APAC
Asia Partnership Conference
of Pharmaceutical Associations

The 10th Asia Partnership Conference of Pharmaceutical Associations

Mission: To expedite the launch of innovative medicines for the peoples in Asia

PROGRAM

Date: April 13 (Tuesday), 2021

Online Conference

Overcoming COVID-19 and Taking on New Innovative

Program

10:30 ▶ 10:40	Curtain-raiser (video)		
10:40 ▶ 10:45	Opening Remarks	George Nakayama	JPMA
10:45 ▶ 10:55	Congratulatory Speech	Thomas Cueni	IFPMA
10:55 ▶ 11:25	Keynote Lecture	Yasuhiro Fujiwara	PMDA
11:25 ▶ 11:35	< Break 1 >		
11:35 ▶ 12:35	Regulations and Approvals (RA) Session "Regulatory agility during/after COVID-19"		
	Keynote speech Panel Discussion	John Lim Shinji Hatakeyama (Facilitator) Vicky Han (Facilitator) Jo-Feng Chi Daisuke Koga Rosilawati Ahmad Sara Wang	Duke-NUS JPMA SAPI Taiwan FDA PMDA NPRA RDPAC
12:35 ▶ 13:15	< Break 2 (Lunch) >		
13:15 ▶ 14:15	Access To Innovative Medicines (ATIM) Session 1 (e-labeling) "Raise an awareness for benefits of e-labeling in Asia"		
	Opening Current and planned e-labeling initiatives in Japan Current and planned e-labeling initiatives in Taiwan Current and planned e-labeling initiatives in Singapore Panel Discussion Conclusion	Junko Sato (Chair) Rie Matsui (Chair) Sayaka Kurihara Po-Wen Yang Mark Wong All speakers + Nguyen Thanh Lam Junko Sato	PMDA JPMA PMDA Taiwan FDA HSA DAV PMDA
14:15 ▶ 14:20	< Break 3 >		
14:20 ▶ 15:30	ATIM Session 2 (Post Approval Change, BCS-based approach) "Promote BE biowaiver based on BCS of ICH M9"		
	Introduction Position paper/BE biowaiver introduction Revisions of Japanese BE Guidelines Explanation of BE study from panelists Explanation of BE study from panelists Panel Discussion Conclusion	 Tomonori Nakagawa Ryosuke Kuribayashi Lusia Rizka Andalucia Chien-Liang Lin All speakers + Ya-Wen Chang Ryosuke Kuribayashi	 JPMA PMDA BPOM Taiwan FDA CDE (Taiwan) PMDA
15:30 ▶ 15:35	< Break 4 >		

Challenges for the Next Decade in Asia.

15:35 ▶ 16:35	**Drug Discovery Alliances (DA) Session** **"Promote cross-border open innovation in Asia to deliver innovative drugs to people in Asia"**		
	Opening	Atsushi Hasuoka	JPMA
	Progress update on DSANA (Drug Seeds Alliance Network Asia)	Toru Yoshikawa Wei-Kuang Chi Jun Terauchi	JPMA DCB JPMA
	Progress update on ANPDC (APAC Natural Product Drug discovery Consortium)	Sirasak Teparkum Suparerk Borwornpinyo Somponnat Sampattavanich Lily Eurwilaichitr	TCELS ECDD Siriraj HP Biotec
	Closing	Wei-Kuang Chi	DCB
16:35 ▶ 16:40	< Break 5 >		
16:40 ▶ 18:10	**Value-based Healthcare (VBH) Session** **"Reconsider Value-based Healthcare amid the Covid-19 pandemic"**		
	Opening	Tomoyuki Otsuka	JPMA
	The digital acceleration of healthcare in Asia	Vikram Kapur	Bain & Co.
	VBH: Recent development and initiatives in Thailand	Jiruth Sriratanaban	Chulalongkorn Univ.
	Value-based Financing towards Universal Health Coverage in Asia	Eduardo Banzon	ADB
	Data-Driven Health Care System Revisited in the Pandemic Stricken World	Yasuhiro Suzuki	MHLW
	Panel Discussion	Toshihiko Takeda (Facilitator) All speakers+	Boston C.
	Closing	Yasushi Okada Yasushi Okada	JPMA JPMA
18:10 ▶ 18:20	Closing Remarks	Kenji Yasukawa	JPMA

