

25th edition of ISPE Singapore flagship conference convenes global stakeholders to explore Quality, Sustainability, and Digital transformation in Biopharma

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Over 2,600 Industry Leaders Gather to Explore Key Themes in Biopharma Advancement, Regulatory Alignment, and Future-Ready Facilities in the Life Sciences Industry



The <u>ISPE Singapore</u> affiliate celebrated its **25th edition** on **August 27-29**, **2025**, with its flagship annual Conference & Exhibition, uniting a diverse assembly of industry leaders at Marina Bay Sand Expo, Singapore. The forum brought together a diverse group of industry leaders to discuss key themes in quality and innovation within the pharmaceutical industry.

More than 2,600 attendees from 32 countries convened to explore advancements in the biopharma industry through 74 sessions led by 109 speakers. Participation surged by 30% compared to 2024, with 50% of Southeast Asia attendees hailing from Malaysia and two-thirds of North Asia participants coming from China.

The official opening of the ISPE Singapore was led by **Shanshan Liu**, International Board Director of ISPE, Conference Chair of ISPE Singapore, and Technical Director at No deviation, Singapore. The forum kick-started with welcoming remarks by **Peiqing Zhang**, President of ISPE Singapore and Scientific Director for Asia at Cytiva.

The ISPE Singapore Affiliate's "Conference and Open Tracks", scheduled between 28-29 August centered on critical themes of quality and innovation in the pharmaceutical industry. Exclusive "Power Hour" sessions and "Lunch 'n Learn Workshops" garnered the attention of visitors and industry experts. Concurrently, the exhibition platform gave a comprehensive outlook on trends and dynamics.

An exemplary gathering of global Biopharma enthusiasts and industry experts convened at the forum:

The Main Conference of ISPE Singapore kicked off on 28th September with a keynote address by *Emer Cooke, Executive Director of the European Medicines Agency (EMA)*, who highlighted the importance of fostering manufacturing innovation in the EU to benefit patients. The session was followed by *Xiaoming Gao from the National Institutes for Food and Drug Control (NIFDC)*, who discussed building quality control (QC) laboratories for medicinal product testing in China.

A panel discussion on "Regulating innovation", moderated by Bob Tribe, APAC Regulatory Affairs Advisor for ISPE Singapore, explored strategies for agility, streamlining, and simplification, featuring insights from regulatory leaders across Asia and Europe.

The event continued with a plenary session on 'Shaping the future of pharma', chaired by Shanshan Liu, featuring a panel of industry experts from AstraZeneca, WuXi XDC, Roche, and ChemT Biotechnology, who shared perspectives on innovation and quality in pharmaceutical development.

The "Facilities of the Future" conference, chaired by *Giacomo Rinaldi, Managing Director of Fedegari Asia*, highlighted "cutting-edge advancements in vaccines and biologics manufacturing". The session included a presentation on *Modulus*, an advanced facility for biologics production, presented by *Prasath Kuppusamy, Head of Engineering and Capital Projects at Sanofi, Singapore*, and *Austin Lock, Technical Director and Group Head of Technology at PM Group, UK*.

The first-day session concluded with a discussion on **Commissioning**, **Qualification**, **and Validation** (**CQV**), moderated by *Pierre Winnepenninckx*, *CQV Community of Practice Lead and CEO of No Deviation*, *Singapore*

A panel discussion, "Building Innovation in Facilities of the Future," was moderated by Giacomo Rinaldi, MD, Fedegari Asia and featured industry leaders, including Mike Martin, President & CEO of ISPE, USA; Denise Tan, Executive Director and Plant Manager at Amgen, Singapore, Jack Lyons, Senior Vice President of Biopharma and Life Science at Exyte, Singapore; and other experts. The session explored strategies for fostering innovation and advancing the design and operation of future-ready pharmaceutical facilities.

