A NUSAGE-PharmEng Pharmaceutical and Biotechnology Training Program

Shaping Human Capital for Challenges in the Pharmaceutical Industry

COMPUTERIZED SYSTEM VALIDATION

Instructor

Mark O'Donnell
Managing Consultant

Date and Time
14-15 March 2013
9 AM – 5 PM

* Instructor and dates may be subjected to changes due to unforeseen circumstances.

Computerized System Validation

Objective

The course is designed to provide a thorough understanding of computer system validation. In addition, the course will address how 21 CFR Part 11 (electronic record/electronic signature requirements) fits into the validation process. The attendee will become familiar with expected content for computer validation deliverables through examination of how to develop the validation rationale for a variety of circumstances.

Description

The course will examine the current GAMP version applied to validating PLC, software and control systems. Both FDA and EU regulatory guidelines will be discussed. Also a discussion will be made on the current 21 CFR part 11 regulations which cover topics such as background & impact of the regulations in industry, details of regulations and implementing a validation program. Furthermore, the course will discuss the computer validation life cycle from design, through construction, installation and live start up for a typical software project will be described with details on the contents of key documents such as URS, FDS, VMP, IQ, OQ, PQ. Finally, the objectives for risk assessment and the various techniques and how to effectively implement to ensure critical risks are identified and correct level of validation is carried out will be discussed.

Course Outline

- Regulations and guidelines for computer system validation
- Electronic signatures and records
- Overview of Software Categories (GAMP)
- Introduction to Computer Validation Life Cycle – Emphasis will be given on the contents of key documents/activities such as URS, FDS, VMP, IQ, OQ, and PQ
- Introduction to System Life Cycle Process
    - Planning
    - Design and Construction
    - Acceptance Testing for developed systems (2 parts) – Acceptance at the supplier site, Factory Acceptance Test (FAT) and Acceptance at the customer site, Site Acceptance Test (SAT)
    - Implementation and Acceptance
    - Ongoing operation
    - Back-up and Restore
    - Disaster Recovery
    - Contingency Planning
    - Business Continuity
    - Preventative maintenance
    - Corrective maintenance (problem reporting)
    - Change control
    - Archiving of the system when replaced
    - Retirement phase
- Risk assessment of computerized systems

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

This course is particularly useful for personnel in the Pharmaceutical/Medical Device/ HealthCare/ Engineering Sector of industry who need to gain an understanding in the principles of GxP in a regulated environment and how to apply these to develop fully compliant systems. The participants will be able to build upon their existing knowledge of computerized system validation concepts and practices to learn how these approaches, concepts and practices can be applied to future projects.

About the Trainer

Mark O'Donnell is Managing Consultant with 25 year' experience in Project Management within the biopharmaceutical industry. As a project manager, Mark has led multiple large and small capital projects both in the US, Europe, and Asia. Working as a project manager for large engineering firms, and as the Manager of Quality Engineering for Merck & Co., has enabled Mark to view projects with a unique perspective.

Mark has utilized his extensive knowledge, hands-on CQV field experience, and excellent interpersonal skills for building integrated project teams, developing project management tools, which has helped companies such as Merck, sanofi pasteur, Pfizer, Bristol Myers Squibb, Biogen Idec, Roche, Eli Lilly, and American Red Cross, achieve their corporate and project objectives.

Mark has both managed and executed various types of CSV projects such as; Distributed Control Systems, Building Management Systems, Emerson DeltaV System, 21 Part 11 Remediation Projects, and various automated stand alone process equipment. He is an active member of ISPE.

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PharmEng Technology

Computerized System Validation

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 without egg / No beef / Halal / No preference)**

* **Circle where appropriate**

Fees:

S$1070 per delegate after GST.

Early bird registration discount 14 days before the course or group discount of 5 or more delegates: 10% off per delegate

Course fee includes course materials, tea breaks and lunch.

Please return completed forms by mail/fax to:
National University of Singapore
NUSAGE
Department of Pharmacy
S4, Level 2
18 Science Drive 4
Singapore 117543

Fax: 67791554

For enquiries, email
phacyj@nus.edu.sg or dial 65165878

Payment:

Only cheques are accepted. Please make cheques payable to:
"National University of Singapore"

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.

Registration is subjected to confirmation. Registrants will be notified upon confirmation on venue and payment matters. We apologize in the event of changes to the instructor or date of event due to unforeseen circumstances, of which registrants will be duly informed and any payment received will be refunded.

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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.

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

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.

"… good course, especially the case studies." Genesys Venture Inc.

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

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

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

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)
- 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

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

www.pharmeng.com

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