RA Session **RA EWG Shinji Hatakeyama**

Regulatory agility during/after COVID-19

It's our great pleasure to be able to reach APAC 10th birthday. We, the Regulation and Approval Expert Working Group (RA-EWG), has pursued "Expedite the launch of innovative medicines for the peoples in Asia" through aiming optimization of the registration processes in Asia since April 2012. The RA-EWG has continuously promoted two main activities, Good Registration Management (GRM) and Regulatory Convergence, in close collaboration with the regulatory authorities and the industries associations in APAC member economies.
Through our 10 years activities, we have collaborated with Taiwan FDA and PMDA for contributing APEC GRM Regulatory Science Center of Excellence (CoE) Workshop, and established APEC Good Submission Practice Guideline and its training programs/tools for APEC GRM CoE Workshop. Concept of "Train the Trainers" is also successfully introduced to the workshop for further dissemination of GRM within APEC/APAC member economies.
In addition, we have facilitated discussion of the reliance scheme for supporting introduction of Regulatory Convergence in Asia. The reliance scheme has been proposed for collaborative procedure in the assessment and national registration of pharmaceutical product by WHO. At 8th APAC in April 2019, we invited WHO representative for introducing the concept of the reliance scheme. At 10th APAC in April 2021, we would like to discuss the importance of regulatory collaboration among the national regulatory authorities and the pharmaceutical industries in Asia. Furthermore, the unexpected pandemic situation by COVID-19 makes us to aware the reliance scheme based on regulatory agility should be definitely accelerated for achieving the early access to innovative medicines. We pick up "Regulatory Agility during/after COVID-19" as the theme of our RA session at 10th APAC. We would like to invite Professor John Lim from Duke-NUS Medical School to give us keynote speech of the RA session, and ask three regulators from Malaysia (NPRA)/Taiwan (TFDA)/Japan (PMDA) and our APAC colleague (RDPAC) as industry voice to have panel discussion about importance of "Regulatory Agility during/after COVID-19".

ATIM Session 1 **ATIM 1 (e-labeling) Task Force Rie Matsui**

Raise an awareness for benefits of e-labeling in Asia

Under the COVID-19 pandemic, various electronic labeling (e-labeling) initiatives have begun worldwide in healthcare and pharmaceuticals fields. E-labeling will improve the accessibility and understanding of approved medical product information, thereby enhancing adherence to medicines and patient outcomes. The availability of the latest labeling on a publicly accessible website is an important first step in improving patient safety and trust in medicines. The adoption of e-labeling will enhance the user's ability to navigate the product information on how to use, handle, and to better understand safety and efficacy information. Eventual transformation from paper labeling in the pack to e-labeling will shorten the lead time to launch the new products, improve efficiencies on reducing operational steps for inserting paper labeling in packs, and support environment friendly practice. In the future, e-labeling will be integrated with the wider digital healthcare system such as electronic medical record, resulting to greater efficiencies, and opportunities across a wide spectrum within the healthcare sector. In Asian region, discussions on e-labeling initiatives have also been started in several countries. In this session, we will have three speakers from PMDA, TFDA, HSA and one panelist from DAV to share the current and planned e-labeling initiatives in Japan, Taiwan, Singapore and Vietnam respectively. During the panel session, we will discuss how to collaborate the implementation of e-labeling within Asian region and seek opportunities to converge and promptly move e-labeling initiatives forward at the regional level by promoting the proper use of medical products.

ATIM Session 2 — ATIM 2 Task Force Makoto Ono

Promote BE biowaiver based on BCS of ICH M9

To achieve the APAC mission "To expedite the launch of innovative medicines for the people in Asia", in the ATIM (Access To Innovative Medicines) TF picked up stability study at 8th APAC. All the authorities participated in a panel discussion agreed to consider this commitment procedure based on science and risk based approach, by keeping regulatory science justification for the commitment. From this APAC, the ATIM separated two sessions. Our session deals with quality management area in ATIM.
Unfortunately, the last APAC could not be held because of COVID-19 pandemic, however, we planned to discuss BE study in PACMP (Post Approval Change Management Protocol). TF members determined to continue discussion about the BE study and expedite the BE biowaiver based on BCS (Biopharmaceutics Classification System) approach in ICH M9.
Moreover, the position paper of ATIM proposed at APAC 2019 will be revised as additional stretched recommendations considering the influence by COVID-19 pandemic. The revised position paper is described the proposals of resolution for delayed approval of innovative medicines and promotion of mutual cooperation used the same inspection information for GMP.
The ATIM activity started at 5th APAC in 2016 and has been continued for 6 years. ATIM TF provides the history of ATIM activity by APAC website as 10th anniversary memorial materials, and also our achievements summarized there. We are happy to share the ATIM journey with all APAC members.

DA Session — DA EWG Atsushi Hasuoka

Promote cross-border open innovation in Asia to deliver innovative drugs to people in Asia

■ **Mission and Strategy**
APAC Drug Discovery Alliances Expert Working group (DAEWG) was established in 2013 to realize its mission "Promote cross-border open innovation in Asia to deliver innovative medicines to patients in Asia". We have been focusing on (1) information sharing about drug seeds, (2) collaboration platform and (3) capacity building of young researcher as a critical factor for successful open innovation in Asia. To address those factors, DAEWG launched and has been promoting two projects, Drug Seeds Alliance Network in Asia (DSANA) and APAC Natural Product Drug Discovery Consortium (ANPDC).

■ **DSANA**
The goal of DSANA is to create an Asian-wide information sharing platform by which academic researchers, bio-ventures and pharmaceutical companies can find the best partners to develop innovative medicines from Asia. As a pilot project, we are now focusing on information sharing between Taiwan and Japan. With great support from Osaka Chamber of Commerce and Industry, the pilot project achieved steady progress in the past two years even under the COVID19 outbreak. Based on the progress in the pilot project, we plan to expand the initiative to other Asian countries.

