Celebrating **Growth** and **Continuous Innovation**

06 – 08 June 2010 | SUNTEC Singapore

www.ISPESingaporeConference.com
Challenges and Shifting Dynamics in the Global Pharmaceutical Manufacturing Industry

The centre of gravity for the global pharmaceutical industry is shifting. Increasingly, many multinational pharmaceutical companies are building up their presence in Asia – a region that provides them with not only new and cost-effective options to site their manufacturing activities, but also their research and development functions and clinical trial activities.

In a 2009 survey report by PricewaterhouseCoopers¹ in which they interviewed 185 multinational (MNC) and domestic pharmaceutical manufacturing companies across nine territories, 55% of the MNC and 62% of the domestic companies believe that Asia will be the centre of gravity for the global pharmaceutical market in the near future. This shifting dynamics will present unprecedented opportunities as well as challenges to the region’s existing pharmaceutical manufacturing community and the associated industry.

¹“Gearing up for a global gravity shift”, PricewaterhouseCoopers, 2009

“Celebrating Growth and Continuous Innovation”

With the theme of “Celebrating Growth and Continuous Innovation” and a programme that is developed by the industry for the industry, the ISPE Singapore Conference 2010 aims to cater to the education and knowledge upgrade needs of the region’s MNC and domestic pharmaceutical manufacturers.

Into the 10th edition, the Conference will provide participants a valuable opportunity to learn, to discuss and to exchange views, ideas and insights on issues relating to the manufacturing processes of the pharmaceutical industry. This will be achieved through a combination of workshops, Keynote presentations and breakout presentations and discussions focused on current and developing trends within the industry and sharing of experiences and insights presented by more than 20 international and regional regulatory and industry speakers. Visit to key manufacturing facilities is also a key highlight to look forward to for participants of the conference. In place of the Pharma Nite, the ISPE Singapore Affiliate will be organising a dinner to celebrate the 10th Anniversary of the Conference and Affiliate.
INTERPHEX ASIA 2010 is held in association with the ISPE Singapore Conference 2010, and is the 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 for visiting to all participants of ISPE Singapore Conference 2010. Visiting Hours are:
Monday 7 June 2010  |  10:00 AM – 06:00 PM
Tuesday 8 June 2010  |  10:00 AM – 05:00 PM

For more information on INTERPHEX ASIA, please visit www.interphexasia.com
Effective Cleaning Validation Program for Biologics Facility

Workshop outline is based on the requirement for developing an effective FDA/EU cleaning validation program for the biological industries. This workshop will focus the key elements in developing a strategy plan for developing and validation of biological products.

Leader:
David Vincent, CEO, Validation Technologies Inc.

Environmental Control & HVAC - Is sustainability and GMP compliance compatible?

Sustainability is the buzz word in all our lives today, personal and business. We have responsibilities to the planet, ourselves, our firms, and of course our customers. Our GMPs are clearly aligned towards patient safety, and don’t take into account the specific needs of sustainability or indeed occupational health. Occupational health and safety is also as essential part of sustainability. We all want our staff to get home in the evening or at the end of a shift. In this workshop session, we will look at the potentially conflicting needs, and see how to merge the demands, and prove we are secure in our operations.

Leader:
Gordon Farquharson, Managing Director, Critical Systems

“Celebrating Growth and Continuous Innovation”

Ray Collyer, Senior Consultant, SeePharma Singapore

Sunday, 6 June 2010

Monday, 7 June 2010

Programme subject to changes
“The Advantages of Leveraging Manufacturing Plant Designs Globally”

This presentation will discuss the advantages of leveraging plant design globally, and in which instances Lonza had to deviate from this concept. It will also analyze which aspects of the plant were changed to account for process requirements and lessons learned, and how Lonza adapted the design over time to ensure that the plant remained relevant to technology and the market progress.

