ISPE Thailand Affiliate

ISPE THAILAND 15TH ANNIVERSARY ANNUAL MEETING 2018
JULY 16TH – 18TH, 2018
AMBASSADOR HOTEL, BANGKOK THAILAND

# SPEAKERS LIST

## B

### Helena Paula Baião

**PIC/S Former Chairperson**

She is a Pharmacist (Lisbon Pharmacy University) with a Master Degree in Pharmaceutical Science.

She worked in Macau Ministry of Health first as Hospital Pharmacist Assessor (coordinator of production, information/education and products management) and later as expert in drug assessment and finally GMP inspector (traditional and modern medicines) before joining INFARMED I.P. in 1997.

The main activities and responsibilities are or was GMP/GCP/GPvP/GDP inspections of human/veterinary MP and API in Portugal and overseas; complaints, quality defects alerts and recalls of the market; Quality Management System, representation of INFARMED I.P. at Communitarian and International level.

From 1998 to 2015 she is a member of PIC/S Committee assessor. She participated at Expert Circles, JVP, JRP among others and consequently organized PIC/S meetings.

She has worked as PIC/S co-rapporteur for EOF – Greece and MHRA- UK and JRP of Swissmedic –Switzerland and KA - Liechtenstein and JRP for Brazil's application.

She was a member of PIC/S Executive Bureau since 2008- 2015.

PIC/S Chairperson 2012-2013. PIC/S Former Chairperson 2014-2015.

She participated since 2012, in several WHO activities, such as reviewing the regulatory systems in Angola, Burundi, China, Egypt, India, Mozambique, Pakistan, Russia, Saudi Arabia, Serbia and Sudan; also facilitating and training national regulatory inspectors through in country inspection workshops organized in Angola, Bangladesh, Brazil, China, India, México, Mozambique and Tanzania.

From February 2013 is Regulatory and Scientific Advice Manager and Quality Manager, at INFARMED I.P.

## C

### Richard Chai Yoke Leong

**Technical Service Manager**
**STERIS Corporation**

As a Technical Service Manager with STERIS Corporation based in Singapore, Richard has been providing technical training to customers in topics related to cleaning and bioburden control for cleanrooms, including disinfectant validation, as well as cleaning and cleaning validation for product contact surfaces. He is also an industry speaker at ISPE events and Interphex Japan.

Prior to joining STERIS, Richard had 13 years of manufacturing and validation experience working in dry powder inhaler plant, biotech sterile fill and finish plant, and medical device and biopharmaceutical facilities. He has in-depth understanding of the requirements of cleaning and disinfection in cleanrooms, as well as best practices in bioburden control. In addition, he also has extensive experience in the cleaning validation of product contact surfaces in various biopharmaceutical and biotech companies. Richard has also worked 3 years as a validation consultant providing validation support to various pharmaceutical customers in the area of equipment validation, cleaning validation for product contact surfaces, disinfectant validation, as well as cleaning procedures for both product and non-product contact surfaces.

### Suchart Chongprasert, PhD.

**Director, Bureau of Drug Control, FDA Thailand**

Dr. Suchart Chongprasert is a registered pharmacist in Thailand. Shortly after serving as a faculty member of the Faculty of Pharmacy, Prince of Songkla University since graduation, he was awarded a prestigious Royal Thai Government scholarship to pursue an advanced degree abroad. He earned his doctorate degree (Ph.D.) 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.

Before having been promoted to be Director, Bureau of Drug Control since 1 October 2017, he was Director, Post-marketing Control Division, where one of his responsibilities was to build up and strengthen the capacities of the local pharmaceutical industry by assuring the full compliance with PIC/S GMP Guide. He 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 addition to GMP inspection, Dr. Chongprasert has actively engaged in international for a on drug regulation issues, including, for example, innovative regulatory framework for self-medication, regulatory pathways of biosimilars, Advanced Therapy Medicinal Products (ATMPs) or Regenerative Medicines, conditional early approval of medicines.

