GMP Facility Design with Good Engineering Practice
Part of the Pharmaceutical and Biotechnology Training Courses

Instructor
Raymond Loke

* Instructor may be subject to change due to unforeseeable circumstances. In case of a change, updated instructor profile will be made available to the organizer and the attendees.

Date and Time
31 May – 01 June 2012
9 AM – 5 PM

Location
Global Classroom
Department of Pharmacy
National University of Singapore
S4 Level 5
18 Science Drive 4
Singapore 117543
Tel: 65162647 / 8
Fax: 67791554
Website: www.NUSAGE.nus.edu.sg

Location:
Please view NUS interactive campus map at http://www.nus.edu.sg/campusmap/, look under Science, Department of Pharmacy.

By taxi/foot:
Please turn into and drive/walk along Science Drive 4, then go under building with "Fire ENGINE ACCESS" sign. Go straight down to loading bay where S4 building will be right in front.

By car:
Please park at the Visitors' lots inside University Hall (Tan Chin Tuan Wing), Carpark 6B along Lower Kent Ridge Road just next to Science Drive 4. Then walk through level 2 of Lee Kong Chian Wing towards Science Drive 4, and walk along to reach S4 as per above.

To Library: Please proceed to S4 Level 2
To Pharmacy Global Classroom: Please proceed to S4 Level 5
GMP Facility Design with Good Engineering Practice

Objective
The objective of this course is to understand the approach to GMP Facility Design and how to employ Good Engineering Practice (GEP) as one of the tools to aid the design process – with an overview of the design process, criteria and good practices like GEP and “risk-based approach” for GMP Manufacturing Facilities with clear future Qualification and maintenance.

Description
The successful delivery of regulated manufacturing facilities poses significant challenges to manufacturers, engineering professionals, facility design/construct contractors and equipment suppliers. A systematic approach to Process/Facility Design is one of the foundations to a “fit for intended use”, compliant and cost-effective operating site. The course steps through the design definition, scope, applying key criteria, clean design principles for a robust front end design package. The application of Good Manufacturing Practice to engineering is essential to ensure that a company manufactures products of the required quality.

Course Outline
• Current International GMP Regulations and Regulatory Requirements
• Good Manufacturing Practices
• GEP – key concepts, common practices, standards, engineering specifications
• Develop environmental and processing – room requirements
• Determine the best room classifications
• Risk-based approach – with respect to engineering and facility design.
• Qualifying facility for sterile, low bioburden and non-sterile products
• Process Design – Process map, URS, Pre-qualification documentation, Clean Design principles, Case Study illustration.
• Facility Design – Building, Layouts (Effective flow of People, Material & Equipment), Utilities, Cost Estimates, Case Study Illustration
• Case Studies – Critical Utilities (Purified water system/WFI/Steam), Sterilization and dust control systems

Learning Outcomes
Upon completion of this course the attendees will be able to:
1. Gain an understanding of how to operate the facility smoothly, with fewer investigations and corrective actions to slow down the day to day operations
2. Gain an understanding of the application of Good Engineering Practice
3. Integrate facility design so it meets the regulatory requirements

Who Should Attend & What Participants will benefit from the course
This course is particularly useful for junior to intermediate pharmaceutical manufacturing professionals, especially those involved in Quality, Engineering, and Validation functions, as well as vendors in the design and construct business, equipment builders. The participants will be able to build upon their existing knowledge of GMP facility, engineering, GxP concepts and practices to learn how these approaches, concepts and practices can be applied to future projects.

Instructor
Raymond Loke, B.Eng. Is Principal Consultant at Tech Process of Australia, a life science consultancy, and GMPtemplates.com, an online shop of process documentation for the GMP industries. As a Malaysian-Australian, Raymond holds a Bachelor of Engineering (Chemical) from the University of Newcastle in Australia, with more than 30 years of experience in process and engineering. He is an expert in Good Engineering Practices, especially in the context of current GMP. In his capacity as an employee or as a consultant, Raymond has served major multinational pharmaceutical companies like Merck, Sharpe & Dohme, Baxter, Biotech Australia Pty Ltd, Astra Zeneca, Pfizer, Schering-Plough, as well as food and chemical facilities such as Huntsman Chemical, Kellogg, Cerebos, Procter & Gamble, Res Med, and more. He has successfully managed multimillion-dollar projects, technology transfer projects, Greenfield projects, and facility upgrade projects, with quantifiable results such as the successful attainment of 100% facility and equipment availability at Schering-Plough, among others. Raymond is an active trainer on GMP and GEP topics in countries including Australia, China, and Malaysia.
# GMP Facility Design with Good Engineering Practice

