GOOD DISTRIBUTION PRACTICE FOR MEDICAL DEVICES IN SINGAPORE (GDPMDS)

Instructor
Tan Hwee Ee

Date and Time
29 October 2014
9 AM – 5 PM

* Instructor and date may be subjected to changes due to unforeseen circumstances.
Objective
To create an understanding of GDPMDS certification for the distribution, import, export and wholesale of medical devices in Singapore to ensure that the quality and integrity of medical devices is not compromised during the process.

Description
As manufacturing industry grows with rising number of distribution, import, export and wholesale activities, it is a requirement that organizations involved should be in compliance with all applicable laws to ensure that the quality and integrity of the medical devices throughout the distribution process are not compromised. Hence, it is important that organizations be GDPMDS certified by certification bodies, accredited by the Singapore Accreditation Council (SAC) and recognized by the Health Science Authority (HSA) under Singapore context, before they can distribute those medical devices.

The course will provide an overview of what GDPMDS is about. The requirements necessary for organization to be GDPMDS certified will be the main focus of this course.

Course Outline
- Singapore Regulatory Framework
- Risk Classification of Medical Devices
- Introduction to GDPMDS
- Overview of TS-01:GDPMDS Good Distribution Practice for Medical Devices – Requirements
- Background and Definitions
- Quality Management Systems
- Resource Management
- Storage and Stock Handling
- Traceability
- Medical Device Complaints
- Field Safety Corrective Action (FSCA)
- Return of Medical Devices
- Disposal of Medical Devices
- Counterfeit, Adulterated, Unwholesome or Tampered Medical Devices
- Internal Audits
- Management Review
- Outsourced Activities
- Secondary Assembly

Learning Outcome
Upon completion of this course, attendees will have an understanding on:
1. The requirements in the TS-01: GDPMDS standards
2. The preparation and management of GDPMDS audits and certification
3. How to support organizations with regards to GDPMDS standard

About the Trainer
Ms Tan Hwee Ee Tan has more than 20 years of experience in the medical industry principally in medical device organizations as a consultant, engineer and senior manager.
She is the Founder of DH RegSys Pte Ltd where she is also the Principal Consultant. The company provides consulting and training services to, as well as conducting audits and management system gap analysis for the medical device and related industries for regulatory bodies such as Singapore HSA, Australia TGA, US FDA, EU and etc. Principle areas of expertise and involvement include:
- External trainer engaged by SGS International Certification Services Singapore Pte Ltd
- Advisor in developing programs and operating procedures to ensure compliance to regulatory requirements like 21 CFR Part 820, ISO 13485 and Singapore HSA’s GDPMDS (Good Distribution Practice for Medical Devices in Singapore)
- Performing Company Audits and Gap Analysis
- Industry Training and Seminars in Regulatory requirements and Quality Management Systems
- Quality Manuals and supporting documentation development
- Project Management
- Regulatory submissions in various countries including EU, USA, China, Singapore etc

She is also a member of Working Group 4 (WG4) of the AHWP (Asian Harmonization Working Party) and is a Certified Biomedical Auditor (CBA) with ASQ. Ms Tan Hwee Ee also passed the WMDO exam for the Certified Medical Device Associate – Clinical Evaluation (CMDA) diploma.
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$856 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 phacwl@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 subject to confirmation. Registrants will be notified upon confirmation on venue and payment matters. We apologize in the event of changes in 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, biotechnological, nutraceutical and medical device 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 biotechnological 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 the relevant industries, governments and academia. Course materials are developed by PharmEng in-house and are constantly updated to remain current with the regulatory environment. As the industry changes, so do the issues and challenges. Our courses, with supporting materials, link:

- Training
- Regulations
- Government
- Industry
- Academia
- International Standards

Conferences

PharmEng offers conferences throughout the year in collaboration with Health Canada, and various professional associations in biotechnological, 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.
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 services include project management, engineering, cGMP, validation, calibration, regulatory compliance and certified training.