## C

Dr. Chongprasert has involved more in building up and strengthening the capacities of the GMP Inspectorate and Surveillance Office in Thai FDA to keep pace with a rapidly changing demand from GMP inspection of domestic and foreign drug manufacturers according to the latest PIC/S GMP Guide. He looks forward to collaborating with other regulatory authorities having a comparable GMP inspection system to minimize any unnecessary duplication of GMP inspection.

### Jesusa Joyce N. Cirunay

**Director of the North Luzon Cluster at the Field Regulatory Operations Office, Philippine**

Jesusa joyce n. Cirunay is an ispe philippine affiliate founding member and its past board of director for several years. She is a registered pharmacist *(cum laude)* with post-graduate studies in pharmaceutical science. She has been with fda ph since 1989 and currently the director of the north luzon cluster at the field regulatory operations office covering four (4) regional field offices. Her government service began as pharmaceutical researcher then as senior drug evaluator before assuming management positions in various timelines, i.e., field cluster director in various parts of the philippines, as head of the gmp inspectorate; as head of the distribution inspectorate and as head of the marketing authorization.
Her repertoire also covers experiences in international collaboration as former oic–fda international affairs office; media relations as former fda spokesperson; former quality manager for the fda quality management system on iso 9001 initially for 2008 version and recently the 2015 version; on asean harmonization in the healthcare sector representing fda ph as head of delegation or delegate. Her publications include, among others, as lead author in several scientific articles published in peer-reviewed international journals (few accepted without correction) covering pharmaceutical science, chemometrics (i.e. Factorial designs, central composite designs) and liquid chromatography; and a recipient of many awards, such as, certificate of appreciation as chairman of the science and technology advisory council - belgium chapter; certificate of commendation for the exemplary role played as food and drug regulation officer; and, certificate of recognition as quality management representative for the exemplary performance.

## D

### Frederic Dietrich

Frederic Dietrich is the managing director of Dietrich Engineering Consultants (DEC). Dec are experts in supplying safe and contained powder handling solutions in the fine chemical and pharmaceutical industries.

Over the past 30 years Dec has gained extensive knowledge and experience concerning health, safety and containment in relation to powder processing. Mr. Dietrich is a frequent speaker at conferences worldwide and his articles promoting safety aspects of powder handling have been published in scientific journals. Mr. Dietrich holds a Master of Science (MSc) in Mechanical Engineering (Swiss Federal Institute of Technology Lausanne/EPFL).

## F

### Gordon Farquharson

Gordon Farquharson, B.Sc.(Hons), C.Eng. is a Chartered Consulting Engineer with more than 35 years experience of quality & safety critical processes and facilities used by industries such as Healthcare, Life Science, Micro-electronics, etc. He is Principal and Managing Director of Critical Systems Ltd, an international consultancy firm with partnerships with PharmOut Pty Ltd, a consulting business based in Australia, FactoryTalk based in Thailand, and CM Plus Corporation of Japan.

He has focused on technologies such as isolators, barrier technology, mini-environments, critical utility systems and bio-containment applications. He has been responsible for the development of technical solutions in product development, primary manufacturing and device and dosage form manufacturing.

Standards and regulatory compliance issues in the Pharma/Life Science sectors are a major interest and responsibility. In this context he has a high degree of expertise in the practical interpretation & application of EU/PIC-S/WHO GMPs and US FDA cGMP requirements. Experience with the variation in expectations gives him an ability to dovetail the differing regulatory requirements. In recent years, he has been heavily involved in the development of the new regulatory guidance and standards. In particular, he is active working on CEN/ISO Cleanroom & Contamination Control Standards, WHO GMP guidance and ISPE Baseline Guides. He is Chairman of BSI's LBI 30 Committee and of CEN Technical Committee 243, and was Convenor of WG1 and a UK expert working on the ISO TC209 and CEN TC243 family of contamination control standards that provide the platform for contamination control standardisation and practice in this millennium. He has worked with the EMA in London to help update and improve the cleanroom classification and monitoring requirements in Annex 1 of the EU and PIC/S GMPs and has contributed writing WHO's Pharmaceutical water GMP Guidance and the revision of the WHO GMP guidance on sterile products.

