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# Advanced GMP 2008

Quality Manufacturing through Validation Excellence

25-26 November 2008 | Sheraton Towers Hotel | Singapore

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before 30 September 2008  
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A Part of:



**PART OF IBC ASIA'S GMP WEEK 2008**  
Co-location with *Pharmaceutical Packaging & Labelling Asia*

## Distinguished Panel of Speakers



Philip Baer, *Corporate Director, Regulatory Affairs and Quality Assurance, MED-EL, Austria*



Umesh Baikunje, *General Manager QA & Validation, Reliance Biopharmaceuticals Pvt Ltd, India*



Dr. Paul L J Tan, *Chief Executive Officer & Chief Operating Officer, Living Cell Technologies, New Zealand*



Judith Villanueva, *Regional Quality Assurance Manager, Zuellig Pharma Asia Pacific, Philippines*



Swapnil Ballal, *Head, Biopharmaceutical Bulk Manufacturing, Intas Biopharmaceuticals Ltd, India*



Dr. Shivraj Dasari, *Vice President - Q.M.R.A, Inno Bioventures Sdn Bhd, Malaysia*



Dr. Mavis Gail Meadows, *Director, Validation, Celltrion Inc, Korea*



Leo Hammendorp, *Director, Siemens AG Antwerp, Belgium*

## Event Highlights

- Gain in-depth understanding of validation issues through **5 mini workshops**, **2 interactive panel discussions** and **case studies**
- **Separately bookable** pre-conference and post-conference masterclasses
- **Co-located events**; 2 times the audience, 4 days of valuable insight into manufacturing excellence
- Expert advice from key industry players across and *beyond Asia!*
- Over 10+ hours of networking opportunities!

## PRE-CONFERENCE MASTERCLASS

Monday 24 November 2008 | 9am-5pm

**UNDERSTANDING, ESTABLISHING & IMPLEMENTING EXCEPTIONAL VALIDATION PROTOCOLS**

## POST-CONFERENCE MASTERCLASS

Thursday 27 November 2008 | 9am-5pm

**MEETING GMP AND GLP STANDARDS IN LABORATORIES**

## Key Benefits of Attending

- **Eliminate bottlenecks** in your manufacturing process by maximising cGMP compliance
- Recognise the **Different Expectations** of Asian and Western GMPs
- **Accelerate Export** of products to international market by meeting the local regulatory criteria
- Establishing GMP-compliant **Bio/Pharmaceuticals, Biologics and Medical Devices** manufacturing facilities
- Address critical issues pertaining to **DQ, IQ, OQ and PQ**
- Perfecting your **Technology Transfer** practices
- Discover the impact of current and evolving trends like **QbD, Computer Validation, and Green Manufacturing** on your organisation
- **Benchmark your Validation Practices** against case studies of industry giants

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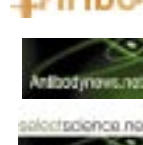
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## DAY ONE TUESDAY 25 NOVEMBER 2008

08:00 Registration & Coffee

09:00 Chairperson's Welcome and Opening Speech

09:10 **KEYNOTE ADDRESS:**  
**Maximise GMP Compliance through Lessons Learned from the EU and USA**

- Understanding the similarities and differences between EU and USA GMP's
- Making the best of system approach adopted by most regulators
- Learn the "Golden Rules" for compliance
- What you do not know will hurt you: keeping current with changes



**Philip Baer**, *Corporate Director, Regulatory Affairs and Quality Assurance, MED-EL Worldwide Headquarters, Austria*

09:55 **PANEL DISCUSSION:**  
**Meeting The Different Local and Regional Regulatory Requirements**

This interactive platform will allow industry professionals intending to establish their manufacturing operations in the following countries to understand the expectations from the respective regulatory authorities to minimise setbacks. Key countries to be discussed include: Austria, New Zealand, Korea, Malaysia, India, Philippines.

Key issues that will be discussed include:

- Meeting the different market entry requirements
- Comparison of validation parameters
- Stability studies requirements
- ICH Q8(R)

**PANELLISTS:**

**Philip Baer**, *Corporate Director, Regulatory Affairs and Quality Assurance, MED-EL Worldwide Headquarters*

**Dr. Paul L J Tan**, *Chief Executive Officer & Chief Operating Officer, Living Cell Technologies*

**Michelle Peake**, *Chief Operating Officer, Alpha Biologics*

**Swapnil Ballal**, *Head, Biopharmaceutical Bulk Manufacturing, Intas Biopharmaceuticals Ltd*

**Judith Villanueva**, *Regional Quality Assurance Manager, Zuellig Pharma Asia Pacific*

10:55 Morning Networking and Refreshments Break

11:35 **MINI WORKSHOP 1:**  
**Establishing a Qualified Biopharmaceutical Manufacturing Facility**

With the advent of human-somatic-cell therapies and tissue engineered products under regenerative medicine, new opportunities are presented to clinicians to help patients with conditions that were thought to be difficult or impossible to treat in the past. Although the potential for these products appear great, they come with sometimes difficult manufacturing challenges and regulatory issues that need to be overcome in order to deliver safe and effective products.

In this session, we will be looking into the manufacturing and regulatory considerations of establishing a biopharmaceutical manufacturing facility, with Malaysia's first cGMP/cGTP facility as a case study.

Key topics to be discussed include:

- Understanding the requirements: cGMP vs. cGTP
- Cell therapies: how different are they from Biopharmaceuticals
- Discussing the different expectations of various regulatory guidelines: 21 CFR 1271, EU-Medical Devices Agency's code etc.
- Review of practical validation and analysis procedures to ensure microbiological safety



**Dr. Shivraj Dasari**, *Vice President – Q.M.R.A., Inno Bioventures Sdn Bhd, Malaysia*

12:35 Networking Luncheon

13:35 **MINI WORKSHOP 2:**  
**Ensuring your Cleaning Procedures Meets International Standards**

The validation of cleaning procedures is not only a critical aspect of manufacturing, but one of ever-raising concern by regulatory bodies. The deficiency has been ranked among the top five of the FDA warning letters statistics in recent years. Despite the abundance of guidelines, manufacturers still struggle with the question "How clean is 'Clean'".

In this mini workshop, get expert advice on cleaning practices and the setting up of a cleaning validation programme for maximum efficiency and compliance.

Key topics to be discussed include:

- Understanding the constitutions of "clean" biopharmaceutical equipment?
- Determining cleanliness criteria for product carryover, bioburden, detergent and endotoxin
- Conducting risk assessment for cleaning validation
- Setting up a compliant cleaning validation program

**Dr. Mavis Gail Meadows**, *Director, Validation, Celltrion Inc, Korea*

14:35 Afternoon Networking and Refreshments Break

15:15 **Setting Up of a Flawless Technology Transfer for GMP Encapsulated Cell Therapeutics**

- Reviewing the process development to final specifications
- Avoiding setbacks in the selection and supply of raw materials
- Ensuring compliant Intellectual Property (IP) rights during technology transfer
- Differences and challenges in validation of in-house vs. 3rd party technology transfers
- Determining the necessity of Co-validation



**Dr. Paul L J Tan**, *Chief Executive Officer & Chief Operating Officer, Living Cell Technologies, New Zealand*


16:00 **Minimising Hiccups in Your DQ, IQ, OQ, PQ**

- Establishing meaningful operational parameters and validation acceptance criteria
- Reviewing critical considerations of equipment specifications
- Maximise efficiency and qualification via good maintenance and calibration of equipment
- Effective management of deviations and out-of-specifications results



**Umesh Baikunje**, *General Manager QA & Validation, Reliance Biopharmaceuticals Pvt Ltd, India*

# Advanced GMP 2008

- 16:45 **Green Manufacturing in the Pharmaceutical Industry: Developing a Sustainable Process To Reduce Your Environmental Footprint**
- Understanding the implications of green manufacturing on your organisation
  - An overview of the initiatives taken behind a green manufacturing facility and process including improvement of quality of water and air
  - Evaluating the cost, benefits and challenges
- 
- Leo Hammendorp**, *Director, Siemens AG Antwerp, Belgium*

