APAC
Asia Partnership Conference
of Pharmaceutical Associations

The 13th Asia Partnership Conference of Pharmaceutical Associations

Theme : We reaffirm the APAC's mission and fulfill it for patients in Asia

PROGRAM

Date: April 23 (Tuesday), 2024

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 13th APAC conference, and we meet both in-person and on-line as same as last year.

The theme for this year's conference is to reaffirm our mission – **To expedite the launch of innovative medicines for the peoples in Asia.**

We have learned a lot from Covid19 pandemic, especially, to establish collaborative networking during normal time and agile response of crisis are critical important.

By fostering strong relationships and partnerships, we believe that APAC activities can leverage the strengths and resources of various stakeholders, ensuring a more resilient and agile response to future challenges.

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

We reaffirm the APAC's mission and fulfill it for patients in Asia

Program

08:30 ► 08:45	Come-in		
08:45 ► 08:50	Opening Remarks	Hiroaki Ueno	JPMA
08:50 ► 09:00	Congratulatory Speech	David Reddy	IFPMA
09:00 ► 09:20	Keynote Lecture	Yasuhiro Fujiwara	PMDA
09:20 ► 09:35	< Picture taking & Break >		
09:35 ► 11:15	RA Session: Further Promotion of Reliance through International Collaboration ~ Examples from WHO and ASEAN initiatives and the path we should take ~		
09:35 ► 09:40	Introduction	Naoyuki Yasuda Janis Bernat	PMDA IFPMA
09:40 ► 09:55	WHO Good Reliance Practices and support to ASEAN joint assessment procedures	Marie Valentin	WHO
09:55 ► 10:10	Forthcoming strategy of ASEAN Joint Assessment	Azuana Ramli	Malaysia NPRA
10:10 ► 10:20	Indonesian Experience in Reliance System and Asean Joint Assessment	Ria Christine Siagian	BPOM
10:20 ► 10:30	Philippine Reliance Experience through the ASEAN Joint Assessment	Jesusa Joyce Cirunay	Philippines FDA
10:30 ► 11:10	Panel discussion "Further promotion of reliance through international collaboration and the path we should take"	All speakers plus: KC Wong	 SAPI
11:10 ► 11:15	Closing	Naoyuki Yasuda Janis Bernat	PMDA IFPMA
11:15 ► 11:20	< Preparation >		
11:20 ► 11:50	DA Session: The microbiome research in Asia		
11:20 ► 11:24	Introduction of DA-EWG	Megumi Ikemori	JPMA
11:24 ► 11:37	Introduction of Microbiome based drug discovery including recent topics and attractiveness of this modality	Jun Terauchi	Japan Microbiome Consortium (JMBC) / Metagen Therapeutics Inc.
11:37 ► 11:50	Introduction of Taiwanese activities and APAC region initiatives	Chun-Ying Wu	National Yang Ming Chiao Tung University
11:50 ► 12:50	< Lunch Break >		

APAC e-labeling EWG Poster session to share e-labeling initiatives across APAC region has been prepared and put in front of the main conference room. Please visit!

