

A NUSAGE-PharmEng Pharmaceutical and Biotechnology Training Program

Shaping Human Capital for Challenges in the Pharmaceutical Industry

FUNDAMENTALS OF PHARMACEUTICAL REGULATORY AFFAIRS

Instructor

Dr. Rick Ng

Date and Time

20-21 May 2013

9 AM – 5 PM

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



Fundamentals of Pharmaceutical Regulatory Affairs

Objective

To provide an overview 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 pharmaceutical regulatory affairs in major international reference environments and select countries in Asia. The course will discuss the major pre-marketing regulatory challenges and potential solutions in key Asian markets.

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

Course Outline

- Introduction to RA – what is the role of RA
- Introduction to major global reference regulations and harmonizations:
 - 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

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

This two-day course is targeted toward technical professionals, particularly those in Research & Development and Regulatory Affairs, in the pharmaceutical industry. The attendees are expected to understand major global reference regulations and harmonization efforts for pharmaceuticals, regulatory environment in key Asian markets for pharmaceuticals, general pre-market and post-market requirements and the legal logics behind the definition and regulation of advanced products after the course.

About the Trainer

Dr. 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.

Fundamentals of Pharmaceutical Regulatory Affairs

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.

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.

“... good course, especially the case studies.” Genesys Venture Inc.

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

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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