Another panel discussion on "adopting a risk-based approach and exploring the advantages and challenges of health-tech tools," was moderated by Pierre Winnepenninckx CQV Community of Practice Lead and CEO of No Deviation, Singapore. The panel included experts such as Dr. Yiming Peng, Global Data Science Lead at Genentech, Hazem Eleskandarani, Dave O'Connor, and Sebastian Scheler, Managing Director and Chief Methodologist at Innerspace, which highlighted the opportunities and challenges of integrating digital tools into CQV processes.

Another session covered regulatory and quality management in the pharmaceutical industry, specifically *Korea's MFDS's approach to international collaboration through GMP* alongside an overview of China's medicinal product sampling and inspection processes by NIFDC. Discussions emphasized the importance of cross-border collaboration and regulatory alignment to ensure drug quality and safety. Key topics explored contamination control strategies in aseptic facilities, with insights from *Sumei Li (CFDI, NMPA, China)* and lessons learned from the 2003 Pan Pharmaceutical Crisis shared by Bob Tribe, ISPE Singapore Regulatory Affairs Advisor. The event also featured an interactive "Ask the Regulator" session chaired by experts from Asia, Europe, and the Philippines, and moderated by Vee Revithi.

In an interesting session, engineering, safety, and sustainability were discussed within the life sciences industry. Chaired by Stephanie Ledwidge of Linesight, Singapore, the session explored the global and local impacts of life sciences benchmarking, the role of good engineering practices in supporting science and risk-based approaches, and the importance of digital work controls in enhancing safety culture while building sustainable infrastructure models for life science company operations. The session also emphasized sustainable biomanufacturing, with Thermo Fisher Scientific demonstrating the environmental and efficiency benefits of single-use technologies (SUT). A panel discussion, moderated by Nick Haycocks, brought together industry leaders from APAC and the USA to emphasize leadership in safety and quality.

ISPE Singapore brought to light key advancements in **CDMO operations and multi-modality manufacturing**, featuring sessions on "**ADC development**" by *Dr. Jun Hu from WuXi XDC* and "**Integration of digital innovation in traditional CDMO operations**

" by Selva G from Thermo Fisher Scientific. A panel discussion, moderated by Chris Lee and featuring experts like Dr. Min Zhu from Zencore, addressed "Challenges in multi-modality manufacturing and strategies for enhancing manufacturing agility."

An enthralling discussion on the "Next-generation of pharmaceutical facilities", concentrated on innovation, sustainability, and flexibility captivated innovators and start-ups. A few highlights included insights from ISPE FOYA on next-generation futuristic facility designs, Bayer's sustainability strategies, and a LEED Platinum project implemented by Philippines Fluor Corporation. Brant Bulgarelli from Exyte shared perspectives on "How fast realization and flexible facilities drive innovation". The event also featured an open Q&A session conducted by industry leaders, such as Mike Martin, President & CEO of ISPE, and Sabrina Xu from Merck Life Science, focusing on advancing novel modalities and investment projects.

In a unique session focused on **Digital transformation and innovation**, participants explored the **integration of AI in pharmaceutical operations**, focusing on topics such as the use of AI agents in connecting operations, revolutionizing quality control and assurance (QC and QA), and leveraging AI in cellular drug discovery for biologics manufacturing. A workshop focused on overcoming challenges in digital transformation projects provided insights from industry leaders, including Christelle Heng from Singapore's GSK Biologics and Kylie Vermeiren from Bluecrux.

The discussions collectively addressed key topics such as aligning quality management expectations between clients and CDMOs, strengthening Marketing Authorization Holders' (MAHs') responsibility for drug quality and safety in China, and exploring strategies to enhance both internal and external quality. A series of panel discussions brought together industry leaders from Asia-Pacific to discuss innovation and collaboration..

A spotlight on Innovative Solutions and Life Science Leaderships

The Life Sciences Leadership meeting brought together industry experts and leaders to discuss innovation, safety, and sustainability in pharmaceutical manufacturing. The conference showcased groundbreaking initiatives and leadership in pharmaceutical manufacturing and safety. Stephanie Ledwidge, Associate Life Sciences South East Asia at Linesight, Singapore, introduced the Lite Science Capital benchmark initiative, emphasizing its role in advancing localized impact.