He is a founding member, management committee member, past Chairman, and Honorary Member of the UK Pharmaceutical & Healthcare Sciences Society (formerly Parenteral Society), and was Editor in Chief of the European Journal of Parenteral & Pharmaceutical Sciences. He is also active in ISPE, the R3 Nordic Association, and PDA. He is a past chair of the ISPE European Education Committee and was voted ISPE International Member of the year 2001, UK Affiliate Member of the year in 2008, and recipient of the Richard B Purdy Distinguished Achievement Award 2009. He was a member of the PDA Science Advisory Board (SAB) and is an honorary senior lecturer at UCL (London) and the University of Manchester PEAT & PIAT programmes.

He lectures and teaches extensively, is an author of many papers, and contributor to books on cleanroom and isolator technology, as well as practical engineering interpretation of GMP philosophies.

## H

### Frans Mardi Hartanto, PhD.

Frans Mardi Hartanto

Education :

1986 Ph.D. in Management (Organization & Staffing, Training, and Development), Industrial Relations Center, Carlson School of Management, University of Minnesota, U.S.A.

1981 Master of Arts in Industrial Relations (MAIR), Industrial Relations Center, Carlson School of Management, University of Minnesota, U.S.A.

1964 -1965 Graduate Study at the School of Industrial Engineering, Georgia Institute of Technology, Atlanta, Georgia, U.S.A.

1964 Sarjana Teknik Mesin (Mechanical Engineering, specializing in Production Techniques), Bandung Institute of Technology, Indonesia.

Profession :

- Professor (Retired) of Management of the Department of Industrial Engineering and Management, Bandung Institute of Technology, Indonesia
- Management Consultant to various national corporations and the public sector.

Professional Associations :

- Academy of Management, U.S.A.
- American Psychological Association (APA), U.S.A.
- British Academy of Management
- INFORMS (Institute of Operations Research and the Management Sciences
- Country Chief Investigator of GLOBE (Global Leadership and Organizational Behavior)
- 1988 - 1998 - Dewan Produktivitas Nasional (National Productivity Council), Indonesia.
- 1993 - 1998 - Dewan Riset Nasional (National Research Council), Indonesia
- 1993 - 1998 - Dewan Latihan Kerja Indonesia (Indonesian Training Council), Indonesia.

## H

### Paul Wan Sia Heng, Professor

**Professor, Department of Pharmacy, National University of Singapore**

Dr Paul W S Heng has a basic degree in pharmacy and obtained his PhD from the National University of Singapore in 1985. He has since joined the Department of Pharmacy, National University of Singapore as a faculty member, and teaches pharmaceutical technology for three decades. He served as Head of Department for two terms, 2000-2004 and is the Principal Investigator for GEA-NUS Pharmaceutical Processing Research Laboratory, a research laboratory focused in process and product development related to pharmaceutical technology. Dr Heng has served several terms as Chairman of the Singapore's Quality Control Advisory Committee which saw the acceptance of Singapore as a member of the PIC/S. Dr Heng has undertaken several consultancy appointments in product manufacturing companies and has been involved in many new product developments and personnel training. His research interest is in pharmaceutical technology, especially research related to solid dosage forms, pellets and tablets. He has expertise with excipients, design of controlled release systems as well as in encapsulation technologies. He has successfully supervised / co-supervised over forty doctorate program students and has authored or co-authored over 270 international refereed research journal articles and has also written several book chapters and patents.

### Sia Chong Hock

**Director of Quality Assurance and Senior Consultant of Audit and Licensing at the Health Products Regulation Group of the Singapore Health Sciences Authority**

**Sia Chong Hock** holds a Bachelor's degree in Pharmacy from the National University of Singapore (NUS), as well as a Master's degree in Healthcare Management (with Distinction) from the University of Wales.

Currently, he is the Director of Quality Assurance and Senior Consultant of Audit and Licensing at the Health Products Regulation Group of the Singapore Health Sciences Authority. He is also an Adjunct Associate Professor with the NUS. At the supranational level, he is the Chairman of the ASEAN Joint Sectoral Committee (JSC) tasked with the implementation of a pan-ASEAN Mutual Recognition Agreement (MRA) on GMP Inspection. Periodically, Mr. Sia contributes review articles to ISPE's *Pharmaceutical Engineering* and other international scientific journals in the field of comparative pharmaceutical regulations for health products, including herbal medicines and health supplements, control of active pharmaceutical ingredients (APIs) and pharmaceutical excipients, supply chain integrity, and ASEAN harmonization on GMP Inspection.

