Cleaning Validation in Active Pharmaceutical Ingredient Manufacturing Plants

Part of the Pharmaceutical and Biotechnology Training Courses

Instructor

Loh Kean Chong, 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

28-29 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

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

NUSAGE - PharmEng 2012 Professional Training Program
Cleaning Validation in API Plants

Objective

As a critical component to a compliance validation program, this course provides an overview of principles and regulatory requirements behind cleaning validation for manufacturers of regulated healthcare products.

Description

Both the theoretical basis and practical applications of the validation process will be discussed. This course provides participants with an understanding of cleaning validation policy which serves as a guideline for company personnel, regulatory authorities and customers as to how the company deals with areas associated with Cleaning Validation. It includes how to establish proper design criteria and specifications to form the basis of process and cleaning validation design compliance elements required for FDA and associated cGMP requirements.

Course Outline

- Cleaning Validation Basics
- Strategies and Approaches for Cleaning Validation
- Potential residues
- Cleaning Validation Policy
- Levels of Cleaning: Level 0, Level 1 and Level 2
- Elements of cleaning validation
  - Establishment of acceptance criteria
  - Chemical determination
  - Physical determination
  - Microbiological determination
  - Cleaning procedures
  - Sampling
  - Analytical methods
  - Validation protocols
  - Validation reports
- Minimum requirements
- Change control
- Post Validation Monitoring of Cleaning Process
- Summary
- Regulatory Concerns and Requirements

Learning Outcomes

Upon completion of this course the attendees will be able to:

1. Gain an understanding of the principles of cleaning validation.
2. Gain an understanding of current regulatory perspective from the US FDA, EU, and PIC/S.
3. Gain an understanding of key cleaning validation concepts, such as cleaning procedure, sampling, validation protocol and validation report.
4. Gain an understanding of post-validation control of the cleaning process.

Who Should Attend & What Participants will benefit from the Course

This course is intended for validation engineers, process engineers, chemists and microbiologists who are directly involved in the development, implementation, analysis and validation of cleaning process in the shop floor to prevent cross contamination in the product lifecycle.

Instructor

Dr LOH Kean Chong has over 20 years of experience in GMP manufacturing facility design, process development, biopharmaceutical manufacturing, validation and laboratory design & set up for biotech industry. Dr. Loh was a key member of the pioneer project team, who was tasked to build the first multi-million dollars cGMP biopharmaceutical manufacturing facility in Singapore.

With a proven track record in research and development, in-depth knowledge and experience in various aspects of GMP manufacturing facility design and construction, manufacturing, facility operation & management, process development, GMP quality system and validation of processes, equipment and facilities, Dr. Loh brings a good understanding of regulatory requirements of GMP manufacturing of biopharmaceuticals and interdisciplinary experience spanning from hybridoma technology to biopharmaceutical/biochemical engineering, as well as experiences spanning from drug development life cycle, regulatory agency requirements & guidelines as well as biopharmaceutical manufacturing technologies.
# Registration Form

Please Print or Type Clearly

<table>
<thead>
<tr>
<th>Full Name &amp; Title* (Prof/Dr/Mr/Mdm/Ms)</th>
<th>% Knowledge on Subject Matter</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Job Title</th>
<th>Company</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Business Address</th>
<th>Business Tel</th>
<th>Mobile No.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>E-mail Address</th>
<th>Special Diet* (Non-spicy / Vegetarian / Vegetarian w/o egg / No beef / Halal)</th>
</tr>
</thead>
</table>

* 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.

---

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.

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
About the Training Provider

“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.

For Certification Programs
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 Standard

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 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)

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.