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**Accelerating Access To Innovative Medicines through advancing collaborative partnership in Asia**

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# **The 6th Asia Partnership Conference of Pharmaceutical Associations**

## **PROGRAM**

**Date: April 5 (Wednesday)**

**Venue: Tokyo Conference Center Shinagawa**

# Accelerating Access To Innovative Medicines

## Program

Wednesday, April 5, 2017

MC : A. Matsubara, JPMA

8:30 ▶ 8:40	Opening Remarks	Y. Hatanaka, JPMA
8:40 ▶ 8:55	Congratulatory Speech	T. Cueni, IFPMA
8:55 ▶ 9:40	Keynote Lecture PIC/S GMP update	Boon M.H., PIC/S (HSA)
9:40 ▶ 10:00	< Break > (Photo session)	
10:00 ▶ 10:10	Introduction of the entire program	H. Hirate, JPMA
10:10 ▶ 12:20	<b>ATIM Session : Sharing Evaluation Process for GMP Compliance Assessment and Finding Opportunities to Improve Efficiency ~Aiming early approvals of innovative medicines in Asia</b>	
	<b>Presentations</b>	<b>Chair:Boon M.H., PIC/S(HSA), S. Sakurai, PMDA</b>
10:10 ▶ 10:25	1 GMP compliance assessment process and future possibility in Japan	<b>M. Yabuki, PMDA</b>
10:25 ▶ 10:40	2 GMP compliance assessment process and future possibility in Korea	<b>M. Choi, MFDS</b>
10:40 ▶ 10:55	3 GMP compliance assessment process and future possibility in Taiwan	<b>Ellen C., TFDA</b>
10:55 ▶ 11:10	4 GMP compliance assessment process and future possibility in Thailand	<b>Suchart C., FDA</b>
11:10 ▶ 11:25	5 GMP compliance assessment process and future possibility in Indonesia	<b>Bayu W., NADFC</b>
	<b>Panel Discussion</b>	
	<b>&lt;Suggestion from Industry&gt;</b>	
11:25 ▶ 11:40	SMF/PMF issues identified by JPMA and potential areas for efficiency in GMP compliance assessment	<b>K. Kamiya, JPMA</b>
11:40 ▶ 12:15	<b>*How Asian authorities &amp; industry can collaborate for efficient GMP compliance ?</b>	<b>all member+ M. Chung, MFDS &amp; floor</b>
12:15 ▶ 12:20	Session closing	<b>Boon M.H., PIC/S (HSA)</b>
12:20 ▶ 13:30	< Lunch >	

# through advancing collaborative partnership in Asia

13:30 ▶ 15:30		DA Session :Dawning Era in Drug Discovery with Natural Resources in Asia
13:30 ▶ 13:35	Introduction to the DA Session	A. Hasuoka, JPMA
	Keynote Lecture	Chair : W.K.Chi, DCB & A. Hasuoka, JPMA
13:35 ▶ 14:05	Continued Efforts to Discover New Drugs using Natural Resources	K. Shinya, AIST
	Presentations	
14:05 ▶ 14:15	1 Drug discovery using natural compounds in Thailand	Wanchai D., Chula. Univ.
14:15 ▶ 14:30	2 Drug discovery using natural compounds in Taiwan	M. Su, SynCore
14:30 ▶ 14:45	3 Application of Natural Resources to Drug Discovery in Eisai	K. Tagami, Eisai
14:45 ▶ 15:00	4 Activities of Pillar 5 (Drug Discovery by Natural Resources) Task Force	Nares D., TCELS
	Panel discussion	
15:00 ▶ 15:25	· Implementation of drug discovery using natural resources in Asia · Issues & solution for drug discovery by natural resources in Asia	all member & floor
15:25 ▶ 15:30	Session closing	W.K.Chi, DCB
15:30 ▶ 15:50	< Break >	
15:50 ▶ 17:20		RA Session : Toward Efficient & High-Quality Registration Process for Innovative Medicines – Campaign for Rolling out the Good Registration Management
15:50 ▶ 15:55	Introduction to the RA Session	O. Inagaki, JPMA
	Presentations	Chair : O. Inagaki, JPMA
15:55 ▶ 16:10	1 GRM Pilot CoE workshop -Reviewers Training	J. Wang, TFDA
16:10 ▶ 16:25	2 Promotion of Good Submission Practice in Asia	S. Hatakeyama, JPMA
	Panel discussion	Chair : J. Sato, PMDA
16:25 ▶ 16:40	<Presentation> Forward-looking approaches & its Experiences of PMDA's ATC*	J. Sato, PMDA
16:40 ▶ 17:15	<Discussion> Challenges on capacity building for quality improvement in new drug registration process	all member + Alice C., PhAMA, Busakorn L., PReMA & floor
17:15 ▶ 17:20	Session closing	O. Inagaki, JPMA
17:20 ▶ 17:35	Closing Remarks	H. Naito, JPMA
18:00 ▶	< Reception >	

\*ATC : Asia Training Center

## Congratulatory Speech

### Thomas B. Cueni

Thomas B. Cueni is Director General of IFPMA since 1 February 2017. Prior to joining IFPMA he was Secretary General of Interpharma, the association of pharmaceutical research companies in Switzerland. For many years Thomas Cueni has been involved in the work of the European Federation of Pharmaceutical Industries and Associations, EFPIA, where he most recently served as Vice-Chair of the European Markets Committee and association representative on the Board. He represented the industry on the EU High Level Pharmaceutical Forum, was Chairman of EFPIA's Economic and Social Policy Committee and Chairman of the EFPIA Task Force on the EU Commission's Pharmaceutical Sector Inquiry. Thomas Cueni also represented Interpharma, which he successfully transformed from the association of Swiss Rx companies to the association of pharmaceutical research companies in Switzerland, on the Council of IFPMA.



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 / Profile (Speaker)

### BOON Meow Hoe

Deputy Chairman, PIC/S (Pharmaceutical Inspection Co-operation Scheme)

**Organisation / authority / company :**  
Singapore / Health Sciences Authority

**Professional background / education :**  
Boon Meow Hoe holds a Bachelor's degree in Pharmacy from the National University of Singapore.

After graduation, he served the commercial pharmaceutical manufacturing industry for 15 years.

He is an active Senior GMP Auditor conducting both local and overseas GMP audits since year 2001. He is also the Deputy Director of Overseas Audit Unit, Audit Branch, Audit & Licensing Division at the Health Products Regulation Group of the Singapore Health Sciences Authority (HSA).

Outside of Singapore, he is an elected Pharmaceutical Inspection Co-operation Scheme (PIC/S) Deputy Chair for year 2016 to 2017, Executive Bureau Member, Chair of the PIC/S Sub-Committee on Training and Chair of the PIC/S Inspectorates' Academy (PIA) Project Management Steering Committee (PMSC).



## ATIM Session

### Profile (Chair)

### Shingou SAKURAI, Ph. D.

- 1985 Department of Pharmacoscience (master degree program), Graduate School of Pharmaceutical Science
- 1985 Worked for mainly in the area of Quality Control and Technology Development for biological products at an industrial firm  
Product Security Pharmacist, Quality Assurance Manager
- 2004 Office of GMP/QMS Inspection, PMDA
- 2007 Director for GMP Inspection, Office of GMP/QMS Inspection, PMDA
- 2010 - Office Director, Office of Manufacturing/Quality and Compliance, PMDA



### Others

Ph. D. (Health Science, Faculty of Medicine, The University of Tokyo)  
Visiting Professor, Graduate school of Medicine, Chiba University  
Research Evaluation Committee, National Institute of Infectious Diseases

## Profile (Speaker)

### Mami YABUKI

April, 2007 Inspector, Office of GMP/QMS Inspection, PMDA

July, 2014 Principal Inspector, Office of Manufacturing/Quality and Compliance, PMDA



## Profile (Speaker)

### Choi Mi Seop

#### Company (Organization) / Department / Job Title

The Ministry of Food and Drug Safety (MFDS) / Pharmaceutical Quality Division / Assistant Director

#### Job experience

2008.6. ~ 2009.4. Recombinant Products Division, Biopharmaceuticals Bureau, KFDA

2009.4. ~ 2010.8. National Lot Release Center, NIFDS

2010.8. ~ 2014.4. Pharmaceutical Safety Information Team, Pharmaceutical Safety Bureau, MFDS

2015.8.31~Present Pharmaceutical Quality Division, Pharmaceutical Safety Bureau, MFDS



#### Title (Presentation)

Current status of GMP review and future possibility in Korea

#### Topic & Contents

As a member of PIC/S and the ICH, Korea secures the safety and efficacy of medicinal products based on its GMP system equivalent to that of PIC/S and internationally harmonized regulations on drug approval.

In Korea, all pharmaceutical manufacturers are required to obtain a product approval and a manufacturing license from MFDS or its regional offices prior to production and sales of medicinal products. And their compliance with the GMP regulation needs to be confirmed by the MFDS in accordance with the relevant statutes such as the Pharmaceutical Affairs Act.

## Profile (Speaker)

### Ying-Hua (Ellen) Chen

Ms. Ying-Hua (Ellen) Chen is the Senior Specialist & Section Chief of Risk Management Division (GXP Inspectorate) of the Taiwan Food and Drug Administration, supervising the GMP compliance of overseas manufacturers of medicinal products, Good Tissues Practice compliance of cell/tissue-based products and Tissue/Cells banking, and international cooperation affairs in the field of GMP for medicinal products. She has been working in the GMP inspectorate over 11 years after receiving M.S. in MBA (Technology & Innovation Management) from National Cheng-Chi University in Taiwan. Before that, she graduated from Pharmacy School of Taipei Medical University in 1999 ; then, worked as a laboratory specialist in Pharmaceutical Chemistry, National Laboratories of Foods & Drugs, Department of Health, Taiwan for about 3 years. She has been actively participating in international harmonization activities and has extensive experience working with PIC/S included being the Taiwan FDA representative in PIC/S.



## Profile (Speaker)

### Suchart Chongprasert

Dr. Suchart Chongprasert is a registered pharmacist by profession. He was the recipient of the Royal Thai Scholarship to pursue his advanced degree in the US in the area of industrial pharmacy. He earned his doctorate degree from School of Pharmacy, Purdue University, US. Immediately after graduation, he entered a post-doctoral program at the University of Colorado Health Sciences Center, CO, US. He was also graduated a bachelor's degree in law (LLB) from the Faculty of Law, Thammasat University, Thailand.



He has served for several positions in the Thai Food and Drug Administration since his doctorate graduation in 1998. His present post is Director, Post marketing Control Division within the Bureau of Drug Control, Food and Drug Administration. He also officially represents the Thai FDA as member of the PIC/S Committee since Thai FDA became the 49<sup>th</sup> Participating Authority of the PIC/S in August 2016. His roles in the Thai FDA currently have involved more in building up and strengthening the capacities of the GMP Inspectorate and Surveillance Office to keep pace with a rapidly changing demand for GMP inspection of domestic and international drug manufacturers according to the latest PIC/S GMP Guide.

## Profile (Speaker)

### Bayu Wibisono

GMP Inspector, Badan POM/National Agency for Drug and Food Control (NADFC)  
Indonesia

He was born in Metro-Lampung, December 24, 1978. Joined in Badan POM since 2003 as staff (2003 - 2008), Section Head of GMP Analysis (2008 - 2012) and Head of Subdirectorat of API Control and GMP Analysis since 2012 up to present.

As a Head of Subdirectorat of API Control and GMP Analysis, he has responsibility in implementation of GMP for API in Manufacturers facility and also to analysis GMP compliance all the pharmaceutical industries in Indonesia. He has qualification in GMP audit in the field of API, Medicinal products including biological products, he also conduct overseas GMP Inspection.



## Profile (Panelist)

### Chung Myung-hoon

**Company (Organization) / Department / Job Title**

The Ministry of Food and Drug Safety (MFDS) /  
Pharmaceutical Quality Division, Pharmaceutical Safety Bureau / Assistant Director

**Job experience**

2006. 9. ~ Present :

Pharmaceutical Safety Bureau, MFDS (GMP inspection, Drug Approval, Establishment of pharmaceutical safety policy)



# DA Session

## Profile (Chair)

### Wei-Kuang Chi, Ph.D.

Distinguished Scientist and Director, Bioengineering Group, Institute of Biologics  
Development Center for Biotechnology, Taipei, Taiwan



