Process Validation for Active Pharmaceutical Ingredients (API)
Part of the Pharmaceutical and 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
16-17 Aug 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
Process Validation for API

Objective

The objective of this course is to provide a comprehensive understanding of the regulatory requirements for process validation, appreciate the benefits of conducting validation studies, understand the key elements of process validation and to develop validation protocols and reports that meet current FDA, WHO, PIC/s and EU regulations.

Description

Process Validation is required in the Pharmaceutical, API and Medical Device Business Sectors. European Regulatory Agencies & the US FDA enforce this requirements stringently. This course provides practical guidance for pharmaceutical, biological and biopharmaceutical manufacturing professionals on compliance with the requirements of process validation. This course stresses the importance of quality, where quality must be designed into the process/product to reduce the risk of non-compliances during/after manufacturing.

Course Outline

- Introduction to Process Validation
- Statutory and regulatory requirements for process validation
- Business benefits of process validation
- Preparing a process validation protocol (API)
- Exercise on validation versus verification
- Statistical methods and tools for validation
- Change control/Revalidation
- Cleaning Validation
  - Introduction to Cleaning Validation
  - How to monitor cleaning procedures at appropriate intervals
- Maintaining a state of validation
- Review of recent FDA Warning Letters

Learning Outcomes

Upon completion of this course the attendees will be able to:
1. Gain an understanding of the principles of process validation.
2. Gain an understanding of current regulatory perspectives from the US FDA, EU and PIC/s.
3. Gain an understanding of developing process validation protocols, executing and maintaining.
4. Gain and understanding of evolutions in process validation concepts, such as how process analytical technology (PAT) can simply process validation, Quality by Design (QbD) concept that harmonizes emphasis on designing quality into the process and product, and more.

Who Should Attend & What Participants will benefit from

This course is designed for persons who are working on Quality and Engineering. The participants will be able to apply their knowledge on device and implement effectively various processes validation as a part of the Quality-by-Design (QbD) concept being promoted by global major regulatory bodies.

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.
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:

SS$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
Past Participants Comments:

“Best instructor and best coverage of this subject that I’ve experienced yet. Great session – so glad I came.” IMRIS Inc.

“... good course, especially the case studies.” Genesys Venture Inc.

“It was a nice change that the instructor had personal experience that I could relate to.” Medicure Inc.

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, 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.