■ **ANPDC**
ANPDC was established in 2018. It is a unique multinational collaboration platform to promote utilization of natural products in drug discovery. Taiwan, Thailand and Japan are the members of the consortium. Capacity building is a key feature of ANPDC. As the first collaboration process, a Japanese pharma company helps a young researcher acquire screening skills and knowledge about drug discovery. After the capacity building, the researcher carries out evaluation of natural products in his or her home country. By taking this process we can effectively advance a multinational collaboration without moving natural products beyond borders. Since its establishment, we have made remarkable progresses. Two Thai researchers finished their internships in Japan and one of them completed the screening of natural products in Thailand. In addition to hand-on training, we will start an online capacity building to cope with the COVID19 outbreak.

VBH Session **VBH Task Force Toshinobu Miwa**

Reconsider Value-based Healthcare amid the Covid-19 pandemic

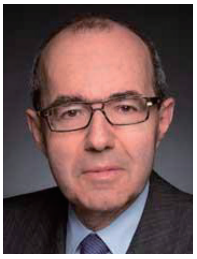
In the context of sustainability of the healthcare system, a discussion was started at the 8th APAC under the broad title of Value Based Healthcare (VBH) with the messaging "invest valued medicine". This encompasses innovation based on the creation of medicinal products but a shift of the business model has been required in order to co-create value with consumers/ patients by providing services and experiences together with the products, as has been depicted by the Concept of Society 5.0 or the Fourth Industrial Evolution. We perceive this time pandemic is accelerating the penetration of mobile technology in our routine healthcare and resides data-driven healthcare beyond its movement to achieve value co-creation. The 10th APAC VBH session invites four guest lecturers from Bain & Company, Singapore; Chulalongkorn University, Thailand; Asia Development Bank, The Philippines and Senior Advisor to the MHLW, Japan, respectively. The lecturers will navigates us to future opportunities, reviewing healthcare policies and implementation, and elucidating investments in proven areas of effect with a focus on VBH. The lectures are designed to emphasize visualization of demand and value judgement as well as prosperity of digital technology. Panel discussion will also confirm further cooperation among stakeholders for the key of realization of sustainable healthcare ecosystem. The taskforce would then break off the team's work at this stage thus paving the way for APAC's to further discuss areas around investment to innovation and reproduction.

VBH journey – 10 years of APAC

Previously, APAC discussed issues around healthcare access and health technology assessment in 2014 and 2016 at the 3rd and 5th conferences, respectively. The taskforce established for the 8th APAC conference (2019) discussed multi-dimensional value evaluation of medicine and prudent spending by incorporating topics re: characteristics of HTA Japan implemented the same year. The team worked at the 9th APAC to compare healthcare value each APAC economy has focused and published its achievements on the APAC homepage since the conference was cancelled due to the COVID pandemic. The goal of the taskforce this time was to elucidate common healthcare values prevailing in Asia. The team have recognized that the goal still remains however, there is a requirement for advanced discussions but not under the banner of VBH.

Congratulatory Speech

Thomas B. Cueni



Thomas B. Cueni is Director General of IFPMA, the global association of pharmaceutical research companies, based in Geneva.

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.

He is Chair of the Business at OECD Health Committee and serves as Industry Co-Chair of the APEC Biopharmaceutical Working Group on Ethics. Thomas Cueni has been instrumental in creating the AMR Action Fund and he is Chair of the Board of the cross-sectoral AMR Industry Alliance.

Prior to joining IFPMA he was Secretary General of Interpharma (Switzerland) and was a member of the Board and Chair 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". He served as a Swiss diplomat with postings in Paris (OECD) and Vienna (IAEA, UNIDO). He studied at the University of Basel, 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

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.

RA Session

Keynote Speech

John CW Lim

Professor John CW Lim is founding Executive Director of the Centre of Regulatory Excellence (CoRE) at the Duke-National University of Singapore Medical School (Duke-NUS), inaugural Chairman of the Consortium for Clinical Research & Innovation Singapore, Senior Advisor at Singapore's Ministry of Health (MOH), and Policy Core Lead at the SingHealth Duke-NUS Global Health Institute. He is Professor of Practice at Duke-NUS and the NUS Saw Swee Hock School of Public Health.
Formerly Chief Executive Officer of Singapore's Health Sciences Authority and Deputy Director of Medical Services in MOH, Professor Lim has also held other senior positions in Singapore's Health and Education ministries. His current roles promote capacity building and scientific excellence for health products regulation and health policies in Southeast Asia and the Asia-Pacific.
Professor Lim is a member of the Singapore Food Agency Board, APEC Life Sciences Innovation Forum's Executive Board, Davos Alzheimer's Collaborative Leadership Group, US Pharmacopoeia Council of the Convention, and Centre for Innovation in Regulatory Science's Scientific Advisory Council.
In 2018, Professor Lim received the Drug Information Association's Global Connector Inspire Award for leadership in promoting global collaboration to advance healthcare products to patients, and the Regulatory Affairs Professional Society's highest Founder's Award recognising substantial sustained impact in shaping regulatory practice and policy over his career.