#### Biography

Dr. Wei-Kuang Chi, Distinguished Scientist and Director of Bioengineering Group in Institute of Biologics since September 2009, Vice President of the Development Center for Biotechnology (DCB) from December 2008 to December 2013, obtained his M.S in Engineering and Ph.D. in Chemical Engineering from the University of Pennsylvania, Philadelphia, USA. Dr. Chi has nearly 30 years of experience in biotechnology process development, including mammalian cell culture (CHO, NS0, hybridoma, 293 cell, insect cell etc.), recombinant yeast (*Saccharomyces cerevisiae*, and *Pichia pastoris*), recombinant *Escherichia coli*, online mass spectrometric off-gas analysis for fed-batch process control, and cell disruption bioseparation technology. In addition to coordinate new biologics and new drug development activities in DCB, he is also responsible for the establishment of DCB's multi-product 500 L mammalian cell culture and 100 L microbial fermentation CGMP Biopharmaceutical Pilot Plant Facility (BPPF), this facility CGMP was certified by Taiwan Department of Health (DOH) on December 2005 and received DMF with USA FDA on March 2006. The CGMP Biopharmaceutical Pilot Plant Facility has joined Boehringer Ingelheim Biopharmaceuticals Production Alliance Network since May 2007. This CGMP facility has been used to conduct bioprocess scale-up/development and to produce clinical trial material for protein drugs (monoclonal antibodies, recombinant proteins), has received eight IND approvals from US FDA, Canadian health authority, Taiwan FDA and EMA. Recently CGMP BPPF has been spun-off into private sector to provide CDMO service on a broader scale. Dr. Chi's new responsibility will focus more on novel biologics drug R&D, international collaboration and novel bioprocess engineering technology development.

## Profile (Speaker)

### Kazuo Shin-ya

#### Present Position :

Chief Senior Research Scientist,  
Assistant Professor, I National Institute of Advanced Industrial Science and Technology (AIST)

#### Education :

1984-1988 :Tokyo University of Agriculture and Technology

1988-1990 : Master of Agriculture, Faculty of Agriculture, Department of Agricultural Chemistry, The University ofTokyo

1990 : Awarded the degree of Master of Agriculture

1990-1993 : Doctor of Agriculture, Faculty of Agriculture, Department of Agricultural Chemistry, The University ofTokyo

1993 : Awarded the degree of Doctor of Philosophy in Agriculture (Ph.D.)

1993-present : Assistant Professor, Institute of Molecular and Cellular Biosciences, The University ofTokyo



#### Brief Chronology of Employment :

1993 April-present : Assistant Professor, Institute of Molecular and Cellular Biosciences, The University ofTokyo

2004 December-present : Visiting Research fellow, Biological Information Research Center (BIRC), National Institute of Advanced Industrial Science and Technology (AIST), Low M.W. Chemical Laboratory (Team leader of Low Molecular Weight Chemical Laboratory)

#### Specialty and Present Interest :

Natural Chemistry

Chemical Biology

Cell Biology : Cancer and Neuron

Research for the development of new drugs : telomerase inhibitors, neuro-protecting agents, regulators of molecular chaperone, etc.

#### Honors and Awards :

The Grant of Kampo Medical Found, 1994

Industrial Technology Research Grant Program in 01A04006b from New Energy and Industrial Technology Development Organization (NEDO) of Japan.

Award for Young Scientist of The Japanese Association for Molecular Target Therapy of Cancer, June, 2001

Award for Young Scientist of 43rd Symposium of The Chemistry of Natural Products, October, 2002

Award for Young Scientist of Japan Society for Bioscience, Biotechnology, and Agrochemistry, March, 2003

Sumiki-Umezawa memorial Award, November 2006

## Membership

Society for Neuroscience, American Association for Cancer Research, Japanese Association for Cancer Research, Japanese Association for Molecular Target Therapy of Cancer, Japanese Society for Neurochemistry, Japanese Society for Bioscience, Biotechnology and Agrochemistry

## Profile (Speaker)

### Wanchai De-Eknamkul, Ph.D.

Speaker : Wanchai De-Eknamkul, Ph.D., Head of the Natural Product Biotechnology Group, Faculty of Pharmaceutical Sciences, Chulalongkorn University, Bangkok, Thailand



Dr. Wanchai De-Eknamkul is a faculty member at Chulalongkorn University, Faculty of Pharmaceutical Sciences. He is presently head of Thailand National Chemical Bank of Natural Products project. He received his Ph.D. (Plant Biochemistry) at the University of Guelph, Canada, and did his post-doc. with Prof. Dr. Meinhard H. Zenk at the University of Munich in Germany. His main research interest has been on the biosynthetic studies of pharmaceutically important natural products, and biotechnological applications of biosynthetic genes and enzymes for yield improvement of useful products. He is the project leader of the Natural Product Biotechnology Network of Chulalongkorn University. He is the recipient of the Alexander von Humboldt Foundation's Research Fellowship (1989-1990), the Thailand Research Fund's Best Research Award (1999), the National Agency's Innovation Ambassador Award (2008), and the National Research Council of Thailand's the Invention Award (2009). He has published more than 80 international research articles and patents from his work.

