ISPE Singapore Conference and Exhibition 2023 – 1st Article

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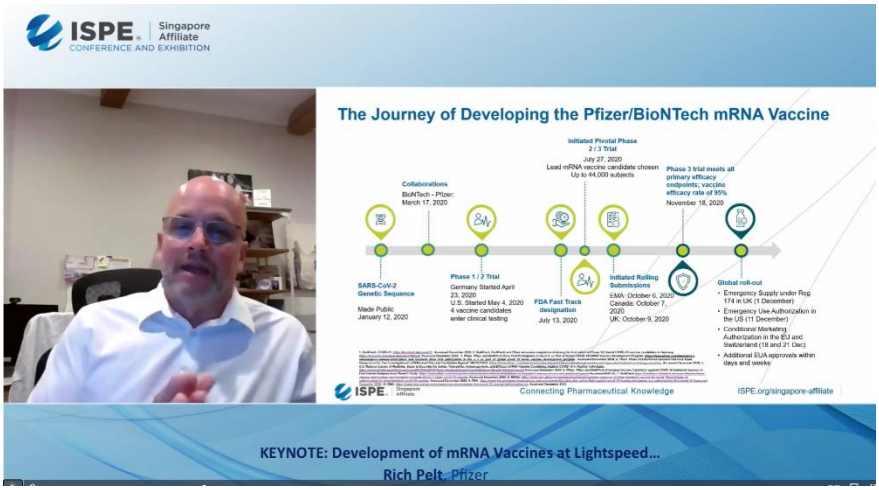
ISPE Singapore Conference and Exhibition 2023 was attended by more than 1800 people, including speakers from regulatory authorities to manufacturers and suppliers. The conference focused on the theme "**Shaping the Future of Pharmaceutical Manufacturing: Trends, Technologies and Beyond"**.



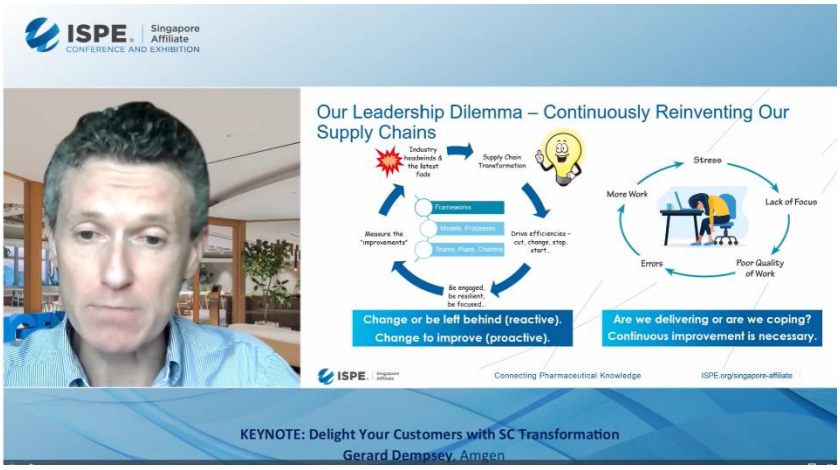
The conference began with an online opening plenary on 23 Aug 2023, with Welcome Remarks by **Alfonsus Karli**, Director, GCMC Vaccines, **Pfizer** & Vice President, **ISPE Singapore** as well as **ISPE International's Strategic Plan** by **Thomas B Hartman,** President & CEO, **ISPE**, USA. The latter spoke on the growth of the pharmaceutical industry worldwide and workforce development needed, as well as ISPE's strategic themes and key implementation initiatives to support this growth.

This was followed shortly by first keynote speaker **Rich Pelt,** Senior Director, Vaccines CMC Regulatory Affairs, **Pfizer**, USA, who spoke on the **Development of mRNA Vaccines at Lightspeed: A Regulatory Perspective**. Key ideas include the development and acceleration of production of COVID-19 vaccines, global authorization including regulatory innovation and flexibilities, experience with rapid updates, and opportunities to provide benefits to patients earlier and more efficiently.



