PRACTICAL APPROACH TO ASIA REGULATORY AFFAIRS - STRATEGY, CMC & HA COMMUNICATIONS

NUSAGE – PharmEng
Pharmaceutical and Biotechnology Training Program
PRACTICAL APPROACH TO ASIA REGULATORY AFFAIRS
- STRATEGY, CMC & HA COMMUNICATIONS

Objective

The course provides an overview and an in-depth understanding of Regulatory Affairs in Asia and the Agency review expectation of the dossier for CMC section. The course focus on the comparison of regulatory requirements in Asia region with emphasize on the GCP, GMP, DMF system, which helps in developing regulatory submission strategy. The course teaches in-depth of the organization of the CTD, detailed information and discussion related in each element in the drug substance and drug product from reviewer’s perspective. The course also provides discussions specific to solving regulatory issues and interacting with health authorities. Interactive Q&A and exercises will be conducted at the end of each section. Whether you are new to the profession or someone who wants to refresh their knowledge in Regulatory Affairs, this course will help you enhance your skills in executing your functions.

Who Should Attend

- Regulatory Affairs Professionals involved in regulatory filing in Asia region
- Regulatory Affairs Professionals involved in preparing/reviewing CMC documents
- Professionals who want to refresh and update their knowledge

Learning Outcome

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

1. Understand the regulatory environment and harmonization efforts for pharmaceuticals in Asia
2. Gain knowledge on regulatory strategy for the submission in Asia region
3. Understand the requirements in CMC section of dossier
4. Gain tips and knowledge in interacting with Health Authorities
5. Gain insights from interactive Q&A
6. Promote excellence in your regulatory affairs profession

Date and Time

22 – 23 November 2018 | 9AM – 5PM
Instructor

James Pierce is currently a Regulatory Affairs Professional with over 24 years of experience in the biological and pharmaceutical industry and has worked for some of the most recognized multinational companies (Sanofi, Amgen, Boehringer Ingelheim and GSK). Throughout his 25 years of experience, Mr. Pierce has worked in Pure Research, Research and Development, Quality Operations, Industrial Operations and 14 years Regulatory Affairs.

Course Outline

With reference to the major Asian countries (Hongkong, South Korea, Singapore, Thailand, Vietnam, Indonesia, Philippines, and Malaysia):

1. International Conference on Harmonisation (ICH)
   - ICH Background
   - ICH Products
   - ICH implementation in various jurisdictions

2. Different Regulatory Requirements in APAC Regions
   - ICH CTD vs ACTD
   - Local Clinical Trial and GCP site inspection
   - GMP system
   - DMF system
   - Packaging Label and language
   - Interactive Q&A

3. CTD Module 3 (Quality Section) --- Agency review expectations
   - Requirements for the Drug Substance
   - Requirements for the Drug Product
   - Analytical Methods and Validation
   - Control of the product
   - Container Closure System
   - Specifications
   - Reference Standards
   - Stability

4. Interaction with Health Authorities
   - HA queries and how to manage response
   - Tips in successful interaction with Health Authorities

5. Conclusions
   - Interactive Q&A
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.
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.