Process Validation for Medical Devices

Part of the Pharmaceutical and Biotechnology Training Courses

Instructor

Kenny Peng

- 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

22-23 November 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
Objective

The objective of this course is to provide an introduction to the fundamentals of process validation, explaining how, when, where and why you should validate. Participants will learn more how to comply with FDA and international regulations for validation protocols. Also included is comparison of major global medical device regulations and updates of US, EU, Canada, A.S.E.A.N, Japan and Singapore.

Description

The FDA guideline on “General Principles of Process Validation” was first issued in May, 1987, and since then, medical device companies have struggled with the principles of process validation as much of the industry focused on pharmaceutical processes. A successful validated process may result in a reduced time to market for new products. Using the tools developed in this course participants will be able to methodically plan and conduct a process validation for medical devices.

Course Outline

• Introduction
• Purpose and scope
• Process Validation Terminology
• Introduction to Process Validation - Process validation requirements
  o Requirements of 21 CFR Part 820.75
  o Recommendations of GHTF N99-10
  o Difference between validation and verification
  o Types of validation (i.e. Prospective, Concurrent and Retrospective Validation)
• Implementing a Process Validation System - Elements of process validation
  o Master Validation Plan (MVP)
  o Installation, Operation, and Performance Qualification (IQ, OQ, PQ)
  o Application of risk management to process validation
• Executing a Validation
  o Process validation steps
  o Validation protocol design and final report
  o Cleaning Validation
• Maintaining a state of validation
  o Monitor and control
  o Changes in process and/or product
  o Continued state of control
• Comparing Medical Device Regulations and Updates of EU, US, Canada, ASEAN, Japan and Singapore

Who should attend and what the participants will learn from the course?

This two-day course is targeted toward professionals directly involved in meeting the international and FDA’S Quality System Validation requirements. This includes professionals in regulatory affairs, quality assurance, process development or manufacturing. This course provides regulatory/quality systems professionals, manufacturing engineering, and process development engineers with the knowledge and skills needed to comply with the process validation requirements of the FDA’s Quality System Regulation, ISO 13485 and GHTF Validation guidance N99-10. The course is also intended for Medical Device professionals who are responsible for performing process validation studies and ensuring compliance with regulatory requirements for validation documentation.

About the Trainer

Kenny Peng, RAC, P.Eng., is Director, Asia, for PharmEng Technology. Kenny is a licensed professional engineer (Canada), a certified regulatory affairs professional, and consults professionally in the Asia-Pacific region. Kenny graduated with a Masters degree in Engineering from the University of Waterloo, Canada. His early career began with research work during university years in biomaterials (University of Toronto) and in nonlinear mechatronic systems (University of Waterloo), where some of the technologies have since been successfully commercialized. His subsequent consulting career began with the design and engineering of pharmaceutical manufacturing equipment and facilities in North America, which led to the commissioning/qualification/validation of pharmaceutical and medical device manufacturing facilities and processes. Since 2008, Kenny has successfully assisted medical devices companies across Asia through 5 US FDA audits, as well as numerous ISO audits. Today, his work involves start-up, technology transfer, regulatory affairs, validation, and engineering for pharmaceutical and medical device companies across Southeast and Northeast Asia. Kenny is a native speaker/writer in English and Chinese.
# Process Validation for Medical Devices

## 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

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**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 PEPharma 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
- 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 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

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.