Profile (Facilitator)

Vicky Han

Vicky Han, the Senior Director, Head of the Global Regulatory Policy 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 global team, 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 (Panelist)

Jo-Feng Chi

Dr. Jo-Feng Chi is the Researcher of Division of Medicinal Products, Taiwan Food and Drug Administration (TFDA), responsible for medicinal products registration and clinical trials. She graduated as a pharmacist from Taipei Medical College and received Ph.D. in pharmacology from National Taiwan University in 1995.
From 2004 to 2007, She had been section chief of generic drugs section in Bureau of Pharmaceutical Affairs, Department of Health. During 2015 to 2017, she served as a senior technical specialist of Division of Medicinal Products, TFDA, in charge of new drug and generic drug registration and clinical trials. In September 2017, she became the Deputy Director of Division of Medicinal Products and got promoted to Researcher in October 2018.
Dr. Chi is currently the presentative of TFDA at ICH member and engaged in pharmaceutical regulatory harmonization.

Profile (Panelist)

Daisuke Koga

Mr. Koga started his career at the Ministry of Health and Welfare of Japan in 1996. He worked in the area of drugs, medical devices, food additives and controlled substances, and for the coordination of the research grant by the Ministry. From 2007 to 2010, he worked as Coordination Officer for review and premarket authorization of new drugs and vaccines at Division of Evaluation and Licensing in Pharmaceutical and Food Safety Bureau. From 2011 to 2014, he served as Technical Officer at WHO HQ in Geneva for the WHO Programme for International Drug Monitoring. After coming back to Japan, he worked as Deputy Director for Medical Devices, Office of International Programs at PMDA until September 2015. Then, he served as a Deputy Director at the office of Global Health Cooperation, International Affairs Division, MHLW until March 2020. In the office, he was responsible for two public private partnerships, which the Ministry contributes, to finance and coordinate research and development of drugs and vaccines, the Global Health Innovative Technology (GHIT) Fund and Coalition for Epidemic Preparedness Innovations (CEPI).

Mr. Daisuke Koga has a master's degree in pharmacy from the University of Tokyo and studied in clinical education and applied pharmacotherapy at the University of Southern California.

Profile (Panelist)

Rosilawati Binti Ahmad

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 29 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 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. Since 2019, Madam Rosilawati is also appointed by JAKIM as Panel Member of Halal Certification Malaysia.

Committed to her duty, Madam Rosilawati has been leading in collaborations of harmonization initiative within ASEAN countries and directly involved in the preparation of paper works on DCA's policies with regard to usage of JAKIM Halal Certificate for traditional, health supplements products and cosmetic.

Profile (Panelist)

Sara Wang

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

ATIM Session 1

Opening (Co-chairperson)

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.

Opening (Co-chairperson)

Rie Matsui

Ms. 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)

Sayaka Kurihara

Current job position
Coordinator, Office of International Programs,
Division of Regulatory Cooperation, Division of Asia I,
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Working experience
Ms. Sayaka Kurihara entered PMDA in 2015 and has worked as an inspector in Office of Non-clinical and Clinical Compliance. Since 2018, she belongs to Office of International Programs, PMDA.
She is currently in charge of:
- the contact point of Taiwan FDA
- coordinating bilateral events between Japan and Taiwan

She's also in charge of ICH and administration of ICH Expert Working Group's activity and also ICH Management Committee member's support.

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 (Speaker)

Mark Wong

Mr. Mark Wong 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)

Nguyen Thanh Lam

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

Mr. Nguyen Thanh Lam currently serves as the Deputy Director General of the Vietnam Drug Administration ("DAV"), Ministry of Health; directly overseeing all medicine, vaccines registration and circulation aspects in Vietnam. He has been working at the DAV since 1997 after graduating from the Hanoi University of Pharmacy.

ATIM Session 2

Profile (Chairperson / Speaker)

Ryosuke Kuribayashi

Institution: Pharmaceuticals and Medical Devices Agency
Division: Office of Generic Drugs
Position: Deputy Review Director

Dr. Ryosuke Kuribayashi is a Deputy Review Director, Office of Generic Drugs at Pharmaceuticals and Medical Devices Agency (PMDA) in Japan. He is responsible for reviewing BE and CMC of Generic Drugs since January 2013. Before that, he served as a researcher, Division of Biological Chemistry and Biologicals at National Institute of Health Sciences from October 2010 through December 2012. Before that, he was a reviewer in the Office of New Drugs II at PMDA from April 2005 through September 2010.
As other activities, he is an expert member of ICH M13 and IPRP BEWGG. In addition, he was an expert member of ICH M9. He is also an expert member of Japanese BE Guideline.

