ISPE SINGAPORE CONFERENCE
IN ASSOCIATION WITH INTERPHEX ASIA
2009

31 May – 02 June
SUNTEC Singapore

Advancing Excellence
And Innovation In
Regional Pharmaceutical
Manufacturing

Jointly Organised by:
A member of:
Held in Conjunction:
Held in:

Media Partners:
With the theme of “Advancing Excellence and Innovation in Regional Pharmaceutical Manufacturing”, the ISPE Singapore Conference 2009 provides the regional pharmaceutical manufacturing industry with the opportunity to learn and gain from the views and insights of international and regional experts on issues pertaining to pharmaceutical manufacturing operations and processes.

Through Workshops, Plenary Keynotes and breakout track sessions, the ISPE Singapore Conference 2009 will feature more than 30 industry speakers who will share practical insights and updates on the global pharmaceutical manufacturing industry, provide regulatory updates on key issues, and share views and lessons learnt on sustainable solutions, contract manufacturing, secondary pharmaceutical manufacturing, C&Q and validation issues, amongst others.

The ISPE Singapore Conference 2009 will not only provide participants with an opportunity to learn, but also the opportunity to refresh old friendships and establish new connections at the Conference Networking Lunch and at PharmaNite, a dedicated networking event of the Conference.

Conference participants will also be provided with an opportunity to visit pharmaceutical manufacturing facilities* located in Singapore, which will include GSK, MSD, Pfizer, Schering-Plough, Novartis and Genentech. Participants will be able to view first-hand state-of-the-art facilities and be able to gain a better understanding of the manufacturing processes within these facilities. (*Please refer to “Pharmaceutical Facility Visits” section of this brochure for eligibility details)

The ISPE Singapore Conference 2008 welcomed 362 participants from 21 countries, with 80% of them being senior to middle managers within their respective pharmaceutical manufacturing operations.

Participate in the ISPE Singapore Conference 2009 if you are a pharmaceutical or biopharmaceutical manufacturing professional specialising in one of the following areas:

- Automation & IT
- Production Engineering & Processes
- Project Management
- Quality Control & Assurance
- Facility / Plant Management
- Laboratory Management
- Regulatory Affairs & Compliance
- Validation
- Energy & Sustainability
- Contract Manufacturing

Snapshot of the ISPE Singapore Conference 2008

DELEGATE BREAKDOWN BY REGION

- ASEAN (Singapore, Malaysia, Indonesia, Philippines, Thailand, Brunei, Vietnam)
- South Asia (India, Pakistan, Bangladesh, Oman)
- North Asia (China, Macau, Hong Kong, Taiwan)
- North East Asia (Japan, South Korea)
- Europe (Belgium, Denmark, Germany, Ireland, Norway, Sweden, Switzerland, UK, France, Spain)
- North America
- Oceania (Australia, New Zealand)

DELEGATE BREAKDOWN BY MANAGEMENT LEVELS

- Senior
- Middle
- Junior

20% 32% 48%
INTERPHEX ASIA 2009 is held in association with the ISPE Singapore Conference 2009, and is Asia's dedicated sourcing platform for the regional pharmaceutical manufacturing industry. INTERPHEX ASIA provides the opportunity to meet with international suppliers to forge partnerships, exchange ideas, and to discover new developments and solutions for related dedicated manufacturing processes within the industry.