John Machulski, Senior Project Director, Lonza Biologics Singapore

“Multi-Product Strategies in a Biologics Plant”

Multi-product control minimizing the risk of cross-contamination in facilities producing multiple biologics products has been in place at Roche Drug Substance manufacturing facilities for several years. A case study will be presented documenting the evolution of systematic risk management principles for multi-product control as utilized at Roche Drug Substance manufacturing facilities. The benefits of implementing a risk-based strategy, as well as the challenges will be discussed.

Dan Hagemies, Director of CHO Production, Roche Singapore Technical Operations

“Quality Management in Biologics Manufacturing”

Biopharmaceutical products are complex, manufactured by either recombinant, monoclonal antibody or other biotechnological methodologies that are highly susceptible to contamination with adventitious agents such as mycoplasma and viruses. Process-related impurities in biopharmaceuticals primarily result from not only potential toxins, but also from immunogenicity and tumorigenicity. These issues in biopharmaceutical products, coupled with ongoing changes in regulations, makes it extremely important for a biopharmaceutical company to have an effective quality management system in place. The requirements of GMP at each stage of drug development in order to assure the safety, purity and efficacy of products produced. This presentation highlights the challenges and pressures facing biopharmaceutical quality unit, and presents the strategic importance and value generated by CBO in their involvement in control of the manufacturing process, testing and release of biopharmaceutical products.

Dr. Praveen Kumar, Director, Quality Assurance & Regulatory Affairs, Alpha Biologics Sdn Bhd

ISPE Article of the Year 2009: “The FDA’s Draft Process Validation Guidance – A Perspective from Industry”

November 2008 saw the draft publication of the FDA’s long anticipated Guidance for Industry on ‘Process Validation: General Principles and Practices’. It outlines the FDA’s current thinking in regard to process validation, setting out the general principles and approaches that the FDA consider to be appropriate elements of process validation for the manufacture of Human and Veterinary drugs, including Biologics. The presentation will discuss the three stages of Process Validation as outlined in the process guidance – Process Design, Process Qualification and Continued Process Validation as well as a review of the guidance with particular emphasis on its impact on the current industry approaches to science and risk-based design and qualification.

Dr. Alice Redmond, CQ Technical Director, PMI Group

“Current Industry and Regulatory Requirements for Biological Process Validation”

This presentation provides practical guidance on compliance with the requirements of process validation that lead to risk-based, reasonable and supportable informed decisions. Compliance with the requirement for process validation must go hand in hand with sound science for the proper evolution of critical processes. The presentation includes process validation examples from biologic manufacturing processes. This includes the manufacturing of the API and the finished drug products.

David Vincent, CEO, Validation Technologies Inc.

“Validation Strategies for a Fast track API Facility”

This presentation will provide insights into innovations to a Validation Quality System for green field facilities. Issues relating to Validation Planning (documentation hierarchy), Defining the differences between commissioning and qualification; incorporating Risk Management into your Validation Programme; cleaning validation and periodic review, and validation will be discussed.

Todd Mabe, Principal Technical Manager, Validations, Roche Singapore Technical Operations

“Use of RABS in Sterile Manufacturing”

The use of RABS is problematic in traditional sterile manufacturing environments. With the need for increased productivity, traditional aseptic processes can no longer sustain the high cost of GMP facilities. RABS provide a means to cost effectively expand the footprint of a facility, while enhancing productivity. The presentation will cover RABS definition, classification, specification, validation and practical examples of how RABS can be used.

Anuj Sharda, Production Manager, Biotechnology Plant, MSD Singapore

“Automation for Aseptic Manufacturing”

Gaurav Mehta, Principal Project Automation Engineer, Alcon Singapore Manufacturing

“Securing the pharmaceutical supply chain: U.S. FDA’s efforts and perspectives”

The presentation will be in two parts, the control of raw materials, ingredients, excipients used for drug manufacturing and the counterfeiting drug issue. An overview of current FDA activities will be provided on GMP (process qualification) and system validation, international supply chain security, our regulatory tools and approaches, standard development for identification, tracking & authentication, some of the pilot study and initiatives.