12:50 ► 14:30	e-labeling Session: Asian e-labeling strategy for digital health ~What to do now and future~		
12:50 ► 13:00	Opening with progress sharing of APAC e-labeling EWG initiatives for APAC regions	Rie Matsui	JPMA
13:00 ► 13:10	Medical digital transformation and product information for patients in Japan	Takayuki Okubo	MHLW
13:10 ► 13:20	Updates of e-labeling initiatives in Malaysia	Azuana Ramli	NPRA
13:20 ► 13:30	E-labeling Update in Taiwan	Po-Wen Yang	Taiwan FDA
13:30 ► 13:40	E-labeling Pilot Project in Indonesia	Rita Endang	BPOM
13:40 ► 13:50	Update on e-labeling for pharmaceuticals in Korea	Yeonhae Han	MFDS
13:50 ► 14:25	Panel discussion	All speakers plus: Jesusa Joyce Cirunay Worasuda Yoongthong Luong Thu Vinh	 Philippines FDA Thai FDA DAV
14:25 ► 14:30	Closing	Takayuki Okubo	MHLW
14:30 ► 14:35	< Break >		
14:35 ► 16:05	MQS Session: Short time frame for additional supplier procedures		
14:35 ► 14:40	Opening and presenter introduction	Shinichi Okudaira Makoto Ono	PMDA JPMA
14:40 ► 14:55	Introduction of session	Aya Shoda	JPMA
14:55 ► 15:10	Presentation: Introduction of PQ KMP in ICMRA	Shinichi Okudaira	PMDA
15:10 ► 15:20	Presentation: Case study in Malaysia	Nur'Ain Shuhaila	MOH Malaysia
15:20 ► 15:30	Presentation: Case study in Thailand	Chaiporn Pumkam	Thai FDA
15:30 ► 16:00	Panel discussion	All speakers	
16:00 ► 16:05	Summary and Closing	Shinichi Okudaira Makoto Ono	PMDA JPMA
16:05 ► 16:25	< Break >		
16:25 ► 18:05	aUHC Session: "Toward the achievement of true UHC in ASIA"		
16:25 ► 16:45	Opening	Toshihiko Takeda	Boston Consulting Group
16:45 ► 16:55	Strategic Purchasing to Achieve UHC in Malaysia	Muhammed Anis Abd Wahab	ProtectHealth Corp
16:55 ► 17:05	Taiwan's National Health Insurance: Pharmaceutical Benefits	Cheng-Hua Lee	MOHW, Chinese Taipei
17:05 ► 18:00	Panel discussion "Can all drugs be covered by public insurance?"	All Speakers	
18:00 ► 18:05	Closing	Toshihiko Takeda	Boston Consulting Group
18:05 ► 18:10	< Preparation >		
18:10 ► 18:40	Special Lecture	Keizo Takemi	MHLW
18:40 ► 18:50	Wrap-up for all program and session	Nobuo Murakami	JPMA
18:50 ► 18:55	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 has been Executive Chairperson and CEO of Daiichi Sankyo Co., Ltd since April 2023.
He previously served as President and COO from 2017 to 2019 and as President and CEO from 2019 to 2023.

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 International Federation of Pharmaceutical Manufacturers & Association since January 2023 and as Vice President of Japan Pharmaceutical Manufacturers Association since May 2023.

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

Yasuhiro Fujiwara

Chief Executive of Pharmaceuticals and Medical Devices Agency (PMDA)

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

Further Promotion of Reliance through International Collaboration
~ Examples from WHO and ASEAN initiatives and the path we should take ~

The main theme of the RA session at the 13th APAC is “Further Promotion of Reliance through International Collaboration”.
The RA session have facilitated discussion of Regulatory Reliance & Regulatory Agility through the 8th ~ 12th APAC meeting as below.

- Reliance Pathway for approval of innovative medicines in APAC (8th APAC, 2019)
- Survey of Reliance in APAC (9th APAC, 2020)
- Regulatory Agility during/after COVID-19 (10th APAC, 2021)
- Concept paper including Reliance and Regulatory Agility (11th APAC, 2022)
- Facilitation of efficient application & review for medicine through Reliance Scheme (12th APAC, 2023)

We would like to go forward our discussion to next stage, International Collaboration, to expand Regulatory Reliance & Regulatory Agility in Asia, widely.

Progress Report 2024: This report describes the progress of APAC member associations' activities in 2023 along the Position Paper 2022. The report can be accessed using the QR code below.

Chair

Naoyuki Yasuda

Pharmaceuticals and Medical Devices Agency (PMDA)

Mr. Naoyuki Yasuda is currently Associate Executive Director (International Affairs) at the Pharmaceuticals and Medical Devices Agency (PMDA), Japan since July 2023.

Mr. Yasuda has been one of the Japanese representatives of ICH and IPRP since 2011 and currently is vice-chair of ICH Management Committee and co-chair of Regulatory Harmonization Steering Committee, Asia Pacific Economic Cooperation.