INTERPHEX ASIA is open to all participants of the ISPE Singapore Conference 2009. For more information on INTERPHEX ASIA, please visit www.interphexasia.com

ISPE Singapore Affiliate Board 2008-09

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GPSG (A J&J Company) Singapore Sourcing Centre

For more information on ISPE membership, please contact the ISPE Asia Pacific Office at +65 64965502 or email to asiapacific@ispe.org or visit www.ispe.org
Sunday, 31 May (Concurrent Workshops)

1:30 PM – 5:30 PM

**Workshop 1: Commissioning & Qualification**
This workshop aims to provide insights into new and developing trends from the ISPE Baseline Guide on Commissioning & Qualification and ASTM E2500 guidelines

*Workshop co-leaders:*
- Dr. Alice Redmond, CQ Technical Director, PM Group
- Joe Eades, Principal Project Engineer at Novartis and Director of PCDS, Singapore
- Robert Steen, Director, Process Design and Commissioning Services Pte Ltd

**Workshop 2: Auditing for GMP**
This workshop aims to provide a regulatory perspective (regulatory GMP audits – what to expect and how to handle) and industry perspective (with a focus on auditing suppliers).

*Workshop co-leaders:*
- Bob Tribe, ISPE Asia Pacific Regulatory Advisor
- Dr. Prasad Kanneganti, Quality Operations Director, Pfizer Asia Pacific

Monday, 1 June

9:00 AM – 1:00 PM

**Plenary Keynote Session**
- Welcome Address and Update on Community of Practices (COP) – Ms. Tracy Clemmer, President, ISPE Singapore Affiliate
- Regulatory Keynote by Food & Drug Administration (FDA) (presentation via videoconferencing)
- EMEA Regulatory Update - Jacques Morenas, Assistant Director, French Agency for the Safety of Health Products (AFSSAPS) / Chairman, PIC/S
- Global Industry Update - Jan Willem Eleveld, Vice President, Consulting & Services, APAC, IMS Health

1:00 PM – 2:30 PM

**Lunch (Gallery West)**

2:30 PM – 6:00 PM

**Concurrent Breakout Tracks**

**Regulatory**
- Jacques Morenas, Assistant Director, French Agency for the Safety of Health Products (AFSSAPS) / Chairman, PIC/S

- "Towards an ASEAN Sectoral MRA on GMP Inspection", Sia Chong Hock, Division Director, Manufacturing & Quality Audit Division, Health Products Regulation Group, Health Sciences Authority
  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.

- "Desk-top Audit initiative", Dr. Dragana Milic, Office of Manufacturing Quality, Therapeutic Goods Administration

- Mr. Joe Eades, Principal Project Engineer at Novartis and Director of PCDS, Singapore

- Md Lukmani Ibrahim, Head of GMP and Licensing, NPCB (invited)

**Sustainable Solutions**
- "Waste Minimisation", Ms. Yang Hong, Senior Environmental Health Executive, National Environment Agency (NEA)
  This presentation will cover the strategies for solid waste management, and the eight steps to a waste minimisation plan for industries.

- "Energy Optimisation", Goh Yong Keng, Engineering Director, Schering-Plough
  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.

- "Energy Management in an API Facility" Yeo Yee Pang, Energy Manager, GSK
  This presentation will discuss the various components of an effective energy management programme, which encompass data collection, analysis, campaign, operations optimisation and waste avoidance.

- "Lonza Case Study – BCA Greenmark Gold & pv Solar Projects", Stephen Keane, Senior Project Manager, Lonza 2 Bulk Bio Facility
  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 & experiences of the project team as they embarked on this journey within a large Bulk Bio project environment.

**Secondary Pharma Manufacturing**
- "A practical approach to retrospective validation of pharmaceutical products", Brad Roberts, Partner & Senior Consultant, SeePharma Pty Ltd
  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 & Process Capability to help manufacturers understand the true capabilities of their manufacturing processes.

  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.

- "Good Practices in EPCMV Cycle in Secondary Pharma Manufacturing”, M. Bala, Senior Engineer Life Sciences,  M+W Zander
  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.

- "Efficient Material Handling is the Key to 'Lean Manufacturing'", David Drew, Group Pharmaceutical Director, Matcon Ltd
  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.

