

## SUNDAY, 6 JUNE

	WORKSHOP 1	WORKSHOP 2
1300 – 1500 1530 - 1730	“Effective Cleaning Validation Programme for Biologics Facility” Leader: <b>David Vincent</b> , CEO, Validation Technologies Inc.	“Environmental Control & HVAC - Is sustainability and GMP compliance compatible?” Leader: <b>Gordon Farquharson</b> , Managing Director, Critical Systems

\* Tea break for workshops will be scheduled from 1500 - 1530

## MONDAY, 7 JUNE

### PLENARY KEYNOTE SESSION

<b>Moderator: Stephen Slater</b> , President, ISPE Singapore Affiliate / Vice President, Asia, Pharmaceutical Services Corp. Pte Ltd (PSC)	
0900 - 0915	Welcome Message: <b>Stephen Slater</b> , President, ISPE Singapore Affiliate
0915 - 1000	FDA Regulatory Keynote: “Ensuring Drug Quality for Public Health: The Implementation” <b>Dr. Brenda Uratani</b> , Assistant Country Director, FDA China Office, Beijing
1000 – 1030	<b>Tea Break</b>
1030 - 1115	EMA Regulatory Keynote: “A regulator’s perspective on ‘Quality by Design’ - Application & Perspectives for Biologics” <b>Dr. Kowid Ho</b> , Biologicals/Biotechnology Unit, AFSSaPS
1115 - 1200	TGA Regulatory Keynote: “Effective Regulation through International Cooperation” <b>Michel Lok</b> , Head, Office of Manufacturing Quality, Therapeutic Goods Administration
1200 - 1245	Industry Overview Keynote: <b>Jan Willem Eleveld</b> , Vice President Consulting & Services, APAC, IMS Health
1245 – 1400	<b>Lunch</b>

### CONCURRENT BREAKOUT SESSIONS

	REGULATORY Moderator: <b>Gus Abdallah</b> , Managing Director, Synertec Asia	API Moderator: <b>Dr. Patrick Yeung</b> , Consultant PPY Pharma Services Pte Ltd	INNOVATION – DAY 1 Moderator: <b>Gearoid Cronin</b> , C&Q and Field Services Manager, PM Group Asia
1400 - 1500	“European regulatory guidelines for similar biological medicinal products” <b>Dr. Kowid Ho</b> , Biologicals/Biotechnology Unit, AFSSaPS	“Design considerations for Optimal Cleanability in API Equipment” <b>Dr. Bassel Iskandarani</b> , Director of Pharmaceutical Technology, MSD Singapore	“Achieving effective containment facilities - primary and secondary containment for chemical & bio-safety applications” <b>Gordon Farquharson</b> , Managing Director, Critical Systems
1500 - 1600	“Aseptic and Sterile Manufacture - Regulatory Challenges” <b>Jenny Hantzinikolas</b> , GMP Auditor, Office of Manufacturing Quality, Therapeutic Goods Administration	“Application of NIR as real time monitoring tool in API manufacturing” <b>Mohammad Nazrin Abdul Samat</b> , Senior Chemical Engineer, Technical Development, GlaxoSmithKline	“Process Analytical Technology (PAT) / Quality by Design (QbD): Integrated Systems in the Future Pharma Business Landscape” <b>Bart Moors</b> , Senior Business and Project Manager Pharmaceutical Industry SEA, Siemens AG
1600 - 1645	<b>Tea Break</b>		
1645 - 1745	“Towards A Quality Assurance System for Drug Regulatory Authorities” <b>Sia Chong Hock</b> , Division Director, Manufacturing & Quality Audit Division, Health Sciences Authority	“API Manufacture and Cost Effective Compliance” <b>Ray Collyer</b> , Senior Consultant, SeerPharma Singapore	<b>ISPE Facility of the Year Award 2009 (Sustainability) – Centocor Case Study</b> <b>Con Leddy</b> , Associate Director, PM Group
1830 – 2130	<b>ISPE Singapore Affiliate 10<sup>th</sup> Anniversary Dinner (Pan Pacific Hotel Ballrooms)</b>		

