

# “Advancing Excellence and Innovation in Regional Pharmaceutical Manufacturing”

Sunday, 31 May (Concurrent Workshops)		
1:30 PM – 5:30 PM	<b>Workshop 1: Commissioning &amp; Qualification</b> Workshop co-leaders: <b>Dr. Alice Redmond</b> , CQ Technical Director, PM Group, <b>Joe Eades</b> , Director, Process Design and Commissioning Services Pte Ltd (PDCS), <b>Robert Steen</b> , Director, Process Design and Commissioning Services Pte Ltd (PDCS)  <i>This workshop aims to provide insights into new and developing trends from the ISPE Baseline Guide on Commissioning &amp; Qualification and ASTM E2500 guidelines.</i>	<b>Workshop 2: Auditing for GMP</b> Workshop co-leaders: <b>Dr. Prasad Kanneganti</b> , Director of Technology, Genentech Singapore & <b>James Frankenfield</b> , Senior Director, Quality Operations, Genentech Singapore  <i>This Workshop aims to provide a regulatory perspective (regulatory GMP audits – what to expect &amp; how to handle) and industry perspective (with a focus on auditing suppliers).</i>
Monday, 1 June		
9:00 AM – 1:00 PM	<b>Plenary Keynote Session</b> <ul style="list-style-type: none"> <li>• <b>Welcome Address and Update on Community of Practices (COP) – Ms. Tracy Clemmer</b>, President, ISPE Singapore Affiliate</li> <li>• <b>Regulatory Keynote by Food &amp; Drug Administration (FDA) - Joseph Famulare</b>, Deputy Director - Office of Compliance (CDER) (<i>video-presentation</i>)</li> <li>• <b>EMA Regulatory Update - Jacques Morenas</b>, Assistant Director, French Agency for the Safety of Health Products (AFSSAPS) / Chairman, PIC/S</li> <li>• <b>Global Industry Update - Jan Willem Eleveld</b>, Vice President, Consulting &amp; Services, APAC, IMS Health</li> </ul>	
1:00 PM – 2:30 PM	<b>Lunch</b>	
Concurrent Breakout Tracks		
	Regulatory	Sustainable Solutions
2:30 PM – 6:00 PM	<b>Track Moderator: Ms. Tracy Clemmer</b> , Director / Consultant, PROTEK <ul style="list-style-type: none"> <li>• <b>“Global Supply Chain: Some thoughts from a Regulator”</b>, <b>Jacques Morenas</b>, Assistant Director, French Agency for the Safety of Health Products (AFSSAPS) / Chairman, PIC/S</li> <li>• <b>“Towards an ASEAN Sectoral MRA on GMP Inspection”</b>, <b>Sia Chong Hock</b>, Division Director, Manufacturing &amp; Quality Audit Division, Health Products Regulation Group, Health Sciences Authority <i>Moving towards an ASEAN Economic Community (AEC), an AEC Framework Agreement was signed in 2004. Amongst other priorities, this agreement identified an ASEAN Mutual Recognition Agreement (MRA) on GMP Inspection as one of the priority initiatives. This presentation will discuss the various challenges in instituting an ASEAN Sectoral MRA on GMP Inspection, and the benefits of the Agreement.</i></li> <li>• <b>“Desktop Audit (Clearance Verification) - the logic and the process”</b>, <b>Dr. Dragana Milic</b>, Audit Team Manager, Office of Manufacturing Quality, Therapeutic Goods Administration <i>The TGA recognised that it is not feasible to conduct on-site audits in all countries where there is no Mutual Recognition Agreement. The presentation will explain the TGA's clearance verification process which involves reviewing recent audit reports undertaken by other regulatory authorities and other key documentation to enable TGA to reach its own informed decision.</i></li> </ul>	<b>Track Moderator: Dr. Patrick Yeung</b> , Consultant, PPY Pharma Services Pte Ltd <ul style="list-style-type: none"> <li>• <b>“Waste Minimisation”</b>, <b>Ms. Yang Hong</b>, Senior Environmental Health Executive, National Environment Agency (NEA) <i>This presentation will cover the strategies for solid waste management, and the eight steps to a waste minimisation plan for industries.</i></li> <li>• <b>“Energy Optimisation”</b>, <b>Goh Yong Keng</b>, Engineering Director, Schering-Plough <i>The presentation will share views and insights on how a pharmaceutical manufacturing facility can maximise the returns from the usage of electricity, steam and water to achieve optimal usage within a facility's processes</i></li> <li>• <b>“Energy Management in an API facility”</b> <b>Yeo Yee Pang</b>, Energy Manager, GSK <i>This presentation will discuss the various components of an effective energy management programme, which encompass data collection, analysis, campaign, operations optimisation and waste avoidance.</i></li> <li>• <b>“Lonza Case Study – BCA Greenmark Gold &amp; pV Solar Projects”</b>, <b>John Machulski</b>, Senior Project Director, Lonza Biologics Singapore <i>In the design and construction of the Lonza 2 Bulk Bio Facility, the BCA Greenmark Gold status and incorporation of a Solar element were identified as key goals. This presentation brings you through the challenges, opportunities &amp; experiences of the project team as they embarked on this journey within a large Bulk Bio project environment.</i></li> </ul>
