ICH Principles in Chemistry, Manufacturing & Controls for Regulatory Approvals







NUSAGE – PharmEng Pharmaceutical and Biotechnology Training Program



ICH Principles in Chemistry, Manufacturing & Controls for Regulatory Approvals

Objective

The course provides an overview and in-depth understanding of ICH regulations, to understand the expectations of regulatory agencies when reviewing the ICH CTD dossier. The course provides detailed information and discussion related in each element in the drug substance and drug product from reviewer's perspective and will focus on drug development, analytical method validation, impurities, specification and stability. 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 preparing/reviewing/authoring CMC documents
- Regulatory Affairs Professionals involved in regulatory filing
- Professionals who want to refresh and update their knowledge in CMC and ICH Principals

Learning Outcome

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

- 1. Understand the requirements and review expectations of CMC section of dossier
- 2. Understand the ICH regulatory environment and harmonization efforts
- 3. Gain tips and knowledge in interacting with Health Authorities
- 4. Gain insights from interactive Q&A
- 5. Promote excellence in your regulatory affairs profession

Date and Time

2018 (refer to website <u>www.pharmeng.asia</u> for latest dates)







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Instructor

Ravi Singh, M.Sc., Ph.D., is a regulatory affairs and quality compliance senior consultant at PharmEng Technology. Dr. Singh possesses combination of expertise and experience in many aspects of drug development and regulatory requirements for drugs and medical devices approvals in US, Canada, EU and ASEAN countries. Dr. Singh is an expert in leading, coordinating and executing complex regulatory affairs projects submissions in CTD and ACTD format. He has strong scientific, clinical and regulatory affairs knowledge to lead drug development program from an early development stage to late clinical stage.

Course Outline

- 1. International Conference on Harmonization (ICH)
- ICH Introduction,
- ICH Guidelines
- Implementation in various jurisdictions
- 2. Requirements for the Drug Substance
- S.2 Manufacture ICH Q11
- S.3 Characterization
- S.4 Control of the Drug Substance-ICH Q2, Q3, Q4 and Q6
- S.5 Reference Standards
- S.6 Container Closure System
- S.7 Stability ICH Q1
- 3. Requirements for the Drug Product
- P.2 Pharmaceutical Development—ICH Q8
- P.3 Manufacture
- P.4 Control of Excipients-ICH Q2, Q3, Q4 and Q6
- P.5 Control of the Drug Product-ICH Q2, Q3, Q4 and Q6
- P.6 Reference Standards
- P.7 Container Closure Systems
- P.8 Stability ICH Q1
- 4. Quality Overall Summary (Module 2 of CTD)
- 5. Interactions with Health Authority
- HA queries and how to manage response (case studies)
- Tips in successful interaction with Health Authorities
- Interactive Q&A





Course Registration

To register for this course online, please go to the Training page at www.pharmeng.asia

Or

Contact PharmEng Technology:

Tel: 68365524

Email: info@pharmeng.asia

Contact NUS Pharmacy: 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.

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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
- 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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