APAC
Asia Partnership Conference
of Pharmaceutical Associations

The 11th Asia Partnership Conference of Pharmaceutical Associations

PROGRAM

Date: April 5 (Tuesday), 2022

Online Conference

Building a platform and delivering valuable innovation

Program

10:30 ▶ 10:40	Photo taking		
10:40 ▶ 10:45	Opening Remarks	Yasushi Okada	JPMA
10:45 ▶ 10:50	Congratulatory Speech	Thomas B. Cueni	IFPMA
10:50 ▶ 11:05	Keynote Lecture	Yasuhiro Fujiwara	PMDA
11:05 ▶ 11:10	< Break >		
11:10 ▶ 12:40	DA Session: "The importance of RWD in the era of precision medicine."		
	Introduction	Wei-Kuang Chi	Taiwan DCB
		Atsushi Hasuoka	JPMA
	Special Lecture	Masayuki Yamamoto	ToMMo
	Presentation	Pui-Yan Kwok	Taiwan Academia Sinica
	Presentation	Tatsuhiko Sunouchi	JICA
		Ugyen Tashi	Bhutan Ministry of Health
	Panel Discussion	Bruno Jolain	Roche
		All presenters	
12:40 ▶ 13:25	< Lunch Break >		
13:25 ▶ 14:55	RA Session: "How we introduce innovative new medicine based on new modality to APAC."		
	Opening by chairs	Junko Sato	PMDA
		Sachiko Nakagawa	JPMA
	Introduction of RA Concept Paper	Shinji Hatakeyama	APAC RA-EWG
	Introduction of GRM Position Paper	Takashi Rikukawa	APAC RA-EWG
	Accelerating Access to Innovative Medicines at the time of the Pandemic	Jesusa Joyce N. Cirunay	Philippines FDA
	China Regulation for Developing Innovative Medicine	Sara Wang	RDPAC
	ENHANCEMENT OF DIGITALIZATION & REAL-WORLD EVIDENCE IN THE PHARMACEUTICAL AREA	Vicky Han	Janssen
	Regulatory Agilities and Lessons Learned from Covid-19	Janis Bernat	IFPMA
	Panel Discussion	ALL presenters	
	Closing by chairs	Junko Sato	PMDA
		Sachiko Nakagawa	JPMA
14:55 ▶ 15:00	< Break >		
15:00 ▶ 16:30	e-labeling Session: Where are we now and What are the Next Steps in APAC?		
	Opening by chairs	Junko Sato	PMDA
	Share the updates from e-labeling EWG (Survey results, blueprint and road map)	Rie Matsui	JPMA
	Expectation and challenges on e-labeling from HCP's point of view	Yoshihiro Aoyagi	National Cancer Center Hospital East
	Current and future e-labeling in Japan	Kaori Ogawa	PMDA
	Current and planned e-labeling Initiatives in Taiwan	Po-Wen Yang	Taiwan FDA
	APAC e-labeling Summit (panel discussion)	Mark Wong	HSA
	All presenters	Jesusa Joyce N. Cirunay	Philippines FDA
		Rosilawati Binti Ahmad	NPRA
		Rubina Bose	CDSCO
	Closing	Junko Sato	PMDA
16:30 ▶ 16:35	< Break >		

for the peoples in Asia - Next decade of APAC

16:35 ► 17:05	**MQS Session: "To discuss expansion of PACMP utilization in Asia for the future."**		
	Presentation: GMP inspection survey result **Presentation: A step of challenge to PACMP**	**Makoto Ono** **Tomonori Nakagawa**	**JPMA** **JPMA**
17:05 ► 17:10	**< Break >**		
17:10 ► 18:30	**aUHC Session: "Toward the achievement of true UHC in Asia."**		
	UHC status and challenges in Japan **UHC to overcome pandemic – overview of South East Asia** **UHC to overcome pandemic – overview of Taiwan** **Panel discussion**	**Toshihiko Takeda** **Patrick Osewe** **Shih-Chung Chen** **Toshihiko Takeda (Moderator)** **Patrick Osewe (Panelist)** **Heather Lin (Panelist)**	**Boston Consulting Group, Senior Advisor** **Asian Development Bank** **Minister of Health and Welfare of Taiwan** **Boston Consulting Group, Senior Advisor** **ADB** **IRPMA**
18:30 ► 18:50	**Special Lecture** **UHC in Asia beyond the Pandemic: Lessons and Future Perspectives**	**Keizo Takemi**	**Member, House of Councillors;** **WHO Goodwill Ambassador for UHC**
18:50 ► 19:00	**Closing Remarks**	**Hiroshi Nomura**	**JPMA**

DA Session — DA EWG Atsushi Hasuoka

The importance of RWD in the era of precision medicine.

Background

The Human Genome Project completed decoding full human genome in April 2003. It was one of the greatest scientific achievements and advanced research on the relationship between genomic characters and diseases. The research progress in the following decade became the foundation to usher in the era of Precision Medicine. The former President Obama announced the launch of the Precision Medicine Initiative in his 2015 State of the Union address.