To expedite vaccines approval during pandemic, Pfizer used the "lightspeed" designation within its organization. This was achieved in various ways, such as via streamlined justification for resource and capital requests, risk-based decisions with bias towards higher probability of success, decisions to use additional resources at the edge of normal vaccine network, and many product and process development activities performed in parallel instead of sequentially.

Next up was second keynote speaker **Gerard Dempsey**, Executive Director, Head of Asia Pacific Regional Supply Chain, **Amgen**, Japan. The topic: **Delight Your Customers with Supply Chain (SC) Transformation**.



He spoke on the leadership dilemma and our fundamental assumptions – knowing who our customers are, and how to relate to our customers. Only then could we go back to basics via three pillars , the foundations (product flow, information flow, data integrity), the cornerstones (standardizing processes, systems and ensuring well-trained people are organized in high performing teams) and the implementation of scorecard(s). By understanding what "good" looks like and focusing on the value chain to differentiate for our customers, we can be ready for the future.

Thereafter, third keynote speaker **Diane L Hustead,** Executive Director, Regulatory Affairs**, Merck & Co, Inc,** & Drug Shortage Initiative Team Chair, **ISPE,** USA spoke on the **ISPE Drug Shortages Prevention Model**. The initiative explores opportunities within ISPE's areas of expertise (i.e. technical, quality and regulatory) for prevention of drug shortage, aiming to advance progress in drug shortage prevention through industry guidance and health authority interactions. The guidance for drug shortage prevention excellence provides a global, modern resource that illustrates risk management opportunities at organizational, operational, and product-specific levels. This includes six (6) quality and manufacturing maturity priorities, four (4) technology and innovation priorities, and two (2) regulatory priorities.



This is followed by regulatory keynote speaker **Jacques Morenas,** Deputy Chair & Chair, Training sub-committee, **PIC/s** & Technical Advisor, Inspection Division, **ANSM,** France, who shared on **Pharmaceutical Inspection Co-operation Scheme** (**PIC/S**) **Update**. The PIC/S strategic plan for year 2023 to 2027 focuses on inspection reliance, preferred forum for GxP harmonization, Centre of Excellence for training regulatory inspectorates, preparing regulatory inspectors for the future, partnership and stakeholder co-operation and PIC/s operational capacity.

The second regulatory keynote speaker was **Andrei Spinei**, Manufacturing Team Lead, Inspections Office, Quality and Safety of Medicines Dept, **European Medicines Agency**, Netherlands, who spoke on **EU Network Approach to Inspection Reliance and Manufacturing Innovation.** Novel manufacturing is a strong strategic priority for the EMRN. The Quality Innovation Group (QIG) is the interface to translate innovation concerning manufacturing technologies into actual products, for the benefits of the patients. The group is consists of experts from three groups – Biologics Working Party (BWP), Quality Working Party (QWP) and the Inspection Working Group (IWG). Unlike the Innovation Task Force (ITF), the QIG focuses more on industry innovations and is a longer-term group. Priority topics for 2023 include continuous manufacturing (specific attention end-to-end drug substance /drug product), decentralized manufacturing, automation, and digitalization. Other topics include individualized therapies, 3-D printing, platform technologies, novel analytical methods and so on.

The morning was concluded with a regulatory panel session by a Global Panel: Regulatory, Policy and Industry Approach to Combat Drug Shortages as moderated by **Diane L Hustead,** Executive Director, Regulatory Affairs**, Merck & Co, Inc,** & Drug Shortage Initiative Team Chair, **ISPE,** USA. Panelists include:



Joyce N. Cirunay, Director IV, **FDA Center for Drug Regulation and Research (CDRR)**, Philippines
Vimal Sachdeva, Senior GxP Inspector, **WHO**, Switzerland

David Churchward, Global Head Sterility Assurance, Cell and Gene Technologies, **Lonza Biologics,** UK
Gerard Dempsey, Executive Director, Head of Asia Pacific Regional Supply Chain, **Amgen**, Japan
Rich Pelt, Senior Director, Vaccines CMC Regulatory Affairs, **Pfizer,** USA
Topics touched on include opportunities for industry and drug shortage prevention, what industry can do to prevent shortage, and what it can do in collaboration with regulators to react to shortage. For example, the understanding of leading indicators to drug shortages enable meaningful mitigations to be taken, so health systems can pivot to potentially alternative sources of supply. Common misperceptions about drug shortage prevention include underestimating the complexity to get out of a negative-inventory situation, the opportunities available for proactive monitoring and collaboration between the industry and regulators, and the common misperception between reporting of shortage versus getting inspected by regulators.

In the afternoon, two concurrent tracks were in place: **Industry Best Practices** and **Digital Transformation**.

For the former track, **Benjamin Sauer**, APAC Lean Academy Lead, **AstraZeneca**, Australia spoke on **Critical Thinking – The what, why and how**. He touched on the Reptilian Brain versus the Thinking Brain, and how the critical thinking models such as the Toyoto Kata could deliver benefits to learning organizations.

This was followed by **Morcos Loka**, Training Manager & GMP Advisor, **Minapharm**, Egypt who spoke on **Design of HPAPI Biomanufacturing Facility** This includes the use of HBEL (Health Based Exposure Limit) in cleaning validation and its corresponding setting of control limits. Common challenges faced in following GMP guidelines, as well as process closure analysis in the design of API facilities were also mentioned.

Next, **Somasundaram G**, Senior Consultant, Global Biopharm Center of Excellence, **Merck Pte Ltd**, Singapore, shared on **Single-use Technology for mRNA Manufacturing** including key factors impacting scalability, adaptability and quality; good practices in risk management and its use in single-use technology, such as during process validation.

Cecilia Pierobon, Technical Service Manager, **STERIS Corp.,** Germany spoke **on Industry Good Practices on Product Grouping for Cleaning Validation.** This is key to achieving repeatable and scalable results, such as during a LEA study for cleanability and Toxicity / Potency.



After the stretch break, keynote speaker **Dr Joerg Block**, GMP Compliance Engineering, **Bayer AG Pharmaceuticals, Germany** spoke on **Good Engineering Practice: Accelerating Project Delivery.** Valuable insights include system boundary definition criteria such as the facilitation of project design and delivery, the inclusion or exclusion of CDEs, consideration of intended use, automation and control systems, and likelihood of future modification. By considering these early on in product cycle, this translates to potential simplification of validations and a better risk-based approach to product and process approvals.

This was followed by **Kalpesh Patel**, Chief Operating Officer, **HYDE**, USA speaking on **Applying Good Engineering Practices (GEP) for CIP Operation**, including how GEP can be used to reduce water usage for manufacturing facilities and reduce average time to repair for equipment and improved time to feedback.



Concluding the track for the afternoon was a panel on **Applying Good Practices for the Project Life Cycle** as moderated by **Pierre Winnepenninckx**, CEO, **No deviation Pte Ltd** & CQV Lead, **ISPE Singapore Affiliate**.
Panelists **Dr Joerg Block**, GMP Compliance Engineering, **Bayer AG Pharmaceuticals**, Germany
Manuel Ungerer, Head of Site Development, APAC, **Novartis**, Singapore and
Paul Si, Head of SGIE Delivery APAC, **Lonza, Singapore** spoke on the various ways to improve project delivery and execution such as stakeholder management, examination of environmental footprint during construction, and early quality involvement to better achieve balance between timelines while meeting quality requirements.

So concludes the first article on ISPE Singapore Conference and Exhibition 2023. Please stay connected and feel free to reach out for corrections and areas for improvement. Thank you.

Authored By:

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