6:00 PM – 7:00 PM

**Pharma Nite**

Programme subject to changes
**Regional Pharmaceutical Manufacturing**

**Tuesday, 2 June**

<table>
<thead>
<tr>
<th>9:00 AM – 12:30 PM</th>
<th>Concurrent Breakout Tracks</th>
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<tbody>
<tr>
<td><strong>Manufacturing Excellence</strong></td>
<td><strong>Automation</strong></td>
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<tr>
<td><em>Product Quality Lifecycle Implementation (PQLI) initiative – An Update</em> (Speaker to be confirmed)</td>
<td>Dr. Dragana Milic, Office of Manufacturing Quality Therapeutic Goods Administration</td>
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<tr>
<td>“Continuous processing – an overview of opportunities and challenges”, Prof. Paul Sharratt, Head, Process Science and Modelling Research Programme, ICES</td>
<td><em>Electronic Batch Record systems (EBR)</em>”, Bob Lenich, Emerson Processing</td>
</tr>
<tr>
<td>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.</td>
<td><em>Cost effective validation with GAMP 5</em>, Uwe Mayer, Director for GMP Regulation, Competence Center Pharmaceuticals, Siemens AG Industry Sector</td>
</tr>
<tr>
<td>“Continuous Processing for API”, George Routhier, Production Director, Pfizer Asia Pacific</td>
<td>The presentation gives practical examples on how to modify your existing validation methodology and how to use the GAMP 5 guide effectively without jeopardising quality and compliance.</td>
</tr>
<tr>
<td>This presentation will discuss the challenges and lessons learnt from continuous processing operations within an API facility.</td>
<td><strong>Contract Manufacturing</strong></td>
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<td><strong>PIC/S Regulatory Update for Emerging Markets</strong></td>
<td><strong>Biopharma</strong></td>
</tr>
<tr>
<td>Facilitator: Bob Tribe, ISPE Asia Pacific Regulatory Advisor</td>
<td><em>Development of a Vaccine Plant – Challenges &amp; Lessons Learnt</em>, David Callaert, Regional Engineering Director, GSK Biologics</td>
</tr>
<tr>
<td>This session will focus on the associated challenges of PIC/S adaption 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.</td>
<td>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.</td>
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<td>Jacques Morenas, Assistant Director, French Agency for the Safety of Health Products (AFSSAPS) / Chairman, PIC/S</td>
<td><em>Science and risk Based Approach to Biopharmaceutical Production</em>, Dr. Harry Lam, Director of Production, Genentech</td>
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<td>Sia Chong Hock, Division Director, Manufacturing &amp; Quality Audit Division, Health Products Regulation Group, Health Sciences Authority</td>
<td><em>The application of disposable single-use equipment, and it’s impact on biopharma plant design</em>, Andy Rayner, Group Director of Technology, PM Group and Andrew Sinclair, Co-Founder, Managing Director, BioPharm Services</td>
</tr>
<tr>
<td>Jesuza Joyce N. Cirunay, Focal Person, ASEAN Harmonization, GMP-PICS Membership Coordinator, Bureau of Food and Drugs, Dept. of Health, Philippines (invited)</td>
<td>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.</td>
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<tr>
<td>Md Lukmanri Ibrahim, Head of GMP and Licensing, NPCB (invited)</td>
<td><strong>Validation: Hot Topics</strong></td>
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<td>Thailand / Indonesia Inspectorates (invited)</td>
<td>&quot;Clearing Validation for Pharmaceutical and Biological Operations&quot;, Steve Williams, Director, SeerPharma Pty Ltd</td>
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<td><strong>Lunch (Gallery West)</strong></td>
<td><em>How a Factory Acceptance Test can reduce on site validation time for a packaged water treatment plant</em>, Mike Gaunt, Technology Manager, Pharmaceutical Competence Centre, Veolia Water Solutions &amp; Technologies</td>
</tr>
<tr>
<td><strong>2:00 PM – 5:30 PM</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Concurrent Breakout Tracks</strong></td>
<td>&quot;Understanding and Implementing the New EU Annex 11”, Dr. Ludwig Huber, Chief Advisor; Global ISO 17025 and FDA Compliance, LabCompliance</td>
</tr>
<tr>
<td><strong>Contract Manufacturing</strong></td>
<td>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.</td>
</tr>
<tr>
<td><em>&quot;Contract Manufacturing – a MNC perspective”, Tony Uhe, Senior Director Quality Operation, External Manufacturing Asia Pacific, GPSS, Johnson &amp; Johnson</em></td>
<td><strong>New FDA Process Validation Guidance Document - What to Expect”, David W. Vincent, CEO; Validation Technologies, Inc.</strong> 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.</td>
</tr>
</tbody>
</table>

