# GMP/EU-GMP WORKSHOP 2026 -

## From Compliance to Proactive Quality Management

5-6 November 2026

Mai House Saigon Hotel

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## DRAFT PROGRAMME

## Thursday, 5 November 2026

8.30 Registration

**9.00 Welcome**

**- Shanshan Liu**, International Board Director, **ISPE**,
Conference Chair, **ISPE Singapore** & Global Process Science and Regulatory Director, **Fedegari**
- Representative of **VNPCA's** Leaders
- Representative of **DAV's** Leaders

### GMP Regulatory Overview

**9.15 Variation Updates, and Changing Trends according to GMP/EU-GMP**

**Differences in the Requirements of EU-GMP/PIC/S-GMP for Medicin & Sterile Medicinal Products**

**9.45 EU- GMP Annex 15 & Annex 19 Updates**
**Shanshan Liu**, International Board Director, **ISPE**, Conference Chair, **ISPE Singapore** & Global Process

10.15 Morning refreshment

**10.45 Current C&Q Approach and Introduction of E-Document & GMP Research Systems**

- Current C&Q approach in compliance with WHO and PIC/S GMP Annex 15
- Contamination Control Strategy (CCS), including microbiological contamination control

**Tahara Shigehiro**, Senior GMP Consultant, **CM Plus Corporation,** Japan
**Bui Thi Hong Loan**, GMP & Validation Assistant, **CM Plus Vietnam**

**11.15 Inspection Process in Line with USFDA and EMA Guidelines**

- Including Audit Trails and Data Integrity

**Shanshan Liu**, International Board Director, **ISPE**, Conference Chair, **ISPE Singapore** & Global Process Science and Regulatory Director, **Fedegari**

**11.45 GMP Annex 1 Reshaping Aseptic Fill-Finish Equipment and Processes for Vials and Syringes**
Revised EU- GMP Annex 1 is transforming aseptic filling through risk-based contamination control, automation, reduced human intervention, and enhanced sterility assurance.
**Giacomo Guidi,** Aseptic Processing Specialist, **IMA LIFE,** Italy

12.15 Lunch

### Computer System Validation & Pharma 4.0

**1.45 Computer System Validation, Classification & Data Integrity in Practice**
Beyond theory, how to get started, priorities, how to leverage GAMP & classification.

**2.15 Transforming Quality with Digital QMS for Life Sciences Manufacturing**
Lessons from project implementations in Vietnam and ASEAN, how it differs.
**David Margetts**, Group Executive Director, **Factorytalk**, Thailand

**2.45 QMS / CSV Case study**
**DHG Pharma**

3.15 Afternoon refreshment

**3.45 Data Integrity and Inspection Readiness**
**Dea Marsendah**, Head Department, **PT Biofarma**, Indonesia

**4.15 Discussion followed by Q&A: Making Safe Medicines: GMP, Quality, and Compliance**
Day 1 Speakers

5.30 End of day 1

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*All presentations will be available for download 1 week before the event*

# DRAFT PROGRAMME
# Friday, 6 November 2026

9.00 Opening Remarks

## Quality & Safety

**9.10 Best Practices in Material Transfer Process**

- Regulatory requirements on Contamination Control in material transfer process.
- Identification and management of contamination risks in material transfer in GMP environment.
- Case studies in material transfer process

**Richard Chai**, Senior Technical Service Manager **STERIS Corporation,** Singapore

**9.40 Mitigating Biofilm Formation in Pharmaceutical Manufacturing Systems**
Understand the risks associated with biofilm contamination and the strategies for biofilm remediation in process equipment.
**Neo Aik Ann**, Area Director, **STERIS Corporation,** Singapore

10.15 Morning refreshment

**10.45 EU GMP Annex 1 Implementation and Practical Considerations in Aseptic Manufacturing**
**Dea Marsendah**, Head Department, **PT Biofarma**, Indonesia

## HVAC & Environmental Controls

**11.15 Overview of Sterile Manufacturing HVAC & Environmental Controls**
Terminal Sterilization Cleanroom and HVAC System

**11.45 Aseptic Processing Cleanroom and HVAC System**

- Barrier and Isolation Technology : RABS , Isolator
- Special Equipment : BFS, FFS, Robotics
- Biosafety, Potent and Hazardous consideration

**Totsapon Santitewagun**, President, **ISPE Thailand Affiliate** & Managing Director, **Global Tech Co**; Thailand

12.15 Lunch

**1.45 Cleanroom Classification and Cleanroom Monitoring Including Airflow Visualization**
**Totsapon Santitewagun**, President, **ISPE Thailand Affiliate** & Managing Director, **Global Tech Co**; Thailand

**2.15 Discussion: EU- GMP Annex 1 & Annex 15: From HVAC Qualification to Contamination Control—Practical Strategies for Sterile Manufacturing**
Mr. Nguyen Van Vien – Head of the Drug Quality Management Division, Drug Administration of Vietnam (DAV) & All speakers

2.45 Afternoon refreshment

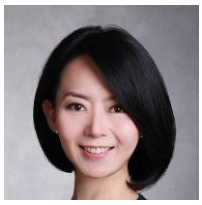
3.15 **Audience Open Q&A –**
Mr. Nguyen Van Vien – Head of the Drug Quality Management Division, Drug Administration of Vietnam (DAV) & All speakers

4.45 Concluding remarks; end of Workshop
Group photo

*Questions may be submitted in writing before and at any time during the event. Submit 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.