In 2012, he was awarded the Pharmaceutical Society of Singapore Industry Pharmacist of the Year Award And in 2016, he received the International Pharmaceutical Society of Pharmaceutical Engineering (ISPE) Singapore Affiliate Lifetime Achievement Award for his contributions to the field of Pharmaceutical Regulatory Practices and for his leadership in driving the harmonization of GMP Inspection standards across the 10 Member States of ASEAN. And more recently, in 2017, an article which Mr Sia co-authored was named the winner of the ISPE *Roger Sherwood* Article of the Year 2016 Award.

## K

### Roland Krebs

Roland Krebs born and raised in Switzerland is Senior Manager Marketing & Sales in the business development department at Nagano Science Co., Ltd. In Osaka, Japan. He is chemist, holds a PhD in laboratory medicine and a bachelor degree in marketing and communication and 2011 a certified risk assessor at Nagano Science.

For more than 25 years Roland worked in various international pharmaceutical and diagnostic manufacturers and providers of analytical and scientific equipment and services for the pharmaceutical, biotech and life science industry and academia. He worked as sales representative, product manager, marketing and sales manager and managing director and acquired very good understanding and knowledge of international business operations at every level and developed excellent communication skills suitable to work successfully in international markets.

Since 1995 Roland works in emerging markets of Eastern Europe, Central Asia and Asia/Pacific and lives since 2000 in various countries of Asia (Kazakhstan, Malaysia and since 2013 in Japan). With working and living in emerging countries he has acquired excellent insight and knowledge about industrial development in emerging markets and understanding of fast changing customer needs in the pharmaceutical industry towards improving international manufacturing and quality assurance standards of GMP and ICH guidelines.

## I

### Muhammad Lukmani Bin Ibrahim

**Deputy Director, Head of Centre for Compliance and Licensing, NPRA, Malaysia**

**Education and training:** Bachelor of Pharmacy (Hons)

**Work experience:**

2010 – 2015
- Deputy Director Enforcement Division
- appointed by the Minister of Health as the Secretary to Malaysian Advertisement Board, Ministry of Health

1985 – 2010
- his scope of responsibilities cover most of the disciplines in Pharmaceutical Services, began with Human Resource (now known as Human Capital Development) in the Service's Head office, moving to State Enforcement, then to National Pharmaceutical Control Bureau (NPCB)

1984/1985
- Intern pharmacist, Kuala Lumpur Hospital

- To this date, he has done more than 50 paper presentations and deliveries within Malaysia and internationally

I

- Has more than three decades of experience in various disciplines in Public Pharmaceutical Services, of which was amongst the receipient of the excellent service award in the year 1995, 2002 and 2014

- As a senior public officer, he is focused on partnering with both internal and external 'clients' to develop, facilitate and manage variety of programmes in pharmaceutical services including in human capital program that is the essence of any organization's success Spent more than half of his career in NPCB and was in the Compliance & Licensing Centre for 13 years, started as auditor for Good Manufacturing, Distribution and Storage Practices (GMP/GSP/GDP) and Leading the centre for 2 years prior to his promotion as Deputy Director of Enforcement in 2010

- Has out reached international front through his work in ASEAN Regulatory Harmonization, WHO Consultant / Trainer on GMP and Committee of Officials (representing Malaysia) at Pharmaceutical Inspection Co-operation Scheme (PIC/S)

- He was one of the Lead Auditors that prepared and participated in the assessment for Malaysia's accession to PIC/s membership in 2001. The country was successfully acceded as of 1st January 2002 and Oct 2010 Lead the Centre for the Reassessment of NPCB's by the PIC/S Joint Reassessment Team.

- He was appointed as a Team Leader in developing Cosmetic GMP training modules In ASEAN Regulatory Harmonization work and the team has successfully developed 14 training modules that are utilized by ASEAN Regulatory Bodies and Industries. These modules contain the essentials and emphasize the simplicity, practicality and effectiveness in the production of safe and quality products, He is now the Chair for the AEAN GMP Task Force for GMP Guideline on TMHS. On the same platform; as a Chairman cum Resource person, the development of 15 GMP Training Modules for Traditional Medicines and Health Supplement in ASEAN Regulatory Harmonization.

- Panel of Expert (POE) for the JSC GMP MRA for ASEAN member states to accede as a Listed Inspection Services.

- The GMP/GSP/GDP framework compelled him to strategically partnered with other Public Services in Malaysia; Ministry of International Trade & Industry, Malaysian Industry Development Authority, Department of Islamic Development, Standard Department and Halal Development Corporation. He is still an active member of the Technical committee for MS 2424:2011 Halal Pharmaceutical Standards – General Guidelines

*Professional Recognition*

- 2018 – Invited speaker in IPFA 3rd Asia Workshop On Plasma Quality and Supply – "Technological, Regulatory and Organisational tools to produce plasma for fractionation – Berjaya Times Square, Kuala Lumpur
- 2018 - Chairperson cum Resource Person in the Asean Traditional Medicines and Health Supplements Good Manufacturing Practice Training Phase 2 Session 5 – Training of Trainers
- 2017 – Invited Speaker for 3rd Korean ASEAN GMP Cooperation Conference, Seoul, KOREA
- 2017 – Co Rapporteur for the PIC/S Assessment to become PIC/S Participating Authority on Saudi Arabia Food & Drug Authority
- 2017 - Chairperson cum Resource Person in the Asean Traditional Medicines and Health Supplements Good Manufacturing Practice Training Phase 2 Session 1 – Training of Trainers
- 2017 - Panel of ISPE Town Hall Meeting 2017

I

- 2017 - Resource Person of Working Group for revision of MS2200: Part 1:2008 – Islamic Consumer Goods – Part 1: Cosmetic and personal care – General Guidelines
- 2017 - Resource Person of Working Group for revision of MS2424:2012 – Halal Pharmaceuticals – General Guidelines
- 2017 - Resource Person of Working Group for development of Malaysian Standards (MS) under the scope of Halal Medical Devices
- 2016 – Panel of selection for Talent Grooming Programme (TGP) for Technical Healthcare Professional, MoH
- 2016 - Committee member for Halal Standard (ISC) in the Industry Standard
- 2016 - Committee member for DUNas Technical Component: Quality, Safety & Efficacy of Medicines
- 2016 - Committee member for Project PEMANDU – QUEST 3+
- 2016 - Resource Person and GMP Expert; The 23rd Asean Consultative Committee for Standard and Quality Pharmaceutical Product Working Group ( ACCSQ PPWG ) meeting
- 2015 - Committee member for Education and Event of ISPE Malaysia
- 2015 – Committee member for 'National Credentialing Committee'
- 2015 - Committee member for National Quality Management Audit Program in Medicine Practices, MoH
- 2015 - Committee member for Medical Device –Drug-Cosmetic-Interface (MDDCI), MoH
- 2015; appointed as Fellow Researcher at The Research and Halal Management Institute, Islamic Science University of Malaysia
- 2015 - Committee for the Development of `Code of Advertisement For Medical Devices
- 2015 - Panel of Judge for Pharmacy Enforcement Lestari Innovation Award 2015
- 2015 - Panel of Judge for Best Case Management Award in Pharmacy Enforcement 2015
- 2015 – Accreditor for My Health Portal - Advertisement of Prescription Medicines and Risk of Puchasing medicine through internet
- 2014 - Self Medication Collaborative ASIAN Regulator Expert Rountable Dicussion at Phuket, Thailand.
- 2011-2014 - Panel of Technical Evaluation & Commercialization of Techno-fund Grants, Ministry of Science and Innovations
- 2011 - Member of the Order of the Defender of the Realm (*Ahli Mangku Negara);* Malaysian Federal Award conferred for extraordinary and meritorious service
- 2011 - Technical Resource Person/Chair; to develop Good Distribution Practice (GDP
- 2011 & 2010 - Member of the NKEA Lab for Pharmaceutical and Halal Pharmaceutical
- 2010 - Resource speaker for `The Malaysian PIC/S Experience' organized by the Philippines Chamber of the Pharmaceutical Industry Inc. and ADIP QC Cooperative, Manila
- 2009 – 2010 - Member of 'Drafting Committee for MS 2424:2011 Halal Pharmaceutical Standards – General Guidelines'
- 2008 - 2010 - Member of PIC/S Working Group for Training of Inspectors
- 2008 & 2009 - Chairperson for the 1st and 4th GMP Task Force Meeting for the ASEAN Consultative Committee for Standard & Quality, Traditional Medicine & Health Supplement (TMHS) Product Working Group
- 2008 - Member of 'SIRIM Technical Committee in Developing Standards – Diaphragms for Contraceptive Use Specification (First Revision MMS 114: 2008)
- 2007 - 2009 - Co-chair and Delegate to the MRA GMP Task Force Meeting at 13th, 15th and 16th ASEAN Consultative Committee for Standard & Quality, Pharmaceutical Product Working Group
- 2007 - International Expert for GMP Cosmetic to moderate and facilitate the Regional Workshop – GMP Guidelines - Specific Guidance for Soap Industry in ASEAN
- 2007 - ASEAN Senior Expert for GMP at Advanced Regional Training on GMP for ASEAN member countries to implement the ASEAN Harmonized Cosmetic Regulatory Scheme
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## I

