

SPEAKERS LIST**A****VIVIANNE J. ARENCIBIA****Arencibia Quality Compliance Associates
Independent Consultant, USA**

Vivianne Arencibia is President of Arencibia Quality and Compliance Associates, LLC based in the Northeast. She brings over 30 years of global leadership, regulatory remediation and compliance experience to the ISPE community. Her prior experience was with Novartis, where she held a variety of leadership positions, most recently as the Global Head of External Engagement for Group Quality at Novartis. Since assuming this role in 2017, Vivianne is responsible for the strategic global engagement plan for GxP related matters across trade, member-based and standards setting organizations. Vivianne joined Novartis in 1997 as a QA Manager in Manufacturing and has since then assumed leadership positions of increasing responsibility across multiple GxP disciplines. Following her initial appointment, Vivianne served as Global Head of Clinical Quality Assurance, Development; Global Head Group Quality Compliance and Audit; and Global Head, Step Change, Integrity and Compliance. Throughout her tenure with the Novartis, Vivianne developed strong relationships with industry associations, trade organizations and regulators, worldwide. Vivianne has been a dedicated ISPE member since 1991. She is currently a member of the RQHC North America Regional Focus Group, Women in Pharma and GPMLF. Within Novartis, Vivianne provided strong advocacy for ISPE and participated in activities such as planning committees for ISPE meetings and as a speaker on industry current topics. She has sponsored Novartis involvement on the Quality Metrics ISPE working group and ISPE's Young Professionals program. Vivianne is passionate about the development and mentoring of future industry leaders and as such is a strong advocate for ISPE's efforts within Novartis and among industry peers. Additionally, Vivianne facilitated the coordination of financial and conference sponsorships for over 400 ISPE members employed by Novartis. Vivianne holds a Bachelor's degree in biomedical engineering from the New Jersey Institute of Technology and has completed several business and leadership development programs at Harvard University, Dartmouth University, and at Bürgenstock, Switzerland.

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SUCHART CHONGPRASERT, PH.D.**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.

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.

BOB CHEW**President & CEO, Commissioning Agents Inc, USA**

In addition to serving as the company's President and CEO, Robert Chew is an internationally recognized compliance consultant in the areas of risk-based qualification, validation, ASTM E2500 (key author of that standard), and ICH-Q9, Quality Risk Management. Mr. Chew has provided quality risk management consulting to some of the largest pharmaceutical and biotechnology companies in the world. Over the past decade, he has spoken at international conferences in the US, Europe, Asia, and South America. He is an official trainer for ISPE's Commissioning and Qualification Baseline Guide. Mr. Chew is an industry leader in creating value-added approaches to qualification. He was ISPE's 2008 Member of the Year. He is a member of the Global Pharmaceutical Manufacturing Leadership Forum. He is the chief architect and prospective patent holder for the company's BioVoke™ GMP Information Management Suite.

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CHRIS CHEN, PHD**CEO, WuXi Biologics (Shanghai) Co., Ltd., China**

Dr. Chris Chen is currently Chief Executive Officer at WuXi Biologics, leading a 1500-member team providing end-to-end biologics services to global partners. At WuXi he has built a world-class open-access integrated mab discovery, development and manufacturing platform serving full spectrum of companies ranging from virtual companies to 12 large pharma. Under his leadership, WuXi has assembled one of the largest biologics development teams with over 700 scientists enabling 40 global INDs in two years. WuXi is also currently building the largest disposable-bioreactor based state-of-the-art commercial manufacturing facility totaling 30,000L bioreactor capacity in the world. He obtained his dual bachelor degrees of chemical engineering and automation at Tsinghua University, Beijing China and his Ph.D. in chemical engineering at the University of Delaware, US. He then gained valuable experience in process development, manufacturing, technology transfer, process validation, quality, and regulatory in the US, where his previous assignments include director and manager positions of bioprocess development, technical service, and pilot plant operations at Lilly and Merck. Dr. Chen later joined Shanghai Celgen Biopharmaceuticals as Chief Operating Officer, successfully developed a high-titer high-quality commercial process for biosimilar Enbrel, and obtained regulatory approval for the program in China in 2011. He chaired multiple conferences in biochemical engineering and mab development in US and China and is frequently invited to speak at multiple conferences. He is also adjunct professor at Shanghai Jiaotong University. Dr Chen is co-author and co-inventor of 40+ publications and patents.

SHAW CHEN**GS1 Thailand**

Shawn Chen is a GS1 Thailand's Section Manager, and taking care of four departments, Industry Engagement, Marketing, AIDC/Training, and Commercial Services. He has over 20 years experienced on consulting, researching, networking, sales, barcode and RFID territories, and including the eight- year experiences in GS1 community.

Shawn Joined Industrial Technology Research Institute of Taiwan, R.O.C (ITRI) in 2009 to hold Long Term Evolution (LTE) project for two years. In the end of 2010, Shawn was working for GS1 Taiwan as a project manager for handling projects that related to GS1 standards such as Barcodes, RFID, and the Internet of Things. Furthermore, he was responsible for providing the barcode and RFID solutions to supply chain, government and healthcare sector.

In GS1 Career, Shawn has assisted GS1 Global Office to build up barcode verification expert group. Due to his experiences, he recruited MCSE, MCDBA, MCSA, MCP and CCNA certificates.

G

SOMASUNDARAM G.