- 17:30 Chairperson's Closing Remarks  
17:45 End of Day 1

## DAY TWO WEDNESDAY 26 NOVEMBER 2008

- 08:00 Registration and Coffee  
09:00 Chairperson's Welcome and Opening Speech  
09:10 **PANEL DISCUSSION:  
Benchmarking of QA/QC Practices**
- This interactive platform will allow industry professionals to share their experience and thoughts among fellow counterparts from Asia and beyond, while providing delegates a platform to discuss pressing concerns. Key issues that will be discussed include:
- Sharing of common findings in audits
  - Harmonisation and recent changes to GMP
  - Analytical method validation
  - Establishing of a flawless technology transfer
- PANELLISTS:**
- Philip Baer**, *Corporate Director, Regulatory Affairs and Quality Assurance, MED-EL Worldwide Headquarters*  
**Dr. Shivraj Dasari**, *Vice President – Q.M.R.A., Inno Bioventures Sdn Bhd*  
**Umesh Baikunje**, *General Manager QA & Validation, Reliance Biopharmaceuticals Pvt Ltd*  
**J. Ramniwas**, *Director – Regulatory and Quality Affairs, PharmaOcean*  
**Dr. Mavis Gail Meadows**, *Director, Validation, Celltrion Inc*

- 10:10 **MINI WORKSHOP 3:  
Understanding The Importance of Documentation in GMP Compliance**
- Documentation plays a very important role of assuring of the quality of the product manufactured. The inadequate quantity and quality of GMP documentation including records, protocols, complaints and recalls has brought more than one international organisations to be under the severe scrutiny of FDA of late.
- In this mini workshop, there will be a complete coverage of GMP documentation to address the fundamentals to in-depth discussion of regulatory issues.
- Key topics to be discussed include:
- An overview of the general principles on GMP documentation
  - Identifying the different types of documents required
  - Regulatory observations on GMP documentation issues
  - Case Study: Traceability of documentation during post-manufacturing activities
- 
- J. Ramniwas**, *Director – Regulatory and Quality Affairs, PharmaOcean, India*

- 11:10 Morning Networking & Refreshments Break

- 11:50 **MINI WORKSHOP 4:  
Towards Effective and Practical GMP Training Program**
- In 2007, Subpart B – Organisation and Personnel has been listed as the second most frequent GMP Deficiencies in Warning Letters. To ensure quality manufacturing, GMP compliance needs to be understood, implemented, and maintain at all levels of the organisation. With the role personnel plays in authoring protocols and systems, auditing and manufacturing, ensuring proper training is vital.

In this mini workshop, gain tips on establishing a successful GMP training programme to eliminate personnel qualification woes.

Key topics to be discussed include:

- Regulatory expectations of GMP Training Program
- Elements of an effective training system
- Implementing your training system
- Keeping training program practical
- Risk-based approach to GMP training
- Effective follow-up strategies to GMP training



**Swapnil Ballal**, *Head, Biopharmaceutical Bulk Manufacturing, Intas Biopharmaceuticals Ltd, India*

- 12:50 Networking Luncheon

- 14:00 **MINI WORKSHOP 5:  
Achieving Quality by Design in Sterile Manufacturing**
- As part of the 21st Century cGMP initiative, FDA introduced the risk-based approach to GMP – Quality by Design (QbD). This approach ensures the quality, performance and safety of product are engineered into the manufacturing process, with critical quality attributes (CQAs) process parameters, and sources of variability identified. It was reported that this approach can not only help pharmaceutical, biotechnology and medical device manufacturers cut time-to-market by 30%, shrink costs by at least 12% and accelerate FDA approval by 63%, but also offers regulatory alleviation.

Through this mini workshop, participants will be addressed on how QbD is applied to a biologics manufacturing facility and the issues to be considered.

Key topics to be discussed include:

- Establishing an biologic manufacturing facility
- Achieving sterile biologic product quality by design
- Minimising risk and maximizing return through strategic production planning
- Assessing critical issues



**Michelle Peake**, *Chief Operating Officer, Alpha Biologics, Malaysia*

- 15:00 Afternoon Networking & Refreshments Break

- 15:40 **Attaining Quality Data While Leveraging on Technology Advancements: Conducting Effective Computer System Validation**
- Reviewing the SOPs required for computer system operation and maintenance
  - Ensuring 21 CFR Part 11 compliance while making use of electronic applications to deliver staff training and store training records
  - Making use of electronic batch record (EBR – electronic inventory and records system
  - The role of network validation in ensuring data integrity and security



**Bart Moors**, *Business Consultant Pharmaceutical Industry SEA, Siemens AG Antwerp, Belgium*

**16:25 Ensuring Product Quality via Post-Market Follow-Through: Establishing an Effective Product Quality Surveillance Strategy**

- Management of complaints- receipt, investigation, tracking, reporting, closing and analysis
- The vital role of Corrective and Preventive Action (CAPA) in continuous improvement
- Effective tools and methods to conduct meaningful Root Cause Analysis



**Judith Villanueva**, *Regional Quality Assurance Manager, Zuellig Pharma Asia Pacific, Philippines*

17:10 Chairperson's Closing Remarks

17:25 End of Conference

His experience in validation includes the establishment of complete quality system for the biotech facilities at Reliance Life Sciences, working with USFDA, EMEA, MHRA, CAP, AABB, Indian regulators and ISO audits, and leading global consultants. Umesh is also a member of PDA, ISPE and various GMP forums.

