GMP/GMP-EU Workshop

6-7 November 2025, Le Méridien Saigon Hotel

Draft Programme

6 November, Thursday

8.30 Registration

9.00 Welcome

Andreas Kappler, Chair, Memberships, ISPE Singapore & Head Vertical Management Pharma ASEAN, Siemens, Singapore
VNPCA, DAV

9.15 Presentation
VNPCA Member Company

GMP Regulatory Overview

9.45 Harmonisation and Reliance of (EU-GMP, PIC/S, US FDA & WHO) GMP Requirements – Benefits for Industry
Vee Revithi, Senior Consultant to Pharmaceutical Regulatory Authorities on GMP, GDP; Greece

10.05 Recent Changes to Part 1 of the EU and PIC/S GMP Guides
Vee Revithi, Senior Consultant to Pharmaceutical Regulatory Authorities on GMP, GDP; Greece

10.30 Morning refreshment

11.00 Recent changes to Annex 1 to the EU and PIC/S GMP Guides
Bob Tribe, APAC Regulatory Affairs Advisor, ISPE Singapore, Australia

Quality and Safety

11.25 Modular Pharma Facilities: the Future of Scalable, Safe and Compliant Manufacturing Chen Jie, Technical Business Manager, **Morimatsu Pharmadule**, Singapore

All presentations will be available for download 1

Audit and Compliance

11.50 Cruciality in Implementing GMP Audits Dr. Nizamil Fairuz Yahya, Managing Director & Principal Consultant, **PharmEng Technology** Malaysia

12.15 Lunch

1.30 How to Work Best with Regulatory Agencies – Compliance Do's and Don'ts
Vee Revithi, Senior Consultant to Pharmaceutical Regulatory Authorities on GMP, GDP; Greece

2.00 Media Fill – Lessons Learnt from Latest Regulatory Observations
Richard Chai, Senior Technical Service Manager, **STERIS Corporation**, Singapore

2.30 From Data to Insights: A Risk-Based Approach to Compliance Monitoring
Sheng Sheng Su, Sr Pharma Market Development Manager ASEAN, **Waters Pacific**, Singapore

3.00 Afternoon refreshment

Quality, Compliance & Regulatory Readiness

3.30 Managing Regulatory GMP Inspections by EU and PIC/S
Bob Tribe, APAC Regulatory Affairs Advisor, **ISPE Singapore,** Australia

4.00 Discussion followed by Q&A: Making Safe Medicines: GMP, Quality, and Compliance Working Together
Day 1 Speakers

5.30 End of day 1

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7 November, Friday

9.0 Opening Remarks
Andreas Kappler, Chair, Memberships, ISPE Singapore & Head Vertical Management Pharma ASEAN, Siemens, Singapore

Technology & Digital Applications for GMP

9.10 Ensuring Compliance in Less Time with Digital Solutions
Vissarut Saksureemongkol, Sales Manager, **Factorytalk**, Thailand

9.30 Smart Tools for Smarter Compliance: Digitalizing EU-GMP with eQMS, MES & LIMS
Krishna Chaitanya, Industry Expert - Pharma & Life Sciences, **Yokogawa Engineering Asia**, Singapore

9.50 Transforming Manufacturing Operations: How to Successfully Implement EBR and MES Systems
Piyaras (Ning) Uboldejpracharak, Head of Sales & Marketing, Asia, **Koerber Pharma Software**, Thailand

10.10 Step-by-Step Guide to Replacing Paper Processes in Your GLP Lab with LIMS
Chamnong Ingsathit, ASEAN Sales Manager, **LabWare**, Thailand

10.30 Morning refreshment

11.00 Digital Transformation of the Laboratory Landscape
Thomas Kamrat, Product Manager of AP Connect, **Anton Paar GmbH**, Austria

11.20 Building an Effective Contamination Control Strategy (CCS) for Sterile Filtration: Expectations and Best Practices
Anand G Ibrahimpur, Senior Manager, Fast Trak™ Validation Services; APAC., **Cytiva,** India

11.40 Apply Cutting-Edge Multiple-Use Packing Solution to Protect Temperature-Sensitive Pharmaceuticals
Marcus Guilhem, CEO, **Cargoteam Pharma**, Vietnam

12.00 Discussion: When GMP Meets Digitalization: Are We Just Checking Boxes—or Creating Real Business Value?

12.30 Lunch

1.45 Cleaning & Disinfection – Annex 1 Requirement & Lessons Learnt from Regulatory Observations
Neo Aik Ann, Area Director &
Richard Chai, Senior Technical Service Manager
STERIS Corporation, Singapore

2.45 Afternoon refreshment

3.15 Audience Open Q&A

4.45 Concluding remarks; end of Workshop
Group photo

Questions may be submitted in writing before and at any time during the event
Submit questions here

About ISPE https://ispe.org/

The International Society for Pharmaceutical Engineering is the world's largest not-for-profit association serving its Members by leading scientific, technical and regulatory advancement throughout the entire pharmaceutical lifecycle. ISPE Singapore Affiliate has over 500 members and is a major enabler of the local manufacturing industry

Speaker Bios

Andreas Kappler, Chair, Memberships, **ISPE Singapore** & Head Vertical Management Pharma ASEAN, **Siemens Pte Ltd**, Singapore
Andreas leads the Pharmaceuticals & Chemicals vertical at Siemens ASEAN. With over a decade of global experience in driving large-scale digitalization and process automation initiatives, he is a recognized expert in transforming operations within the pharma and chemical sectors.