Many countries, researchers and industries have been making great efforts to realize Precision Medicine that enables us to take tailored treatment based on our unique characteristics including our genome data and health history, etc. The UK established Genomics England in 2014. It is the world-first large scale genome database of 100,000 cancer and rare disease patients and has been making great contribution to the genomic healthcare research.

Goal of DA-EWG Session

Followed by western countries, Asian countries have also tried to promote many initiatives useful for Precision Medicine such as creation of biobank, collection of PHR, genotyping and whole genome sequencing. In our session we will focus on some of those initiatives. Five panelists who have been leading very important initiatives for Precision Medicine in Asia will talk about the details of their initiatives. At the panel discussion we will discuss how their initiatives would affect our future path of Precision Medicine.

RA Session — RA EWG Shinji Hatakeyama

How we introduce innovative new medicine based on new modality to APAC

RA session to invite panelists for dialog based on a new APAC RA-EWG concept paper toward the next decade.

<Citation from the new APAC RA-EWG concept paper to be introduced at 11th APAC RA session>

In the 21st century, various technologies are being developed to improve people's lives. These technologies have also been applied to health sciences, dramatically improving the modality for research and development of medical products including medicines. Industry and academia are promoting the research and development of innovative medical products based on new modality to provide the world with new treatment opportunities as well as medicines using small molecule compounds as before. However, traditional pharmaceutical frameworks may not be sufficient to evaluate innovative medical products based on new modality. In addition, the harmonized standards for reviewing them in each country have not yet been established, and it is difficult to develop and launch them simultaneously or continuously all over the world.

In 2020, which is totally unexpected, the global pandemic of the novel coronavirus has made a strong need to develop new and effective medicines. Although still in the development stage, a new modality, mRNA technology, was applied to vaccine development in a very short period. Through industry-government-academia collaboration, we have realized the urgent development of mRNA vaccines and their launch in various countries around the world.

Our mission is to expedite the launch of innovative medicines for the people in Asia. We are promoting efforts to bring innovative medical products based on new modality to people in Asia not only in emergencies but also in normal times for the health and benefit of people. It's an unexpected pandemic experience, but we need to apply this experience as well to establish an integrated process and approach to deliver innovative medical products based on new modality.

Please refer the following URL for obtaining the new APAC RA-EWG concept paper.

https://apac-asia.com/groups/ra/publications.html

e-labeling Session — e-labeling EWG Rie Matsui

Where are we now and What are the Next Steps in APAC?

Where are we Now and What are the Next Steps in APAC?
Under the COVID-19 pandemic, various electronic labeling (e-labeling) initiatives have been accelerated worldwide in healthcare and pharmaceuticals fields. APAC e-labeling Expert Working Group (APAC e-labeling EWG) has been successfully established in July 2021 consisting of 13 member associations and more than 30 participants, which was agreed after the 10th APAC event.
We, APAC e-labeling EWG, are very excited to have APAC e-labeling summit. In this session, we will have 3 speakers coming from National Cancer Center East in Japan, PMDA, and TFDA respectively to give a short presentation on the challenges and expectations on e-labeling from the healthcare professionals' point of view and the updates on e-labeling initiatives in Japan and Taiwan. Furthermore, we will also have APAC e-labeling summit as a panel discussion. All speakers and 5 panelists from HSA, Philippines FDA, NPRA, CDSCO, and a representative from the industry association will discuss e-labeling initiatives in 6 economies which are Japan, Taiwan, Singapore, Philippines, Malaysia, and India respectively. During the panel session, we will discuss the importance of risk communication and how e-labeling for the COVID-19 vaccines has been utilized during the pandemic. In addition, there will also be discussions on which e-labeling areas would be focused more in order to move forward in the next couple of years.
Lastly, it is a great pleasure to share our achievements, the APAC e-labeling survey result to understand the current status on e-labeling in 12 economies across Asia and the e-labeling roadmap at the upcoming 11th APAC event.

MQS Session — MQS Task Force Makoto Ono

To discuss expansion of PACMP utilization in Asia for the future.

In the last year's APAC, we discussed about BE study for the change control of drug product. As our achievement, it was agreed to expedite the BE biowaiver based on BCS (Biopharmaceutics Classification System) approach as in ICH M9 with the panelists. In addition, we introduced the revised position paper considering the influence by COVID-19 pandemic and our achievements for 10th year anniversary.
This year, in MQS* session, we picked a discussion theme on the potential expansion of PACMP (Post Approval Change Management Protocol) in Asia. Our speaker introduces summary and benefits of PACMP system by short presentation in this APAC and we will plan to conduct a full-scale discussion in the next APAC. Moreover, the results of survey on GMP inspection to manufacturing site that was carried out as a reference for theme selection is reported.
*: Our team decided to change the name of task force team for the next 10 years. We have been active as ATIM (Access To Innovative Medicine)-TF for 6 years, however we have mainly discussed about manufacturing and quality control. Our task force name is applied "Manufacturing, Quality control and Supply" (MQS) according to the activity contents from 11th APAC.

aUHC Session **aUHC Task Force Hirokazu Matsukami**

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.