**POST-CONFERENCE MASTERCLASS**  
THURSDAY 27 NOVEMBER 2008 | 9am-5pm

**MEETING GMP AND GLP STANDARDS IN LABORATORIES**

**OVERVIEW**

The quality of drugs is tested by means of analysis during development and production. As such, the maintenance of compliant laboratories is a vital integral part of producing safe and effective drug products and is governed by principles of Good Laboratory Practices (GLP).

This highly interactive masterclass is suitable for those working in non-clinical laboratories, those involved in design of laboratories and personnel responsible for Validation and Quality Assurance. The topics will focus on the sound application of regulatory principles to ensure data integrity in safe and compliant operating environment.

This masterclass will cover aspects of Laboratory Design, Validation and Operation to ensure that your laboratory meets the regulatory expectations.

**TOPICS COVERED IN THIS MASTERCLASS INCLUDE:**

- Types of laboratory and differing regulatory standards
- How to ensure the design is fit for purpose and compliant
- Designing for containment
- Specific requirements for biological culture
- Validating laboratory equipment and automated systems
- Analytical Method Validation
- Operating in a GLP environment



**MASTERCLASS LEADERS**

**Steve Slater**, *Vice President, Asia Operations, Pharmaceutical Services Corporation Pte Ltd*

Steve Slater is a microbiologist with more than 25 years of experience in laboratories and the pharmaceutical industry. Steve is highly experienced at conceptual and detailed design of Biotechnology and Pharmaceutical plants and laboratories. He has been responsible for laboratory validation and compliance activities for companies throughout Europe, South East Asia, India and China.

**Tim Marshall**, *Senior Validation Manager, Pharmaceutical Services Corporation Pte Ltd*

Tim Marshall has 16 years of experience in analytical quality operations, computer system design, development, implementation and validation, and pharmaceutical process, equipment and facility design and validation. His skills have been developed through 10 years pharmaceutical QC operational and management experience.



**PRE-CONFERENCE MASTERCLASS**

MONDAY 24 NOVEMBER 2008 | 9am-5pm

**UNDERSTANDING, ESTABLISHING & IMPLEMENTING EXCEPTIONAL VALIDATION PROTOCOLS**

**OVERVIEW**

Validation is establishing documented evidence that equipment, a system or process does what it purports to do.

A Validation Master Plan (VMP) outlines the scope of work, general objectives, extent of validation/qualification to be followed and allocation of resources, while specific validation protocols detail tests and instructions that are executed for a process, equipment validation or analytical method validation.

These road maps are important to establish the foundations for effective validation of equipments and systems, and hence quality manufacturing, by not only providing a guide for the validation team, but also to monitor progress. Having an effective VMP and protocols (development and execution) may also help in instilling confidence in regulatory authorities by reassuring them that effort has been put in to assure quantity in your manufacturing processes.

In this interactive masterclass, you will be addressed on the purpose of validation/qualification before being guided through the essential steps of establishing meaningful validation protocols.

**TOPICS COVERED IN THIS MASTERCLASS INCLUDE:**

- Understanding of validation/qualification
- Conceptual design, basis design and detailed design of facility
- Validation Master Plan (VMP) and Clinical Quality Management Plan (CQMP)
- User Requirement Specification (URS)
- Impact assessment
- Design Qualification (DQ)
- Factory Acceptance Testing (FAT) and Site Acceptance Testing (SAT)
- Compliance Test Plan (CTP), Installation and Operational Qualification (IOQ) and Process Qualification (PQ)

**MASTERCLASS LEADER**



**Umesh Baikunje**, *General Manager QA & Validation, Reliance Biopharmaceuticals Pvt Ltd, India*

Umesh has been in the pharmaceutical and biopharmaceutical industry for 14 years, and taken up management roles in Validation, QA/QC and Production at leading Indian companies and MNCs such as Cipla, GSK and AstraZeneca.