## Profile (Speaker)

### Muh-Hwan Su, Ph. D.

#### Personal Profile :

As an associate professor in university, I have had plenty experiences in development of pharmaceutical dosage forms especially transdermal delivery and liposomal preparations. As CSO and Director in biotechnology company, I have had global experiences in R&D of botanical new drugs, including evaluation, strategic innovation, planning and partnership. Also, I had successfully led R&D teams to accomplish projects of investigational new drug (IND) approved by USFDA and TFDA in phase I and Phase II, by EMA in Phase III as well as NDA approved by CFDA.



#### Current Position :

- General Manager, SynCore Biotechnology Co., Ltd.
- Adjuncted Associate Professor, School of Pharmacy, National Defense Medical Center

#### Education :

- University of Utah, Salt Lake City, UT., 1987-1992
- Ph.D. in Pharmaceutics and Pharmaceutical Chemistry
- The Ohio State University, Columbus, OH 1984-1986
- M.S. in Pharmaceutics and Pharmaceutical Chemistry
- National Defense Medical Center, Taipei, Taiwan, ROC., 1974-1978
- B.S. in Pharmacy

#### Experience :

- Chief Operating Officer, Sinphar Group, 2012-2013
- Chief Scientific Officer, R&D, Sinphar Group, 2001-2012
- Obligation Board Director and Standing Director, Pharmaceutical Industry Technology and Development Center (PITDC), Taiwan, 1998-to date



- Supervisor, Controlled Release Society Taiwan Chapter, 1993-1996
- Associate Professor, School of Pharmacy, National Defense Medical Center, February, 1993-2001
- Instructor and Teaching Assistant of Pharmacy, National Defense Medical Center, 1978-1993

**Researches :**

- Transdermal drug or peptide deliveries by using polymers or liposomes
- Biopharmaceutical and pharmacokinetic studies of drugs and their metabolites
- Analytical method development of HPLC
- Research development of new formulations, indications, or new drugs of Chinese herbal medicine
- Published Articles >20 articles
- Published Abstracts >30 abstracts

**Awards :**

- 15<sup>th</sup> Award for Industrial Technology Advancement, Ministry of Economic Affairs, R.O.C.
- Outstanding Alumni's Prize, School of Pharmacy, National Defense Medical Center
- Display Thesis Excellent Grade Prize at Taiwan Association of Pharmaceutical Conference

**Professional Memberships :**

Primary Institute Representative to the Consortium for Globalization of Chinese Medicine

**Profile (Speaker)**

**Katsuya Tagami, Ph.D.**

Executive Director, API Research Japan, Pharmaceutical Science & Technology Function Unit, Medicine Development Center, Eisai Co., Ltd.



**Education**

1986 : Master of Engineering, Tohoku University, Japan

1999 : PhD of Engineering, Tohoku University, Japan

**Career**

1986 - 1996 : Discovery Research, Eisai Co., Ltd.

1992 - 1994 : Department of Chemistry, Harvard University (Prof. Yoshito Kishi)

1996 - 2009 : Process Research, Eisai Co., Ltd

**Award**

2013 : The Pharmaceutical Society of Japan Award for Drug Research and Development, 2013

**Profile (Speaker)**

**Nares Damrongchai**

Dr. Nares Damrongchai is the Chief Executive Officer of Thailand Center of Excellence for Life Sciences (TCELS), a public organization with a mission to foster the life sciences industry in the country known as Asia's medical hub. Nares also serves as Co-Chair of Life Science Innovation Forum, APEC's leading initiative on health and health sciences innovation. His leadership in APEC science and technology extends back to the early 2000s when he was the Executive Director of the APEC Center for Technology Foresight when he led the Center's successful international foresight research and trainings together with the Rockefeller Foundation, the Rand Corporation, the Institute of Alternative Futures, Asian Foresight Institute and others. Nares was elected to become Lead Shepherd of the APEC Industrial Science and Technology Working Group (ISTWG) during the early 2010s and led the Group's transformation into APEC Policy Partnership in Science Technology and Innovation. Earlier in his career Nares was a laboratory scientist then he turned to pursue his career as policy researcher. He was instrumental in the success of Thailand first and second National Biotechnology Policy. Currently he is on the Editorial Board of Asian Biotechnology and Development Review, published by RIS, New Delhi and supported by UNESCO. Nares obtained the degree of Master of Philosophy in Technology Management from the University of Cambridge and holds a doctorate from Tokyo Institute of Technology with research focused on tissue engineering. Nares lives in Bangkok with his family.