Profile (Speaker)

Lusia Rizka Andalucia

EDUCATION

Bachelor degree & Profession:	Faculty of Pharmacy Universitas Airlangga Surabaya
Master degree:	Magister of Hospital Administration – Faculty of Public Health Universitas Indonesia
Doctoral degree:	Faculty of Medicine Universitas Gadjah Mada

CARRER

1994 - 2004	Functional Pharmacist in “Dharmais” Cancer Hospital
2004 - 2016	Head of Research and Development in “Dharmais” Cancer Hospital
2016 - 2018	Head of Pharmacy in “Dharmais” Cancer Hospital
2018 - current	Director of Drug Registration in National Agency of Drug and Food Control (NADFC / BPOM)

Profile (Speaker)

Chien-Liang Lin

Mr. Chien-Liang Lin is the Director of Division of Medicinal Products, Taiwan Food and Drug Administration (TFDA). He was graduated as a pharmacist from China Medical University, Taiwan in 1991. He got his master degree in pharmacology from National Taiwan University in 1993.
He has been working in TFDA since 1996 until now. He started his career as an associate technical specialist for new drug and generic drug registration in 1996 and had been appointed to be section chief of Division of Medical Devices and Cosmetics in 2010. From 2012 to 2019, he was in charge of the medicinal products registration, clinical trials and GMP inspection in Division of Medicinal Products and Division of Quality Compliance and Management. In May 2019, he had been the Deputy Director of Division of Controlled Drugs and got promoted to Director of Division of Medicinal Products in March 2020, in charge of the life cycle management of medicinal products.

Profile (Panelist)

Ya-Wen Chang

Ms. Ya-Wen Chang is the Senior Pharmacokinetic Reviewer of Pharmaceutical Science, Center for Drug Evaluation (CDE). She graduated as a pharmacist from Kaohsiung Medical University, Taiwan in 2006. She got her Master degree in Clinical Pharmacy and Pharmaceutical Sciences from National Cheng Kung University in 2008.
Ms. Ya-Wen Chang has been working in CDE since 2011 to present. She started her career as a primary pharmacokinetic reviewer for new drug and generic drug registration in 2011. From 2015 to 2021, she was senior secondary reviewer for the generic products registration. She has much work experience in review of pharmacokinetic documents of ANDA and PAC, including bioequivalence study, in vitro study for biowaiver, and BCS based biowaiver.

Profile (Speaker)

Tomonori Nakagawa

Otsuka Pharmaceutical Co., Ltd.
Production Headquarter CMC Strategy Team

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 for sustained supply of the products. A member of Quality and Technology Committee of Japan Pharmaceutical Manufacturing Association (JPMA) since 2007, and participated various ICH Quality topics as an expert. JPMA Topic leader for ICH Q12 since 2014.

DA Session

Profile (Speaker)

Toru Yoshikawa

Osaka City University Graduate School of Business
DSANJ / DSANA Program Director

APAC DSANA, a scientific-based trust-cultivating system, started its one-on-one meeting in Taiwan in July 2015. In the past five years, we have conducted various pilot projects to establish an information sharing system for drug seeds and/or technology, mainly between Japanese pharmaceutical companies and Taiwanese Biotech companies and academia. In the past five years, we have analyzed the possibilities and challenges of DSANA information sharing system.
In 2021, DSANA shifted to one-on-one meetings based on the web to realize cross-border open innovation, and held the DSANA partnering Conference in January 2021. At this conference, 16 drug seeds and/or technology were invited, and total 31 one-on-one meetings were held.
In the 10th APAC, we would like to report the results of this web based DSANA partnering Conference and design the future form of DSANA and propose it to all participants.

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)

Jun Terauchi

Dr. JunTerauchi serves as the sub-leader of APAC DA-EWG since 2016 as well as Senior Manager of Research Portfolio and Resource Management Office of Ono Pharmaceutical Co. Ltd. He is also the Steering Committee Chair of the Japan Microbiome Consortium which includes more than 30 companies, aiming to promote industrialization of human microbiome research.
In APAC DA-EWG, he has been engaging in creating information sharing platform for open innovation among Asian region in order to connect academic researchers/principal investigators and pharmaceutical companies.

After receiving Ph. D from Kyoto University, he has been working pharmaceutical companies more than 30 years, including Ono Pharmaceutical Company and Takeda Pharmaceutical Company. His background by training is organic chemistry and synthesis. In his early career, he engaged in medicinal chemistry research projects as a medicinal chemists for many different therapeutic areas including CNS, Metabolic disease and inflammation, etc. He also engaged in research strategy, research portfolio/resource management as well as promotion of open innovation. Recent his focus is promoting pre-competitive collaboration framework/platform aiming to create basic infrastructure of drug discovery activities with various different stakeholders.

