EFFECTIVE QUALITY ASSURANCE: AUDITS, ANNUAL REVIEWS, EVENTS HANDLING AND CAPA

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

To have an understanding of current QA topics in post-market maintenance of pharmaceutical products, and which are of key importance for QA management and personnel to consider.

Description

This course provides an understanding of the principles and practice of pharmaceutical quality assurance and control and of specific topics, which have become important because of regulatory interest or recent technological achievements.

This course provides: an understanding of the basic principles and practice of the QA function in a commercial manufacturing environment, covering their role during product design, production, storage and distribution, with the role during production being addressed in particular detail, consisting of reviews, first of broad current quality issues including major regulatory agency’s activities, and then the QA aspects of a number of specific issues including: handling of laboratory controls, validation (equipment, processes, computers, cleaning and test methods), label and labeling, water systems, change control, electronic records and signatures, deviations and discrepancies, (including OOSs), regulatory agency inspections, internal and supplier audits, vendor and contract supplier qualification, annual product reviews, and training. The QA aspects of stability program operation and also documentation are presented as well.
**Course Details**

**Josephine Wray BSc MRSC** is a Quality Assurance Professional with over 15 years of experience in the pharmaceutical industry. Josephine completed her degree in Chemistry in Scotland and worked in the chemical industry field for a few years before moving into the pharmaceutical field. She has worked in the Pharmaceutical, Biotech and Medical Device industry in UK, Singapore and Canada for both small and multinational companies (GSK, Pfizer, Abbot, ThermoFisher). Josephine has expertise in GxP Quality Assurance Processes within FDA, Health Canada, EU and Asian Regulations in Validation, Laboratories, Manufacturing, Packaging and Distribution areas. She has extensive experience in auditing (internal and external), process/equipment/cleaning validation, analytical processes, change controls, deviations and CAPA, process improvements, product lifecycles, product recalls, stability programs, documentation systems, and regulatory submissions.

**Date and Time:**
25 & 26 July 2018 | 9AM – 5PM

**Course Outline**

- Quality Function
- QA’s Role in Production
- Laboratory Controls
- Label and Labeling Control
- QA Aspects of Water
- Change Control
- Deviation/Discrepancy Handling
- Electronic Records and Signatures
- Regulatory Inspections and Their Impact on QA
- Internal and Supplier Audits
- Corrective Action and Preventive Action (CAPA) program
- Training Programs and Their Impact on QA
- Vendors and Contract Suppliers
- Annual Product Reviews
- QA Aspects of Stability Programs
- QA Aspects of Documentation

**Learning Outcome**

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

1. Understand the concepts and methods in designing clinical trials
2. Understand the Quality Function, as well as the role of QA and QC units in manufacturing/production
3. Understand essential QA programs, such as change control, deviation handling, internal and supplier audits, CAPA
4. Understand the responsibility of vendors and contract suppliers, and QA’s role in managing these relationships
5. Understand stability programs
6. Understand documentation practices
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.