- 2005 – 2006 - ASEAN Senior Expert in cGMP implementation Task Force and Team Leader in developing cosmetic GMP training module for Regulatory Body & Industry
- 2005 - Resource person for the ASEAN-EU Program for Regional Integration Support Training in GMP and PIC/S requirements
- 2004 - Resource person for the 2nd Edition of Good Storage Practice (GSP) Guideline for the Manufacturer, Importer and Distributor of Registered Products and cosmetic
- 2003 - WHO Consultant/Trainer on GMP compliance for Department of Drug Administration, Ministry of Health, Nepal
- 2002 - WHO Consultant/Trainer in the Assessment of the Implementation of Cosmetic GMP Guidelines for Drug Inspectors of Philippines Bureau of Food & Drugs
- 1995 - Officer responsible to develop the 1st Edition of Good Storage Practice (GSP) Guideline for the Manufacturer, Importer and Distributor of Registered Products

## M

### Sergio Mauri

**Director, Marketing & Business Intelligence at Fedegari Group**

Sergio Mauri holds a Chemical Engineering degree. He has been involved in cleanroom technologies since 1980 and is currently, in charge of Marketing & Business Intelligence at Fedegari Group, after many years dealing with the design and the supply of new solutions for the sterile drug manufacturing including GMP robotics. His Scientific Technical Association activities include member of the board of the Italian association of contamination control (ASCCA: www.ascca.net) since 1986, President 2018-2020 term, and ISPE and PDA member since 2001. Promoter and responsible of the training course on “General introduction on Clean Room Technology, isolation concepts and critical parameters definition”. He is Trainer on pharmaceutical HVAC design for students of chemical and pharmaceutical technology at Italian Universities. Author of several papers on clean technologies and experienced giving training lectures to AIFA GMP Italian inspectors.

## M

### Anthony Margetts, PhD.

**Vice President of ISPE Thailand Affiliate**

Dr. Anthony Margetts is Principle Consultant for Factorytalk's Compliance department and a highly experienced and leading international Pharmaceutical and Chemical engineering practitioner and project manager with +30 years working experience in the chemical/pharmaceutical/medical device industries.

**Professional Qualifications:**

- BSc Chemical Engineering, Birmingham, UK, 1967
- PhD Chemical Engineering, Birmingham, UK, 1971
- Chartered Engineer 1979

**Relevant professional experiences**

As Principle Consultant, Dr Margetts leads key compliance consulting assignments. He is considered a global expert in the fields of GMP compliance and validation for the Pharmaceutical and regulated industries.

