Risk-Based Approach to Inspecting Quality Systems

Part of the Pharmaceutical and Biotechnology Training Courses

Instructor

Jerry Holatko
Senior Consultant, PharmEng Technology
Former Health Canada Regional Head

Date and Time

13 & 14 April, 2010
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
Risk-Based Approach to Inspecting Quality Systems

Objective
The objective of this course is to understand the Quality Systems concept used by regulatory agencies and the characteristics of the subsystems involved. It covers six types of systems as well as its elements, characteristics and features of the various sub-systems that constitute this system and their inspections. In addition, participants will get understand of the impact of the QS on Quality Assurance.

Synopsis
Regulatory agencies are using system approach for both domestic and foreign inspections. The approach consists of classifying a firm’s operation into six types of systems: The Quality System, Facilities and Equipment System, Materials System, Production System, Packaging and Labeling System, and Laboratory Control System. The systems inspected depend upon the purpose of the inspection and agencies prior experience with the firm but always includes the Quality System for which compliance is mandatory. It will cover the system which includes following sub-systems: Deviations, Stability Failure Handling, Change Control, Product Release, Validation and Annual Product Reviews, Rework and Reprocessing Returned and Salvaged Goods, Complaints, Personnel, Training as well as preventive and product improvement activities. Responsibilities for these sub systems include QA. The need for integrating the design, operation and responsibilities for each of the systems and sub-systems will be emphasized throughout.

The case studies are based on current scenarios that industry professionals will be able to relate to.

Outline
- The Quality Systems
- Materials System
- Production System
- Packaging and Labeling System
- Laboratory Control System
- Importance of each of the Quality System’s components
- Regulatory Requirements, and industry practices for:
  - SOPs, records and report requirements
  - Product Release, Validation, Reprocessing and Rework, Returned and Salvaged Goods, Product Complaints, Annual Product Reviews
- Other quality system components: training, preventive activities and product improvement
- Roles and Responsibilities for the Quality System Components: Departmental rules and responsibilities including QA
- Impact of other systems on QA: regulatory requirements, current practices
- Tools for the system owners: FMEA, HACCP, HAZOP, etc.

Who Should Attend & What Participants Will Benefit From
Intermediate-level managers and industry professionals with 3-10 years of experience would benefit from the full-spectrum of current theories covered, and case studies they will be able to relate to their experiences.

Junior-level attendees may find certain theories difficult to grasp immediately but are welcomed if they wish to significantly broaden their knowledgebase.

Instructor
Jerry Holatko, B.Sc. Chem, is a Senior Director at PharmEng Technology and a former Health Canada Regional Head. Accomplished trainer in auditing, project management, design controls, risk management, Quality Systems implementation, GMPs, transportation validation, coaching, analytical analysis, inspecting and investigation of issues involving all dosage forms and commodities (Drugs, Medical Devices, Natural Health Products, Cells, tissues and organs) as regulated in Canada, US and Europe. Teaching skills are reinforced with over thirty years of experience in regulatory positions with Health Canada and PharmEng Technology Inc- Regulatory and Consultant Services.
Registration
Risk-Based Approach to Inspecting Quality Systems, 13 – 14 April 2010

Please Print or Type Clearly

Full Name_________________________________________Title (Prof/Dr/Mr/Mdm/Ms)_____________________

Job Title_________________________________________Years of experience_____________________________

Company__________________________________________

Business Address__________________________________

City / State / Country ______________________________Postal Code ________________

Business Tel______________________________________Business Fax______________________________

E-mail Address____________________________Special Diet__________________________

Fees:

S$1000 per delegate before GST.
Early bird discount by 1 April 2010: 10% off per delegate
Group discount of 5 or more delegates: 10% off per delegate
Early bird cum Group discount: 20% off per delegate

Course Fees includes course materials, tea breaks and lunch

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.

Please return completed forms by mail/fax to:

National University of Singapore
Department of Pharmacy
54, Level 2
18 Science Drive 4
Singapore 117543
Fax: 67791554

Attn: Chen Yee Ju, Manager
NUS, Department of Pharmacy
phacyj@nus.edu.sg, DID: 65165878
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:

1. The Biopharmaceutical Technology Certificate Program for the University of Waterloo and the National Tsing Hua University College of Life Science in Taiwan

2. 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.
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.