In 2016, at the G7 Ise-Shima Summit and G7 Kobe Health Ministers' Meeting, Japan became the first G7 country to set the promotion of UHC as a major theme at a summit-level meeting. Japan expressed its commitment to support the establishment of UHC in Africa, Asia, and elsewhere in cooperation with the international community and organizations, as well as to play a leading role in international discussions.

At the core of achieving, sustaining, and expanding UHC is fiscal sustainability, which was confirmed in the G20 Osaka Leaders' Declaration in June 2019. Huge pharmaceutical expenditures are a key issue for Asian countries. In OECD countries, pharmaceuticals account for an average of 16% of total health care expenditures, compared to 30% in many Asian countries including India, Indonesia, Thailand, the Philippines and Vietnam.

On the other hand, the realization of UHC may also increase pharmaceutical expenditures. For example, in Thailand, the five-year average growth rate of pharmaceutical expenditures immediately before the introduction of the Universal Coverage Scheme (UCS) in 2002 was 9% and rose to 34% immediately after the introduction of the UCS. Controlling the ballooning expenditure on medicines, driven by population aging and the rise of non-communicable diseases such as heart disease and diabetes, is an urgent priority for Asian countries working to achieve and sustain UHC.

For sustainable development in the future, governments must lead national efforts to build not only a financially sustainable system, but also a system of cooperation among regulatory authorities based on regulatory science, and a system that improves the quality of healthcare and the quality of life of the patients. Discussions on equalization and equitable distribution mechanisms are also essential.

Starting with the 11th APAC, we have launched a new session “the aUHC session” to discuss UHC in Asia. In this aUHC session, we will discuss the current status and issues of UHC in Asian countries, and the construction of true UHC necessary for Asian countries in the future, in a series of three sessions starting this year.

In the first session of aUHC, we will discuss the current status and challenges of UHC in Asian countries under the COVID-19 pandemic and the lessons learned. In addition, we will go over the idea of the construction of UHC in Asia from a medium- to long-term perspective under the theme of "Resilience" and "Sustainability" of UHC in Asian countries.

Congratulatory Speech

Thomas B. Cueni

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

Thomas B. Cueni is Director General of IFPMA, the global association of pharmaceutical research companies, based in Geneva and is Secretary of the global Biopharmaceutical CEO Roundtable (BCR). In this capacity, Thomas Cueni was instrumental in creating the AMR Action Fund. A ground-breaking partnership, launched in 2020, that has raised nearly $1 billion to bring 2-4 new antibiotics to patients by 2030. These treatments are urgently needed to address the rapid rise of antibiotic-resistant infections – also called antimicrobial resistance, or AMR.

Thomas Cueni represents the innovative biopharmaceutical industry on the ACT Accelerator, the Access to COVID-19 Tools (ACT) Accelerator, a unique global collaboration to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines.

Thomas Cueni is Chair of the Business at OECD Health Committee, and also serves on the Board of Directors of the City Cancer Challenge (CCan), an initiative aiming to improve cancer care in major cities in low- and middle-income countries. Cueni also serves as Industry Co-Chair of the APEC Biopharmaceutical Working Group on Ethics. Furthermore, he is Chair of the Board of the cross-sectoral AMR Industry Alliance, a group committed to tackling the threat of antimicrobial resistance, which includes more than 100 companies and associations representing Rx pharma, generics, biotech, and diagnostics.

Prior to joining IFPMA he was Secretary General of Interpharma, the association of pharmaceutical research companies in Switzerland, and for many years was a member of the Board and Chair of a key committee of the European Federation of Pharmaceutical Industries and Associations.

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

Keynote Lecture

Yasuhiro Fujiwara

Chief Executive,
Pharmaceuticals and Medical Devices Agency (PMDA)

Dr. Yasuhiro Fujiwara has been Chief Executive, PMDA since April 2019. He is a medical oncologist, specializing in breast cancer. He was previously Director-General, Strategic Planning Bureau of the National Cancer Center, and the Deputy Director of the Hospital (Research), National Cancer Center Hospital (NCCH). Before joining NCCH, he was a deputy director of the Evaluation Division II, PMDEC, from 1997 to 2002. PMDEC was a predecessor of PMDA. From 2011 to 2013, he was a Deputy Secretary General of Office of Medical Innovation, Cabinet Secretariat of Japan, and led health policy issues regarding life science.

DA Session

Profile (Speaker)

Wei-Kuang Chi

Vice President, R&D
Director, Digital Health Planning Group
Development Center for Biotechnology, Taipei, Taiwan

Biography

Dr. Wei-Kuang Chi, Vice President Since November 20, 2019 of the Development Center for Biotechnology (DCB), obtained his M.S in Engineering and Ph.D. in Chemical Engineering from the University of Pennsylvania, Philadelphia, USA. Dr. Chi has over 30 years of experience in biotechnology process development. He established DCB's multi-product 500 L mammalian cell culture and 100 L microbial fermentation CGMP Biopharmaceutical Pilot Plant Facility (BPPF) and certified by Taiwan Department of Health (DOH) on December 2005 and received DMF with USA FDA on March 2006. The CGMP BPPF has been spun-off on 2013 into private sector to provide CDMO service on a broader scale. Dr. Chi's new responsibility will focus on new drug R&D, international collaboration, novel bioengineering technology, CAR-T/iPSC development, application of deep learning/AI on drug discovery and /biomanufacturing process.