## Registration Form

Please Print or Type Clearly

<table>
<thead>
<tr>
<th><strong>Full Name &amp; Title</strong>* (Prof/Dr/Mr/Mdm/Ms)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Job Title</strong></td>
<td><strong>% Knowledge on Subject Matter</strong></td>
</tr>
<tr>
<td><strong>Company</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Business Address</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Business Tel</strong></td>
<td><strong>Mobile No.</strong></td>
</tr>
<tr>
<td><strong>E-mail Address</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Special Diet**: (Non-spicy / Vegetarian / Vegetarian w/o egg / No beef / Halal)

*Delete where appropriate*

---

### Fees:

- S$1070 per delegate after GST.
- Early bird discount 14 calendar days before the course / group discount of 5 or more delegates:
  - 10% off per delegate ($963 after GST)
- Course Fees includes course materials, tea breaks and lunch.

### Payment:

- Only cheques in SGD$ are accepted. Please make cheques payable to: “National University of Singapore” If invoice is required, please write to phacyj@nus.edu.sg with full billing and contact details.
- Payments must be received at least one week prior to event.
- Cancellations must be made in writing. If cancellations are received 2 weeks prior to course, a full refund, minus a handling fee of $75 will be issued. No refunds will be granted thereafter. Substitutions are acceptable if the registrant is not able to attend.
- Registered participants will be informed in case of postponement or cancellation due to unforeseen circumstances, and any payments received will be refunded.

Please return completed forms by mail/fax to:

NUSAGE
National University of Singapore
Department of Pharmacy
S4, Level 2
18 Science Drive 4
Singapore 117543

Email: phacyj@nus.edu.sg,
DID: 65165878
Fax: 67791554
PharmEng Technology (“PharmEng”), a division of PE Pharma Inc., provides professional development and certification training programs throughout North America and Asia. We deliver over 35 courses to the pharmaceutical, biotechnology, nutraceutical and medical devices industries in the areas of:

- cGMPs
- Validation
- Engineering
- Project Management
- Medical Devices
- Quality Compliance
- Quality Assurance
- Regulatory Affairs
- Manufacturing

Why PharmEng Professional Training?
Unique curriculum that covers key areas critical to the success of the industry, through courses that integrate theory and practice.

Advisory committee that includes members from industry, academia and government, ensuring that important regulatory and industry issues are addressed.

Custom courses that cover both general and basic “know-how” as well as current challenges, issues and new developments in the industry.

Instructors that have been selected among industry leaders and subject experts who will provide challenging course work and valuable hands-on experience.

PharmEng delivers courses to two distinct groups:

1. Corporate Training: Experienced industry professionals who require current best practices in order to keep up-to-date with industry standards, Good Manufacturing Practices (GMP’s) and regulations.

2. Career Training: Next generation individuals seeking careers in the industry who need practical skills and “know-how” for the pharmaceutical and biotechnology workforce.

For those individuals requiring one day professional development programs, courses are available through any of the PharmEng offices located throughout North America and Asia with access to course listings, course availability and registration through the PharmEng website www.pharmeng.com.

Certification Programs
For career training and certification, PharmEng offers programs through national and internationally-recognized universities delivering certificate programs such as:

- The Biopharmaceutical Technology Certificate Program for the University of Waterloo and the National Tsing Hua University College of Life Science in Taiwan
- The Biotechnology and Pharmaceutical Technology Program for Cape Breton University

Instructors and Course Materials
All instructors are subject matter experts with direct industry experience. Instructors include guest speakers from industry, government and academia. Course materials are developed by PharmEng in-house and are constantly updated to keep current with the regulatory environment. As the industry changes, so do the issues and challenges. Our courses, with supporting materials, link together:

- Training
- Regulations
- Government
- Industry
- Academia
- International Standards

Conferences
PharmEng offers conferences throughout the year in collaboration with Health Canada, and various professional associations in biotechnology, pharmaceutical, medical devices, nutraceutical and healthcare industries.
PharmEng Technology, a division of PE Pharma Inc., headquartered in Toronto, Canada, is a full-service consulting company that serves the pharmaceutical and biotechnology industries internationally. Consulting services include project management, engineering, cGMP, validation, calibration, regulatory compliance and certified training.