	Secondary Pharma Manufacturing	
6:00 PM – 7:00 PM	<b>Track Moderator: Gearoid Cronin</b> , Commissioning & Qualification Manager, PM Asia <ul style="list-style-type: none"> <li>• <b>“A practical approach to retrospective validation of pharmaceutical products”</b>, <b>Brad Roberts</b>, Partner &amp; Senior Consultant, SeerPharma Pty Ltd <i>The presentation discusses a practical “Value Added” approach to the dilemma of validating existing, “older” products and processes and focuses on using the concepts of Process Stability &amp; Process Capability to help manufacturers understand the true capabilities of their manufacturing processes.</i></li> <li>• <b>“Increasing Process Understanding in OSD Using Visual ‘Multi-Level’ Methods”</b>, <b>Dr. Paul Sharratt</b>, Programme Manager &amp; Principal Scientist, Process Science and Modelling Research Programme, ICES <i>This presentation will discuss The BRITEST approach to process design originated in research to support innovation in batch chemicals and API manufacture, which have been developed to support all stages of design and operation, from conception to equipment selection and troubleshooting, which have shown benefits in understanding several pharmaceutical solid dose processes.</i></li> <li>• <b>“Good Practices in EPCMV Cycle in Secondary Pharma Manufacturing”</b>, <b>M. Bala</b>, Senior Engineer Life Sciences, M+W Zander <i>Pharmaceutical companies as well as EPC contracting companies are facing a continual need to reduce costs and improve efficiencies while executing capital projects. In this presentation, the author presents some good practices being followed in other domains like manufacturing, IT, Quality will be presented, and the feasibility of adopting these good practices into the EPCMV cycle explored.</i></li> <li>• <b>“Efficient Material Handling is the Key to ‘Lean Manufacturing’”</b>, <b>David Drew</b>, Group Pharmaceutical Director, Matcon Ltd <i>This presentation will discuss and compare potential new trends in the industry in relation to efficient material handling - Continuous, Semi-continuous or Batch processing; Manufacture to Order or Campaign Manufacture, amongst others.</i></li> </ul>	
	Pharma Nite (Ballrooms Foyer)	

**Tuesday, 2 June**

**Concurrent Breakout Tracks**

	<b>Manufacturing Excellence</b>	<b>Automation</b>	<b>Contract Manufacturing</b>
<b>9:00 AM – 12:30 PM</b>	<p><b>Track Moderator: Lee Hong Ping</b>, Business Development Manager, CH2M HILL Singapore</p> <ul style="list-style-type: none"> <li>• <b>“Product Quality Lifecycle Implementation (PQLI) – Current status and Future Plans”, Dr. John Berridge</b>, European Regulatory Affairs Advisor, ISPE (video-presentation) <i>This presentation will provide an introduction to PQLI, describing its origins and how it is of vital importance and value to the Industry in supporting the understanding and implementation of recent ICH guidelines. The presentation will continue by showing how PQLI is providing clarity and pragmatism through the provision of conference materials and publications which address the many different ways that the principles of Quality by Design as described in ICH guidance Q8(R) can be implemented. PQLI is not restricted to simple product realisation of small molecules, but is contributing to all sectors of the industry including existing products and biotechnology. The presentation will conclude by describing the breadth and depth of the PQLI activities current and planned.</i></li> <li>• <b>“Continuous processing – an overview of opportunities and challenges”, Dr. Paul Sharratt</b>, Programme Manager &amp; Principal Scientist, Process Science and Modelling Research Programme, ICES <i>This presentation will provide insights on both the technical and commercial benefits of continuous processing, the challenges of the skill base needed, to the organisation and management.