Dr. Brenda Uratani, Assistant Country Director, FDA China Office, Beijing

“Ensuring Quality in the Supply Chain”

Tony Uhe, Senior Director, Quality Operations, External Manufacturing, Asia Pacific, GSPG, Johnson & Johnson

“Proactive Strategies for Managing Your Distribution Network”

This presentation will discuss recent issues prompting more regulatory scrutiny on distribution networks; GDP guidelines - Therapeutic and Medical Devices; what to expect from Regulatory enforcement; proactive strategies for managing GDP compliance.

Darren Freestone, Senior Consultant, SeerPharma

“Containment – is an Isolator Just an Expensive Box?”

This presentation will take a look at the design of containment solutions and the external processes which play significant roles in the technology selection and design development.

Simon White, Sales Director, Pharmaceutical Services Corporation Ltd

“Green Pharmaceutical Manufacturing”

The pharmaceutical industry is increasingly under pressure to improve its environmental performance. Primary pharmaceutical processes are inherently inefficient, with typically only 1% of input raw material ending up in the API. Secondary processes are prone to failure, leading to rejected product that often has to be incinerated – as well as requiring the manufacture of more API than is strictly necessary. Recently there has been an increasing focus on these issues, not only from regulators and as recognition of the importance of “corporate social responsibility”, but also as a means of accessing cheaper and more efficient processes. One example of increasing concern from the sector is the recently announced $933 million funding for environmentally oriented research - the “GSIP Singapore Partnership for Green and Sustainable Manufacturing”. This paper reviews the issues and some of the approaches that are or will be contributing to the greening of manufacturing in the pharmaceutical industry.

Dr. Paul Sharratt, Programme Manager, Process Science & Modelling Institute, Institute of Chemical & Engineering Sciences, A*STAR

ISPE Facility of the Year Award 2010 for Project Execution: Case Study of Genentech Singapore facility

This presentation will be a case study of the innovative technologies employed in the execution of the project on the challenges the project presented and lessons learnt-

Tim Petch, General Manager – Pharmaceutical Asia, Bovis Land Lease

“Implementation of An Electronic Batch Record System in a Biologics Production Facility”

Lorain Biologics Tuas is in the process of implementing the Emerson Process Management Electronic Batch Record system (Syncade). The system has previously been implemented at Lonza’s Visp and Portmouth (UK) facilities. This discussion will address the implementation strategy, navigating project challenges, and the benefits of the installed system in a running Biologics Production facility.

Mike Pelletier, Associate Director of Engineering, Lonza Biologics Singapore

“PAT, the enabler for Continuous Manufacturing Processes – An Innovative Way of Developing and Producing Drugs”

This presentation will highlight some real continuous process applications developed together with top Pharmaceutical companies and important OEM vendors supported by a real PAT IT infrastructure.

Bart Moors, Senior Business and Project Manager Pharmaceutical Industry SEA, Siemens AG
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.

The schedule calls for the plant to be finished construction 2Q2010 with GMP operations in 2Q2011. Total investment in the facility is S$480 Million.

MSD West Campus (API Operations)

The MSD facility at Tuas West Drive, Singapore encompasses the former Schering-Plough’s local active pharmaceutical ingredient manufacturing facilities and currently consists of five buildings. One of these buildings is dedicated to the manufacture of steroids (identified as Steroids Building in Attachment), two buildings for the production of a range of synthetic chemical ingredients (identified as Synthesis Building and MPP-1 Building in Attachment) and one Research & Development Building for the production of clinical trial materials with a segregated and dedicated area for the production of the Mometasone esters.

A fifth building has been constructed to complement the current chemical synthesis capability but it is currently not in operational mode. These five buildings are collectively referred to as Active Pharmaceutical Ingredient (API) Operations.

Roche Singapore Technical Operations Building 1 (Bacterial Plant)

Roche Singapore Technical Operations Building 10 (CHO Plant)

Pharmaceutical Facility Visits

Wednesday, 9 June 2010 | 09:00 AM - 12:00 PM

Pharmaceutical facility visits are open to conference delegates who register for a minimum of a 2 Day 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.