Programme subject to changes
Important Notes for Conference Delegates

Cancellation & Substitution Policy
Notice of withdrawal must be given in writing at least 14 working days (15 May 2009) before the commencement of the Conference. Failure to do so will result in your registration being billed for the registration despite “non attendance”. No refund of fees will be made for cancellations on or after 16 May 2009 or “non attendance” participants. Substitutions are acceptable in writing to the organiser. However, no members substituting for members must pay the difference in fees prior to the Conference.

Confirmation Details
Entry to the Conference is subject to FULL PAYMENT being received before the commencement of the Conference. It is therefore important to ensure that payment reaches the Organiser at least 5 working days before commencement. Outstanding payment may be made at the Conference registration counters in CASH or by CREDIT CARD only.

Delegate Administration Letters will be provided to each registered delegate at least two weeks before the commencement of the Conference. The Letter will provide details of delegate administration at the venue. Registered delegates who do not receive the Letter one week before the Conference, please contact the Organiser.

Important Notes to all Participants
1. Early Bird Rate will expire at end of workday, Friday, 17th April (Singapore Time). Early Bird Rates will only be accorded to registrations received with FULL PAYMENT by 17th April.
2. 1 year ISPE membership is not included in Non Member participation rates. For current membership rates, please visit www.ispe.org for more information.
3. All rates displayed are in Singapore Dollars. All payment must be made in Singapore Dollars.
4. The prevailing GST rate will apply to all registrations received from Singapore-based organisations or individuals.
5. All registration must be accompanied by full payment. The registration fee includes lunches, tea breaks and related conference materials.
6. Workshops are conducted concurrently. Registration to attend workshops only are acceptable, or in combination with a 1 Day Conference Fee only.
7. In moving towards being environmentally friendly, all registered conference delegates will receive a set of the conference proceedings in CD format instead of the printed version.
8. The Organiser reserves the right to refuse acceptance of any registration without prejudice.

Notes on Academic Rates
1. For Academic rates, multiple registrations from the same organisation are not eligible for group discounts. Only full time staff students and faculty members of the following Singapore based institutions are eligible for Academic rates:
   a. Singapore public tertiary institutions and polytechnics – NUS, NTU, SIM / SP, RP, NP, TP, NYP
   b. Institute of Technical Education
   c. A*STAR and the associated research organisations; and institutions funded directly by A*STAR or through the associated organisations.

*Discount on Delegate Fees
For organisations with group registrations, please note the following:
1. Basic fees apply to registration of 1st & 2nd delegates, from the same organisation.
2. An additional 10% discount rate will apply to the relevant Basic Fees for registration of 3rd & 4th delegates, from the same organisation
3. An additional 15% discount rate will apply to the relevant Basic Fees for registration of the 5th delegate onwards, from the same organisation.

General Notes on Sale Of ISPE GAMP 5 And Baseline Guides
1. Members received 15% discount off regular member rates if they purchase a technical guide with their early bird registration. (Order must be received 2 weeks before the conference)
2. Limited supply of technical guides will be available for purchase at the conference on a first come basis. Cost will be at regular member/non-member rates
3. Non-member price will be the same if they pre-order or purchase at the conference. Pre-order reserves a guide for them – if they wait until the conference it will be subject to availability.
4. The ISPE Singapore Affiliate will contact you with regards to payment of your purchase. Publications can be collected at ISPE booth/day at the conference.
5. Website with details on the publications: http://www.ispe.org/cs/gamp_publications_section/gamp_publications_overview

Information on Accommodation for Foreign Delegates
The Organiser of the ISPE Singapore Conference 2009 is pleased to be able to offer conference registration + accommodation packages to all foreign delegates to the Conference. The following are brief information of the two hotels for foreign delegates.