The event brought together experts from across the globe to discuss **key challenges and innovations shaping the industry**. A major highlight was the panel on **Safety & Quality Leadership**, moderated by Nick Haycocks, Senior Specialist in Quality Assurance from the UK. The panel featured insights from industry leaders, including Matthew Shippey from IPS-Integrated Project Services, Hazem Eleskandarani from CSL Behring, Craig Docherty from Fusion Safety, and Nicholas Scully from Novartis Singapore.

Further, the session explored strategies to **foster robust safety cultures and enhance quality standards** through science-based approaches and digital advancements. **Sustainability and innovation** were central themes, with sessions on **sustainable biomanufacturing and next-generation project execution**

Yvonne Lim and Melinda Seah from Thermo Fisher Scientific presented tools for sustainable biomanufacturing, while Mike Martin from ISPE USA discussed strategies for future-ready facilities. Cecilla De Guzman and Jasmin Rajak addressed innovation in flexible facilities, and Brant Bulgarelli shared insights into drug product realization.

The event concluded with forward-looking approches to future facilities and next-generation project execution over a dynamic open Q&A session moderated by Chris Lee and Mike Martin, reflecting on the challenges and opportunities in multi-modalities and CDMO operations. Speakers like Dr. Jun Hu from WuXi XDC and Sabrina Xu highlighted collaboration and agility in meeting industry demands, leaving attendees inspired by the latest advancements in the life sciences.

Denise Tan, Executive Director and Plant Manager at Amgen, shared her insights on **innovation and leadership in the pharmaceutical industry** during the panel discussion centered on enhancing agility, sustainability, and resilience through infrastructure reshaping, emphasizing both technological advances as well as a forward-looking mindset. Additionally, Tan led a roundtable on personal branding and leadership influence during the **Women in Pharma session**, where she highlighted authenticity, visibility, and resilience in overcoming challenges.

Industry leaders discussed advanced strategies to tackle critical challenges in pharmaceutical manufacturing and logistics. A number of topics were discussed at the conference, including automated material identification, high-performance single-use alternatives for biomanufacturing, and optimizing data center performance with regular audits and health checks. The

conference also focused on innovations in temperature control for pharmaceutical logistics, precision engineering, and future-ready automation through Module Type Packages (MTPs).

The conversation also focused on AI-driven transformations in the supply chain, aseptic assurance in material transfers, and advancements in predictive maintenance. Other aspects of Pharma 4.0 included innovations in container closure integrity testing (CCIT), drones and robotics, and practical solutions to autoclave challenges. The conference also covered contamination control strategies for antibody-drug conjugates (ADC) manufacturing, advanced autoclave applications, PUPSIT implementation, and emerging cleanroom design trends, demonstrating industry's commitment to precision, compliance, and operational excellence.

Exhibition Zone: A Grand Showcase of Innovation and Excellence in the Pharmaceutical Industry

Power-packed 'Power Hours' at the Exhibition Illuminate Next-generation Innovation

The event featured a diverse range of exhibitors, workshop facilitators, and contributors, showcasing ISPE's extensive engagement across the pharmaceutical industry. Participants represented various sectors, with 22% from manufacturing industries including pharma, biopharma, and CDMOs, 13% from EPCM companies, and a growing presence of digital and automation providers alongside equipment suppliers.

The ISPE Singapore Affiliate event featured a diverse range of exhibitors showcasing expertise across various fields, including process engineering, automation, IT solutions, regulatory compliance, quality assurance, laboratory and analytical services, consulting and design, supply chain and logistics, environmental sustainability, cleanroom equipment, contract services, chemical and raw materials, advanced therapy medicinal products (ATMP), Good Automated Manufacturing Practice (GAMP) and more.

ISPE organized 'Exhibition Power Hours' Talks, featuring presentations by industry leaders focusing on key advancements in pharmaceutical manufacturing and digital transformation.

