Technological University, Singapore. With more than 10 years of work experience in the biopharmaceutical industry, she is currently a Senior Regulatory Specialist (Senior GMP Inspector) at HSA. In her current role, she leads and conduct Good Manufacturing Practice, Good Distribution Practice and Pharmacy inspections. Her responsibilities in the Overseas Unit also include collaborative efforts with international regulatory authorities on GMP inspections matters. She was also a member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) Working Group on Remote Assessment and served as a Workshop Leader in the PIC/S 2023 Seminar held in Thailand.

aUHC Session

Overview — aUHC-EWG Osamu Kagawa

Realize True UHC in Asia

To facilitate the achievement of true Universal Health Coverage (UHC) across Asia, Japan's experience offers a valuable model. Japan's journey began in 1927 with the introduction of a public insurance system for specific population segments. Over time, the scope of coverage was progressively expanded, culminating in the comprehensive revision of the National Health Insurance Law in April 1961, which established a public health insurance system for all citizens. This universal system, combined with improved healthcare access, has significantly contributed to Japan's world-leading healthy life expectancy.

Beginning with the 11th APAC, we launched a dedicated session, "the aUHC session," to discuss UHC in the Asian context. This session aims to examine the current status and challenges of UHC in Asian countries and identify their future needs.

Our previous discussions have highlighted the varying definitions of UHC across countries and the critical role of financing. This year, we will explore how to utilize Health Technology Assessment (HTA), private insurance, and funding scheme for high-cost innovative drugs to discover diverse financial strategies.

Chair

Toshihiko Takeda

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

Keizo Takemi

Chairperson, Liberal Democratic Party (LDP) Members' General Assembly in the House of Councillors, and the former Minister of Health, Labour and Welfare.

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). 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 was 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 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

Seung-Rae Yu

Professor
College of Pharmacy, Dongduk Women's University

Education
Ph.D. in Pharmacy (Health Social Pharmacy)

Professional Experience
- Professor, College of Pharmacy, Dongduk Women's University (2023–Present)
- Senior Officer, Drug Management Department, National Health Insurance Service (NHIS) (2011–2023)
- Research Planner, Chong Kun Dang Pharmaceutical Corp. (2007–2011)
- Researcher, BK21 Project Team, Sungkyunkwan University (2006–2007)

Honors & Awards
- Commendation for Contributions to Health Insurance System Improvement, Ministry of Health and Welfare (2014)
- Commendation for Excellence in Public Administration, Ministry of Personnel Management (2019)

Committee & Review Activities
- Korean Academy of Social & Managed care Pharmacy
- Health & Medical committee, Public Procurement Service
- Long-Term Care Insurance Assessment Committee, NHIS
- Health Insurance Performance Evaluation Committee, NHIS
- Government Performance Evaluation Committee, Office for Government Policy Coordination

Research Interests
- Value-based drug pricing and reimbursement
- Rational post-listing pharmaceutical management
- Advancing health insurance drug expenditure policies

Speaker

Pattara Leelahavarong

Researcher & Deputy Director
Siriraj Health Policy Unit
Faculty of Medicine Siriraj Hospital
Mahidol University
Thailand

Pattara Leelahavarong, a researcher at Siriraj Health Policy Unit, Faculty of Medicine Siriraj Hospital, Mahidol University, graduated with a Ph.D. in health economics from the University of Glasgow, United Kingdom, in 2018; a Master's degree of science in pharmacy (pharmacy administration); and a Bachelor's degree of science in pharmacy from Mahidol University. She has experienced working on Health Technology Assessment (HTA) using economic modelling in pharmaceutical, medical devices, and health promotion programs for a wide range of health policy processes since 2008.

Speaker

Alec Morton

Visiting Professor
National University of Singapore

Alec Morton is Visiting Professor in the School of Public Health, National University of Singapore, and Professor in the Business School, University of Strathclyde. He has degrees from the University of Manchester and the University of Strathclyde. He has worked for Singapore Airlines, the National University of Singapore, and the London School of Economics, has held visiting positions at Carnegie Mellon University in Pittsburgh, Aalto University in Helsinki, the University of Science and Technology of China (USTC) in Hefei, and the UK National Audit Office. His main interests are in decision analysis and health economics. His research has been funded by the European Commission, the UK Department of Health, the UK Medical Research Council and Engineering and Physical Sciences Research Council, the Chief Scientist's Office of the Scottish NHS, and PRECISE, the National Precision Medicine Programme of the Republic of Singapore.

Speaker

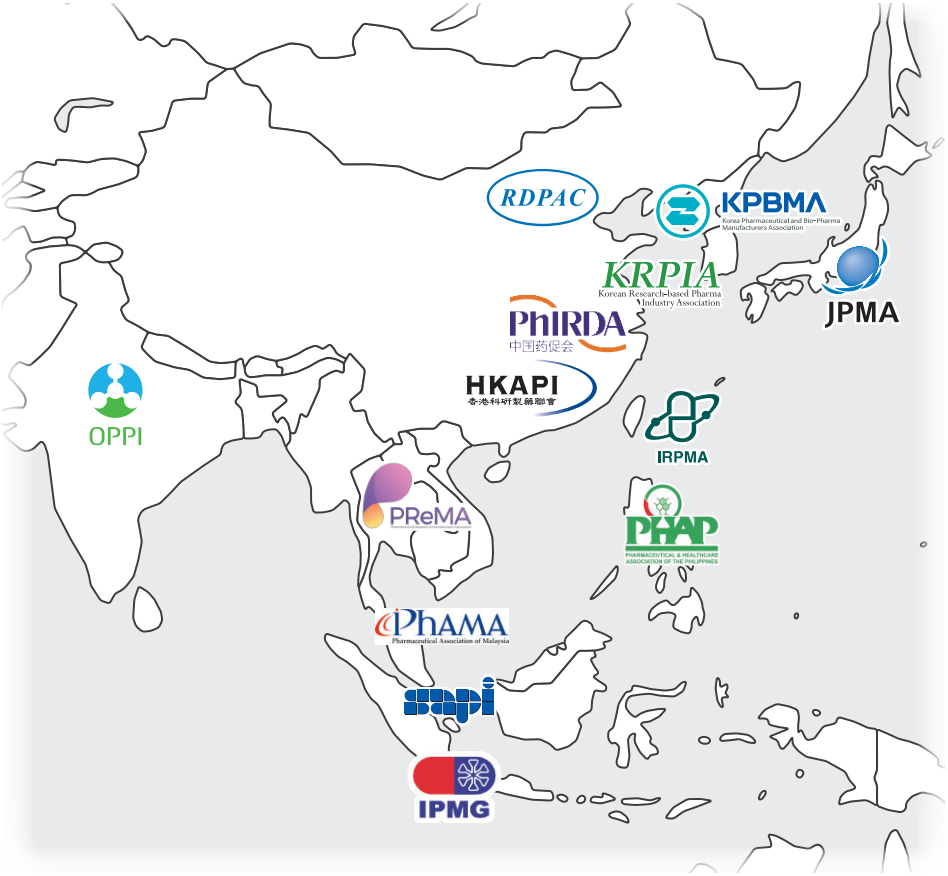
Chung-Liang Shih

Director General
National Health Insurance Administration, Ministry of Health and Welfare (Taiwan)

Dr. Chung-Liang Shih has served as Director General of the National Health Insurance Administration, Ministry of Health and Welfare, since February 2023. He earned his M.D. from Kaohsiung Medical University in 1991 and his Ph.D. from National Taiwan University in 2006. Dr. Shih also received training at the Lee Kuan Yew School of Public Policy in Singapore in 2010 and the Federal Executive Institute in the United States in 2013.

Before transitioning to government roles, Dr. Shih was an attending physician in emergency medicine at National Taiwan University Hospital (1998–2007). He has held key positions in the Ministry of Health and Welfare, including Director-General of Planning and Medical Affairs, Secretary General, and Vice Minister (2020–February 2023). His extensive experience spans healthcare policy, planning, and administration.

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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