Carlton Hotel Singapore (4 Star hotel)
The Carlton Hotel is conveniently located at the crossroads of Singapore’s largest underground shopping mall, busiest financial and Convention centres and just minutes away from Cultural and Entertainment zones. Changi International Airport is approximately 20 minutes by car, and City Hall Mass Rapid Transit (MRT) for island-wide commuting is only a 5 minute walk away. All 630 elegant guestrooms offer contemporary comfort with personalised services on the Carlton Club Floor. An outdoor swimming pool with a two-tiered sundeck amidst cabanas and a cascading waterfall beds. A suite of stylish restaurants is set to delight your gastronomic palate. (http://www.carlton.com.sg)

Link Hotel Singapore (3 Star Boutique hotel)
Located at Tong Bahru estate, you will wake up to the sights and sounds of the heartlands at the biggest boutique style hotel in Singapore. The melodious chirping of the birds at the bird arena beckons as mouth-watering local cuisines awaits you at the nearby market. Whatever the purpose of your stay, we aim to make you feel at home at Link Hotel Singapore. (http://www.linkhotel.com.sg)

Travel & Accommodation for Foreign Delegate - Official Travel Agent
Foreign delegates may make accommodation arrangements on their own accord, take up the accommodation package with us or contact the ISPE Singapore Conference 2009 Official Travel Agent, Orient Explorer (E) Pte Ltd, for travel and accommodation assistance. Please contact Ms. Jeron Ong at +65 6339 8887 or email her at jeron@orient-explorer.com.

Important Notes for Conference Rates (inclusive of accommodation)
1. This package is specially prepared for foreign delegates of the conference and is inclusive of delegate fees and accommodation.
2. Delegates may select the package according to their choice of hotel and suggested duration of stay, with option for additional nights.
3. Delegates are advised to ensure that the accommodation duration selected will enable them to participate fully in their selected conference participation (eg – 2 Day Conference + facility visit).
4. Additional Room night at Link Hotel and Carlton Hotel is priced at S$140.00 nett and S$226.00 nett respectively.
5. Delegates may also register for the Conference and make alternative accommodation arrangements on their own accord, or through the Conference Official Travel Agent (OTA).
6. All rates are in Singapore Dollars and are nett rates. All payment must be made in Singapore Dollars.
7. Shuttle bus service will be arranged for delegates from Hotel to conference venue and vice versa daily.
8. Room situation is expected to be critical in the period of the event, kindly submit all registrations by Monday, 4 May 2009 in order to secure the room at the Hotel. Please note that booking is subject to availability by the hotel.
9. Room sharing (additional occupant) may be subjected to additional charges by the respective hotels.
10. Please register early to ensure your hotel reservations. All reservations will only be processed upon full payment being received by the Organiser.
11. Link Hotel Package is inclusive of daily breakfast. Breakfast is NOT inclusive in the Carlton Hotel Package.
12. The hotels’ official check in time is 1400 hours onwards and check out time at 1200 hours (or before).
13. Requests for early check in and late check out are subject to room availability. Additional charges will apply for guaranteed early check-in or late check-out.
14. In the event the reservation is cancelled after 8 May 2009 (Friday), there will be a cancellation charge of the entire duration booked (3 nights).

About the Organisers
Reed Exhibitions is the world’s leading events organiser, with over 470 events in 37 countries. In 2008 Reed brought together over seven million industry professionals from around the world generating billions of dollars in business. Today Reed events are held throughout the Americas, Europe, the Middle East and Asia Pacific, and organised by 38 fully staffed offices.