For more information on the Pharmaceutical Facility Visits, please visit www.ISPESingaporeConference.com

ISPE Singapore Affiliate 10th Anniversary Dinner

Date:    Monday, 7 June 2010
Venue:   Pan Pacific Hotel
Time:    6:30PM

The 10th Anniversary Dinner is a celebration of the Affiliate’s history. All registrations to attend the conference includes participation in the dinner (except for workshop and academic registrations).

For non-conference participants who wish to purchase dinner tickets or delegates who wish to purchase additional tickets, please visit www.ISPESingaporeConference.com
**Important Notes for Conference Delegates**

**A. Cancellation & Substitution Policy**
Notice of withdrawal must be given in writing at least 14 working days (by 14 May 2010) before the commencement of the Conference. Failure to do so will result in your organisation being billed for the registration despite “non attendance”.

No refund of fees will be made for cancellations on or after 14 May 2010 or “non attendance” participants. Substitutions are acceptable in writing to the organiser. However, non members substituting for members must pay the difference in fees prior to the Conference.

**B. Confirmation Details**
Enter to the Conference is subjected to FULL PAYMENT being received before the commencement of the Conference. It is therefore important to ensure that payment reaches the Organiser by 1st June 2010. 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.

**C. Payment Details**
1. Early Bird Rate will expire at 6:00PM, Friday, 23rd April (Singapore Time). Early Bird Rates will only be accorded to registrations received with FULL PAYMENT by 23rd April.
2. All rates displayed are in Singapore Dollars. All payment must be made in Singapore Dollars.
3. The prevailing GST rate will apply to all registrations received from Singapore-based organisations or individuals.
4. All registration must be accompanied by full payment. The registration fee includes lunches, tea breaks, related conference materials and 10th Anniversary Dinner (where applicable).
5. Entry into the conference sessions is subjected to full payment being received prior to commencement of the Conference. Please note that all payment must be received by 1st June 2010.
6. The organiser reserves the right to refuse acceptance of any registration without prejudice.

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

**E. Notes on Academic Rates**
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:
1. Singapore public tertiary institutions and polytechnics—NUS, NTU, SMU, SP, RP, NP, TF, NYP
2. The Academic rates includes lunches, tea breaks and related conference materials. 10th Anniversary dinner tickets may be purchased separately.
3. A*STAR and the associated research organisations; and institutions funded directly by A*STAR or through the associated organisations

**F. Notes on Workshops**
1. Fees for Workshop only registrations includes workshop materials and tea break. 10th Anniversary dinner tickets may be purchased separately.
2. Workshops are conducted concurrently. Registration to attend workshop only are acceptable, or in combination with a 1 Day Conference Pass only.

**G. Travel & Accommodation – Official Travel Agent**
Foreign participants of the ISPE Singapore Conference 2010 can contact the Official Travel Agent, BCD Travel, for travel and accommodation assistance. The contact person is Ms. Maureen Goh (maureen.goh@bcdtravel.sg or +65 6215 6050). Rooms are subjected to availability and Hotel reservations need to be made by 3rd May 2010 on a first-come-first served basis.

For more information, please visit www.ISPESingaporeConference.com

---

**About the Organisers**

**Reed Exhibitions**
Reed Exhibitions is the world’s leading events organiser, with over 440 events in 36 countries. In 2009 Reed brought together over six million active event participants 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 35 fully staffed offices.

Reed organises a wide range of events, including trade and consumer exhibitions, conferences and meetings. Its portfolio of over 440 events serves 44 industry sectors, including:
- Aerospace & aviation
- Automobiles, beauty & cosmetics
- Broadcasting, building & construction
- Electronics, energy, oil & gas
- Engineering & manufacturing
- Food service & hospitality
- Healthcare, interior design, IT & telecoms
- Jewellery, life science & pharmaceuticals
- Machinery, marketing, business services & training
- Medical education, printing & graphics
- 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 2009, Reed Elsevier made an adjusted profit before taxation of £1,279 million on turnover of £6,071 million.