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

Marie Valentin

Team Lead, Facilitated Product Introduction
Regulation and Safety Unit [REG]
Regulation and Prequalification Department [RPQ]
World Health Organization
Geneva, Switzerland

Pharmacist specialized in drug product regulation with over 22 years of experience in regulatory affairs and product development, acquired both in the private and public sectors.
Since September 2023, Marie is the Team Lead for the Facilitated Product Introduction supporting the Member States in implementing various facilitated pathway, including collaborative procedures, reliance approaches, and joint activities to facilitate and accelerate the introduction of priority medical products in countries. She previously worked in the WHO Regulatory Convergence and Networks Team towards convergence, harmonization, reliance and system strengthening activities.
Before joining WHO in May 2019, Marie worked for 9 years at the European Medicines Agency in London as a Regulatory Affairs Officer. Before that, she worked in the pharmaceutical industry, contract research organization and consultancies in the United Kingdom, Spain and France.

Speaker / Panelist

Azuana Binti Ramli

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

Dr. Azuana has amassed over 20 years of experience with the Ministry of Health, initially serving as a hospital pharmacist before transitioning into roles involving the management of the MOH Formulary. She later assumed the position of Deputy Director for Pharmacy Research. As the Head of Pharmacovigilance during the onset of the COVID-19 pandemic, she spearheaded critical safety surveillance for COVID-19 vaccines in Malaysia.

Presently, she serves as the Deputy Director at the Centre of Product and Cosmetic Evaluation in NPRA, concurrently acting as the Secretary to the Drug Control Authority (DCA). Her team conducts product evaluations to inform DCA's regulatory decisions.

Dr. Azuana's leadership extends to regional roles, where she previously held the position of Deputy Country Coordinator for ASEAN Health Cluster 3 and currently serves as the Chairperson of the ASEAN Joint Assessment Coordinating Group (JACG). Her diverse interests encompass Health Technology Assessments (HTA), pharmaco-economics, Multi-criteria Decision Analysis (MCDA), medicines utilization research, and patients' adherence, as evidenced by her numerous publications in these domains.

Speaker / Panelist

Ria Christine Siagian

Director of Drug Registration, Indonesian FDA (BPOM)

ACADEMIC BACKGROUND
Doctor of Public Health, Universitas Indonesia. 2019
Master of Biopharmaceutical Science, The University of New South Wales, Sydney, Australia. 2006
Pharmacist, Universitas Indonesia, Depok, Indonesia. 1997.
Bachelor in Pharmacy, Universitas Indonesia, Depok, Indonesia. 1996.

WORKING EXPERIENCE

May 2023 - date	Director, Directorate of Drug Registration, Badan Pengawas Obat dan Makanan (BPOM) / Indonesian Food and Drug Authority
2019 – 2023	Evaluator, Biological Products and New Chemical Entity Products Registration, BPOM
2018	Principle content development, Creating a “Good Clinical Practices Inspection” Authentic Online Learning Opportunity, WHO-BPOM. http://www.epela.net/epela_web/egcp/credits.php
2009 - 2019	Facilitator of WHO Global Learning Opportunities (GLO) for GCP Inspection course and Clinical Trial Authorization course. Facilitator of GCP training course.
May 2009 - March 2017	Head, Clinical Trial Section, BPOM
1999 - April 2009	Evaluator, Generics and Biological Products Registration, BPOM
2010 - 2013	Lecturer, Universitas 17 Agustus 1945

Speaker / Panelist

Jesusa Joyce Cirunay

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

Registered Pharmacist (cum laude) with graduate studies on Pharmaceutical Science at the Vrije Universiteit van Brussel in Belgium; Started as drug evaluator before heading key FDA offices at various timelines, i.e., Field Cluster Director, GMP Inspectorate; Distribution Inspectorate; Marketing Authorization. A former OIC–FDA International Affairs Office; former FDA Spokesperson; former Quality Manager for the FDA Quality Management System (ISO 9001:2008, and the 2015 versions; ASEAN Harmonization (Healthcare Sector) as PH Delegation Head or Delegate; APEC as PH Delegate. Publications include, as lead author in several scientific articles published in peer-reviewed international journals. Resource speaker in local & international engagements; Recipient of government and academe recognitions; Part time Pharmacy faculty member.

Panelist

Wong Kum Cheun

Head Asia Pacific
Regulatory & Development Policy
Regulatory Affairs, Global Drug Development
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, and regulatory intelligence for Asia Pacific. 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 was Co-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), DIA Asia Labelling Community member, and DUKE-NUS Centre of Regulatory Excellence (CoRE) Visiting Expert.

KC was former Drug Registration Branch's Deputy Head responsible for the 'Quality Evaluation and Submissions Section' of the Centre for Drug Administration at the Singapore Health Sciences Authority (HSA). In HSA he was involved in the development of HSA's product registration guidance and introducing the Variation Guideline and BA/BE Guideline. KC participated actively in the ASEAN Harmonization of Pharmaceutical Products technical development and was Co-Lead in developing the ASEAN Process Validation Guideline.

DA Session

Overview — DA-EWG Megumi Ikemori

The microbiome research in Asia

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). ANPDC concluded its activities last year. Over the course of five years, two pharmaceutical companies in Japan collaborated with academia and government agencies in Thailand to train young researcher and transfer their drug discovery know-how. In one project, they even succeeded in discovering drug candidate seeds.

This year, we will focus on the microbiome. Recent research has revealed that the gut microbiome influences health and disease, leading to expectations for elucidating disease mechanisms, developing prevention and treatment methods, and contributing to healthcare. Research on the microbiome is actively conducted in various Asian countries.

Chair

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

Jun Terauchi

JPMA DA-EWG member
Chair at Japan Microbiome Consortium (JMBC)
Chief Scientific Officer at 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 JPMA DA-EWG since 2014. One of his major contributions at DA-EWG is to create the Drug Seeds Alliance Network Asia, DSANA. He has more than 30 years' experience in drug discovery field. 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.

Speaker

Chun-Ying Wu

National Yang Ming Chiao Tung University

Education:
M.D., Ph.D. National Taiwan University
LL.B., MPH Harvard University

Current Important Academic Positions:
Director, Institute Biomedical Informatics, National Ying Ming Chiao Tung University (NYCU)
Director, Health Innovation Center, NYCU
Director, Microbiota Research Center, NYCU
Director, National Human Microbiota Core Facility, National Science & Technology Council
President, Taiwan Microbiome Consortium

Awards:
Outstanding Research Award, 2015 & 2021, Taiwan National Science & Technology Council
Medical Model Award, 2018, Taiwan Medical Association
National Innovation Awards, 2016, Taiwan Institute for Biotechnology & Medicine Industry
Emerging Leadership Lectureship Award, 2015, Asian Pacific Association of Gastroenterology

Research Interests:
Digestive cancers
Big data research and AI
Microbiome
Law

Medical Publication:
Prof. Wu is listed as one the World's Top 2% Scientists with H-index=63 and > 14,000 citations.

e-labeling Session

Overview

e-labeling-EWG Rie Matsui

Asian e-labeling strategy for digital health ~What to do now and future~

Dynamic progress for e-labeling initiatives in Asian region has been made through 2023. It is an amazing year for APAC e-labeling Expert Working Group (APAC e-labeling EWG) after the EWG has been established since 2021. Eight (8) APAC markets have started to implement or pilot for e-labeling initiatives. The other 4 markets have been discussing the e-labeling initiatives. However, there are a couple of challenges for most of the markets. E-labeling initiatives are implemented on a voluntary basis in many markets in Asia. The discussion on the structured contents of labeling based on international electronic common standard has just started in a few markets. Furthermore, currently, the adoption of e-labeling is mainly for health professionals, not much for patients.
In this session, we will have 5 regulator speakers from Japan MHLW, Malaysia NPRA, Taiwan FDA, Indonesia BPOM, and S. Korea MFDS. They will be giving presentations on the experience following the Medical digital transformation and product information for patients in Japan, the progress of e-labeling initiatives in the 4 markets. Followed with a panel session with all speakers from HAs and 3 panelists from Philippines FDA, Vietnam DAV and Thai FDA providing update on their respective e-labeling initiatives. The panelists will also discuss the current challenges mentioned above, 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 - organizing the regulators' e-labeling workshop which 160 regulators from 10 health authorities participated and sharing the survey results in 2023 which will be presented at the poster session. Please visit our poster session, where you will also learn about the progress of e-labeling initiatives in all APAC markets via digital measures.

Chair / Speaker / Panelist

Takayuki Okubo

Director for Office of Safety Promotion, Division of Pharmaceutical Safety, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare.

Mr. Okubo joined Ministry of Health, Labour and Welfare (MHLW) of Japan in 2002 and currently serves as Director for Office of Safety Promotion, Division of Pharmaceutical Safety, Pharmaceutical Safety Bureau.
He has worked mainly for safety in the areas of pharmaceuticals, chemicals and foods in MHLW. He currently oversees pharmacovigilance (including medical devices) and patient safety related to medical products.
Along with his work in MHLW, he has participated in various international fora, such as ICH, OECD Chemicals and Biotechnology Committee and UN Commission on Narcotic Drugs. He is a member of MedDRA Management Committee of ICH.
He holds Master of Pharmaceutical Sciences and Master of Public Health.

Chair

Rie Matsui

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

Rie 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 / Panelist

Azuana Binti Ramli

Please refer to RA Session part.

Speaker / Panelist

Po-Wen Yang

Senior Technical Specialist,
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 13 years. He is currently the Senior Technical Specialist, at the Division of Medicinal Product. His experience includes pharmacovigilance, drug analysis, and pharmaceutical services.

Speaker / Panelist

Rita Endang

Deputy Chairperson of Drug, Narcotics, Psychotropics, Precursors, and Addictive Substances Control, Indonesian FDA (BPOM)

Working Experience

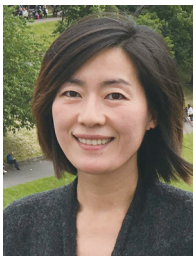
February 28, 2024 - present	Deputy Chairperson of Drugs, Narcotics, Psychotropics, Precursors, and Addictive Substances Control
October 2020	Deputy Chairperson of Proccessed Food Control
October 04, 2020	Deputy Chairperson of Drugs, Narcotics, Psychotropics, Precursors, and Addictive Substances Control
August 05, 2019	Director of Drugs, Narcotics, Psychotropics, and Precursors Production Control
May 13, 2019	Director of Drug, Narcotics, Psychotropics, and Addictive Substance Control
October 13, 2015	Head of Data and Information Center of Indonesian Food and Drug Administration
October 06, 2008	Head of Division of Information Technology - Data and Information Center of Indonesian Food and Drug Administration
October 06, 2007	Section Head of Countermeasures against Illegal Production - Directorate of Drugs, Narcotics, Psychotropics, and Precusors Distribution and Services Control
December 02, 2004	Section Head of Certification of Drugs, Narcotics, Psychotropics, and Precusors Distribution Facilities - Directorate of Drugs, Narcotics, Psychotropics, and Precusors Distribution and Services Control
June 07, 2001	Head of Administration Section - Directorate of Medical Devices, Diagnostic Products & PKRT Assessment Ministy of Health
March 01, 1991	Staff of Directorate of Drug Registration

Academic Background

Master's Degree in Health	Public Health Science	University of Indonesia
Pharmacist Profession (Apothecary)	Apothecary	University of Indonesia
Bachelor of Pharmacy	Pharmacy	University of Indonesia

Speaker / Panelist

Yeonhae Han



Ministry of Food and Drug Safety (MFDS)