## About the Speakers



**Shanshan Liu**, International Board Director, **ISPE**, Conference Chair, **ISPE Singapore** & Global Process Science and Regulator Director, **Fedegari,** Singapore
Shanshan leads the advancement of manufacturing systems for emerging and complex modalities and collaborates closely with global regulatory authorities. Over more than 20 years, she has held technical and consulting roles across major pharmaceutical organizations, including Novartis, and expanded her expertise into quality, compliance, and regulatory strategy, partnering with manufacturers and regulators worldwide to strengthen quality systems, address compliance risks, and support innovation in life sciences.

**Tahara Shigehiro**, Senior GMP Consultant, **CM Plus Corporation,** Japan
Senior GMP consultant with over 40 years of experience in pharmaceutical engineering, GMP consulting, and project management. Extensive expertise in designing, validating, and managing API, sterile, medical device, and manufacturing facilities across Japan, Singapore, Vietnam, Indonesia, and the United States, ensuring international GMP compliance.

**Bui Thi Hong Loan**, GMP & Validation Assistant, **CM Plus Vietnam**
Over 15 years of experience in pharmaceutical Quality Assurance, Quality Control, GMP, and Validation. Strong expertise in CSV, qualification, validation, and sterile manufacturing projects. Proven ability to lead cross-functional projects, support GMP compliance, and improve quality systems in multinational pharmaceutical companies.

**Giacomo Guidi,** Aseptic Processing Specialist, **IMA LIFE,** Italy
Giacomo is an expert in aseptic processes and a strategic marketing leader at IMA LIFE, a division of the IMA Group. With over 20 years of experience in barrier technology, he has focused on aseptic processing and sterility assurance for sterile pharmaceutical and radiopharmaceutical injectable drugs. His work has been dedicated to advancing drug product fill-finish operations by integrating automation, high-containment systems and regulatory compliance. He is actively pushing the evolution of aseptic technologies, offering expertise in process design, cutting-edge decontamination solutions and Pharma 4.0 digital transformation

**David Margetts**, CEO, **Factorytalk**, Thailand
An advisor, consultant, and technical expert in compliance and information technology, David's wide experience spans IT solutions for GxP applications. In Asia since 2004, he helped to start Factorytalk, worked in engineering and validation for Industrial Technology Systems Ltd., engineering roles for AstraZeneca and was Asia MD for Werum/Koerber Pharma. David is an ISPE certified trainer for computer validation.

**Dea Marsendah**, Head Department, **PT Biofarma**, Indonesia
With over 15 years of experience in GMP manufacturing and workforce capability development, Dea is passionate about leveraging human factors, learning frameworks, and quality systems to enhance contamination control, strengthen quality culture, and drive sustainable operational excellence.

**Richard Chai,** Senior Technical Service Manager, **STERIS Corporation,** Singapore
Richard has been providing technical support and training related to contamination control for cleanrooms and process equipment cleaning & sterilization process. Richard has more than 20 years of pharmaceutical industry experience in manufacturing, validation, consultancy and technical support.

**Aik Ann Neo,** 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.

**Totsapon Santitewagun**, President, **ISPE Thailand Affiliate** & Managing Director, **Global Tech Co**; Thailand
A founding contributor who helped establish the Thailand branch of the International Society for Pharmaceutical Engineering over two decades ago. He serves as an ISPE Qualified Instructor specialized in Heating, Ventilation, and Air Conditioning (HVAC) systems for pharmaceutical environments.

(Panel discussion)
**Dr Sasivimol Kittivoravitkul**, Secretary, **ISPE Thailand** & Managing Director, **Advance Pharmaceutical Manufacturing**, Thailand
Dr Pu has over 15 years experience, which includes project leader in constructing a new non-sterile plant (APm) design, commissioning, qualification and validation. She is also the company's Quality Management Representative (QMR), holds a PhD in Computer Science, is accredited by CQI and IRCA for Certified ISO 9001:2015 Lead Auditor and Certified Quality Management System ISO 13485:2016 Lead Auditor.

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## This workshop is supported by:


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