Profile (Speaker)

Atsushi Hasuoka

Atsushi Hasuoka Ph.D., MBA joined Takeda Pharmaceutical Company Limited in 1993 as a researcher after graduating from Osaka University. He participated in many research projects in the areas of oncology and gastroenterology. In his research career he invented Vonoprazan, a novel potassium-competitive acid blocker. After working as a researcher for 15 years he was assigned as a member of Takeda's oncology research management office. After being a Shonan Site Head of Oncology Drug Discovery Unit for 2 years from 2013, he was transferred to General Manager Office of Pharmaceutical Research Division. He has been R&D External Collaboration Director, Takeda Development Center Japan since 2020. He joined the industry activity of JPMA in 2015 and has been leading APAC DAEWG to promote open innovation in Asia.

Profile (Speaker)

Masayuki Yamamoto

Masayuki Yamamoto was graduated from Tohoku University School of Medicine in 1979 and Graduate School of Medicine in 1983. In 1983-1986, Yamamoto was a postdoctoral fellow at Northwestern University with Professor Engel. In 1989, Yamamoto revisited the Engel laboratory and in collaboration identified the GATA family of transcription factors, which are now widely studied as one of the prototype transcription factor families regulating lineage commitment and cell differentiation. In 1991, Yamamoto returned to Japan and starts analyses of the *Gata1* and *Gata2* genes. In 1995, Yamamoto started a series of analyses on CNC-sMAF family of transcription factors and in 1997, he identified and established the KEAP1-NRF2 system regulating the cellular response against electrophilic and oxidative stresses. Since then, he has been addressing many questions related to this important regulatory pathway. Yamamoto has received many prizes, including Medal of Honor with Purple Ribbon (The Emperor of Japan, 2012), Japan Academy Prize (2014), Award for Research Excellence (FAOBMB, 2020), and Lester Packer Award (2021). He also has established the Tohoku Medical Megabank organization in 2012 aiming to support constructive regeneration of the tsunami devastating area from the Great East Japan Earthquake and has been serving as an Executive Director.

Profile (Speaker)

Pui-Yan Kwok

Distinguished Research Fellow and Director, Academia Sinica
Henry Bachrach Distinguished Professor, University of California, San Francisco

- A.B. – Chem (1979), M.S. – Hum Bio (1981), Ph.D. – Org Chem (1985), University of Chicago, Chicago, IL
- M.D. (1987), Pritzker School of Medicine, University of Chicago, Chicago, IL
- Intern – Internal Medicine, Rush Medical Center, Chicago, IL (1988)
- Resident and Chief Resident – Dermatology (1991), Research Fellow (1990-1992), Washington University School of Medicine, St. Louis, MO
- Visiting Scientist – Molecular Biotechnology (1992-1993), University of Washington, Seattle, WA
- Assist Prof (1993-1999), Assoc Prof (1999-2002), Washington University School of Medicine
- Henry Bachrach Distinguished Professor (2002-present), University of California, San Francisco
- Dist Res Fellow and Director (2017-present), Institute of Biomedical Sciences, Academia Sinica
- Member, American Dermatological Association (elected 2008)
- Distinguished Service Award, Pritzker School of Medicine, University of Chicago (2017)
- Academician, Academia Sinica, Taiwan (elected 2018)
- Fellow, American Association for the Advancement of Science (elected 2020)
- Fellow, UNESCO The World Academy of Sciences (2022)
- 2022 Chen Award for Distinguished Academia Achievement in Human Genetic and Genomic Research, Human Genome Organization (HUGO)

Profile (Speaker)

Tatsuhiko Sunouchi

Tatsuhiko SUNOUCHI is Director of South Asia Division 1, South Asia Department, JICA (Japan International Cooperation Agency). He is responsible for JICA's operation in India and Bhutan.

JICA, as an incorporated administrative agency of the government of Japan, is Japan's sole Official Development Assistance (ODA) implementing body. JICA has about one hundred offices overseas, in addition to fifteen offices in Japan.

Sunouchi has 19 years of total work experience at JICA and JBIC (Japan Bank for International Cooperation). He has been engaged mainly on development assistance to South Asian countries. As for overseas postings, he served as the Representative of JICA Bangladesh Office (2009-12).

Profile (Speaker)

Ugyen Tashi

Chief Program Officer
Essential Medicines and Technology Division
Department of Medical Services
Ministry of Health
Thimphu, BHUTAN

Mobile: +975-17481763; Email: utashi@health.gov.bt

PERSONAL DETAILS

FULL NAME: Ugyen Tashi (Mr.)
NATIONALITY: BHUTANESE
DATE OF BIRTH: 02 JULY 1984

ACADEMIC QUALIFICATION

Bachelor of Pharmacy, 2003 - 2007, Jamia Hamdard University, New Delhi, India

PROFESSIONAL EXPERIENCES

1 January 2008 - December 2013

- Clinical Pharmacist at Regional Referral Hospital, Mongar, Eastern Bhutan

January 2014 - December 2016

- Chief Procurement Officer, Medical Supplies Procurement Division, Department of Medical Supplies & Health Infrastructure, Ministry of Health, Thimphu, Bhutan

January 2016 - present

- Chief Program Officer at Essential Medicines & Technology Division, Department of Medical Services, Ministry of Health, Thimphu, Bhutan
- Vice Chair of Drug Technical Advisory Committee (DTAC) of Bhutan
- Member of Registration Committee for registration of competent person of Bhutan
- Technical working group for the review of Bhutan Medicines Rules and Regulation, 2019

Profile (Panelist)

Bruno Jolain

Chief Medical Officer
Roche Pharma India

Academic Qualifications:
-Medical Doctorate, Rene-Descartes University (France)
-Diploma Pharmaco-epidemiology, McGill University (Canada)
-BSC Computer Science, Paris

Summary:
-M.D. with 30 years of experience in the pharma industry in Europe, North-America and Asia, I want to make a difference to improve health and well-being for people in the world most in need.
-Expertise in quality management, medical affairs, clinical research, health-economics, real-world evidence and medical informatics. Experience and leadership in global, regional and affiliates roles, with significant line and functional management responsibilities in 3 MNCs (BMS, Sanofi and Roche).
-I bring to the table my global citizen experience, my medical background applied to pharmaceuticals, my deep belief in the capacity of people to shape the future, my creativity leadership and energy towards a meaningful purpose.

Professional Associations: ISCR, OPPI, USISPF

RA Session

Profile (Facilitator/Speaker)

Junko Sato

Dr. Junko Sato is an Office Director of Office of International Program at Pharmaceuticals and Medical Devices Agency (PMDA).
She joined Regulatory Agency in 1998. She became a review director of Office of New Drug in 2004 and moved to Office of Safety in 2009 to develop a new risk management system through life cycle of drugs. During the period, she visited U.S.FDA as a guest reviewer from September 2002 to March 2003. From May 2012 to April 2014, she was dispatched to EMA as MHLW/PMDA Liaison. She enhanced collaboration between EMA and MHLW/PMDA and brought a huge success as the liaison.
She contributed to some global harmonization activities, for example, ICH, CIOMS etc. She also contributes many DIA activities. She received DIA Outstanding Service Award 2010.
She led the activities of PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) including planning/conduct of all the trainings, and contributes to building stronger bilateral relationship with ASEAN countries by playing the role as the contact point. She also works for AMR project like EMA-FDA-PMDA tripartite meeting to discuss convergence on approaches for the evaluation of antibacterial drugs. She is an Infection Control Doctor certificated by The Japanese Association of Infectious Disease.

Profile (Facilitator/Speaker)

Sachiko Nakagawa

Sachiko Nakagawa is a Managing Director of Japan Pharmaceutical Manufacturers Association (JPMA). She joined JPMA in 2020 and has been mainly in charge of International Affairs Committee including Asia Partnership Conference of Pharmaceutical Association (APAC) and Intellectual Property Committee. Previously, she served as the Vice President and Head of China Business Management Department at Mitsubishi Tanabe Pharma Corporation, Japan. During her term of office, she contributed to the approval of rare disease drug in China. Prior to her role at China business, she was involved in drug development for both pharmaceutical company and medical device company. She is a pharmacist. She got her master's degree of Public Health from Kyoto University School of Public Health.

Profile (Speaker)

Takashi Rikukawa

Regulatory Affairs, Kyowa Kirin Co., Ltd.

Mr. Takashi Rikukawa joined Kyowa Kirin Co., Ltd. (formerly Kirin brewery Co., Ltd.) in 2004. He started his carrier as a clinical research associate. He has 14 years' experiences in regulatory affairs, focusing on new drug development and registration activities for Japan/Asia-Pacific region. He has also been a member of APAC RA EWG since 2017.

Profile (Speaker)

Jesusa Joyce N. Cirunay

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

Profile (Speaker)

Sara Wang

Executive Director
Science & Regulatory Affairs
RDPAC

Sara Wang has over 30 years of working experience in the healthcare industry including Regulatory Affairs, Research and Development, Clinical Operations and Medical Affairs. Sara joined RDPAC (R&D-based Pharmaceutical Association Committee) in July, 2018 as the Head of Science & Regulatory Affairs.

Sara led RDPAC member companies to actively participate in the regulatory advocacy activities, support the implementation and transformation of ICH guidelines in China, and advance China's participation in the simultaneous R&D and registration of global innovative drugs. She has led a number of research projects in RDPAC, which have conducted in-depth research and analysis on relevant topics in drug review and approval and clinical research system, sharing international experience and put forward suggestions.

Before joined RDPAC, Sara worked in Novartis, GSK and Baxter for many years, taking different roles in Regulatory Affairs and R&D. She started her carrier in the Institute of Material Medica, Chinese Academy of Medical Sciences, and worked there for 5 years in research and development.

Profile (Speaker)

Vicky Han

Vicky Han, the Senior Director, Head of the Global Regulatory Policy & Intelligence for Asia Pacific, Global Regulatory Affairs, Janssen Pharmaceuticals since 2016

Vicky's extensive regulatory experience spans different countries in Asia Pacific and Europe, encompassing a wide range of products, including chemical and biological products, vaccines, biosimilars, and generics.

Vicky dedicated 18 years of her career to GSK where she held several positions in various countries. She has led the RA team in pharmaceuticals and vaccines' in GSK China before move to GSK vaccines headquarters in Belgium in 2018. In GSK Bio Global, she led the cross-product regulatory affairs team to deal directly with the European Medicines Agency (EMA) regarding vaccines registration. In 2011, she relocated to GSK Pharmaceuticals headquarters in London as the Senior Director to oversee the regulatory strategies in China/Asia. Vicky returned to Asia in 2014 to head up the Asia regulatory affairs in Hospira (now a Pfizer company) in Singapore before joining in Johnson and Johnson.

Profile (Speaker)

Janis Bernat

Janis Bernat is Director of Scientific & Regulatory Affairs at IFPMA where she leads the strategy, policy and technical work of the Regulatory Science Committee. She is head of the organization's regulatory team and empowers their work on key issues involving regulatory reliance and systems strengthening, advanced therapies, clinical trials, quality and regulatory convergence. Prior to joining IFPMA, she worked for a US-based multi-national food company in quality assurance and regulatory compliance. Janis holds a Masters of Science in Mass Communications and a degree in Agriculture & Food Science from several US Universities.

e-labeling Session

Profile (Facilitator/Panelist)

Junko Sato

Please refer to RA session part

Profile (Facilitator/Panelist)

Rie Matsui

Rie Matsui is Senior Director, Regional Labeling Head for APAC of International Labeling Group (ILG), Global Regulatory Affairs at Pfizer Japan. She is also the Head of External Engagements for ILG. She is the founder of Asia Labeling Hub at Pfizer. The Asia Labeling Hub has created various local label updates for more than 25 countries in Asia ever since its launch and she works with 15 affiliates in Asia. She served as a member of the Advisory Council of DIA Japan until June 2020 and she won the DIA Japan regional award in 2015. 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 several medical/scientific journals including “Therapeutic Innovation & Regulatory Science”. She has more than 25 years experiences in labeling, regulatory, and pharmacovigilance areas.

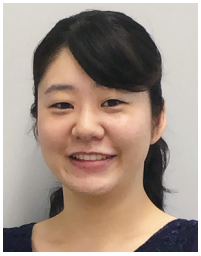
Profile (Speaker)

Yoshihiro Aoyagi

Mr. Yoshihiro Aoyagi is the section head in Information Technology Management Section at National Cancer Hospital East in Japan. His main areas of expertise are Integrating healthcare and research environments, data management, and digital transformation for clinical trials. He developed various information systems such as open-source EDC or Remote SDV environments to improve the utilization of information resources in the hospital. Yoshihiro has also belonged division of medical information and researched the usage of hospital information system data to improve its reliability and transparency. Previously, he had worked for a clinical pharmacist as a drug information specialist.

Profile (Speaker)

Kaori Ogawa



OGAWA Kaori, Pharmaceuticals and Medical Device Agency, Japan

Ms. OGAWA Kaori is currently a Regulatory Cooperation Officer, in the Office of International Programs in Pharmaceuticals and Medical Devices Agency (PMDA), Japan. She started her work there in July 2019. She is tasked with projects related to bilateral cooperation.
She was formerly an Inspector of the Office of Manufacturing Quality and Vigilance for Medical Devices of PMDA (2016-2019). She has experience in the post marketing safety measures of medical devices.

Profile (Speaker)

Po-Wen Yang

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

Profile (Panelist)

Mark Wong

Mark is a Regulatory Consultant in the Therapeutic Products Branch and has been with the Health Sciences Authority, Singapore for the last 12 years. Trained as a pharmacist, his main work in HSA includes the clinical review of new drug and variation applications. He currently leads a team in the management of post-approval variations, including the reclassification of medicines to facilitate public access to safe and effective treatments. He has worked in collaboration with both local industry stakeholders and international regulators to provide digital solutions to streamline business and review processes. Since 2019, he has been driving the e-labelling initiative for prescription medicines supplied in Singapore in consultation with industry representatives.

Profile (Panelist)

Jesusa Joyce N. Cirunay

Please refer to RA session part

Profile (Panelist)

Rosilawati Binti Ahmad

PROFILE

Madam Rosilawati Binti Ahmad holds a Bachelor of Pharmacy from University of Science Malaysia and a Master of Pharmaceutical Analysis from the University of Malaya, Malaysia. She has 30 years of vast experiences within the Ministry of Health Malaysia.

Since 2018, Madam Rosilawati serves as the Deputy Director of Product and Cosmetic Evaluation of National Pharmaceutical Regulatory Agency (NPRA) and appointed as the Secretary of Drug Control Authority (DCA) by Minister of Health Malaysia which responsible to ensure the registered pharmaceutical, traditional and health supplements products are safe, efficacious and of quality.