Profile (Speaker)

Sirasak Teparkum

CEO
Thailand Center of Excellence for Life Sciences
SPE Tower Building, 9nd Fl.
252 Phaholyothin Road, Samsennai, Phaya Thai, Bangkok, Thailand 10400

EDUCATION
Plant Science. Biology, Molecular Genetics
- B.S. (Horticulture) Kasetsart University, Thailand
- B.S. (Biology) Concord College, USA
- M.S. (Horticulture) Virginia Polytechnic Institute and State University, USA
- Ph.D. (Horticulture) Virginia Polytechnic Institute and State University, USA

PROFESSIONAL EXPERIENCES
Top Executive Management: Business Development: Strategic Planning: Research Coordination: Scientific Writing: Book Editing

Dr.Sirasak Teparkum is the CEO of Thailand Center of Excellence for Life Sciences (TCELS) which aims to drive Thailand as the leader of life science industry in ASEAN and promote life science industry to be one of the top ten highest industry by 2027. He has joined TCELS since 2016 as a Deputy CEO, responsible for research and innovation department including four programs, Bio-Pharmaceutical & Regenerative Medicine Program, Natural Product and Cosmeceutical Program, Medical Device and Medical Robotic Program, and Medicopolis Program. He is also a Principal Investigator (PI) for Washable Innovative Nanomasks (WIN-Masks) and KN-95 Masks development during COVID-19 pandemic and transferred these innovations to commercialization.
Dr. Sirasak Teparkum had long experience of various technology transfer projects related to nanotechnology translational research, creating both income and economic impacts to Thailand more than seven billion Baht (7,000 Million Baht) and had experiences in top executive management at the national research center including chief of editor of books and journals. Before joining TCELS, he had worked at the National Nanotechnology Center (NANOTEC), National Science Technology Development Agency (NSTDA) for 12 years, including to serve as a Deputy Executive Director for 8 years.

Dr. Sirasak Teparkum received the Bachelor degree of Horticulture at Kasetsart University and B.Sc. in Biology from Concord College, West Virginia. Afterwards, he pursued his Master and Ph.D Degree, at Virginia Polytechnic Institute and State University in the field of plant tissue culture and plant-insect molecular interaction.

Profile (Speaker)

Suparerk Borwornpinyo

Dr. Suparerk Borwornpinyo graduated from Chiangmai University with B.Sc. in Animal Science in 1995. He earned his M.Sc. in 2000 and Ph.D. in 2006 from North Carolina State University, Raleigh, USA in the area of specialization in the production of transgenic chickens to express bacterial β-galactosidase and the subsequent utilization of lactose as a feed stuff. During 2010 -2011, he, as a visiting scientist, had been trained in cell and gene therapy for beta-thalassemia at the Institut des Maladies Emergentes et des Thérapies Innovantes, CEA de Fontenay aux Roses, France. He serves as a full-time lecturer in the Department of Biotechnology, Faculty of Science, Mahidol University and a scientific consultant in cell and gene therapy unit, Ramathibodi Hospital Research Center, Faculty of Medicine, Ramathibodi Hospital, Bangkok. In 2015, he led a group of scientists and physicians in the field of drug development to establish Excellent Center for Drug Discovery (ECDD) in the cooperation among TCELS, Faculty of Science and Faculty of Medicine, Ramathibodi Hospital, Mahidol University. ECDD has become one of the active working members of the innovative drug discovery and development ecosystem (NPDD ecosystem) under the Asia Partnership Conference of Pharmaceutical Associations (APAC) to find the use of natural products for research and development of innovative drug. Currently, he serves as a director of ECDD.

Profile (Speaker)

Somponnat Sampattavanich

Dr. Sampattavanich is an instructor at the Department of Pharmacology, and a co-director of the Siriraj Systems Pharmacology Center, Mahidol University, Thailand. Before returning to Thailand in 2014, he received his PhD in Medical Engineering form the Harvard-MIT HST program, and did his postdoctoral training in the Department of Systems Biology under supervision of Prof. Peter Sorger, Harvard Medical School. In addition to leading Siriraj phenomic screening facility, Dr. Sampattavanich oversees the Siriraj Initiative on cancer avatars for precision oncology and drug repurposing.
His current research program implements the quantitative systems pharmacology concept to better understand sources of drug response heterogeneity in different cancer types. In addition to identifying potential treatment options for Thai patient-specific cancer types such as cholangiocarcinoma, his lab has developed live biobanks of patient-derived organoids from Thai patients with breast, colorectal, and ovarian cancer. His lab also actively investigates the dynamics of key hub proteins such as FoxO3, FoxM1, NRF2 at single cells, to revisit how these transcription factors involve in various disease contexts. Apart of academic work, Dr. Sampattavanich works closely with cancer patient advocate groups to promote the public awareness of cancer and to educate the public about novel cancer treatment and recent diagnostic technologies.