Ms. Han Yeonhae is deputy director of Pharmaceutical Management Division of the Ministry of Food and Drug Safety (MFDS) and is in charge of regulations on pharmaceutical imports and overseas manufacturing sites registration and their inspection. She is also leading a pilot project in collaboration with the pharmaceutical industry to introduce e-labeling for pharmaceuticals in Korea.
She has over 15 years of extensive experience in pharmaceutical regulation. She joined MFDS in 2006 and has been serving in pharmaceutical and biopharmaceutical regulatory sector. She also has experience working as a special judicial police officer specializing in pharmaceutical crimes. She recently moved from the Biopharmaceuticals and Herbal Medicine Bureau to the Pharmaceutical Safety Bureau. She holds a bachelor's degree in pharmacy from Seoul National University.

Panelist

Jesusa Joyce Cirunay

Please refer to RA Session part.

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.

Panelist

Luong Thu Vinh, M.Pharm

Deputy Head of Registration Department
Vietnam Drug Administration (DAV)
Ministry of Health

Ms. Luong Thu Vinh is currently the Deputy head of Registration department, Vietnam Drug Administration ("DAV"), Ministry of Health ("MoH"), overseeing registration of vaccines, biologicals and locally manufactured drugs. She has been working in the MOH since 2002 after graduating from Hanoi University of Pharmacy, and started working for DAV from 2005.

MQS Session

Overview — MQS-Task Force leader Makoto Ono

Short time frame for additional supplier procedures

Our team is addressing topics related to manufacturing, quality control and supply in order to achieve the APAC mission “To expedite the launch of innovative medicines for the Asian Patients”.
Due to the COVID-19 pandemic, the pharmaceutical supply chain has been greatly affected. Events such as the spread of infectious diseases and natural disasters caused by climate change are expected to disrupt the supply chain in the future. We recognize the importance for pharmaceutical companies to secure second suppliers even in normal times as part of their responsibility for ensuring the stable supply of medicines. However, it may be difficult to secure second suppliers for all raw materials due to cost increases and regulations, etc.
In this MQS session, we would like to discuss the support from the government related to the procedures for adding second suppliers as an issue that pharmaceutical companies alone cannot cover, in order to ensure the stable supply of medicines in times of crisis and to prepare for the future.
We will discuss in order to make beneficial suggestions for ensuring a stable supply of pharmaceuticals to patients even in times of crisis, as a preparation for the future.

Chair / Speaker / Panelist

Shinichi Okudaira

Pharmaceuticals and Medical Devices Agency (PMDA)

Dr. Shinichi Okudaira is currently Division Director of Division of Regulatory Cooperation, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA). He is one of ICH management committee representatives of MHLW/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/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

Aya Shoda

Regulatory Affairs Dept., Development & Medical Affairs Div., Mitsubishi Tanabe Pharma Corporation

Joined in Mitsubishi Tanabe Pharma Corporation as a chemist for pharmaceutical research, then worked for CMC development and CMC document preparation for clinical trial authorizations. I am in Regulatory Affairs Dept.(RA) since 2012 and have been in charge of RA for marketed drugs in Japan and foreign counties, such as supplements and/or notifications in Japan and other counties to change manufacturing sites, manufacturing process(s), and/or specifications, and also those related GMP submissions. I also participated in of Regulatory Affairs Committee of JPMA from 2013 to 2019 and in the MQS team since 2020.

Speaker / Panelist

Nur'Ain Shuhaila Shohaimi

Deputy Director
Pharmacy Policy Subdivision
Pharmacy Policy & Strategic Planning Division
Ministry of Health Malaysia

Nur'Ain Shuhaila Shohaimi is a pharmacist, graduating from the University Sains Malaysia in 1996. She currently serves as the Deputy Director of Pharmacy Policy & Strategic Planning Division at the Ministry of Health Malaysia. In this role, she oversees the implementation of the Malaysian National Medicines Policy (DUNas) and acts as the secretariat for the Malaysian Pharmacy Programme Strategic Plan.