At the 'Power Hours' Talks, leading companies in the pharmaceutical and biotech industrie sectors shared insights on cutting-edge technologies and strategies for enhancing manufacturing and sustainability. The points of discussion ranged from designing next-generation API manufacturing facilities and exploring advanced configurable process plants, innovations in pMDI filling technologies and the adoption of low global warming potential (LGWP) propellants. Discussions also delved into the importance of reducing embodied carbon and embracing circular economy principles as critical components of sustainability.

The discussions furthur included topics such as the incorporation of far-UVC technology in life science and pharmaceutical facilities for container closure integrity testing (CCIT) and the development of upcoming sustainability standards for sterile filtration.

Other key topics included advanced fluid handling for biologics production, strategies to mitigate disruptions in achieving sustainability goals, and the use of digital tools like Kneat to streamline regulatory audits. Regulatory compliance and cleanroom standards were central, with discussions about future sterilization methods such as hydrogen peroxide and steam. The integration of multi-functional, modular, and intensification-ready cGMP benchtop platforms was also highlighted.

Additionally, **workshops** on **implementing virus filters for continuous processes** and the environmental efficiency of single-use technologies (SUT) by *Merck* and *Thermo Fisher* emphasized the industry's focus on innovation, sustainability, and compliance in pharmaceutical manufacturing to shape the future of the industry.

At the "**Power Hours**" exhibition, Cytiva and Siemens led **workshops** highlighting key advancements in pharmaceutical manufacturing. *Cytiva*'s session focused on optimizing recovery processes for both high-potency drugs and traditional products, showcasing their Next-Generation Solutions. *Siemens*' workshop addressed the integration of intelligence, resilience, and sustainability into smart manufacturing, emphasizing efficiency and innovation in pharmaceutical production.

The panel addressed the transition from paper-based systems to digital systems in cleanrooms, optimizing resources through data-driven strategies, and the critical role of packaging in ensuring precision and protection. Speakers also discussed virtual reality for operator training, predictive maintenance strategies, and innovations in containment and safety for antibody-drug conjugates (ADCs). Participants gained practical insights into overcoming challenges in building management systems (BMS) and environmental management systems (EMS), as well as adopting hygienic, compliant solutions for aseptic processing and

material transfer. The sessions provided practical approaches for overcoming obstacles and enhancing operational efficiency of pharmaceutical manufacturing by implementing hygienic, compliant materials handling and aseptic processing solutions.

At ISPE Singapore 2025, **Avantor** highlighted its integrated solutions—ranging from buffers to single-use systems—that support scalable and reproducible biologics manufacturing. The company also delivered a Power Talk titled "Advanced Fluid Handling Transforming Biologics Production," emphasizing how innovations in fluid management enhance reliability and efficiency in biomanufacturing workflows. Avantor expressed its commitment to collaborating with industry leaders to advance science and support the development of life-changing therapies.

Envirotainer showcased advanced passive solutions like Proofpak and Onepak, alongside its full range of temperature-controlled solutions. Attendees explored technologies shaping the pharmaceutical industry, connected with peers and shippers, and discovered solutions to enhance compliance, product integrity, and efficiency. These solutions were designed to provide flexibility, reliability, and compliance across the pharmaceutical supply chain.

Lotte Biologics' *Dr. Hyungduk Yoo, COO of the Business Expansion Division*, highlighted the critical role of transparent communication in aligning client and CDMO quality standards and fostering trust-based partnerships through collaboration and shared quality goals. He emphasized the importance of transparent communication in aligning with client and CDMO quality standards. Dr. Yoo also joined a panel discussion, sharing insights into building trust-based partnerships through collaboration and shared quality goals. At the exhibition booth Lotte Biologics contributed to discussions on quality excellence and strengthening client-CDMO relationships in biomanufacturing.

Esco Lifesciences, the global life science company, demonstrated groundbreaking laboratory and pharmaceutical solutions, including advanced bioreactor systems, innovative incubators, cutting-edge biosafety cabinets, and more. Visitors experienced tailored solutions for bioprocessing, cell culture, containment, and pharmaceutical applications.

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