Profile (Speaker)

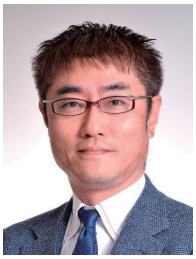
Lily Eurwilaichitr

Dr. Lily Eurwilaichitr is Vice President (for International Collaboration) of the National Science and Technology Development Agency (NSTDA). Currently, she serves as a member of the World Federal on Culture Collection (WFCC) Executive Board, and a TISI (Thai Industrial Standards Institute) expert on ISO/TC276. Dr. Eurwilaichitr received her Ph.D. from the Research School of Bioscience, University of Kent at Canterbury, on molecular genetics in yeast. She also led a team of researchers to establish and optimize technology for gene discovery from unculturable microorganisms from environments. She has published over 80 international scientific papers. She also received several awards namely, L'Oreal Fellowship For Women In Science, Taguchi award from Foundation for the Promotion of Biotechnology in Thailand and The Innovation awards from The National Research Council of Thailand (NRCT).

VBH Session

Profile (Speaker)

Tomoyuki Otsuka



Mr. Tomoyuki Otsuka (Senior Director, Global Public Affairs, Takeda Pharmaceutical Company)

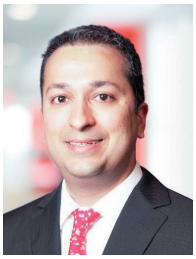
Mr. Otsuka was born in 1963. He graduated from Waseda University in 1987 and took bachelor of Arts in Law.

Mr. Otsuka has a professional career in Takeda since 1987 and had various business experience especially in Asia. He spent more than ten years in Singapore and Indonesia and managed overall business operations from production to sales. He was also an executive committee member of IPMG (Indonesia) and contributed as a head of Marketing Practice there.
Since 2015 he took a role of Global Public Affairs in Takeda and served as a member of International Affairs Committee of JPMA, International Working Group of EFPIA and various working groups of PhRMA. Currently he is a vice chair of International Affairs Committee of JPMA, International Board Sponsored Committee of EFPIA and chair of APAC from this time. Since 2020, he devoted himself to advocate Virtual Only AGSM in Japan as an option to prevent pandemic expansion, which is going to be realized through law revision this year.

He aspires to make necessary medicines available and accessible to the people in the world.

Profile (Speaker)

Vikram Kapur



Vikram Kapur is a partner in Bain & Company's Singapore office. He is the leader of Bain's APAC Healthcare practice and a leader in Bain's Private Equity and M&A practices.
Vikram has ~20 years of management consulting experience delivering strategies that work for changeoriented business leaders across the Americas, Europe and Asia.
Within healthcare, he primarily advises clients in the services, medical technology and payer and provider healthcare sectors, with additional expertise in healthcare private equity transactions. His clients range from large global multinationals, and leading local champions to digital healthcare insurgents and financial investors.
Vikram holds deep expertise in strategy development, operational improvement, acquisition due diligence and complex cross-border M&A and integration efforts.
Vikram joined Bain's Chicago office in 2001 and, in addition to Singapore, has spent time working in Bain's Dallas, Stockholm, New York, Seoul and Hong Kong offices.
In addition to his experience with Bain, he has worked in private equity with the Texas Pacific Group and in investment banking with Citigroup.
Vikram received an MBA at the Wharton School at the University of Pennsylvania, an MS in Industrial Engineering from Northwestern University and a BS in Electrical Engineering from Case Western Reserve University.

Profile (Speaker)

Jiruth Sriratanaban

Dr. Sriratanaban was graduated from the Faculty of Medicine, Chulalongkorn University with first-class honor, and board-certified in preventive medicine. He has an MBA—major in finance and marketing— from Sasin Graduate Institute of Business Administration, and a Ph.D. in Health care organization and financing from Johns Hopkins University in health care organization and financing. He is currently working at the Department of Preventive and Social Medicine, Faculty of Medicine, Chulalongkorn University in Bangkok, Thailand. He is also the Director of the Thailand Research Center for Health Service System, which was established as the joint research collaboration between the Faculty of Medicine, Chulalongkorn University, the Health Systems Research Institute (HSRI), and the Institute for Healthcare Accreditation (HA) in Thailand.

Dr. Sriratanaban has wide range of experiences in health system research and management, including more than 30 pieces of research studies and reviews in the areas of health service systems, hospital quality management, and universal health coverage (UC). He was on the HSRI taskforce in developing the Thai universal coverage policies, and was an editor of the report. He took active roles in the UC evaluation program under HSRI for many years, including developing a proposal for the master plan for managing quality under the National Health Security Scheme. Dr. Sriratanaban used to serve on the Medical Board of the Social Security Scheme from 2008-2012, and worked in many initiatives in reforming the Civil Servant Medical Benefit Scheme in Thailand. Currently, he chairs the Thailand Hospital Indicator Project (THIP) of the HA institute, and is also in the Prime-Minister's Public Health Reform Subcommittee on Health Sector Financing and Health Security Schemes.

In addition, Dr. Sriratanaban has been on the Performance Negotiation Committee of the Office of The Public Sector Development Commission for the Ministry of Public Health (MOPH) and Banpaew Hospital (Autonomous public hospital) for more than 10 years. Furthermore, he was appointed as the Assistant Director of King Chulalongkorn Memorial Hospital of the Thai Red Cross (KCMH)—the 1,500-bed university-affiliated medical center in Bangkok—from 1999 to 2007, the Assistant to the President of Chulalongkorn University from 2008 to 2011, and the Deputy Director, Strategy and Quality Improvement Affairs, of KCMH from 2011 to 2015, during which the hospital won the Thailand Quality Class (TQC) Award in 2013. Since 2009, he has been a lead assessor of the Thailand Quality Award program—the Baldrige National Quality Program equivalent in Thailand—and a member of the technical subcommittee of the program in 2015.

