Execution Excellence in Industry -
Healthcare, Pharmaceutical and Medical Devices

NUS National University of Singapore

PharmEng Technology

NUSAGE – PharmEng

Pharmaceutical and Biotechnology Training Program

National University of Singapore
Academy of GxP Excellence

Execution Excellence in Industry - Healthcare, Pharmaceutical and Medical Devices

Objective

This hands-on course aims to provide an 'end-to-end' appreciation of product businesses in a birds-eye view thereby shaping the mindset for being a 'master in execution'. Besides connecting diverse functional elements along the chain and highlighting the challenges, it would bring out the financial performance of the business in simple yet powerful terms.

Description

Commencing from the opportunity to innovate as per market needs, this interactive course imparts much needed awareness on strategy formulation, fit, market positioning, lean execution, cost efficiency, productivity and concluding with a financial perspective of the business.

Besides outlining the key challenges in regulatory compliance, effective and efficient running of the business, it exposes the significance of seamless communication and cross functional decisions, breaking silos in-between. In addition to honing critical thinking skills, it drives home the power of simplicity in making a difference in the market place.

Driven by case examples, the workshop-type engagement of attendees from different backgrounds and friendly flow of topics, ensures learning from each other and in cross pollinating ideas. Insights developed from the course may help the attendees evolve comprehensive strategies for their own organizations, generate a pipeline of ideas and smartly launch new products for sustained profitable growth.

No matter which part of the business they are from, each participant will have gained knowledge on key ingredients in running a successful business in the healthcare arena.

For those hungry for contemporary tools and approaches to accomplish their missions, this practical program offers a fair spread and would help imbibe such with ease.

What to expect?

Opportunity to network with fellow professionals to broaden perspectives, teaming up to analyze scenarios, a simulation game to learn concepts while having fun and role plays to 'walk in the shoes' of *other* functions – in addition to nuggets of business knowledge from the facilitator.

Who should attend?

Functional leaders and Executives of multinational organizations from R&D, Technology, Engineering, Manufacturing, Supply Chain, Customer Service, Sales or Marketing as also entrepreneurs in small to medium sized businesses in the healthcare and medical device arena, would stand to benefit.

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Instructor:

Kalyan Vaidyanathan

As a six sigma quality expert with Master Black Belt skills from GE Medical systems, Kalyan assists diverse businesses in the areas of operations excellence, processes quality and performance improvement. Based in Singapore, he delivers Workshops, Training and Coaching assignments across Asia-pacific. He is adept at technology transfer, performance diagnostics, capability assessments and building, instituting processes and systems end-to-end of supply chains commencing from Product Design thru Engineering, Manufacturing Supply and After-market support, in compliance with befitting Regulatory needs of the clients. Kalyan held Asia-pacific and Global leadership roles across functions and initiatives with leading corporates such as GE, ICI, Philips and GSK. He is an Engineer and has an MBA from Rutgers Business School. He's attended Executive programs in Universities such as Cranfield and Carnegie Mellon.

Date and Time:

27 and 28 June, 2016, 9 am to 5 pm @ NUS

Outline

- Introduction & overview
- The market opportunity to innovate
    - Voice of customer
    - Strategy formulation, Strategic fit
    - Perceived Value, Key accounts
- Execution
    - Speed to market
    - Regulatory compliance
    - The operations game
- Performance
    - Customer Satisfaction & Loyalty
    - Slip-ups and remediation
- Money trail
    - Cash flow, P&L and Balance sheet
    - Key metrics and ratios
- Action planning
    - How do we do ours?

(Case studies and examples interspersed)

Learning Outcome

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

1. Get a simplistic cum realistic end-to-end view of business in the healthcare and medical device arena
2. Recognize the importance of breaking cross-functional silos
3. Appreciate the financial implications of such
4. Dovetail the significance of regulatory compliance
5. Understand pitfalls and remedial measures in compliance
6. Gain insights from the cases examples

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.