

## **Course Outline for ISO 13485:2003 Training**

### **Course objective**

This course gives an overview of all important aspects for managers of an organization in order to implement and maintain an ISO 13485:2003 compliant management system.

### **Course length**

1-3 days are required to complete the ISO 13485 course (doing a couple of hours/day).

### **Who should attend?**

This is the ideal course for anyone who does NOT have time to allocate a full day to take a LIVE course on ISO 13485:2003, and who wants to quickly and efficiently understand what ISO 13485:2003 is about. You want to upgrade your knowledge and expertise from ISO 13485:1996 to ISO 13485:2003.

### **The structure of the training is as follows:**

- The Standard
- The Process Approach
- Scope
- Quality Management System
- Management Responsibility
- Resource Management
- Product Realization
- Measurement, Analysis and Improvement

### **Worldwide Course Recognition:**

CALISO online training courses are recognized by all registrars and hiring companies as objective evidence of effective training on the particular standard and regulation. Since 1999, they have been the most popular and most widely used training courses in English, with over 15,000 trainees in the US and worldwide. The standards and regulations are provided online under licensing of the American National Standard Institute (ANSI), SAE International, or courtesy of the Federal Drug Administration (FDA).

**Course requirements**

The training is optimized for Microsoft Internet explore 5.0 or higher and Netscape 4.5 or higher.

### **Certificate requirements**

The course uses a continuous evaluation method with on-going quizzes to facilitate the information retention. If your final average is equal or greater to 70% you will be issued a **training certificate**. If your final average evaluation is less than 70%, you will have to take a final exam and score above 70% to be issued the training certificate.