The 6th Asia Partnership Conference of Pharmaceutical Associations

Date: April 5 (Wednesday)
Venue: Tokyo Conference Center Shinagawa
The 6th Asia Partnership Conference of Pharmaceutical Associations (APAC)

# Accelerating Access To Innovative Medicines

**Program**

**Wednesday, April 5, 2017**

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

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<tr>
<td>13:30</td>
<td>DA Session: Dawning Era in Drug Discovery with Natural Resources in Asia</td>
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<td>Introduction to the DA Session</td>
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<tr>
<td>13:35</td>
<td>Continued Efforts to Discover New Drugs using Natural Resources</td>
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<td>14:05</td>
<td>Keynote Lecture</td>
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<td>14:05</td>
<td>K. Shinya, AIST</td>
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<td>14:15</td>
<td>1 Drug discovery using natural compounds in Thailand</td>
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<tr>
<td>14:30</td>
<td>2 Drug discovery using natural compounds in Taiwan</td>
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<td>14:45</td>
<td>3 Application of Natural Resources to Drug Discovery in Eisai</td>
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<td>14:45</td>
<td>4 Activities of Pillar 5 (Drug Discovery by Natural Resources) Task Force</td>
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<td>14:45</td>
<td>Nares D., TCELS</td>
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<td>15:00</td>
<td>Panel discussion</td>
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<td>15:25</td>
<td>Implementation of drug discovery using natural resources in Asia</td>
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<tr>
<td>15:25</td>
<td>Issues &amp; solution for drug discovery by natural resources in Asia</td>
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<tr>
<td>15:30</td>
<td>Session closing</td>
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<tr>
<td>15:50</td>
<td>RA Session: Toward Efficient &amp; High-Quality Registration Process for Innovative Medicines – Campaign for Rolling out the Good Registration Management</td>
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<td>15:55</td>
<td>Introduction to the RA Session</td>
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<td>Chair: O. Inagaki, JPMA</td>
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<td>16:10</td>
<td>1 GRM Pilot CoE workshop - Reviewers Training</td>
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<td>16:25</td>
<td>2 Promotion of Good Submission Practice in Asia</td>
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<td>16:25</td>
<td>S. Hatakeyama, JPMA</td>
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<tr>
<td>16:40</td>
<td>Panel discussion</td>
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<td>16:40</td>
<td>&lt;Presentation&gt; Forward-looking approaches &amp; its Experiences of PMDA’s ATC*</td>
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<td>16:40</td>
<td>J. Sato, PMDA</td>
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<td>16:40</td>
<td>&lt;Discussion&gt; Challenges on capacity building for quality improvement in new drug registration process</td>
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<td>17:15</td>
<td>Session closing</td>
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<tr>
<td>17:20</td>
<td>Closing Remarks</td>
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<td>18:00</td>
<td>&lt;Reception&gt;</td>
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*ATC: Asia Training Center
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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
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.
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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 49th 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 of Tokyo
1990 : Awarded the degree of Master of Agriculture
1990-1993 : Doctor of Agriculture, Faculty of Agriculture, Department of Agricultural Chemistry, The University of Tokyo
1993 : Awarded the degree of Doctor of Philosophy in Agriculture (Ph.D.)
1993-present : Assistant Professor, Institute of Molecular and Cellular Biosciences, The University of Tokyo

Brief Chronology of Employment :
1993 April-present : Assistant Professor, Institute of Molecular and Cellular Biosciences, The University of Tokyo
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. Meinhart 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 leaded 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
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- 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

Research:
- 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:
- 15th 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
1992 - 1994: Department of Chemistry, Harvard University (Prof. Yoshito Kishi)

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
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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