



SINGAPORE QUALITY INSTITUTE

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ROS Ref No: ROS 245/1970 TAP GST Reg No: M90010688N

ISO 14971:2007 MEDICAL DEVICES APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES

INTRODUCTION:

The concepts of risk management are particularly important to medical devices because of the variety of stakeholders including medical practitioners, the organizations providing health care, governments, industry, patients and members of public.

ISO 14971:2007 is an International Standard which provides manufacturers with a framework within which experience, insight and judgement are applied systematically to management the risks associated with the use of medical devices.

ISO 14971:2007 : Medical Devices – Application of Risk Management To Medical Devices” is an essential requirement specified in ISO 13485:2003 (Ref: Clause No.: 7.1: Planning of Product Realization)

OBJECTIVE

This program is designed to equip the participants with the basic knowledge to apply risk management to Medical Devices in accordance with ISO 13485:2003.

COURSE CONTENT:

1. Scope
2. Terms and Definitions
3. General Requirements for Risk Management
4. Risk Analysis
5. Risk Evaluation
6. Risk Control
7. Evaluation of Overall Risk Acceptability
8. Risk Management Report
9. Production and Post-production Information relevant to Product Safety
10. Overview of The Risk Management Process for Medical Devices
11. Worked Examples and Discussion
12. Class-room Exercise

WHO SHOULD ATTEND?

This program is designed for Production & QC /QA/RA Supervisors, Executives and Managers who are involved in applying risk management to medical devices.

AWARD OF CERTIFICATE

Certificate of Attendance will be issued to participants who have attended at least 75% of the course.

COURSE DATES (9.00 AM – 5.00 PM)

12 April 2010

COURSE FEES

S\$ 214 (For SQI Member), S\$235.40 (For Non-Member)
GST is not applicable. Price is inclusive of two tea breaks.

TRAINING VENUE: SQI, 66 Tannery Lane #06-07, Sindo Bldg, S347805

For Reservation: Contact Jeffrey Tan via Mobile: 98183736 or email: jeffreytan@sqi.org.sg



Certificate No: 6655731205

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