



PSB Thailand

**Choose certainty.
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New EC Directive 2007/47/EC (an impact of the change to MDD 93/42/EEC)

4-5 February 2010 (08:00 - 17:00 hrs.)

at Miracle Grand Convention Hotel (Vibhavadi Rangsit Road)

Introduction

This 2 days special training course "New EC Directive 2007/47/EC (an impact of the change to MDD 93/42/EEC)" will provide knowledge to participants on the requirements of the new EC Directive 2007/47/EC which will soon come into effect. From March 21, 2010 onwards, the new provision must be applied without any transitional periods or extensions. Every manufacturer declaring conformity of his products to 93/42/EEC should be aware that medical devices according to 90/385/EEC (Active Implantable Medical Device Directive) and 93/42/EEC (Medical Device Directive) must also comply with the new EC Directive from March 21, 2010, otherwise the products cannot be placed on the European market.

During the seminars, high caliber lecturer will inform you about the following issues:

- What change will the new Directive involve?
- What must be implemented, and by when?
- What will be changed in Notified Body audits?
- What do you have to expect in the future?

Our seminar will address the regulatory framework from a variety of perspectives. In addition, the seminar offers you the opportunity of discussing your personal questions and of exchanging your ideas and experience with other participants.

Seminar Overview :

- Introduction : Provision of Directive 2007/47/EC
- Compliance of medical devices with the new requirements
- Evaluation of medical devices
- Classification of medical devices
- Essential Requirements
- Technical Documentation

Seminar Materials :

Seminar Manual and New 93/42/EEC Medical Device Directive will be provided.

What do participant gain :

- Understanding of New EC Directive 2007/47/EC which will impact of the change to Medical Device 93/42/EEC
- Be able to prepare technical documentation according to new EC Directive

Who Should Attend :

- Managers, Executives, Supervisors of various departments
- Quality Assurance, Production, Regulatory Affairs, Laboratory
- Logistics, Purchasing, Management Representatives
- Inspectors and Internal Auditors

TÜV SÜD PSB (Thailand) Limited

TÜV®





Training Profile

Experience

Parivat Akarapimarn is one of TÜV SÜD PSB qualified trainers who has an extensive experienced in working, auditing and training for Medical Health Services.

Position

Deputy Manager for Medical Health Services

Qualification

- MBA. General Management, Ramkhamhaeng University
- B.Sc. Chemistry Prince of Songkla University
- 4 years of experience in Quality Assurance Lead Supervisor Position at Kimberly – Clark Safeskin Thailand
- 3 years of experience in Assistant QA Manager Position at Johnson & Johnson Thailand
- 4.5 years of experience in Deputy Manager – Medical Health Service Position
- Ability to communicate in Thai and English

TRAINING COURSES CONDUCTED TO CUSTOMERS

- New Pharmaceutical Affairs Law – In-house Training
Client: Kawasumi Laboratories (Thailand) Ltd., Kendall Gammatron Co., Ltd.
- Canadian Medical Device Regulations – In-house Training
Client: Siam Sempermed Corporation Ltd., Infus Medical (Thailand) Co., Ltd. Safeskin Thailand
- ISO 13485:2003 Internal Audit
Clients: Ansell Thailand, Pacific Biotech, Thai Hospital Products, Infus Medical, i+Med Laboratories
- ISO 9001:2000 Internal Audit
Client: EGAT
- Quality System Regulation (21 CFR Part 820) – In-house Training
Clients: M.E. Nikkiso, Kendall Gammatron, Thai Hospital Products, Kawasumi Laboratories (Thailand) Ltd., Peters Surgical International Co., Ltd.
- Risk Management for Medical Devices (ISO 14971) – Public and In-house Training
Client: Pacific Biotech Co., Ltd., Molnlycke Healthcare (Thailand) Ltd., Kimberly Clark Safeskin Thailand, M.E. Niikiso, M.E. Meditek, Thai FDA, Kawasumi Laboratories
- Medical Device Directive (MDD, 93/42/EEC) – In-house and Public Training
Clients: Kimberly Clark Safeskin Thailand, Infus Medical Thailand (In-house Training), Emerald Nonwovens International
- Process Validation – In-house and Public Training
Clients: Infus Medical, Pacific Biotech, Thai FDA (In-house Training)
- Software Validation – In-house Training
Clients: IDS Manufacturing Limited
- Corrective and Preventive Action – Public Seminar organized by Thai FDA





Our profile

TÜV SÜD PSB Thailand is part of TÜV SÜD Group, the global technical service company serving customers in a wide range of industries. With more than 140 years experience it has developed to become the world largest independent providers of testing and certification.

3 Easy ways to apply ...NOW!

☎ Telephone: +66 (2) - 564 - 8041

☎ Fax: +66 (2) - 564 - 8042

✉ Email: training@tuv-sud-psb.co.th

Payment Method

Please include payment or proof of payment (copy of cheque or cheque request form) with your registration form:

Cheque make payable to: TÜV SÜD PSB (Thailand) Limited

Bank transfer to: TÜV SÜD PSB (Thailand) Limited

- Bangkok Bank, Klong Luang Branch
- Saving Account # 222-0-843599

■ Regular Fee	5,700
■ Early Bird (until January 20, 2010)	5,200
■ TÜV SÜD PSB Customer	4,700

Remark: This price already includes certificate, one lunch and two coffee breaks (not include VAT 7%)

Cancellation / Refund Policies:

You must notify the company at least 5 working days before the seminar in order to be eligible for a credit or a refund. No refunds or credits will be given for late cancellations, or no-shows for the course. If you cannot attend, you may send an alternate from your organization at no charge. The company reserves the right to postpone or to cancel the course due to unforeseeable circumstances. We will notify all registrants by phone and will provide a full refund for cancellation of the seminar.

First Come First Served!
Limited Seat

SEMINAR REGISTRATION FORM

Please register the following delegate for the seminar.
(Kindly fill in the registration form in English.)

Name - Surname : _____

Position : _____

Business Email : _____

Company : _____

Address : _____

Tel : _____ Fax : _____ Mobile : _____

Company Website / Email Address : _____

Nature of Business : _____

TÜV SÜD PSB Thailand reserves the right to amend the date, time and location of training courses depending on the number of participants. We advise you to check the update schedule at our website www.tuv-sud-psb.co.th

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