Reed organises a wide range of events, including exhibitions, conferences, congresses and meetings. Its portfolio of over 470 events serves 44 industry sectors, including: Aerospace & aviation, automobiles, broadcasting, building & construction, electronics, energy, oil & gas, engineering, manufacturing, environment, food service & hospitality, gifts, healthcare, interior design, IT & telecoms, jewellery, life science & pharmaceuticals, machinery, medical education, printing & graphics, property & real estate, security & safety, sports & recreation, travel.

Working closely with professional bodies, trade associations and government departments Reed ensures that each and every event is targeted and relevant to industry needs. As a result, many Reed events are market leaders in their field.

Reed Exhibitions is part of Reed Elsevier Group plc, a FTSE-100 company and world-leading publisher and information provider. In 2007, Reed Elsevier made an adjusted profit before taxation of £998 million on turnover of £4,584 million.

ISPE, the International Society for Pharmaceutical Engineering, is the Society of choice for 25,000 pharmaceutical science and manufacturing professionals in 90 countries. ISPE aims to be the catalyst for “Engineering Pharmaceutical Innovation” by providing Members with opportunities to develop technical knowledge, exchange practical experience, and collaborate with global regulatory agencies and industry leaders. Founded in 1980, ISPE has worldwide headquarters in Tampa, Florida, USA; its European office in Brussels, Belgium; its Asia Pacific office in Singapore; and its newly established office in Shanghai, China. Visit www.ISPE.org for additional Society news and information.
ISPE SINGAPORE CONFERENCE 2009 REGISTRATION FORM

www.ISPESingaporeConference.com   ISPESingaporeConference@reedexpo.com.sg   +(65) 6780 4601   +6(6) 6588 3808

Reed Exhibitions, c/o ISPE Singapore Conference 2009, The Signature, 51 Changi Business Park Central 2, #07-01 Singapore 486066

For multiple registrations, please make copies of this registration form.

Registration

(Please print or write legibly. Illegible information may result in processing delay of your registration)

Mr  Mrs  Ms  Mdn  Dr  Others (please specify__________________________

First Name: ___________________________  Last Name: ___________________________

Job Title: ___________________________  Organisation: ___________________________

Address: ___________________________

Postal/Zip Code: ___________________________  State: ___________________________  Country: ___________________________

Tel: ___________________________  Fax: ___________________________

Email: ___________________________

Management Level:  Senior  Middle  Junior

ISPE Membership Number: ___________________________

Note: The above rates are inclusive of conference participation and accommodation. Please refer to “Information on accommodation for Foreign Delegates” for hotel details.

*Please refer to “Discount on Delegate Fees” under the “Important Notes to all Participants” for more information.

†For Academic rates, multiple registrations from the same organisation are not eligible for group discounts.

Conference Workshop and/or Track(s) Selections

Check one box:

Track 1: Regulatory

Track 2: Sustainable Solutions

Track 3: Secondary Pharma Manufacturing

Track 6: Contract Manufacturing

Note: please refer to “discount on Delegate Fees” under the “important Notes to all Participants” for more information.

Conference Rates Please indicate your selected conference rate with a tick (✓) in the appropriate box:

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<tr>
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<th><strong>EARLY BIRD</strong></th>
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<td>Workshop</td>
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<tr>
<td>NA</td>
<td>$179.00</td>
<td>$169.15</td>
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<tr>
<td>1 Day Conference (2 or 3 June)</td>
<td>$1,064.00</td>
<td>$1,124.50</td>
</tr>
<tr>
<td>Package Rate (2 Day Conf 1 Workshop)</td>
<td>$1,031.00</td>
<td>$1,101.50</td>
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*Please refer to “Discount on Delegate Fees” under the “Important Notes to all Participants” for more information.

