National University of Singapore Academy of GxP Excellence (NUSAGE) and PharmEng Technology Presents

ICH Q7 – GMP for Active Pharmaceutical Ingredients

Part of the Pharmaceutical Biotechnology Training Courses

Instructor
Rick Ng, Ph.D. *

* 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
26-27 Apr 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
ICH Q7 – GMP for Active Pharmaceutical Ingredients

Objective
ICH Q7 standards are used by all Active Pharmaceutical Ingredients (API) manufacturers operating in regulated markets to implement Good Manufacturing Practices (GMP). This course is specially designed to enable participants realize the benefits of GMP and ICH Q7 guidelines. Practical implementation of GMP concepts on critical aspects of the pharmaceutical and biotechnology operations will be addressed, as well as the latest updates on GMP and validation requirements.

Description
This course presents the GMP concepts and their practical applications in the active pharmaceutical ingredients industry. The presentation will focus on engineering, production, QC/QA and validation aspects of the GMP requirements. Opportunities for optimization of GMP and pharmaceutical processes are illustrated with practical design concepts and examples. This practical course is filled with recommendations that can be put into actions by engineering, production quality, validation and management personnel.

Course Outline
• Introduction to Q7: Good Manufacturing Practices
  o Objective, Scope, Quality Management, Personnel
• Building and Facilities
• Process Equipment
• Documentation and Records
  o Records of Raw Materials, Intermediates, API Labeling and Packaging Materials
  o Master Production and Control Records
  o Batch Production and Control Records
  o Laboratory Control Records
• Material Management
• Standard Operating Procedures (SOP)
• Production and In process controls
• Storage and Distribution (Warehouse Management)
• Laboratory Controls
• Validation
• Case Studies/ Self Inspection
• Inspections and Violations (Examples and Strategy)

Learning Outcomes
Upon completion of this course the attendees will be able to:
1. Gain an understanding of GMP for API’s that is core to the current Singapore’s pharmaceutical industry
2. Improve productivity and enhance effectiveness
3. Improve quality of processes and output
4. Enhance preparedness for inspections

Target Audience
This course is designed for people connected with production and control of Active Pharmaceutical Ingredients. Professionals involved in functions such as quality, auditing, pilot and commercial production, process development, regulatory affairs and validation.

Instructor
Dr Rick Ng holds degrees in BSc (Honours), PhD and MBA. He has worked in senior positions in Clinical, Quality, Regulatory Affairs and Business Development in the biotech and pharmaceutical industry in Australia and Singapore for more than 20 years. Currently Rick provides consulting and training services in GCP, GMP, Quality, Regulatory and Validation. Rick is the author of one of the best selling medicine/pharmacology books, Drugs: From Discovery to Approval, which is a recommended text in a number of universities/colleges.
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Registration Form

Please Print or Type Clearly

Full Name & Title* (Prof/Dr/Mr/Mdm/Ms)

Job Title % Knowledge on Subject Matter

Company

Business Address

Business Tel Mobile No.

E-mail Address

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.
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

**Engineering**
- Commissioning and Validation of Pharmaceutical and Biotechnology Facilities
- Design and Validation of Critical Utility Systems
- Process Analytical Technology (PAT)
- Design and Commissioning and Validation of Pharmaceutical and Biotechnology Facilities

**Quality and Compliance**

PharmEng® also provides customized Good Laboratory Practices (GLP) and Good Clinical Practices (GCP) training to clients in order to assist companies in moving forward with their pre-clinical and clinical trials.
- Master Plan – Roadmap to Compliance
- Good Laboratory Practices (GLP)

- Pharmaceutical Quality Assurance and Control
- GMP Programs – Planning and Implementation
- Audit Programs and Annual Review
- Recall and Compliant Systems
- Standard Operating Procedures
- Corrective and Preventative Actions (CAPA)
- Risk-based Approach to Inspecting Quality Systems

**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

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