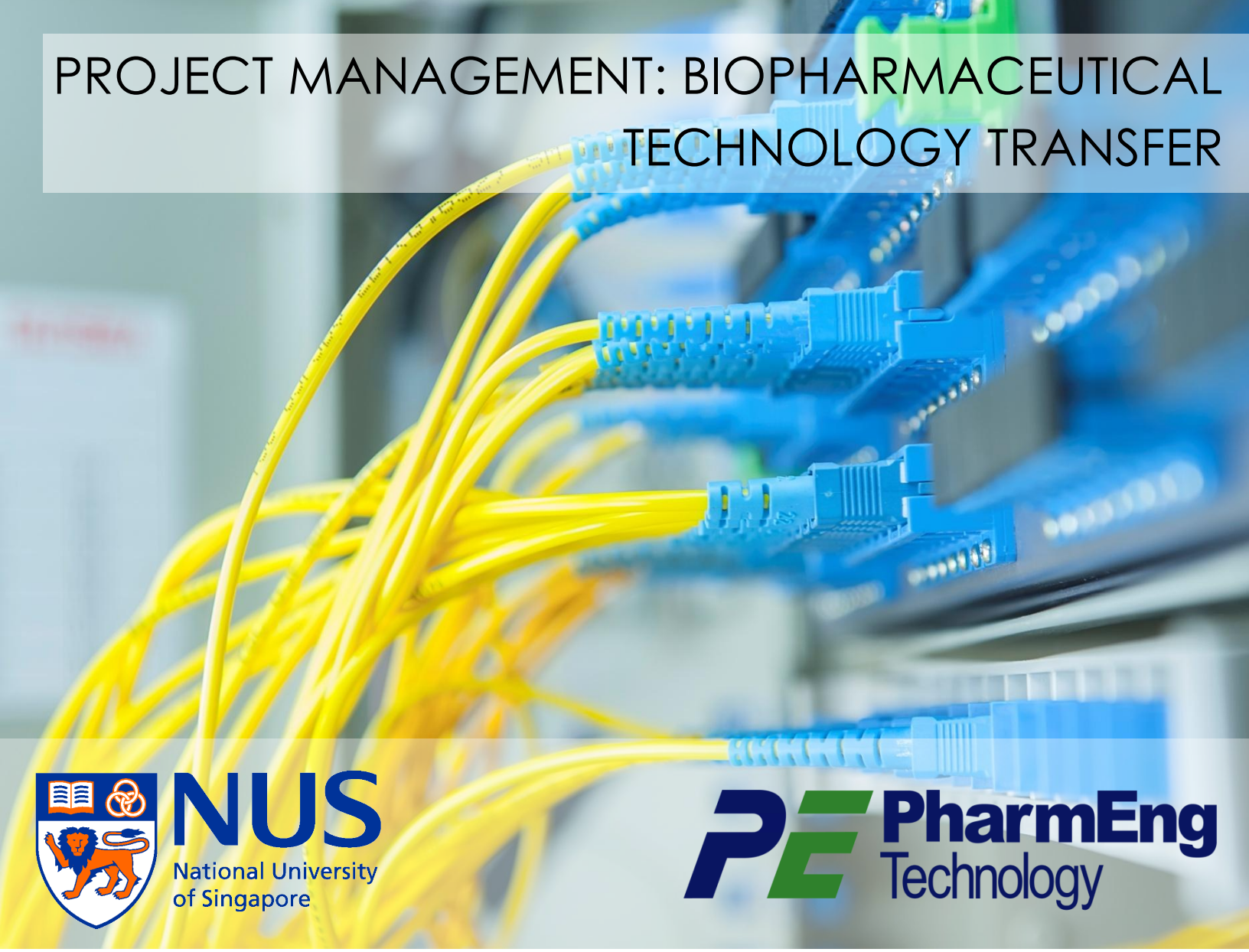
PROJECT MANAGEMENT: BIOPHARMACEUTICAL TECHNOLOGY TRANSFER



National University of Singapore

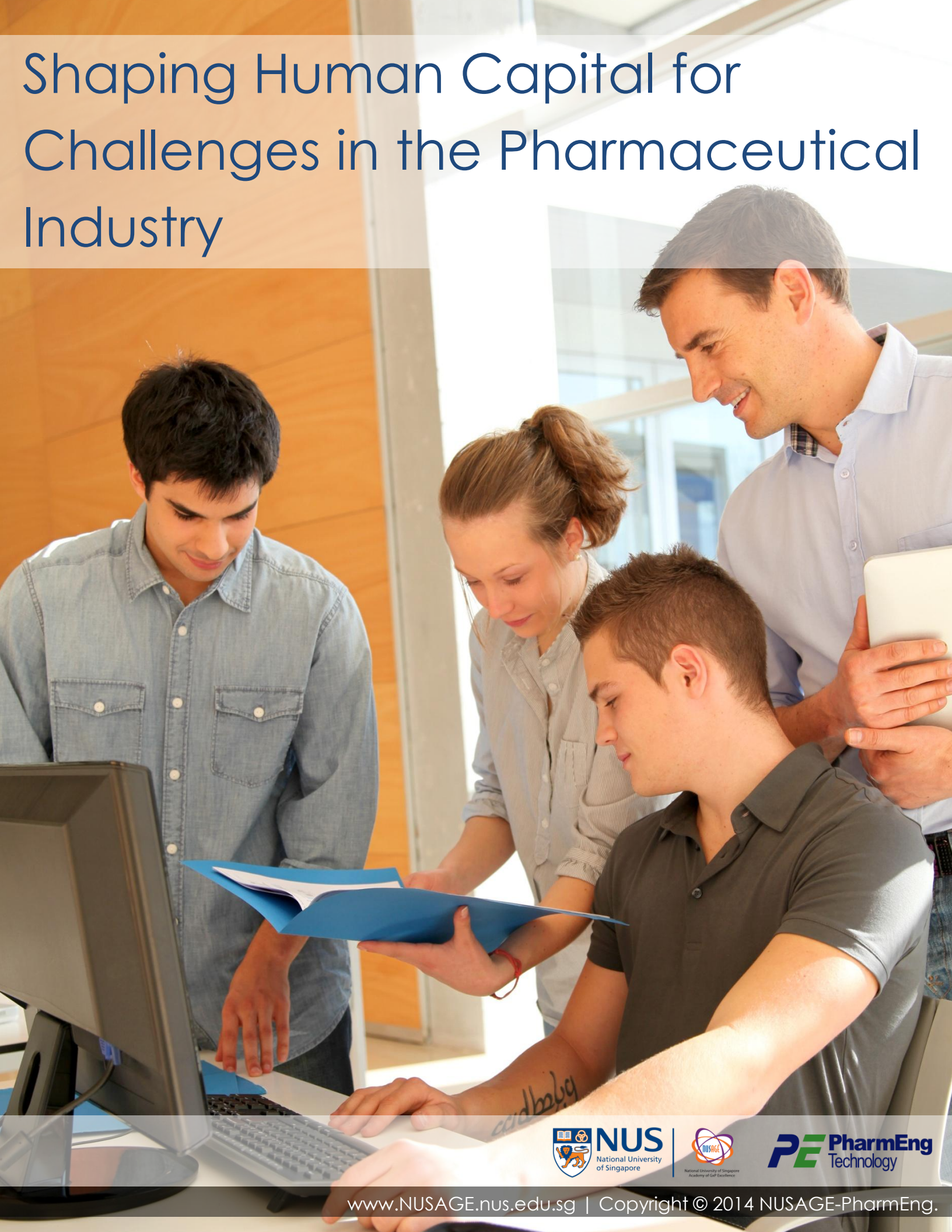
PharmEng Technology

NUSAGE – PharmEng

Pharmaceutical and Biotechnology Training Program

National University of Singapore
Academy of GxP Excellence

Shaping Human Capital for Challenges in the Pharmaceutical Industry



NUS National University of Singapore | NUSAGE National University of Singapore Academy of GoP Excellence | PharmEng Technology

PROJECT MANAGEMENT: BIOPHARMACEUTICAL TECHNOLOGY TRANSFER

Objective

To benefit project managers and technical professionals in understanding the advantage of technology transfers, the adverse consequences that may be associated with improper planning and the approach to successful technology transfers.

Description

There are an increasing number of technology transfers in pharmaceutical industry today due to its impending benefits such as creating a competitive edge against its competitors. However, improper planning and implementation of such activity can lead to unnecessary monetary loss, compliance issues and disruption in operation for both companies. This course will explore the types of technology transfers among companies and the issues affecting the transfer within and among companies, including the regulatory requirements that are associated with it. In order to cope with such movements, strategies justified with examples, will be explored.

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Course Details

Instructor:

Dr. Loh Kean Chong

Date and Time:

27 - 28 August 2015 | 9AM – 5PM

Course Outline

- Product and technology transfers - intellectual property, technology transfer, skills transfer, regulatory considerations
- Benefits of technology transfer
- Variation procedures - types of variations, advantages and disadvantages
- Challenges
    - Technical Challenges - Manufacturing process, validation, stability studies, risk Management and technology transfer
    - Logistical challenges
    - Suppliers, raw materials, shipment
    - Human challenges - team membership and team roles, cross-cultural issues
- Approach to successful technology transfers
    - Process understanding and information
        - Quality-by-Design (QbD)
        - Critical Process Parameters (CPP)
    - Product understanding and information
    - Project management, planning and scheduling
        - Identify the technology transfer critical path etc

Learning Outcome

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

1. Appreciate where Technology Transfer will fit into the life cycle of a pharmaceutical product
2. Understand the regulatory requirements for technology transfers
3. Understand the importance of planning technology transfer and the requirements for successful technology transfers
4. Gain an understanding of the challenges faced in technology transfer

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Registration Form

Please complete details below 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 inquiries, email
phacyy@nus.edu.sg or dial 65168977

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.

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.

"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.