Conference Workshop and/or Track(s) Selections Please indicate your selected conference workshops and/or tracks with a tick (✓) in the appropriate box:

Workshop on 31 May, Sunday

Workshop 1: Commissioning & Qualification

Workshop 2: Auditing & GVP

Concurrent Breakout Tracks on 1 & 2 June, Monday & Tuesday

Concurrent Breakout Tracks on 1 & 2 June, Monday & Tuesday

Concurrent Breakout Tracks on 1 & 2 June, Monday & Tuesday

Concurrent Breakout Tracks on 1 & 2 June, Monday & Tuesday

Chemical Facilities Visit – Wednesday, 3 June 2009 (9 am – 1 pm)

Please tick (✓) ONE facility only:

- GlassSteel - Production Building 2 & R&D Pilot Plant
- MSD Pharmaceutical Formulation (Tablet) Facility
- Genetech Singapore Product Operations
- Pfizer Asia Pacific API Manufacturing Facility
- MSD API Manufacturing Facility
- Novaris Solid Dosage Manufacturing Facility
- Abbott Nutritional Manufacturing Facility
- Lanza Bio Bulk Bio Manufacturing Facility

NOTE: Chemical facility visits are open to conference delegates who register for a minimum of 2 days Conference Pass, for one facility selection per registration. Each facility visit will have limited seats allocated, and each seat will be allocated on a space available basis. A written confirmation accompanied with visit instructions, will be provided to each delegate.

ISPE GAMP 5 And Baseline Guidelines

The following publications are available to all registered delegates of the ISPE Singapore Conference 2009. Please select the quantity for each of the publications that you wish to purchase, and the ISPE Singapore Affiliate will contact you with regards to payment and collection of your order:

<table>
<thead>
<tr>
<th>Title</th>
<th>QTY</th>
<th>Member Price</th>
<th>Non-member Price</th>
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<tr>
<td>GMP 5</td>
<td>$530</td>
<td>$598</td>
<td>$720</td>
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<tr>
<td>CRP Study Guide</td>
<td>$553</td>
<td>$562</td>
<td>$593</td>
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</tbody>
</table>

*Please refer to “General Notes on sale Of ISPE GAMP 5 And Baseline Guides” for more details.
Pharmaceutical Facility Visits

GSK Jurong Facility

Production Building Two

GlaxoSmithKline’s factory in Jurong is part of a global network of 78 factories in Global Manufacturing and Supply (GMS). The site was opened in 1982 for the manufacture of ranitidine hydrochloride, the active ingredient for Zantac for the treatment of stomach ulcers. It is now one of just two New Product Introduction (NPI) sites for Active Pharmaceutical Ingredients (API) within the GMS network and plays a key role in bringing GSK’s new products to market.

Since 1982 the site has continued to develop and now comprises 3 main production buildings for commercial operations and a two-stream pilot plant for the supply of clinical trial materials and for the final development of processes prior to full-scale manufacture. To date, we have invested a total of $5.1bn in Singapore.

Production Building Two (PB2) is the second production building to be constructed at GSK’s site in Jurong. It is a multi-purpose plant and was opened in 1994 at a cost of $525.4 million and we are about to invest a further $100m to improve the capability and flexibility for the building in its role as an Industrialisation Facility for new products. PB2 produces the Active Pharmaceutical Ingredients (API) that are used in the manufacture of the products such as Zofran (Ondansetron), Imigluz (Miglure) and Serevent (Formoterol).

Pfizer API Manufacturing Plant

Pfizer Asia Pacific Pte Ltd is the newest of the Pfizer Global Manufacturing (PGM) division’s active pharmaceutical ingredient (API) manufacturing facilities. The plant site is located on 40 acres in the Tuas Biomedical Park and employs more than 250 highly skilled engineers, chemists, technicians and other professional employees.

The facility consists of a general purpose Organic Synthesis Plant (OSP) and all the supporting facilities such as warehouse, dispensary, engineering maintenance and stores facility; utilities plant, solenoid tank farm and solvent recovery area, drum storage, wastewater treatment plant, quality control laboratory, administration and cafeteria building. The facility is fully automated recipe drive control system.