She is involved in the development and reviews of pharmaceutical policies, including those for ensuring access to Hepatitis C medicines in Malaysia. She is also currently participating in a pilot project to improve patient access to pharmacy services through public-private partnerships, highlighting her commitment to enhancing healthcare accessibility and efficiency. Additionally, she is a member of the WHO Technical Advisory Group on Pricing Policies for Medicines (TAG-PPM).

During the COVID-19 Pandemic, she managed the Operations Room for the Pharmacy Programme, coordinating the supply & distribution of vaccines for the Malaysia COVID-19 Immunization Programme.

Speaker / Panelist

Chaiporn Pumkam

Pharmacist, Senior Professional Level Head of Pharmaceutical Substance Promotion Subdivision Medicines Regulation Division, Food and Drug Administration, Ministry of Public Health Thailand

Education

- Bachelor of Science in Pharmacy, Chulalongkorn University
- Master of Pharmacy Program in Community Pharmacy, Naraesuan University
- Master of Health Administration, University of South Carolina, USA
- Doctor of Philosophy in Health Services Policy and Management, University of South Carolina, USA

Professional experience

- Evaluate applications for registration and amendment of pharmaceutical products and applications for notification of active pharmaceutical substances.
- Provide guidance to pharmaceutical industry on regulatory and technical documentation and procedures for the registration of pharmaceutical products and the notification of active pharmaceutical substances.
- Develop regulations and guidelines to govern pharmaceutical products and pharmaceutical substances.
- Collaborate with national and international organizations to regulate pharmaceutical products and pharmaceutical substances.

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.

Based on the discussions so far, we understand the differences of definition of UHC by each country and the importance of financing. This year, we will discuss the importance of public insurance, and how we can supplement the part public cannot fund by utilizing private insurance. And, we would like to confirm how essential medicines including innovative drugs should or can be covered by public and private insurance.

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
Policy Advisor, Cabinet Secretariat’s Office of Health and Medical Policy
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.
In September 2023, he was appointed as a policy advisor to the Cabinet Secretariat's Office of Health and Medical Policy.

Speaker / Panelist

Muhammed Anis Bin Abd Wahab

ProtectHealth Corporation

Dr Muhammed Anis is a medical doctor with a degree from the International Medical University Malaysia. He received an international scholarship to undergo clinical attachment in organ donation and transplantation with the DonateLife organisation in Australia. He also received a Chevening Award to do his Masters in Health Policy, Planning & Financing from both the London School of Hygiene and Tropical Medicine, as well as the London School of Economics and Political Science, UK. He was a Deputy Director at the Planning Division and headed the National Health Financing Section of the Ministry of Health Malaysia (MOH). Currently, he has been seconded to ProtectHealth Corporation, a not-for-profit strategic purchaser owned by the MOH. He is the Head of both the Quality Assurance Department and the Health Financing Department.

Speaker / Panelist

Cheng-Hua Lee

Deputy Director-General
National Health Insurance Administration
Ministry of Health and Welfare
Taiwan, R.O.C.

Education
- DrPH in Health Finance and Management, Johns Hopkins University
- M.S., National Taiwan University
- M.D., National Yang-Ming University

Experience
- Deputy Director-General, National Health Insurance Administration, Department of Health, Executive Yuan
- Adjunct Professor, National Yang-Ming University
- Convener and Supervisor, Healthcare Division, Consumers' Foundation
- Counselor, Department of Health, Executive Yuan
- Director, Deputy Director General, Acting Director General, National Health Insurance Administration
- Associate Professor, National Yang-Ming University

Biography

Dr. Cheng-hua Lee serves as Deputy Director General of the National Health Insurance Administration, Taiwan since 2003. He is also an adjunct professor at the Institute of Hospital and Health Care Administration in National Yang Ming University since 2007.