## RA Session

### Profile (Speaker)

#### Chao-Yi (Joyce) WANG

**Current Position :**

Director, Division of Medicinal Products, Taiwan Food and Drug Administration, Ministry of Health and Welfare, Taiwan

**Education :**

LL. M., Department of Law, Soochow University, Taipei, Taiwan  
MS, Preventive Medicine, Ohio State University, U.S.A

**Professional Experience :**

Director, Division of Planning and Research Development, Taiwan Food and Drug Administration, Ministry of Health and Welfare

Deputy Director, Division of Medicinal Products, Taiwan Food and Drug Administration, Ministry of Health and Welfare



### Profile (Speaker)

#### Junko Sato

Dr. Junko Sato is an Office Director of Office of International Cooperation at Pharmaceuticals and Medical Devices Agency (PMDA). She also works for International Cooperation including coordination of Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC).

She started her job at Jikei University, School of Medicine as an instructor. She was involved in the education and the research. In 1997, she gained her doctoral degree from Jikei University. Next year, she joined Office of New Drug, Pharmaceutical and Medical Devices Evaluation Center (PMDEC), and started to work in regulatory agency. She became a review director and moved to Office of Safety to introduce a new risk management system through life cycle of drugs. During the period, she visited 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-E2C (R2) as the co-rapporteur, E2E, E2F, M5, and also CIOMS VII and IX. She also contributes many DIA activities. She received DIA Outstanding Service Award 2010.

She now leads the activities of 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 is also the member of the APEC RHSC (APEC Regulatory Harmonization Steering Committee) which is tasked to achieve regional convergence on regulatory approval procedures for medical products by 2020.



### Profile (Panelist)

#### Busakorn Lerswatanasivalee

**Education**

1983-1985 Thammasart University  
Master of Business Administration

1971-1976 Chulalongkorn University  
Bachelor of Sciences, Faculty of Pharmaceutical, Second Class Honor

**Experiences**

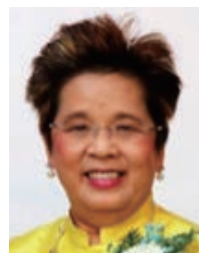
Pharmaceutical Research and Manufacturer Association 2013 - Present :Chief Executive Officer

Takeda (Thailand), 2000 - 2013

Pfizer Inc, 1976 - 2000

**Award**

- Honors 2015 Outstanding Alumnus of Thammasat University
- First Takeda Global Awards
- 2006 Hall of Fame, Alumni of Faculty of Pharmacy, Chulalongkorn University
- 2007 Marketing Pharmacist of the Year, 4th Pharmacy Congress, Thai Pharmaceutical Association



## Profile (Panelist)

### Alice Chee

Alice Chee is a registered Pharmacist with the Pharmacy Board of Malaysia and a member of the Malaysian Pharmaceutical Society (MPS). She obtained her degree in Pharmacy at the Universiti Sains Malaysia in Penang, and a Master of Science degree in Pharmaceutical Analysis at Strathclyde University in Glasgow, United Kingdom.

She is presently the Regulatory Consultant for the Pharmaceutical Association of Malaysia (PhAMA). She started her career in the Ministry of Health, Malaysia with the National Pharmaceutical Control Bureau, NPCB (now known as National Pharmaceutical Regulatory Agency, NPRA), and moved through several positions during her 14 years in the Ministry. These included being Pharmaceutical Analyst in NPCB's Analytical Laboratory, Registration Pharmacist in NPCB's Registration Division and GMP Inspector in NPCB's GMP & Licensing Unit. She had also worked in the Ministry's Government Medical Store as Head of Quality Control Laboratory and in the Seremban General Hospital.

She later moved over to the industry as Regulatory Affairs Manager for Glaxo Wellcome (Malaysia) Sdn Bhd, and then worked in Roche (Malaysia) Sdn Bhd as the Regulatory Affairs & Quality Assurance Director for 16 years which covered regulatory responsibilities for Malaysia, Vietnam, Cambodia, Laos and Myanmar.





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through advancing collaborative partnership in Asia



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