</i></li> <li>• <b>“Continuous Processing for API”, George Routhier</b>, Production Director, Pfizer Asia Pacific <i>This presentation will discuss the challenges and lessons learnt from continuous processing operations within an API facility.</i></li> </ul>	<p><b>Track Moderator: Eugene Yeo</b>, Business Development Manager, IIA Competence Centre Pharma – Asia Pacific, Siemens</p> <ul style="list-style-type: none"> <li>• <b>“Computerised System Validation: An Auditor’s View on Getting it Right”, Dr. Dragana Milic</b>, Audit Team Manager, Office of Manufacturing Quality, Therapeutic Goods Administration <i>The presentation will discuss commonly observed deficiencies in validation of automated/computerised systems using real life case studies. It will also use examples to illustrate misunderstandings regarding regulatory requirements for validation of automated systems.</i></li> <li>• <b>“Cost effective validation with GAMP 5”, Uwe Mayer</b>, Director for GMP Regulation, Competence Center Pharmaceuticals, Siemens AG Industry Sector <i>The presentation gives practical examples on how to modify your existing validation methodology and of how to use the GAMP 5 guide effectively without jeopardizing quality and compliance.</i></li> <li>• <b>“Accelerated Change Management in Automation Projects”, Declan Lynch</b>, Operations Manager, Zenith Technologies Singapore <i>With the modern day project schedule and cost expectations getting more and more demanding, the effective control of accelerated change can be a key success factor in projects. This paper examines, with the use of practical case studies, the key challenges faced in such an environment and through the deployment of ACM techniques, how the risks to project schedules and costs can be significantly reduced or eliminated altogether.</i></li> </ul>	<p><b>Track Moderator: Gus Abdallah</b>, Managing Director, Synertec Asia Pte Ltd</p> <ul style="list-style-type: none"> <li>• <b>“Contract Manufacturing - a MNC perspective”, Tony Uhe</b>, Senior Director Quality Operation, External Manufacturing Asia Pacific, GPSG, Johnson &amp; Johnson <i>This presentation will provide a MNC views on the selection of a new External Manufacturer - the business case, due diligence process, technology transfer and validation, risk assessment and monitoring. It will also discuss the MNC expectations for contract manufacturers, future directions for contract manufacturing and other related issues.</i></li> <li>• <b>“Contract Manufacturing – A manufacturer’s perspective on issues, challenges and solutions”, Ms. Zarina Noordin</b>, Senior Manager, International Manufacturing, Pharmaniaga</li> <li>• <b>“Biologics Outsourcing – Challenges and Lessons Learnt”, Dan Hagewiesche</b>, Director of CHO Production, Singapore Product Operations, Genentech <i>The presentation will focus on proven approaches used for the planning and management of technology transfers to CMO's. It will also cover some of the common pitfalls, challenges and the strategies used to minimize risks and ensure successful technology transfers.</i></li> </ul>
<b>12:30 PM – 2:00 PM</b>	<b>Lunch</b>		
	<b>PIC/S Regulatory Update for Emerging Markets</b>	<b>Biopharma</b>	<b>Validation: Hot Topics</b>
<b>2:00 PM – 5:30 PM</b>	<p><b>Track Moderator: Ms. Linda Ambrose</b>, Director, Ambrose Consulting Ltd</p> <p><i>This session will focus on the associated challenges of PIC/S adoption within the ASEAN region, with views and insights provided by the regional inspectorates on related issues, which includes Training issues, for both inspectors and the industry. Hear the regulators as they share their views on the challenges of PIC/S adoption, and participate in the interactive discussion.