VALIDATION OF PHARMACEUTICAL FACILITY

NUSAGE – PharmEng
Pharmaceutical and Biotechnology Training Program
Shaping Human Capital for Challenges in the Pharmaceutical Industry
Validation of Pharmaceutical Facility

Objective

To provide managers and technical professionals in process development, QA, production, QC and technology transfer with an excellent overview of key aspect of validation principles and practices of pharmaceutical facility. The course will highlight the various regulatory validation requirements e.g., from PIC/S, ICH, EU and FDA.

Description

Validation of pharmaceutical facility is critical to ensure consistency in manufacturing and to provide assurance of product quality. It is also important to meet the regulatory GMP requirements. Therefore, validation activities should be properly planned and conducted so as to ensure every step of the process is operated in a controlled manner to ensure that the product manufactured will meet its pre-determined safety, efficacy and quality specifications.

This course is designed to cover various principles and practices of validation from preparation of validation master plan, writing of qualification and validation protocols, executing the validation protocols, resolving the deviation, preparing the validation reports to performing re-validation. The course also highlights validation lifecycle approach, risk-based approach and critical aspects of Process Validation. Selected validation case studies will be discussed in the course.
Course Details

Instructor:
Dr. Loh Kean Chong

Dr. LOH Kean Chong holds degrees in B.Eng in Biochemical Engineering and PhD in Chemical Engineering. He has over twenty years of experience in business development, laboratory design & renovation, GMP manufacturing facility design, process development, biopharmaceutical manufacturing and validation for biotech and life science industries. He held several senior positions in project management, process development, validation, GMP production and facility management in the biopharmaceutical companies.

He is currently an independent consultant to a number of life science companies with good consultancy track records – local and overseas. Dr Loh is also an Executive Advisor of National University of Singapore Enterprise.

Date and Time:
28 – 29 August 2018 | 9AM – 5PM

Course Outline
• Method Validation Background
• Validation Principles
• Regulatory concerns and requirements
• Validation Master Plans
• Strategies and Approaches for Validation
• Preparation and execution of IQ, OQ and PQ protocols
• Process Validation
• Deviation
• Management of validation activities
• Revalidation
• Case studies

Learning Outcome
Upon completion of this course the attendees will be able to:
  1. Appreciate the important of validation
  2. Understand the various aspects of validation activities
  3. Know the critical aspects to achieve a successful validation of the pharmaceutical facility
  4. Gain an understanding of preparation and execution of validation master plan and validation protocols
  5. Understand the regulatory validation requirements e.g., risk-based approach and validation life cycle approach
Course Registration

To register for this course or for any other course enquiries, please contact:

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PHARMENG TECHNOLOGY

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 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.

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

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

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

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

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

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

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.