Committed to her duty, Madam Rosilawati has been involved in the collaborations of harmonization initiatives within ASEAN countries, specifically on Joint Assessment Coordinating Group (JACG) serves as the Chair. Besides, Madam Rosilawati actively participate as a member of Malaysia Medicine Advertisements Board, Malaysian Adverse Drug Reactions Advisory Committee (MADRAC), Malaysia Pesticide Board and Panel Member of JAKIM Halal Certification Malaysia. In addition, Madam Rosilawati is actively involved in initiating new policies related to pharmaceutical regulatory.

Profile (Panelist)

Rubina Bose

Rubina Bose has regulatory experience of more than 21 years, working in Central Drugs Standard Control Organisation (CDSCO), the National Regulatory Authority of India in various capacities as head of zones , head of division of import registration, new drug, quality assurance of vaccines . She started her career in CDSCO as Drugs inspectors conducting GMP, GCP, GLP inspections. She has five years experience of working in production of Injectable drugs prior to joining CDSCO.

She is presently working in CDSCO (HQ), New Delhi as the head of the division of International Co-operation . She has worked in WHO Prequalification vaccine assessment team as Technical officer at WHO(HQ), Geneva and was involved in vaccine dossier assessment, and inspection of vaccine manufacturer as a member of prequalification team. She is working as WHO temporary advisor and has worked (i) in various national and international Advanced Good Manufacturing Practices (GMP) Training of inspectors (ii) for developing GMP guidelines of biological, Good Regulatory Practices guideline, QMS guidelines National Regulatory Authorities (NRA) assessment tools etc. and nominated to represent Govt of India in various WHO meetings/training abroad. She is presently involved as CDSCO representative (Topic leader) in ICH guidelines preparation working groups and also working as WHO temporary advisor and Govt.of India's representative in various WHO meetings on guidelines preparation.

MQS Session

Profile (Speaker)

Makoto Ono

Daiichi Sankyo Co., Ltd.
Quality Assurance Department

Profile: 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. ATIM (current MQS)-TF leader since 2020.

Profile (Speaker)

Tomonori Nakagawa

Otsuka Pharmaceutical Co., Ltd.
Production Headquarter CMC HQ

Profile: Joined Otsuka Pharmaceutical Co., Ltd. as an API process chemist and afterward, spent about 10 years in the quality area for the responses to overseas GMP inspections, quality/CMC inquires, and company GMP policies. Currently working on the various projects to develop CMC and supply strategy as a part of product lifecycle management. A member of Quality and Technology Committee of Japan Pharmaceutical Manufacturing Association (JPMA) since 2007, and participated various ICH Quality topics as an expert. Currently, a member of ICH Q12 implementation working group and an ICH Q9 (R1) expert working group.

aUHC Session

Profile (Speaker/Moderator)

Toshihiko Takeda

Former Director-General, Health Policy Bureau.
The Ministry of Health, Labour and Welfare (MHLW), Japan
Current Position
Boston Consulting Group, Senior Advisor
Visiting Professor, Iwate Medical University
Advisor, Tokyo Marine & Nichido Fire Insurance Co., Ltd.

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 broad areas that include health policy, health insurance policy, industrial policy for health industries, and overall social security policy.

In addition to them, he had other experiences with other Ministry, special public corporation, and local Government. At the Ministry of Finance, he was in charge of researching and planning fiscal policy. In Hokkaido Government, which is the second largest one of the 47 prefecture Governments, he worked for welfare services policy for the elderly.

In New York, as the Director of Health and Welfare Dept. of JETRO New York Center, he worked with Japanese and American health industry to enhance the mutual understanding and promote good trade and cultural relationship between two countries.

Mr. Takeda served as an Administrative Secretary to the Minister for Health and Welfare, Mr. Niwa, from 1999 to 2000.

He had been working on health care related policies in various offices since 2000 to 2018, mainly in Health Policy Bureau and Health Insurance Bureau.

After serving 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. He retired at the end of July, 2018.

He joined the Boston Consulting Group and the Tokyo Marine & Nichido Fire Insurance Co., Ltd. in 2019.

*MHW is now the Ministry of Health, Labour and Welfare (MHLW).

Profile (Speaker/Panelist)

Patrick Osewe

Chief of Health Sector Group, Asian Development Bank

Dr. Patrick L. Osewe is the Chief of the Health Sector Group at the Asian Development Bank (ADB). He provides leadership on policy, technical, and operational matters. In close collaboration with the Sector Committee, he leads the application of evidence based and innovative approaches to address priority and emerging health issues in Asia and the Pacific. Since the outbreak of the coronavirus disease (COVID-19), Patrick has provided leadership and guidance in the implementation of ADB's $20 billion commitment to respond to COVID-19 and $9 billion for Developing Member Countries (DMCs) to obtain and deploy Covid-19 vaccines. His work related to COVID-19 includes providing technical assistance to operational teams and DMCs, convening global partners to reach consensus on key implementation issues, prioritize investments and mobilizing leading private sector firms to support a range of preparedness and response activities.