He worked for AstraZeneca (formerly Zeneca and ICI Pharmaceuticals) since 1988. He has been responsible for a variety of international projects, e.g. leading teams responsible for technical transfers, new product introductions and preparations for international, European and US FDA pre-approval and regulatory inspections. During his time at ICI/Zeneca/AstraZeneca he managed the introduction of new medical device products, including setting up global supply chains and ensuring their compliance to international standards.

During the 1990's he managed the introduction of new world-wide validation procedures and was the Chairman of a UK Pharmaceutical Industry Group charged with writing a Guideline on Computer Systems Validation which evolved over a number of editions and expanded from UK through Europe, USA and Japan and is now called the Good Automated Manufacturing Practice (GAMP) Guide. Dr Margetts was chairman for the editorial review of the latest version GAMP 5, published in 2008 which has now become the worldwide reference for Computer Validation in the Healthcare Industries.

## M

### Yanglin Mok

**Manager, Manufacturing Science and Technology, Merck Life Science, Singapore**

Yanglin Mok is the MSAT Manager of Merck Life Science, Singapore, with 12 years of experience in biotech industry. She provides consultation and hands-on support in process development, scale up and scale down of downstream processes. Yanglin was involved in several major biotech accounts start-up process implementation and troubleshooting support in Singapore and Asia Pacific region. She is also a certified trainer under the Singapore Government accredited WDA course for downstream processes. Yanglin holds a degree in Chemical Engineering from the University of Melbourne, Australia.

## P

### Michael Payne

**Principal Technical Consultant, Life Sciences/Biopharmaceutical Group Merck Millipore**

Michael is currently a Principal Biosafety Technical Consultant; his background is B.E. (Chem) (Bioprocess Engineering)

38 Years with Millipore/ Merck Millipore including

- 3 years as Global Biosafety Consultant
- 7 years as Regional Technical Consultant
- 7 yeas as Asian Validation Support Manager
- 10 years heading Global Technical Training Department

Written and executed qualification protocols and provided process and compliance reviews to regional and global pharmaceutical companies.

Presented to a number of regulatory agencies throughout Asia on areas of compliant filtration and separation processes

## S

### Christopher Sweeney

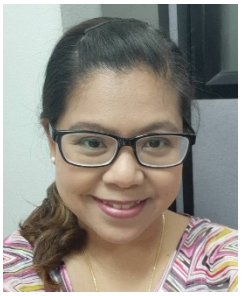
**A biopharma professional with over 30 years' experience in the industry**

He has worked in practically every aspect of the industry and can cover such diverse range of topics from cell line generation, cell bank generation, process development, Facility design, process design, validation, Quality Management System generation and implementation, cell culture, bioreactors, roller bottles, purification and fill finish.

In 2004 he was the EU GMP expert for ASEAN and trained the ASEAN Health Authorities in PIC/S GMP. These included Thai FDA, Philippine FDA, Indonesian BPOM and Vietnamese DAV

He designed, built, validated and started up our international multi award winning facility.

### Duangratana Shuwisitkul, PhD.



**Lecturer at Department of Pharmaceutical Technology, Faculty of Pharmacy, Srinakharinwirot University, THAILAND**

**Professional experience:**

| | |
|---|---|
| 2001 – present | Lecturer at Department of Pharmaceutical Technology, Faculty of Pharmacy, Srinakharinwirot University, THAILAND |
| 2004 – 2009 | Doctoral candidate at College of Pharmacy, Freie University Berlin, GERMANY, Co-advisor of the erasmus students and participation in some research projects |
| Apr 2012 and 2013 | Research experience in Faculty of Pharmacy, Ege University, Izmir, TURKEY )1 month( |
| Nov 2015 | Research stays for university academics and scientists, German Academic Exchange Service )DAAD(, College of Pharmacy, Freie University Berlin, GERMANY )2 months( |
| Feb 2016 | Research stays, Austrian Agency for International Cooperation in Education and Research )OeAD(, Institute for Pharmacy, University of Innsbruck, AUSTRIA )6 months( |