</i></p> <ul style="list-style-type: none"> <li>• <b>Jacques Morenas</b>, Assistant Director, French Agency for the Safety of Health Products (AFSSAPS) / Chairman, PIC/S</li> <li>• <b>Sia Chong Hock</b>, Division Director, Manufacturing &amp; Quality Audit Division, Health Products Regulation Group, Health Sciences Authority</li> <li>• <b>Mr. Apichai Hoonchamlong</b>, Chief of Inspectorate Unit, Drug Control Division, Food &amp; Drug Administration, Ministry of Public Health, Thailand</li> <li>• <b>Ms. Dra. Togi Hutadjulu</b>, Head, Sub-Directorate of Control of Raw Material and GMP Analysis, National Agency of Food &amp; Drug Control (NADFC), Indonesia</li> </ul>	<p><b>Track Moderator: Dr. Patrick Yeung</b>, Consultant, PPY Pharma Services Pte Ltd</p> <ul style="list-style-type: none"> <li>• <b>“Development of a Vaccine Plant – Challenges &amp; Lessons Learnt”, David Callaert</b>, Regional Engineering Director, GSK Biologics <i>This presentation will provide insights on the challenges and lessons learnt in the development of a vaccine plant, in relation to the recent development and construction of the GSK biologics facility.</i></li> <li>• <b>“Science and risk Based Approach to Biopharmaceutical Production”, Dr. Harry Lam</b>, Director of Manufacturing &amp; Technology, Genentech Singapore</li> <li>• <b>“The application of disposable single-use equipment, and it’s impact on biopharma plant design”, Andy Rayner</b>, Group Director of Technology, PM Group <i>The presentation will focus on applicability of single use equipment for bulk biologic applications. It will identify which unit operations are best considered for utilizing disposable equipment, identifying some of the latest trends and will identify some key considerations in selecting, procuring, installing, commissioning and validating disposable equipment. The presentation will go on to identify the impact of providing single use equipment on plant layout, utilities and plant operations, as well as highlighting the potential impacts on both capital investment and on cost of goods.</i></li> <li>• <b>“Application of membrane bioreactor in the chemical-pharmaceutical industry for the removal of micro-pollutions”, Michel Buser</b>, Managing Director, EcoSign <i>This presentation will provide insights into occurrence and effects of micro-pollutions on the aquatic system, the trends in environmental legislation and how to approach the stringent legal requirements in a cost effective and sustainable manner, principle of a membrane bioreactor (MBR) system including advantages/disadvantages and application of MBR in the chemical-pharmaceutical industry including some case studies.</i></li> </ul>	<p><b>Track Moderator: Dr. Belinda Braggs</b>, Managing Director, SeerPharma (Singapore) Pte Ltd</p> <ul style="list-style-type: none"> <li>• <b>“Cleaning Validation for Pharmaceutical and Biological Operations”, Steve Williams</b>, Director, SeerPharma Pty Ltd</li> <li>• <b>“How a Factory Acceptance Test can reduce on site validation time for a packaged water treatment plant”, Mike Gaunt</b>, Technology Manager, Pharmaceutical Competence Centre, Veolia Water Solutions &amp; Technologies <i>This presentation will look at the use of a Factory Acceptance Test for a packaged water treatment plant and how this impact on the validation documentation required to be completed on site. We will look at the experience gained from completing a Factory Acceptance Test for differing users in the Pharmaceutical Industry and how their requirements may differ from each other.</i></li> <li>• <b>“Understanding and Implementing the New EU Annex 11”, Dr. Ludwig Huber</b>, Chief Advisor, Global ISO 17025 and FDA Compliance, LabCompliance <i>This presentation will provide insights on Annex 11: the European equivalent of FDA's Part 11, including key points of the new Annex, comparison with FDA's new approach for Part 11, specific validation requirements, requirements for electronic records and signatures, how to ensure and demonstrate data integrity and the strategy for combined implementation of the 'new' Part 11 and Annex 11.</i></li> <li>• <b>“New FDA Process Validation Guidance Document - What to Expect”, David W. Vincent</b>, CEO, Validation Technologies, Inc. <i>The new FDA Process Validation guidance will have a major impact on all aspect of the life science industry. The presentation will discuss which industries will be impacted by the new draft “Process Validation” guidance document; it will also highlight major concepts, and potential industry impact. This topic will detail the differences between the current Process Validation and the new draft guidance document.</i></li> </ul>