Prior to his time at ADB, Patrick was a Global Lead for the World Bank's Healthy Societies. In this role, Patrick provided technical and operational guidance to countries, World Bank teams and the global health community to address public health challenges. These included developing strategies for achieving universal health coverage (UHC), combatting the emerging burden of non-communicable diseases, and addressing health security as both an economic issue and as a major threat to achieving UHC.

Patrick has led major global and regional multi-sectoral efforts to address health challenges. He has over 25 years of experience as a global leader in health, including having previously worked for USAID and the US Centers for Disease Control and Prevention as well as providing technical support to developing member countries in different parts of the world. Patrick holds an MD from the University of Nairobi and an MPH from the Harvard University.

Profile (Panelist)

Heather Lin

Current Position:
Chief Operating Officer, International Research-Based Pharmaceutical Manufacturers Association (IRPMA), Taiwan

Experience:
Market Access Director, Bristol-Myers Squibb (Taiwan) Ltd.
Corporate Affairs Director, Pfizer Ltd. Taiwan
Senior Executive Officer, Director, Section Chief, Department of Health

Education:
Ph.D. Health Education, National Taiwan Normal University

Specialty:
Public Health Policy

Profile (Speaker)

Shih-Chung Chen

Minister of Health and Welfare

Education
D.D.S, School of Dentistry, Taipei Medical College 1971-1977

Experience
Minister of Health and Welfare 2017.02.08-
National Policy Advisor to the President 2016-2017.02
Director, Taipei Medical University 2004-2017.02
Consultant, Taiwan Dental Association 1999-2005 2009-2017.02
Consultant, Taipei City Dentists Association 1999-2005 2009-2017.02
Deputy Minister, Department of Health, Executive Yuan 2005-2008
Commissioner, National Health Insurance Medical Expenditure Negotiation Committee, DOH 1996-2008
Commissioner, National Health Insurance Supervisory Committee, DOH 1996-1999 2005-2006
Executive director, chief executive officer, Taiwan Dental Association 1999-2005
Commissioner, Dentist Advisory Committee, DOH 1993-1998 1999-2000
President, Taiwan Dental Association 1995-1999
Commissioner, medical review committee, Taipei City Health Department 1995-1996
President, Taipei City Dentists Association 1993-1995
Executive director, Taipei City Dentists Association 1991-1993
Director, Taipei City Dentists Association 1987-1990

Keynote Lecture

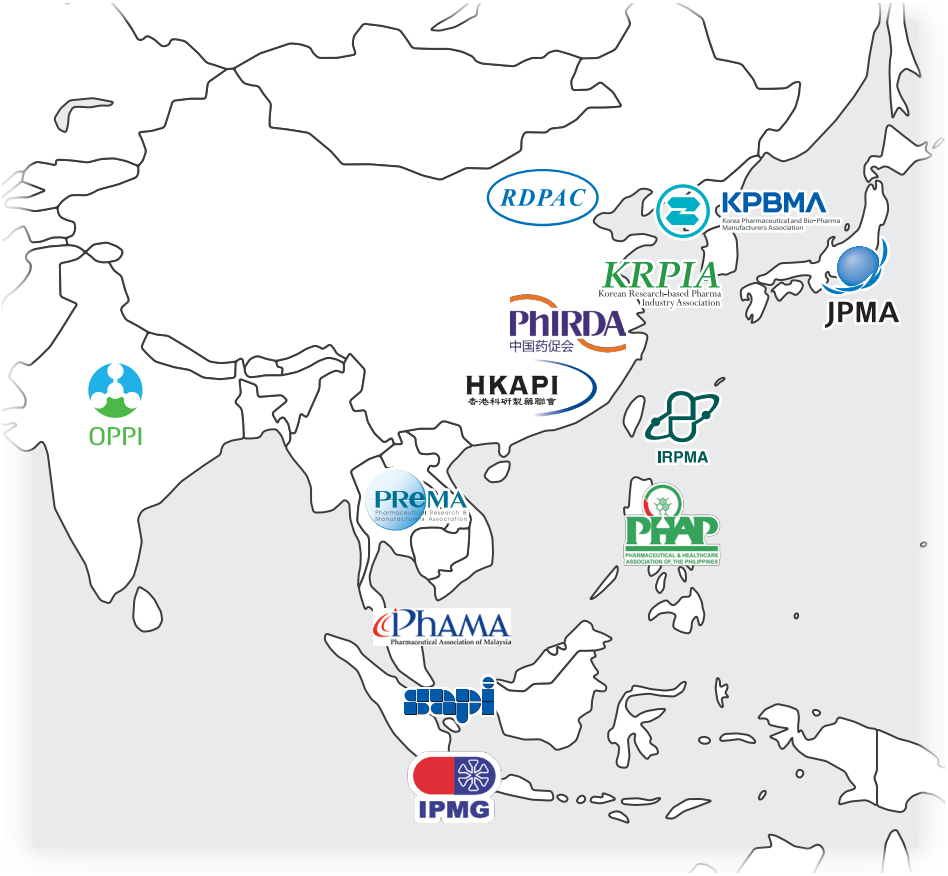
Keizo Takemi

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

MEMO

MEMO

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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