Profile (Speaker)

Eduardo P. Banzon

Dr. Eduardo P. Banzon or Dodo Banzon champions Universal Health Coverage and has long provided technical support to countries in Asia and the Pacific in their pursuit of this goal.

He is a Principal Health Specialist in the Southeast Asia Regional Department (SERD) of the Asian Development Bank. Prior to that he was with the Sustainable Development and Climate Change Department of ADB. Before joining ADB in 2014, he was President and CEO of the Philippine Health Insurance Corporation, World Health Organization (WHO) regional adviser for health financing for the Eastern Mediterranean region and WHO health economist in Bangladesh, and World Bank senior health specialist for the East Asia and Pacific region. He is also a former faculty member of the University of the Philippines' College of Medicine and Ateneo Graduate School of Business.

He completed BS Biology in University of the Philippines Diliman and MD Medicine in the University of the Philippines College of Medicine, and an MSc in Health Policy, Planning and Financing from the London School of Economics and the London School of Hygiene and Tropical Medicine. He has been awarded the Distinguished Alumni Award for Medicine and Health Systems Development by the University of the Philippines.

Profile (Speaker)

Yasuhiro Suzuki

Dr. SUZUKI Yasuhiro (Senior Advisor to the Minister, Ministry of Health, Labour and Welfare)

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

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

He previously served as Vice-Minister for Health, Chief Medical & Global Health Officer at the MHLW from July 2017 to August 2020.

Profile (Facilitator)

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 (Panelist)

Yasushi Okada

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

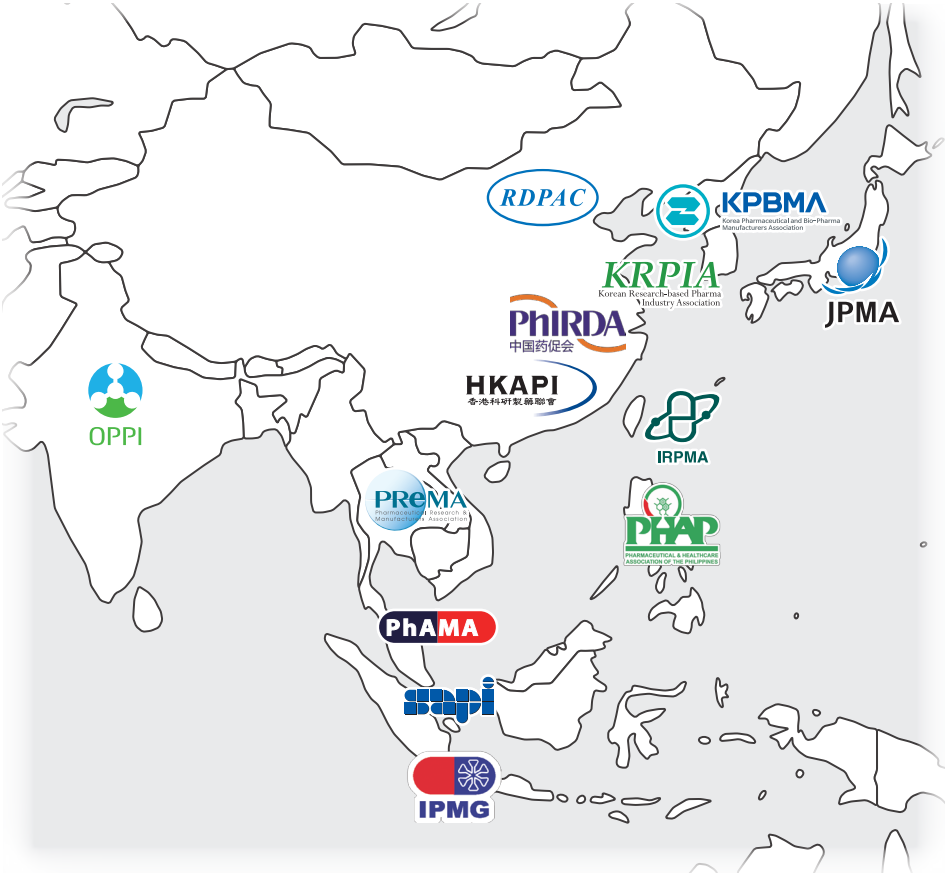
Yasushi Okada joined Eisai in 1981, immediately after his graduation from Kwansei Gakuin University. His experience in Eisai covers broad areas including sales and marketing of pharmaceutical products in Japan, Corporate Planning, Asia, Oceania and Middle East business, Human Resources, General Affairs,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

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

Mr. Okada has served as Vice President of Japan Pharmaceutical Manufacturers Association since 2019.

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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