

FACILITY DESIGN CONSIDERATIONS FOR BEST PRACTICES IN ENGINEERING, MANUFACTURING & COMPLIANCE



NUS
National University
of Singapore

PE PharmEng
Technology

NUSAGE – PharmEng Pharmaceutical and Biotechnology Training Program



National University of Singapore
Academy of GxP Excellence

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Shaping Human Capital for Challenges in the Pharmaceutical Industry



FACILITY DESIGN CONSIDERATIONS FOR BEST PRACTICES IN ENGINEERING, MANUFACTURING & COMPLIANCE

Objective

The objective of this course is to understand the approach to GMP Facility Design and how to employ Good Engineering Practice (GEP) as one of the tools to aid the design process.

This course provides an overview of the design process, criteria and good practices like GEP and "risk-based approach" for GMP Manufacturing Facilities with clear future Qualification and maintenance in mind.

Description

The successful delivery of regulated manufacturing facilities poses significant challenges to manufacturers, engineering professionals, facility design/construct contractors and equipment suppliers. A systematic approach to Process/Facility Design is one of the foundations to a "fit for intended use", compliant and cost-effective operating site. The course steps through the design definition, scope, applying key criteria, clean design principles to develop a strong front end design package, so as to prevent the need for major remediations in future.

The last few years have seen several initiatives to best use of resources whilst being cost effective and compliant with regulatory requirements. These initiatives are consensus with inputs from industry, ISPE, ASTM, FDA, ICH and so on. This course applies some of the initiatives and other tools to enhance the facility design process:

- GEP – ISPE has released the good practice guide on GEP and its principles are promoted in ASTM E2500 and ISPE's "Science and Risk-Based approach for the Delivery of Facilities", to name a few. The course applies these principles, methods and standards to the design process. Advantages are clear defined deliverables, avoiding the "re-inventing the wheel" syndrome and reducing equipment qualification burden. GEP – once established is for the long term, saving resources, time and cost
- Risk-based approach – applying a rational approach to emphasize on critical process parameters.
- Project quality system – to enhance the communication and design deliverables between Client and Contractor

Therefore, the course participants will learn the key criteria and tools to Process/Facility Design illustrated with case studies to develop a strong front-end design package. The standards and documents generated are transportable to the Qualification process.

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Course Details

Instructor:

Raymond Loke, B.Eng. has more than 30 years of experience in process and engineering. He is an expert in Good Engineering Practices, especially in the context of current GMP, and has served major multinational pharmaceutical companies like Merck, Sharpe & Dohme, Baxter, Biotech Australia Pty Ltd, Astra Zeneca, Pfizer, Schering-Plough, as well as food and chemical facilities such as Huntsman Chemical, Kellogg, Cerebos, Procter & Gamble, Res Med, and more. He has successfully managed multimillion-dollar projects, technology transfer projects, Greenfield projects, and facility upgrade projects, with quantifiable results such as the successful attainment of 100% facility and equipment availability at Schering-Plough, among others. Raymond is an active trainer on GMP and GEP topics in countries including Australia, China, and Malaysia.

Date and Time:

11 – 12 Oct 2018 | 9AM – 5PM

Course Outline

- Overview of regulatory and statutory requirements to Facility & Equipment
- Good Engineering Practice – key concepts, common practices, standards, engineering specifications. Examples of Drawing/Equipment Control, Material of Construction, Piping Specifications.
- Risk-based approach – with respect to engineering and facility design.
- Facility/Process Design – Life Cycle Model, Industry Trend, User Requirement Specification (examples).
- Process Design – Process map, URS, Pre-qualification documentation, Clean Design principles, Case Study illustration.
- Facility Design – Building, Room Classifications, Layouts (People, Material & Equipment Flow), Utilities, Cost Estimates, Case Study illustration
- Case Studies – Critical Utilities (Purified water system/WFI/Steam), Liquids/Cream Facility, Solid Dosage/Liquids Facility
- Quiz and group participation
- Course Handouts – comprehensive templates and examples to help you with implementation.

Learning Outcome

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

1. Gain an understanding of a practical approach to process and facility design and development of a design “front-end” package
2. Gain an understanding of the application of Good Engineering Practice
3. Understand the pre-requisites to a smooth Equipment Qualification process, operations and maintenance.

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Course Registration

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

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ABOUT THE TRAINING PROVIDER

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.



ABOUT THE TRAINING PROVIDER

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.

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“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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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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