**Education:**

| | |
|---|---|
| 1996 - 2001 | B.Sc. )Pharm( )First honor( Faculty of Pharmacy, Mahidol University, THAILAND |
| 2004 - 2009 | Dr.rer.nat. )Pharmaceutical Technology( )2011( Freie University Berlin, GERMANY )Granted by the Royal Thai Government Scholarship from the Civil Service Commission( |

## T

### Bob Tribe

**PIC/S Former Chairperson**

Bob Tribe joined the Therapeutic Goods Administration (TGA), Australia in 1971 as a GMP inspector after having worked in the pharmaceutical industry in a senior Quality Assurance position. He became Chief GMP Inspector in 1980, a position he held until his retirement in 2004. While at TGA he was elected Chairman of PIC/S in 2000-2001.

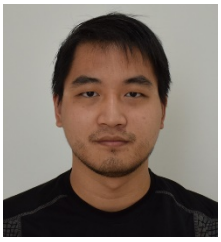
After retiring from TGA he established "Bob Tribe Consulting" and has assisted many GMP regulatory authorities around the world reach the PIC/S level of regulatory control. Of the 17 regulatory authorities that he has assisted to date, 12 have obtained PIC/S membership. He also consults to pharmaceutical manufacturers wishing to achieve compliance with PIC/S GMP requirements.

Bob is a member of the WHO Expert Committee on Specifications for Pharmaceutical Preparations and undertakes GMP inspections for the WHO under its Pre-qualification Programme.

He is also the ISPE Regulatory Affairs Advisor for the Asia-Pacific region.

## V

### Wittawat Viriyabancha



**Thai FDA pharmacist, Bureau of Drug Control, FDA Thailand**

Wittawat Viriyabancha is a pharmacist in Biological Product Unit in Bureau of Drug Control at Thailand Food and Drug Administration; known as "Thai FDA". He is working on both biological product registration and regulatory system development for biological products. By now, he serves as a focal point from Thai FDA to work on Advanced Therapy Medicinal Product (ATMP) regulatory system establishment in Thailand.

Due to the trend and emerging of newly developed technology used in my rare or severe diseases, he is interested in research and development for advanced technology used in medical fields as a way to serve unmet medical needs or give better efficacy compared to existing therapies. He also likes to hear stories about new techniques and technologies used in production for biological products as well as global trend for regulatory science concerned about biological products.

With his 5 years' experience, he has involved in a wide range of work in a field of regulatory science for biological products from National Drug Policy Unit for the policies related to biological or biotechnological products to Biological Product Unit where he is currently working in. He took part as a co-researcher in a research of Thai FDA

## V

funded by the National Research Council of Thailand in order to strengthening and improving Thailand's regulatory system specifically for biological products, and also, he has collaborated in research of university research units in Thailand for drug discovery and development.

Wittawat received his bachelor's degree in PharmD program from Chulalongkorn University, Thailand, and earned his master's degree in Pharmaceutical Science from University of Southern California, USA, where he got his graduate certificate in Regulatory and Clinical Affairs at the same year of his master.

## W

### Dr. Tin Wah Wah Win

**Deputy Director (Drug), Department of Food and Drug Administration, Myanmar**

Education : M.B., B.S, M.Med.Sc (Pharmacology)

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|---|---|---|
| Working Experience : | 2000-2004 | Medical Officer in Hospital |
| | 2005-2009 | Drug Control Officer in FDA |
| | 2010-2012 | Assistance Director (Drug) in FDA |
| | 2013-Present | Deputy Director (Drug) in DFDA |

## W

### Pierre Winnepenninckx

**Past Chair of ISPE Asia Pacific and Chair ISPE Singapore Conference 2017**

With a degree in chemistry and chemical engineering, Pierre combines the scientific mindset with the practical approach of the engineer. Applying analytical skill and practical sense has proved the perfect fit for design and commissioning activities in a field that requires accuracy and productivity. After working in several projects around Europe as consultant for one of the leading pharmaceutical company, he opened his own service company in 2007, and is currently providing services on 3 different projects in Singapore and China. He believes in People skill and manages them at their best, to optimize the available competences. His customer is his concern, whom he advises and supports throughout all project phases, according to identified needs.