



QUALITY MANAGEMENT INTERNATIONAL, INC.
www.QMII.com

MEDICAL DEVICE MANAGEMENT SYSTEMS LEAD AUDITOR COURSE Using ISO 13485

We teach you how to use auditing to improve your organization

Each class covers:

- Management System Principles
- Interpretation Of ISO 13485
- Applying Risk-Based Thinking
- Auditing Management Systems
- Planning the Audit
- Managing The Audit Process
- Leading the Audit Team
- Performing The Audit
- Reporting The Audit
- Corrective Action And Follow-Up
- Registration, Accreditation and Auditor Certification

The workshops include:

- Analyzing Processes
- Analyzing Operational Risk
- Reviewing System Documentation and Preparing an Audit Plan
- Reviewing Processes and Preparing Checklists
- Verifying Facts
- Writing Nonconformity Statements
- Audit Investigation
- Chairing a Closing Meeting
- Reporting the Audit
- Taking Corrective Action

Attendees successfully completing the examinations provided in conjunction with this course receive a Certificate of Attainment for these Exemplar Global knowledge competency units:

MD - Medical Device Management Systems
AU – Auditing Management Systems
TL – Leading Management Systems Audit Teams



The Certificate of Attainment provides evidence of knowledge competency defined by Exemplar Global for certification as an Medical Device Management Systems Lead Auditor.

Even though ISO 13485 is used as the model for teaching systems and audit, this course enables students to develop and apply auditing skills using any applicable management system standard.

Call **888.357.9001** today to schedule training or get more information about our training, consulting, and auditing services.

You can also visit our website: www.QMII.com.