

# ISO 13485:2003 FOUNDATION TRAINING COURSE (1-day)

## 2 Workshops

### Objective

The successful delegate will understand the ISO 13485:2003 requirements, its underlying philosophy and principles, and concepts.

The 1-day course opens with a discussion about Quality Management Systems. This is followed by discussions on:

- Benefits to organizations using ISO 13485:2003
- Quality Management Process Model
- Quality Management Principles
- ISO 13485:2003 components

Persons who should attend this course include:

- Those responsible for managing their current Quality Management Systems
- Individuals designing and implementing new Quality Management Systems, and
- Persons who may be training others in the disciplines of the ISO 13485:2003

### Overview

ISO 13485:2003 Standard represents the latest result of the medical devices industry's adaptation of ISO 9001:2000 (2008).

This International Standard specifies requirements for a quality management system that can be used by an organization for the design and development, production, installation and servicing of medical devices, and the design, development, and provision of related services.

It can also be used by internal and external parties, including Certification Bodies / Registrars, to assess the organization's ability to meet customer and regulatory requirements.

In addition to the specifics of the individual Standard clauses, this 1-day course discusses the following issues ... and more:

- Continual Improvement
- Root Cause Analysis
- Risk Assessment
- Quality Management Principles

This course examines these issues, identifies areas Quality Management Systems – Medical Devices must review to ensure conformance, and assists Quality Management Systems during their development.

This course contains two workshops designed to examine and explore the eight Quality Management Principles and the ISO 13485:2003 Standard.

Course Content ... See Reverse



# Course Content

**9:00 a.m. - 5:00 p.m.**

## Introduction

- Course Programme
- Course Learning Objectives
- Delegate Responsibilities
- Continuous Assessment Process

## Management Systems

- Quality Management System
- Key Vocabulary
- Quality Management Process Model

## What is Continual Improvement?

### Root Cause Analysis

### Risk Assessment

## Quality Management Principles

*Workshop - Case Study 1 ... Quality Management Principles*  
*Roundtable Discussion*

## ISO 13485:2003 ... The Components

*Workshop - Case Study 2 ... ISO 13485:2003*  
*Roundtable Discussion*

## Questionnaire No. 1

Delegate Review and Wrap-up ... *General Knowledge Review*

## Close