## TUESDAY, 8 JUNE

### CONCURRENT BREAKOUT SESSIONS

	BIOLOGICS Moderator: <b>Dr. Patrick Yeung</b> , Consultant PPY Pharma Services Pte Ltd	VALIDATION Moderator: <b>Stephen Slater</b> , Vice President, Asia, PSC	INNOVATION – DAY 2 Moderator: <b>Dr. Belinda Braggs</b> , Managing Director, SeerPharma (Singapore) Pte Ltd
0900 - 1000	“The Advantages of Leveraging Manufacturing Plant Designs Globally” <b>John Machulski</b> , Senior Project Director, Lonza Biologics Singapore	<b>ISPE Article of the Year 2009: “The FDA’s Draft Process Validation Guidance – A Perspective from Industry”</b> <b>Dr. Alice Redmond</b> , CQ Technical Director, PM Group	“Containment – Is an isolator just an expensive box?” <b>Simon White</b> , Sales Director, Pharmaceutical Services Corporation Ltd
1000 - 1100	“Multi-Product Strategies in a Biologics Facility” <b>Dan Hagewiesche</b> , Director of CHO Production, Roche Singapore Technical Operations	“Current Industry and Regulatory Requirements for Biological Process Validation” <b>David Vincent</b> , CEO, Validation Technologies Inc.	“Green Pharmaceutical Manufacturing” <b>Dr. Paul Sharratt</b> , Programme Manager, Process Science & Modelling Institute, Institute of Chemical & Engineering Sciences, A*STAR
1100 - 1130	<b>Tea Break</b>		
1130 - 1230	“Quality Management in Biologics Manufacturing” <b>Dr. Praveen Kumar</b> , Director, Quality Assurance & Regulatory Affairs, Alpha Biologics Sdn Bhd	“Validation Strategies for a Fast track API Facility” <b>Todd Mabe</b> , Principal Technical Manager, Validations, Roche Singapore Technical Operations	<b>ISPE Facility of the Year Award 2010 for Project Execution (Genentech Singapore facility) – case study</b> <b>Tim Petch</b> , Managing Director - Asia, Bovis Lend Lease & <b>William McNamara</b> , Project Manager, Bovis Lend Lease
1230 – 1330	<b>Lunch</b>		
	SECONDARY PHARMA MFG Moderator: <b>Gerald Brogan</b> , Quality Validation Manager, Zenith Technologies	SUPPLY CHAIN Moderator: <b>Gearoid Cronin</b> , C&Q and Field Services Manager, PM Group Asia	AUTOMATION Moderator: <b>Eugene Yeo</b> , Director, Business Development, Life Sciences, Siemens
1330 - 1430	“The basics of Aseptic Processing, and trends in Aseptic techniques” <b>Martin R. Dyxenbourg</b> , Senior Production Manager, Insulin Filling Plant, Tianjin, China, Novo Nordisk A/S	“Securing the pharmaceutical supply chain: U.S. FDA’s efforts and perspectives” <b>Dr. Brenda Uratani</b> , Assistant Country Director, FDA China Office, Beijing	“The role of Automation in Global Pharmaceutical anti-counterfeiting” <b>Bryan McSwiney</b> , Director, Asia & Middle East, Zenith Technologies
1430 - 1530	“Use of RABS in Sterile Manufacturing” <b>Anuj Sharda</b> , Production Manager, Biotechnology Plant, MSD Singapore	“Ensuring Quality in the Supply Chain” <b>Tony Uhe</b> , Senior Director Quality Operations, External Manufacturing, Asia Pacific, GPSG, Johnson & Johnson	“Implementation of an Electronic Batch Record system in a Biologics Production Facility” <b>Mike Pelletier</b> , Associate Director of Engineering, Lonza Biologics Singapore
1530 - 1600	<b>Tea Break</b>		
1600 - 1700	“Automation for Aseptic Manufacturing”, <b>Gaurav Mehta</b> , Principal Project Automation Engineer, Alcon Singapore Manufacturing	“Proactive Strategies for Managing Your Distribution Network” <b>Darren Freestone</b> , Senior Consultant, SeerPharma Singapore	“PAT, the enabler for continuous manufacturing processes - An innovative way of developing and producing drugs” <b>Bart Moors</b> , Senior Business and Project Manager Pharmaceutical Industry SEA, Siemens AG

## WEDNESDAY, 9 JUNE

0900 – 1300	<b>FACILITY VISITS</b>
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\*Programme subject to change