As Deputy Director General, Dr. Lee supervises various divisions of the National Health Insurance Administration, including Enrollment Division, Finance Division, and Information Management Division. Dr. Lee participates as well in the financial reform and pharmaceutical benefits reform of the 2nd Generation National Health Insurance Act in 2013/4. Dr. Lee received a medical doctor degree from National Yang Ming University and a master degree from the National Taiwan University. He also completed his Dr. P.H. degree from the Department of Health Policy and Management at Johns Hopkins University.

Upon completing his doctoral degree in the United States, he started teaching health insurance and health care management in National Yang Ming University since 1993. Dr. Lee was one of the founding members of the National Health Insurance system in Taiwan. He served as the Director of Planning and Evaluation in the National Health Insurance Bureau from 1995-1997, and the executive secretary to the Health Minister from 1997-1999. Dr. Lee became one of the faculty of National Yang Ming University in 2000. He was an associate professor in the School of Medicine, and he was also a researcher in the Department of Planning and Management, Taipei Veterans General Hospital from 2000-2003.

Special Lecture

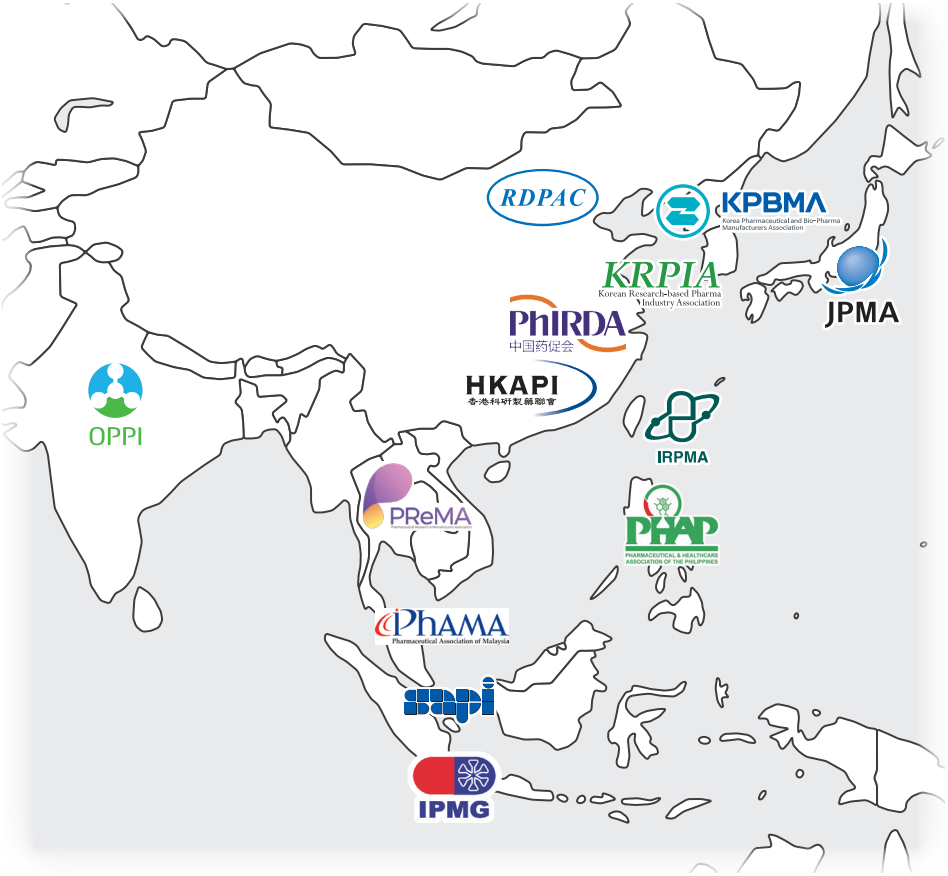
Speaker

Keizo Takemi

Minister of Health, Labour and Welfare

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). 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 was a senior fellow with the Japan Center for International Exchange (JCIE), from 2007 to 2023, where is Chair of the Executive Committee of the Global Health and Human Security Program. Professor Takemi is Minister of Health Labour and Welfare, 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].

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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