FDA - THE QUALITY SYSTEM REGULATION & 510K TRAINING

This program would introduce the participants to the basic understanding of definitions within FDA QSR which is warranted under CFR Part 820 regulated by Center for Device & Radiological Health, FDA. This program is aimed at transferring overview about QSR and the related guidance standards through lectures followed by second part which emphasizes in understanding the 510k application process.

DATE : 30 June 2011 (Thursday)

TIME : 8.30am - 5.30pm

VENUE : MREPC Multi Purpose Hall

OBJECTIVES

The objective of this program is to provide the participants with an understanding of the FDA QSR and how it shall be applied as Quality Management System (QMS) framework to achieve optimum benefit by the medical device manufacturer in obtaining US FDA 510k Premarket approvals for sale of medical device in USA.

Upon completion of this program, the participants should be able to:

- Understand all requirements contained in FDA's QSR
- Revise a Quality Management System (QMS) to comply with FDA's QSR
- Appreciate the 510k application process subsequent to implementation of FDA QSR based QMS
- Apply this knowledge to the design of their own QSR based quality system

COURSE STRUCTURE

- FDA history, organization and foreign inspection history
- Overview of the QSR 21 CFR 820
- FDA's QSR requirements
- How to prepare for and manage an FDA inspection
- 510K application process
- Complaint handling and medical device reporting 21 CFR 803 and 804

WHO SHOULD ATTEND?

- Quality assurance personnel
- Company personnel who are responsible and perform any regulated function including design, manufacturing, training, purchasing and who may be required to answer questions from FDA investigators
- Regulatory affairs professionals

For enquiries please call Ms Uthaya (uthaya@mrepc.com) or Ms Izni (izni@mrepc.com) at 603-27805888

SPEAKER PROFILE

Mr Jegathesan S, Associate Trainer with BSI specializing in ISO 9001, 13485, ISO 14001, GMP/FDA regulations, CMDCAS Training and etc.

He holds an Honours Degree in Science, majoring in Industrial Chemistry and minoring in Management and a Diploma in Process Quality Management System Lead Auditor certified by SIRIM. Has more than 18 years working experience in Manufacturing concerns at various management level capacities.

Mr Jega has provided training services to more than 100 manufacturing concerns specializing in ISO 9000 (QMS), ISO 14000 (EMS) and GMP/FDA regulations, ISO 13485 & CMDCAS.

He has more than 10 years managerial experience managing production, quality assurance, quality control & process control disciplines.

Proficient in the following quality assurance related work:

- Preparation and set up of 510k Technical file for FDA application
- Preparation and set up of EC Directive Technical File
- Application of principles of product quality evaluation and control
- Ability to use Quality Engineering techniques to implement an effective QC system or to enhance existing in house QC system
- Process control using Statistical process control techniques
- Validating and commissioning of new processes and process

Name (1) :

Designation (1) :

Name (2) :

Designation (2) :

Name (3) :

Designation (3) :

Company Name :

Contact Person :

Email :

Telephone : Fax No:

Date: Company Stamp

Confirmation note will be sent via email

REGISTRATION FORM

SEMINAR ON FDA - THE QUALITY SYSTEM REGULATION & 510K TRAINING

30 June 2011

Participation Fee : RM50.00 per participation

Kindly complete and fax this form to Ms Uthaya or Ms Izni at 03-2780 5088 on or before 24 June 2011 (Friday)
THANK YOU

Hurry! Limited Seats
THREE persons per company

Organized by

MREPC