Objective

To learn to establish validation programs; acquire understanding of the regulatory requirements and expectations for the validation of computer systems used in pharmaceutical and biological industry; learn and understand the process and methodologies on computer system validation and be able to apply the knowledge and principles to specific systems and cases.

Description

This course is designed to provide an overview of the various aspects of computer systems validation and related validation documents and to provide the basis for compliance and implementation. The course addresses the rules, tools, and techniques to develop and implement a validation program or to validate a specific system. The course provides the principles for computer validation and offers a framework and the methodologies to conduct validation projects.

The emphasis is on the most recent rules and techniques focusing in the relevant regulations, the system life cycle including requirements, design/build, testing, qualifications and maintenance, 21 CFR Part 11 Electronic Records and Electronic Signatures and the journey this regulation has taken, vendor audit, acquired and developed systems, retrospective validation, validation master plan, the validation project, risk assessment and management, SOPs, requirements documentation, the traceability matrix, and related FDA Guidance documents.
Course Details

Instructor:
David McSweeney

Mr. McSweeney is a Project Manager / Senior Computer Validation Specialist with over 20 years’ of experience in a scientific discipline. He has 12 years’ experience in software validation / compliance with 5 years’ as a Project Manager. Prior experience includes 3 years focused on vaccine development / production and 6 years’ in biomedical / pharmaceutical research. Mr. McSweeney’s major strengths include strong leadership, excellent communication skills, attention to detail, excellent problem solving abilities, competent and strong team player with a thorough knowledge of current IT and manufacturing practices. He is recognized for his high personal standards of performance and integrity. Mr. McSweeney is also a mentor, presenter, and initiator; he possesses the ability to quickly grasp complex concepts and adapt well to changing environments.

Date and Time:
2018 (refer to website www.pharmeng.asia for latest dates)

Course Outline

- Validation Overview
- Regulations and Regulators
- GAMP (Good Automated Manufacturing Practices)
- 21 CFR 11 Electronic Records and Electronic Signatures
- EU EMA Annex 11
- Qualifications, IQ/OQ/PQ
- Risk Assessment and Management
- The System Life Cycle and Validation Strategies
- Vendor Audit
- Validation Plan and Project Management
- Retrospective Validation
- Spreadsheet Validation
- SOPs and Training
- Case Studies: Validation Requirements for
  - Applicative Software
  - COTS or stand alone softwares
  - Automated Spreadsheet Calculation Templates
  - Computerized Equipment
  - Computerized Laboratory Systems (LIMS, Chromatography Systems)
  - MRP and ERP Systems
  - Automated Control and Monitoring Systems
  - Computer Network Qualification

Learning Outcome

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

1. Understand the various regulations and guidelines from regulatory bodies and industrial bodies such as 21 CFR 11, GAMP, Annex 11
2. Understand all the elements in a System Life Cycle approach
3. Understand the different classifications and types of computer systems, from the simple GAMP Class 1 systems to complex, bespoke Class 5 systems; from personal computer-based systems to industrial PLC systems.
Course Registration

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

Ms CHEW Ying Ying
Senior Manager
Office: S4A 03
Tel: 65168977
Email: phacyy@nus.edu.sg
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.
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.