Vee Revithi, Senior Consultant to Pharmaceutical Regulatory Authorities on GMP, GDP; Greece Senior international Consultant to GMP regulatory authorities. Vee has worked as Head of the Inspectorate in the Medicines Authority of Greece for more than 3 decades, involved in EU meetings and procedures. Has also participated in PIC/S, and managed Greece's EOF assessment by PIC/S. Vee has also worked in ROCHE, Switzerland for 5 years, assisting the implementation of GMP regulations by the industry.

Bob Tribe, APAC Regulatory Affairs Advisor, **ISPE Singapore,** Australia
International Consultant to GMP regulatory authorities. Has assisted and currently assisting many regulatory authorities around the world to obtain PIC/S membership. Former Chairman of PIC/S. Former Head of GMP at TGA, Australia.

Chen Jie, Technical Business Manager, **Morimatsu Pharmadule**, Singapore
Chen Jie has over 7 years of engineering experience with a strong background in pharmaceutical facility project development, including design, construction, and compliance.

Dr. Nizamil Fairuz Yahya, Managing Director & Principal Consultant, **PharmEng Technology** Malaysia
With over 25 years experience, Nizamil has led start-up plant commissioning and qualification across Malaysia, Singapore, and Indonesia, managing technology transfer projects from construction to FDA and ISO approval. His expertise spans C&Q, process validation, cleaning validation, CSV, and serialization in pharmaceutical and medical device industries, with capabilities in SOP development, CAPA management, and regulatory compliance.

Richard Chai, Senior Technical Service Manager, **STERIS Corporation**, Singapore
Richard provides technical support and training to customers related to contamination control for cleanrooms, process equipment cleaning process and sterility assurance & maintenance. A frequent industry speaker, he has more than 20 years of pharmaceutical industry experience in manufacturing, validation, consultancy and technical support.

Sheng Sheng Su, Sr Pharma Market Development Manager ASEAN, **Waters Pacific**, Singapore
Supporting customers across the ASEAN region, with deep insight into the challenges faced by regulated industries, Sheng Sheng is dedicated to empowering organizations enhance compliance and operational efficiency. He collaborates closely with customers to explore and implement new technologies that foster innovation and support sustainable growth in regulated environments.

Vissarut Saksureemongkol, Sales Manager, **Factorytalk**, Thailand
Vissarut leads digital solution accounts and has driven key initiatives, introducing eQMS and EBR to a range of clients, from start-ups and global pharmaceutical companies to government regulatory agencies.

Krishna Chaitanya, Industry Expert - Pharma & Life Sciences, **Yokogawa Engineering Asia**, Singapore
With 20 years' experience in GMP Manufacturing, Quality Compliance, Data Integrity, Validation and Digital Transformation, working with Pfizer, Roche, MSD, AbbVie, Samsung Biologics and Dr. Reddy's. Krishna supports co-innovation in Pharma, F&B & Life Sciences, solving process bottlenecks with digital transformation and driving smart industry readiness with quality compliance at the core.

Piyaras (Ning) Uboldejpracharak, Head of Sales & Marketing, Asia, **Koerber Pharma Software**, Thailand
In her role for 5 years, based in Bangkok, Piyaras has a Bachelor degree in Business Administration and a Master's degree in Strategic Marketing in the UK. She provides consulting and technical sales support to Pharma/ Biotech customers in the Asia region.

Chamnong Ingsathit, ASEAN Sales Manager, **LabWare**, Thailand
Since joining LabWare in 2011, Chamnong has played a key role in supporting the ASEAN business team, contributing to LIMS projects across the pharmaceutical, food, service laboratory, clinical diagnostics, and clinic sectors.

Thomas Kamrat, Product Manager of AP Connect, **Anton Paar GmbH,** Austria
Thomas studied Technical Chemistry at Graz University of Technology. With professional experience in Quality Management and Regulatory Affairs in the cosmetic industry, he set his focus as a recognized expert in digitizing the laboratory landscape. He is currently Product Manager of AP Connect, Anton Paar's innovative lab software.

Anand G Ibrahimpur, Senior Manager, Fast Trak™ Validation Services; APAC., **Cytiva,** India
With over 18 years in the pharmaceutical industry, Anand brings deep expertise in aseptic processing, filtration, GMP, and validation. He leads Cytiva's APAC validation services team, supporting pharma and biotech clients across the region.

Marcus Guilhem, CEO, **Cargoteam Pharma**, Vietnam
Marcus, with 20+ years in logistics and a strong pharmaceutical background, founded Cargoteam Pharma in 2018. Under his leadership, it has become a key player in specialized pharmaceutical logistics in Vietnam, ensuring safe, efficient, and compliant transport of medicines, clinical trials, biological samples, and medical equipment.

Neo Aik Ann, Area Director, **STERIS Corporation,** Singapore
Neo currently manages the Formulated Chemistries products for Asia Pacific. He provides commercial, supply chain and technical support for customers in the region, providing solutions for their requirements in cleaning, disinfection and sterilization.

This workshop is supported by: