

ISPE
15 YEARS
IN SINGAPORE



Connecting a World of
Pharmaceutical Knowledge

**Singapore
Affiliate**

28-30
MAY 2015
Suntec Singapore

CONFERENCE AND EXHIBITION

Biotech, Construction and the Risk Based Approach



ISPE Singapore Conference & Exhibition

500+ attendees

8 Workshops over 3 days

2 Production Facility Site Tours

FREE 2-day Exhibition with technical sessions

Pharmanite Networking (28 May)

Organised by the Singapore affiliate of the International Society for Pharmaceutical Engineering (ISPE), this annual meeting is open to all pharma and bio manufacturing professionals. It is the 'must-attend' industry event which highlights best practices, technology and services from manufacturing facility design to finished product.

It's where the industry gathers, to manufacture safely, efficiently and productively.

PLENARY & WORKSHOP THEMES FOR 2015 INCLUDE:

- A: QbD Workshop**
- B: Biotech**
- C: Construction & Design**
- D: Risk Based Approach / Cleaning**
- E: Risk Based Approach**
- F: SOP & Writing**
- G: Autoclave C&Q**
- H: Regulatory Audits**

NEW! Join ISPE as it celebrates its 15th year in Singapore!

To mark its anniversary, ISPE Singapore will be holding Dinner to follow the annual Pharmanite Networking.

Also featuring The Asian Projects Showcase, of groundbreaking developments from the region, the stage is set for an eventful evening!

Organised by:



**Singapore
Affiliate**



Sponsors:



Exhibitors:



REGISTER at www.ispesingapore.org

+65 6508 2401

register@ibcasia.com.sg

ISPE Singapore Annual Conference 2015

Biotech, Construction and the Risk Based Approach

Pre-Conference: Wednesday, 27 May

1330-1730	Site Visit 1: Tiger Breweries Tour (APB) Discover the brewing and production process involved on this tour. The Packaging Gallery provides visitors with an up close view of the beer packaging process, adopting the flow of how a Tiger Beer bottle journeys through the process of packaging till distribution.	Site Visit 2: Mead Johnson Nutrition The new US\$325m facility in Tuas opened in 2014 as the single largest capital project in the company's more than 100-year history. This tour takes you through a viewing gallery designed specifically to showcase the latest in state-of-the-art design.
-----------	--	---

Conference Day 1: Thursday, 28 May

0900	Opening Remarks from the Chairman & ISPE Singapore Welcome Address Pierre Winnepenninckx , <i>President, ISPE Singapore Affiliate</i>		
0915	ASEAN MRA on GMP Inspection and its Implementation : AEC 2015 and Beyond SIA Chong Hock , <i>Division Director, Audit & Licensing Division, Health Products Regulation Group, Health Sciences Authority, Singapore</i>		
1000	Industry Panel Discussion: Opportunities and Challenges for Singapore in Asia's Biomedical Sector - Investment and financing beyond early stage - Manpower considerations such as talent crunch and requirement for technical skillsets - Resourcing for management capabilities in commercialisation phase MODERATOR: Ong Siew Hwa , <i>Vice Chairman, BioSingapore</i>		
1045	Opening of ISPE Singapore Exhibition & Morning Refreshments		
	A: QBD MODERATOR: Gearoid Cronin , <i>Director, Process Engineering Specialists, Singapore</i>	B: Biotech MODERATOR: Howard Yu , <i>Validation Manager, Novartis BiopharmOps, Singapore</i>	C: Construction & Design MODERATOR: Alex Zhang , <i>QA/QC Engineer, Lend Lease Project Management and Construction, Singapore</i>
1130	A Framework for Implementing QbD in Product Development to Satisfy the New FDA/EU PV Guidance Bikash Chatterjee , <i>President and Chief Scientific Officer, Pharmatech Associates, USA</i> - The new process validation paradigm- USFDA, EMA, PIC/S - Comparing the USFDA 1987 and 2011 guidance's, EMA Annex 15 and PIC/s Annex 15	PrIME Biologics: the Realisation of Small Volume Blood Plasma Fractionation Dr Hari Nair , <i>Executive Chairman, PrIME Biologics Pte Ltd, Singapore</i> Damian Thornton , <i>Vice President, Asia Operations, CAI International, Singapore</i>	Disposable Solutions in Design & Construction Dave Wolton , <i>Biopharma Technology Consultant, PM Group, Ireland</i> Louise Cogan , <i>Commissioning & Qualification Engineer, PM Group, Singapore</i>
1215	- What is QbD? ~ Juran Concepts ~ ICH Q8(R2) ~ Robust Design Concept vs Tightening Specifications ~ Integration of risk management tools - QbD process Activities and deliverables	Manufacturing of the Future Mike Greening , <i>Director, Engineering, Amgen Singapore Manufacturing Pte Ltd</i>	Lean Construction in Singapore David Glenister , <i>Project Manager (Amgen) & James Croke</i> , <i>Project Manager (Abbvie), Lend Lease Project Management and Construction, Singapore</i>
1300	Lunch in the Exhibit Hall		
1400	- Stage 1: Process Design ~ Process Understanding, Knowledge Space, Design Space, Process Characterization Study ~ Identifying CPPs and CMAs ~ Sampling plan techniques ~ Establishing acceptance criteria	MODERATOR: Jennifer Soriano , <i>Area Manager, Bioquell Asia Pacific, Singapore</i> Quality and its Impact on Green Field Projects Sanjay Nanjundaiah , <i>Quality Manager, Biocon Sdn Bhd, Malaysia</i>	MODERATOR: Howard Yu , <i>Validation Manager, Novartis BiopharmOps, Singapore</i> Design Priorities Across Different Food Industries The fact that different food industries are focused on different priorities during the design process. However, the design principles remain the same across all industries – feasibility, concept, basic and detailed design. The industries discussed will be infant nutrition, dairy, brewery, beverage and other foods. David Parker , <i>Engineering Manager Life Sciences, M+W Group, Singapore</i>

REGISTER BEFORE 30 APRIL TO SAVE WITH SPECIAL RATES!

PLUS: ISPE MEMBER & GROUP DISCOUNTS (attend with your team to take advantage of the group rates)

	A: QBD	B: Biotech	C: Construction & Design
1445	Session continued...	Prevention of Contamination in a Biologics Plant. Improving Operations and Reducing Risk. Owning Biodecontamination Equipment Vs Outsourcing Service Arnaud Serfass , Managing Director, Bioquell Asia Pacific, Singapore	Sustainability in Designing Modern Pharma Facilities - Convenient use of water and energy - Operational savings influenced by design - Case studies of different scenarios Marco Bolognini , Director of Pharmaceutical Division, Amec Foster Wheeler, Asia Pacific, Singapore
1530	Afternoon Refreshments		
1615	(Session timings may vary) - Criticality Throughout the PV Lifecycle - Weighted CQAs, Continuum of Criticality and its Impact on Continued Process Verification - Questions	Biologics Tech Transfer Antonio Carion , Head of Manufacturing Science & Technology, Novartis BiopharmOps Singapore	Importance of Local Service Support when selecting a Pharmaceutical Process Equipment Alfio Gullifa , Managing Director, 1Supplier, Singapore
1700		Risk Assessment of Single Use Systems in Bioprocessing Nishant Soni , Head of Asia Pacific, Fluid Management Technology, Sartorius Stedim Biotech, India	Integrated Planning for GMP Capital Projects Planning and developing an integrated design, procurement, construction, commissioning and qualification program. Gearoid Cronin , Director, Process Engineering Specialists, Singapore
1730	Pharma Night Networking Reception & Student Poster Awards		
1900	ISPE 15th Year Anniversary Dinner & Asian Projects Showcase (Last few tickets on sale at the Registration counter S\$85 per person)		

Conference Day 2: Friday, 29 May			
	A: QBD (continued)	D: Risk Based Approach / Cleaning	E: Risk Based Approach
	MODERATOR: Dr Julia Gandhi , Senior Specialist, Skills Development Division, WDA Singapore	MODERATOR: Pierre Winnepeninckx , Managing Director, No deviation Pte Ltd	MODERATOR: Jennifer Soriano , Area Manager, Bioquell Asia Pacific, Singapore
0900	A Framework for Implementing QbD in Product Development to Satisfy the New FDA/EU PV Guidance Bikash Chatterjee , President and Chief Scientific Officer, Pharmatech Associates, USA (Session timings may vary) Recap of Day 1	Quality by Design Principles for Tangential Flow Ultrafiltration Operation Dr. Renato Lorenzi , Senior Bio-manufacturing Engineer, BSN Europe, Merck Millipore Process Solution, Italy	Ensuring GMP Compliance Across the Project Life Cycle Basic principles such as GEP, design review, change control, specific deliverables, C&Q plans and flows will be covered with the emphasis that these activities cannot be left at the end of the project life cycle. It must be planned and seamlessly integrated into our design, construction, commissioning and quality plan. Asanul Farhan , CQV Manager Life Sciences, M+W Group, Singapore
0945		Quality Risk Management in the Design and Qualification of a New Aseptic Manufacturing Process – The Clearlab Experience - Introduction and background - Aseptic Manufacturing (Lens Care Product) - Quality Risk Management Tan Kah Chin , Head of Quality and Regulatory Affairs / Project Lead - Lens Care Product, Clearlab SG Pte Ltd, Singapore Aurelien Martin , Lead Process Consultant, No deviation Pte Ltd, Singapore	Biopharmaceutical Equipment Validation Leveraging a Risk Based Approach Gregory Sukay , Director, Manufacturing, Amgen Singapore Manufacturing Pte Ltd, Singapore
1030	Morning Refreshments		

	A: QBD (continued)	D: Risk Based Approach / Cleaning	E: Risk Based Approach
1115	• Stage 2: Process Performance Qualification ~ Determining the number of PPQ lots ~ Setting Acceptance Criteria	Risk-Based Approach in Commissioning & Qualification of New / Refurnished Legacy Facilities Miguel Noguerras , Site Quality Director – Hangzhou Divisional QA Microbiology & Compliance Quality & Compliance, Abbott Medical Optics, Inc , China	Risk-Based Compliance in the Analytical Laboratory Paul Smith , Global Strategic Compliance Program Manager, Agilent Technologies , UK
1200		Sprayball Patterns: Why and How The science behind the use of riboflavin and the do's and don'ts on sprayball pattern Pierre Winnepenninckx , Managing Director, No deviation Pte Ltd , Singapore & President, ISPE Singapore Affiliate	Risk-based Approach to Scheduling Regulatory Inspections – Industry Perspective Dr Vee Revithi , Head of External Relations Europe, F. Hoffmann-La Roche , Switzerland
1245	Lunch in the Exhibit Hall		
1400	• Technology Transfer ~ Applying principles to new products and legacy products	MODERATOR: Pierre Winnepenninckx , Managing Director, No deviation Pte Ltd	MODERATOR: Howard Yu , Validation Manager, Novartis BiopharmOps , Singapore
		Current Topics in Cleaning and Cleaning Validation for Pharma and BioPharma Manufacturing John M Hyde , Chairman & Founder, Hyde Engineering + Consulting , USA	HVAC System Installation & Commissioning Flow Sequence – to Facilitate Mitigation of HVAC Qualification Failure Risks David Stoddart , Independent Service Provider to Lilly Suzhou through PM Group China
1530	Afternoon Refreshments		
1600	• Stage 3- Continued Process Verification ~ New products ~ Legacy products • Benefits/Cost of Poor Quality (COPQ) ~ Components of COPQ • Questions	The cleaning of processing equipment and interconnecting piping systems is an essential process in pharmaceutical and biopharmaceutical manufacturing facilities. Cleaning is used to remove post production and cleaning agent residues to acceptable levels prior to the production of the next batch or product. This session will comprise of a presentation on current topics in cleaning and cleaning validation principles and practices including contemporary approaches to cleaning cycle and equipment design, cleaning process development, cleaning cycle qualification and ongoing cleaning process monitoring. It concludes with a Q&A session	Cloud Computing: State of the Nation from a Risk Perspective • Advantages & disadvantages associated with the different aspects of Cloud Computing • How to assess whether a Cloud solution is effective from a risk point of view • Regulatory and Best Practice Landscape Pierre Noel , Chief Security Officer, Asia, Microsoft Corporation , Singapore
1645			Making the Big Switch – Cloud IT Panel: MODERATOR: David Margetts , Managing Director and Co-Founder, FactoryTalk , Thailand Pierre Noel , Chief Security Officer, Asia, Microsoft Corporation , Singapore Bryan McSwiney , Chief Technology Officer, Zenith Technologies , Singapore
1730	Close		
Post-Conference: Saturday, 30 May			
0900-1230	F: Writing Clear, Concise and Effective Standard Operating Procedures (SOPs)	G: Autoclave C&Q Autoclave Thermal Sterilization Workshop	H: Regulatory Audits
	MODERATOR: Geoff Brown , Reliability and Validation Engineer, CAI International , Singapore	MODERATOR: Pierre Winnepenninckx , Managing Director, No deviation Pte Ltd , Singapore	MODERATOR: Katja Boodeea , Quality Assurance Manager, CIRC - Clinical Imaging Research Centre , Singapore
	For quality and compliance, all pharmaceutical companies strive to produce clear, concise and effective Standard Operating Procedures (SOPs). From cleaning a machine to running a production process to testing a product, SOPs guide all critical processes. Although SOPs have a direct impact on a company's quality, reliability and compliance, many SOPs are too wordy, complex and unclear to be totally effective. This in turn increases the quality and compliance risks. This workshop will equip you with the necessary skills to write effective SOPs. It includes the following modules: 1: Qualities of well-written, effective SOPs 2: 3-step process for writing effective SOPs 3: Best practices for high-quality SOPs Atul Mathur , Owner, Content Alive , Singapore	From understanding design choices to performance optimization • Define the correct autoclave type for your application • Pilot / Laboratory versus production, where the difference lies • Cycle development; the cost and risk of customization and its production benefit • Case study and exercise Pierre Winnepenninckx , Managing Director, No deviation Pte Ltd , Singapore & President, ISPE Singapore Affiliate Simone Riva , Validation Manager & Senior Project Specialist, Qualitech , Italy Howard Yu , Validation Manager, Novartis BiopharmOps , Singapore	1 HSA's PIC/S Approach to GMP Audits BOON Meow Hoe , Deputy Director, Audit & Licensing Division, Health Products Regulation Group, Health Sciences Authority , Singapore 2 Upcoming GMP Changes to the EU and PIC/S GMP Guides Dr Vee Revithi , Head of External Relations Europe, F. Hoffmann-La Roche , Switzerland 3 Handling Regulatory Audits Bob Tribe , Former Chairman of PIC/S & Asia Pacific Regulatory Affairs Advisor, ISPE , Australia 4 Q & A session



Connecting a World of
Pharmaceutical Knowledge

**Singapore
Affiliate**

CONFERENCE AND EXHIBITION
Biotech, Construction and the Risk Based Approach

NEW! Onsite Visitors' programme* with free technical talks and demonstrations in the exhibit hall.

Scheduled throughout the 2 days and open to all, sessions will highlight new technologies, processes and services. The full listing will be online in May. Interested in sharing your technology / demonstration? Contact Yvonne Leong to reserve your slot:
+65 6508 2489 / Yvonne.leong@ibcasia.com.sg

CALL FOR POSTERS!

ISPE Student Poster Competition & Awards

Open to all students majoring in the field of Science and Engineering, this year's winner will present their poster in the ISPE Annual Meeting in Philadelphia, Pennsylvania USA from 8-11 November 2015.



2014 Student Poster Winner Ms Aparna Saigal and fellow poster competition participants

ISPE Singapore 2015 Student Poster Competition Submission deadlines:

Registration form: **Friday, 24 April 2015, 6pm** • Poster: **Friday, 8 May 2015, 6pm**

Contact: Kristina Autenrieth at Tel: +65 6826 1105 • Email ispesingaffiliate@gmail.com



**Visitors want
to meet
YOU!**

Exhibits showcasing technology, goods and services from design and construction to the safe manufacturing of quality finished products.

80%
of visitors came to
gather industry
updates / product
information

Over **40%**
wanted to meet
new contacts or
source suppliers



Featured Pavilions for:

- » Architects
- » Design & Build Consultants
- » Packaging & Labelling
- » Quality & Validation Consultants
- » Staffing & Recruitment

LIMITED EXHIBITION and SPONSORSHIP OPPORTUNITIES

Contact: Yvonne Leong
Tel: +65 6508 2489
Email: Yvonne.leong@ibcasia.com.sg

Media Partners:

ASIA PACIFIC
BIOTECH

ASIAN HOSPITAL &
MANAGEMENT
Healthcare

ASIAN SCIENTIST
News and information from the Asian scientific community

BENTHAM
SCIENCE

生物探索
biodescover.com

BioPharma
Asia

BioSpectrum

Biotech
東 East

CONTROL
ENGINEERING
ASIA

ICPC.biz
Asia's Pharma Channel
www.icpcbiz.com

KONG POSH
PUBLICATIONS
The Pharma Review

Life SCIENCES
INDUSTRY NEWS

lingmed 灵医医药

luxresearch

PHARMA
FOCUS ASIA

Technology
Networks.com
Scientific Communities

PHARMA CHINA
www.pharmachinaonline.com

Official Media Partner: **PharmaAsia**

REGISTER at www.ispesingapore.org

+65 6508 2401

register@ibcasia.com.sg