**ISPE**
ISPE, the International Society for Pharmaceutical Engineering, is the Society of choice for 24,000 technical professionals working in or serving the manufacturing sector or drug development in the pharmaceutical industry in 90 countries. ISPE aims to be the catalyst for “Engineering Pharmaceutical Innovation” by providing Members with opportunities to develop their technical knowledge, exchange practical experience within their community, enhance their professional skills, and collaborate with global regulatory agencies and industry leaders. Founded in 1980, ISPE offers online learning opportunities for a global audience and has its worldwide headquarters in Tampa, Florida, USA; its European office in Brussels, Belgium; an Asia Pacific office in Singapore; and its newest office in Shanghai, China. Visit www.ISPE.org for additional Society news and information.

**Benefits of membership includes:**
- Online Membership Directory
- Regulatory Information and News
- Discounts on all ISPE Products and Services
- Communities of Practice
- ISPEAK E-Newsletter
- Industry Journals through SpringerLink
- Pharmaceutical Engineering Magazine
- Technical Documents
- Volunteer Opportunities
- Continuing Education and Training
- Technology-Based Learning
- PQ LI

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

---

For more information, please visit www.reedexpo.com.sg
**ISPE SINGAPORE CONFERENCE 2010 REGISTRATION FORM**

5 simple ways to register for the ISPE Singapore Conference 2010

- www.ISPESingaporeConference.com
- ISPESingaporeConference@reedexpo.com.sg
- +65 6780 4601
- +65 6588 3808

Reed Exhibitions, c/o ISPE Singapore Conference 2010, The Signature, 51 Changi Business Park Central 2, #07-01 Singapore 486066

For multiple registrations, please make copies of this registration form

Please provide the following details if the invoice is to be directed to another person for payment action:

- Name:
- Job Title:
- Email:
- Tel:

Invoicing Instructions

Please provide the following details if the invoice is to be directed to another person for payment action:

- Name:
- Job Title:
- Email:
- Tel:

Conference Rates

All rates shown are in Singapore dollars, less the prevailing taxes payable where applicable. Please indicate your selected conference rate with a tick (✓) in the appropriate box:

<table>
<thead>
<tr>
<th>Mode of Payment</th>
<th>Conference Rate</th>
<th>EARLY BIRD</th>
<th>NORMAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cheque Payment</td>
<td>$120.00</td>
<td>$189.50</td>
<td>$178.50</td>
</tr>
<tr>
<td>Credit Card Payment</td>
<td>$268.00</td>
<td>$241.50</td>
<td>$227.80</td>
</tr>
<tr>
<td>Telegraphic Transfer</td>
<td>$315.00</td>
<td>$299.00</td>
<td>$285.00</td>
</tr>
</tbody>
</table>

The registration fees for Conference (1 and 2 days) and Package include lunches, tea breaks, related conference materials, and 10th Anniversary Dinner.

• Please refer to Section D: Discount on Group Registrations for more information.

Conference Workshop and/or Track(s) Selections

Please indicate your selected conference workshop and/or track(s) rate with a tick (✓) in the appropriate box:

| Workshop 1: Effective Cleaning/Validation Programme for Biologics Facility |
| Workshop 2: Environmental Control & HVAC - Is sustainability and GMP compliance compatible? |

**Note:** All conference delegates will attend the Plenary Keynote Session on 7 June. Please refer to the conference programme for more details.

**Pharmaceutical Facility Visits – Wednesday, 9 June 2010**

- Please tick (✓) ONE facility only:
  - MSD West Campus
  - Lonza Biologics Facility
  - Roche Singapore Technical Operations Building 1 (Bacterial Plant)
  - Roche Singapore Technical Operations Building 10 (CHO Plant)

**Note:** Pharmaceutical facility visits are open to conference delegates who register for a minimum of a 2 Day 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 letter with visit instructions, will be provided to each delegate.