Associate Director, SE Asia & Oceania Technology Management, Singapore

Somasundaram, heads a Technology Management Group for Singapore, South East Asia & Oceania. He is based in Singapore supporting customers in product adoption, customer training & applications. Earlier to this assignment Som was based in Bangalore doing similar role for Indian subcontinent.

Som has worked in different functions within Merck for the last 16 years in Tech Service, Provantage Lab, Sales & Business Development areas. He also worked for a year in QA/QC & one year of academic experience in Microbiology.

Som has M.Phil in Food & Industrial Microbiology & Post graduate in Business Management. **Som** leads the Technology Management team for SEA & ANZ and has been with Merck for 16 years. His areas of expertise include Aseptic Processing and Single-use processing. He is also responsible for the customer training in Singapore. Prior to Merck, Som taught Microbiology at Bangalore University and has an experience in QA/QC in a pharmaceutical company.

Som has a Master of Philosophy in Food and Industrial Microbiology.

H

PAUL WAN SIA HENG, PHD



**GEA-NUS Pharmaceutical Processing Research Laboratory
Department of Pharmacy, National University of Singapore**

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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 fifty doctorate program students and has authored or co-authored over 285 international refereed research journal articles and has also written several book chapters and patents.

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ASHOK KUMAR N.

**Head - Mobius Single Use Solutions, India and South East Asia,
Merck Life Sciences Pvt. Ltd,**

Ashok Kumar leads the Single Use technology team for India, South East Asia and has been with Merck for 9 years. His areas of expertise include Single-use processing. He is also responsible for customer training in India and Singapore.

Prior to Merck, Ashok was a Process Engineer at Sartorius Stedim India and had held the responsibility for all custom engineered Fermentation systems.

Ashok has a Master of Science in Biotechnology and also holds the master degree in Operations and Marketing Management.

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MAULICE PARLANE

Principal/Director, New Wayz Consulting Ltd, Australia

Maurice Parlane is Principal of New Wayz Consulting Ltd in New Zealand and a Director of CBE Pty Ltd in Australia. He is a professional engineer with 30 years' experience within the biopharmaceutical industry, including 20 years as an industry consultant providing support to manufacturing and compliance management; validation and operational excellence projects in Australasia and the Asia Pacific region. Prior to this, he held senior engineering and manufacturing roles within the Glaxo group of companies. He has a Bachelor of Manufacturing Technology (Hons) as well as mechanical and electrical engineering qualifications.

Maurice is past president and current director of the ISPE Australasian Affiliate. He is the co-lead of ISPE's Asia Pacific Regulatory and Quality Harmonization committee and leader of the Process Validation Team and is a member of the Guidance Documents Committee. He is an ISPE PV Instructor and was named ISPE Member of the year in 2016.

R

RAMESH RAJU

**Head of BioReliance® validation lab
Merck India**



Ramesh Raju. In the current role as the Head of BioReliance® validation lab India operations at Bangalore, Ramesh is accountable for providing the best-in-class services to the Biopharmaceutical manufacturers in Asia Pacific, LATAM and India. His key strengths and experience include the aseptic processing of sterile pharmaceutical dosage forms and validation of aseptic filtration process in the biopharma industry. In his earlier role at Merck, Ramesh was heading the technology management team for India focussing on the strategic and tactical planning for classical pharma and biotech markets.

By academic qualification he is master's in pharmacy (Industrial Pharmacy), Mysore University, India and MDP from SP Jain Institute of Management & Research, Mumbai. Currently following Doctorate Program from Kuvempu University.

V

BART VANSTEENKISTE

Domino, UK



Bart Vansteenkiste has worked for Domino for over 17 years in different commercial roles. A master degree of Electromechanical Engineering and his former role as Pharmaceutical and OEM key account manager for Belgium gave him the perfect background to join the head quarters based FMD group in 2011. Within this group Bart has been focussing on the legislative and technical challenges facing the healthcare sector. Bart regularly attends and presents at conferences on behalf of Domino.

- Bart is fluent in Dutch, English, French and Spanish which is a big benefit in his current role, advising Domino's customers and sales channels on the implications of the legislative requirements and the implementation of 2D coding, serialisation, aggregation and Track & Trace projects. Bart works in close co-operation with a number of leading OEM partners in Germany and Italy and with trade associations like EFPIA and the EGA.
- Since February 2016 Bart has been appointed Global life sciences sector manager, taking the lead for developing Domino's Life Sciences business and strategy. Bart also liaises with Domino's pharma key accounts.

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SABRINA XU



Head of Single Use Technology APAC in Merck Life Science

Sabrina works in Merck life science as head of single use technology, mainly lead the team to provide the best solutions for Biopharma companies, from upstream to downstream, how to use single use technology to save cost, improve efficiency, delivery the safety drugs. Before this role, Sabrina worked as associate director in APAC for Emerging Biotech development, during that period, she helped lots of Emerging biotech companies to get financial support from VC, and helped them solve the toughest problem when their drug from discover to development to production. Sabrina worked in Merck life science since 2010 and supported Sanofi, GSK, Novartis, BI Pfizer, Eli Lilly, build their facility, smoothly tech transfer and complete the drug registration etc. Sabrina understood the application and challenge in vaccine, mAb, Gene therapy development and manufacture production. Her knowledge and experience will help more and more companies to optimize their process and accelerate their drug discovery to manufacture production.