Good Laboratory Practices and Biosafety Considerations

Part of the Pharmaceutical and Biotechnology Training Courses

Instructor
Peter Doherty*
Senior Consultant, PharmEng Technology

Location
Global Classroom
Department of Pharmacy
National University of Singapore
S4 Level 5
18 Science Drive 4
Singapore 117543
Tel: 65162047 / 8
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* 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
03-04 March, 2011
9 am – 5 pm

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
Good Laboratory Practices and Biosafety Considerations

Objective
This course was designed to improve knowledge and understanding of the requirements of GLP regulations. Insight into assessing current GLP status as well as achieving compliance with GLP regulations in a cost effective manner will be gained.

Description
This course focuses on the requirements of the Good Laboratory Practice (GLP) regulations imposed by the Food and Drug Administration (FDA). These regulations will be compared and contrasted to international rules for GLP studies (predominantly OECD regulations). This interactive presentation encompasses facility and equipment requirements, documentation requirements, roles and responsibilities, plus outsourcing relationships. Practical real world examples are used to emphasize key aspects of the regulations.

Course Outline
- Introduction; GLP History
- GLP Principles, Terms, Definitions
- ISO vs. GLP
- Management’s Role in Achieving Compliance
- Study Director Responsibility
- Standard Operating Procedures
- Protocols/Study Plans
- Data Quality and Integrity
- Quality Assurance Unit
- Facility Requirements
- Laboratory Operations
- Product Chemistry
- Special Applications of GLP
- Data Auditing/Report Issuance
- Archives/Record Retention
- The Regulatory Inspection Process

Learning Outcomes
Upon completion of this course the attendees will be able to:
1. Understand the principles of GLP and its regulatory basis
2. Understand the structure of GLP as compared to ISO
3. Understand the responsibility of key stakeholders and unit operations, such as the Study Director, QA Unit, etc.
4. Understand the requirements of a laboratory facility
5. Understand the QA programs documentations, such as Standard Operating Procedures, protocols, study plans, data quality and integrity, auditing, archival, etc.
6. Understand the regulatory inspections

Who Should Attend & What Participants will benefit from
This course is particularly useful for those new to the pharmaceutical and biotech manufacturing industry, for R&D, quality, and engineering personnel who are developing a process for commercial production, and for existing professionals who want a broader exposure to different types of manufacturing techniques. Suitable for personnel from R&D, Quality, Engineering, new graduates

Instructor
Peter Doherty, BSc (Hons), is a consultant with 18 years of experience in validation and quality systems in the pharmaceutical and biotechnology industries. Peter started his career in the role of an analytical chemist, performing quality control and stability studies. In this capacity, he took on projects to enhance turn-around time for manufacturing lifecycles, as well as initiating various control systems to improve system efficiencies. Validation of computer systems and laboratory equipment led Peter to the consulting firm of PharmEng Technologies Inc. As a GMP / Validation consultant, Peter’s validation projects have expanded to encompass process validation, method validation, cleaning validation, and equipment validation. Peter has also implemented various control systems and performed a wide range of audits. Peter frequently conducts training courses through PharmEng technology’s affiliation with academic institutions, including the University of Toronto, Cape Breton University, and the University of Waterloo.
Good Laboratory Practices and Biosafety Considerations

Registration Form

Please Print or Type Clearly

Full Name _________________________________ Title (Prof/Dr/Mr/Mdm/Ms) __________

Job Title _________________________________ % knowledge on subject matter __________

Company ________________________________________________________________

Business Address _________________________________________________________

City / State / Country ___________________________ Postal Code __________

Business Tel ______________________________ Business Fax _______________________

E-mail Address ______________________________ Special Diet _________________

Fees:

S$1070 per delegate including GST.

Early bird discount 14 days before the course/group
discount of 5 or more delegates: 10% off per
delegate

Course Fees includes course materials, tea breaks
and lunch.

Payment:

Only cheques are accepted. Please make cheques payable to:
"National University of Singapore"

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.

Please return completed forms by mail/fax to:
National University of Singapore
Department of Pharmacy
S4, Level 2
18 Science Drive 4
Singapore 117543
Fax: 67791554
Attn: Chen Yee Ju, Manager
NUS, Department of Pharmacy
phacyj@nus.edu.sg, DID: 65165878
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.
About the Training Provider

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.

PHARMENG CORE TRAINING COURSES

Current Good Manufacturing Practices

• GMP – Get More Productivity
• GMP – Concepts and Implementation
• cGMP’s for Drugs and Active Pharmaceutical Ingredients Manufacturers

cGMP training is tailored to meet your company’s specific needs in one or all of the following areas:
• Engineering
• Production
• Packaging
• Quality Assurance
• Quality Control
• Regulatory Affairs
• Clinical Research
• New Drug Submission/Application
• Natural Health Products
• Active Pharmaceutical Ingredients
• Medical Devices
• Blood and Blood Products
• Practical cGMP

Validation

• Analytical Methods Validation
• Process Validation
• Cleaning Validation
• Computer Systems Validation
• Validation of Sterilization Processes

Project Management

• Project Management in a Regulatory Environment
• Project Management for Clinical Research Studies

Medical Devices

• Medical Device Regulatory Requirements
• Quality System Requirements – ISO 13485
• Quality Systems for Medical Devices

Manufacturing

• Manufacturing Control in the Pharmaceutical Related Industries
• Pharmaceutical and Biotech Manufacturing Processes
• Active Pharmaceutical Manufacturing
• Solid and Semi-Solid Dosage Manufacturing
• Aseptic Manufacturing
• Sterile and Septic Processes

Regulatory Affairs

• Good Clinical Practices (GCP)
• New Drug Application/Submission
• Chemistry, Manufacturing and Control
• Natural Health Products Registration