# Advanced GMP 2008



## JOIN US AT ADVANCED GMP 2008 TO BE RID OF YOUR MANUFACTURING AND VALIDATION WOES!

Recently, there has been strong step-up in scrutiny of the quality of drugs in the region. The production of substandard medicines not only compromises the drug efficacy, and safety of consumers, but is also a waste of money for both the latter and the manufacturer. Most importantly, it will lead to the loss of confidence in investors, consumers and regulatory authorities in the manufacturer, which will in turn lead to severe financial consequences.

At IBC Asia's **Advanced GMP 2008**, we examine the methods of mitigating risks to quality and regulatory concerns while improving efficiency by having an intensive examination of the **validation** of the manufacturing process. We will also be exploring current and evolving trends such as **QbD**, **computer validation**, **biologics** and **green manufacturing** and what it means to your organisation. Also learn how to establish an effective **product quality surveillance strategy** to ensure product follow-through.

The unique **mini workshop** format of our conference, together with interactive **panel discussions** and **case study** presentations is designed to provide delegates with the opportunity of having in-depth discussions on real-life problems encountered during day-to-day operations, and to **benchmark** their validation practices against key industry players from the region and beyond!

**REGISTER NOW at [www.ibt-asia.com/gmp2008](http://www.ibt-asia.com/gmp2008)  
or call our registration hotline at +65 6514 3180**

### Who should Attend

CEO/President/Director • Management Professionals

### With Responsibilities In

Quality Assurance/Quality Control  
Regulatory Affairs Validation/Compliance  
Plant/Facility Management • Process Development  
Manufacturing/Production/Operations • Research & Development • Supply Chain Management  
Contract & Outsourcing/Transfers • Engineering

### Industry

Bio/Pharmaceutical • Biotechnology  
Medical Devices • Healthcare • Contract Manufacturing • Consultancy

### Sponsorship and Exhibition Opportunities

Enhance your corporate profile and promote your products and services to potential market and key decision-makers

This focused event presents an excellent opportunity to showcase your expertise, products and solutions for manufacturing to an exclusive audience of key decision-makers.

Various sponsorship and exhibition packages are available:

For further discussion, please contact  
Ms Catherine Wong, Tel: +65 6732 1970,  
Email: [catherine.wong@ibcasia.com.sg](mailto:catherine.wong@ibcasia.com.sg)

## ABOUT GMP WEEK 2008

**First time 2 co-located events: 4 full days dedicated to Manufacturing Excellence**

GMP Week 2008 comprises of two main conferences; 'Advanced GMP 2008' and 'Pharmaceutical Packaging & Labelling Asia'. The latter will discuss industry key issues and challenges on packaging and labelling, effective regulatory compliance, achieving industry best practices, new trends in GMP and packaging, critical defence mechanism against pharmaceutical counterfeiting, patient safety, brand security and credibility. The conference provides a platform for industry players to identify and understand challenging issues and problems with labelling and packaging of drugs, that can potentially contribute to patient injuries and death. It also offers a platform for open discussion on how to tackle the issue of lack of security that has contributed to the growth of the counterfeit drug market – estimated to be worth \$75 billion globally by 2010 according to the WTO.

**Register Today!** Tel: (65) 6514 3180 Fax back to (65) 6733 5087 / 6736 4312

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## ADVANCED GMP 2008

### HOTEL INFORMATION

**Sheraton Towers Hotel Singapore**  
39 Scotts Road  
Singapore 228230  
Tel: +65 6837 6888  
Fax: +65 6733 4366  
Contact Person: Joanne Leong  
Email:  
Joanne.leong@sheraton.com

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Yes! I/We will attend the **ADVANCED GMP 2008** • 25-26 November 2008, Sheraton Towers Hotel, Singapore

Ist delegate \_\_\_\_\_ 2nd delegate \_\_\_\_\_  
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E-Mail \_\_\_\_\_ E-Mail \_\_\_\_\_  
Job Title \_\_\_\_\_ Job Title \_\_\_\_\_  
Mobile no \_\_\_\_\_ Mobile no \_\_\_\_\_  
Department \_\_\_\_\_ Department \_\_\_\_\_  
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I cannot attend this event but  I would like to purchase the conference documentation @ S\$904/S\$967.28 (with 7% GST)  
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**SUBSTITUTION** Registrations cancelled less than seven days before the event must be paid in full.

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