FUNDAMENTALS OF PHARMACEUTICAL REGULATORY AFFAIRS

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

The objective of this course is to provide an overview to technical professionals, particularly those in Research & Development and Regulatory Affairs, on the general legal requirements to bring a pharmaceutical product to market – whether it is the creation of a new product, or import/export of a product to a new market – and maintaining it afterwards.

Description

This course will discuss regulatory requirements for prescription, generics/biosimilars and OTC pharmaceutical products in major international reference environments and select countries in Asia. Submission dossiers in accordance with ICH CTD will be discussed. The course will also present pre and post-market compliance and pharmacovigilance in key Asian markets.

Advanced products such as combination products are interpreted differently by different agencies, and there tend to be more disparity among Asian countries compared to more mature Western agencies. This course will also discuss some of the challenges with such advanced products.
Course Details

Instructor:

Rick Ng

Dr. Rick Ng holds degrees in BSc (Honours), PhD and MBA. He has worked in senior positions in Clinical, Quality, Regulatory Affairs and Business Development in the biotech and pharmaceutical industry in Australia and Singapore for more than 20 years. Currently Rick provides consulting and training services in GCP, GMP, Quality, Regulatory and Validation. Rick is the author of one of the best selling medicine/pharmacology books, Drugs: From Discovery to Approval, which is a recommended text in a number of universities/colleges.

Date and Time:

26 - 27 March 2015 | 9AM – 5PM

Course Outline

• Introduction to RA – what is the role of RA
• Introduction to major global reference regulations and harmonization:
  • US, Europe, ICH
• Overview of regulatory environment in major Asian reference countries:
  • ASEAN, Japan, Singapore
  • Future trends in regulatory development
• Classification of drugs and formulations
• Pre-market requirements
• Authorization procedures for drug products
• Quality systems and regulatory inspection process
• Post-market requirements and compliance
• Advanced products:
  • Orphan drugs
  • Named-patient drugs

Learning Outcome

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

1. Understand major global reference regulations and harmonization efforts for pharmaceuticals
2. Understand regulatory environment in key Asian markets for pharmaceuticals
3. Understand general pre-market and post-market requirements
4. Understand the legal logics behind the definition and regulation of advanced products
Course Registration

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

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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.
ABOUT THE TRAINING PROVIDER

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.

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