The plant has a number of facilities that contribute to protecting the natural environment, including a regeneration plant which reduces carbon dioxide emissions by 17%, as well as solvent recovery systems, a wastewater treatment plant and a regenerative thermal oxidizer, all designed to conserve resources or minimize waste.

Novartis

Novartis has invested in a new PMDA/EMA-compliant plant in Singapore for the bulk manufacture of solid dosage forms (tablets), for distribution primarily to Japan and the US. Construction began late 2004, validations set in 2007 and commercial production began in December 2008.

The production focus will be on growth products, in line with the TechOps capacity optimization strategy. Investment of approximately USD 180 million will provide production capacity for 3.5 billion units (tablets), with the potential for expansion after 2008 to 6 billion units (or 20% of the overall solids manufacturing capacity in Pharma).

Schering Plough Singapore Facility

The first global science-based health care company to set up operations in Singapore, Schering-Plough is also Singapore’s largest pharmaceutical investor, having invested significantly in developing manufacturing and R&D capabilities on the island.

Since 1995, Schering-Plough has leveraged Singapore’s solid infrastructure, skilled workforce and pro-business environment to expand to its current six manufacturing facilities, producing a range of key active pharmaceutical ingredients, as well as finished drug products.

Schering-Plough is the first pharmaceutical company to set up an R&D pilot plant in Singapore which is also its first in the Asia-Pacific region, a testament to the nation’s commitment to research and the robust intellectual property regime that has been put in place here.

Genentech Singapore Product Operations Facility

In March 2007 Genentech announced plans to build a 1,000 liter capacity E. coli manufacturing facility in Singapore. Groundbreaking commenced in late June 2007 and GMP production began in February 2009 with licensure expected by early 2010.

The Genentech facility will be used initially for the production of Lucentis bulk drug substance. Lucentis is approved for the treatment of neovascular (wet) age-related macular degeneration (AMD), AMD is a major cause of gradual or sudden, painless, central visual loss in the elderly, brought on by deterioration of the macula.

Abbott Nutritional Manufacturing Facility

Founded in Chicago in 1888 by Dr. Wallace Abbott, Abbott is a global broad-based healthcare company based in the US, employing 68,000 people worldwide and markets its products in over 130 countries, with a comprehensive range of products includes nutritional products, laboratory diagnostics, medical devices and pharmaceutical therapies, addressing health needs from infancy to the golden years.

In Singapore, Abbott’s new plant in the Tuas Biomedical Park is the company’s first major capital investment in Asia as well as its largest nutritional investment ever. To date, the plant is also the largest investment in a nutritional facility in Singapore by a single company. The plant manufactures a wide range of infant nutritional products, such as Similac Advance, Pedialyte, Gain and Grow for Abbott’s fast-growing markets in Asia. When fully operational in late-2009, the plant will have more than 300 employees.

Lonza Biologics Facility

Lonza Biologics is a global leader in contract manufacturing of biopharmaceutical products using mammalian cell culture and microbial fermentation. Lonza is constructing a new 27,000 m2 large scale biologics manufacturing facility located at Tuas Biomedical Park in Singapore. This new facility will be a licensed multi-product cGMP manufacturing plant for production of monoclonal antibodies and recombinant proteins.

The facility will incorporate 4 x 20,000L bioreactor trains, with four 1K and 5K seed reactor trains. Coupled with this is a flexible downstream purification with capability over a range of product titers and separation technologies. Also included on the site to support operations are administrative facilities, quality control (QC) labs, warehousing and utilities.

In March 2007 Abbott announced plans to build a 1,000 liter capacity E. coli manufacturing facility in Singapore. Groundbreaking commenced in late June 2007 and GMP production began in February 2009 with licensure expected by early 2010.

The schedule calls for the plant to be finished construction 2010 with GMP operations in 202011. Total investment in the facility is $480 Million.