



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 QMII training units:

13485 - Medical Device Management Systems  
AUDITOR – Auditing Management Systems  
TEAMLEAD – Leading Management Systems Audit Teams



*This course is recognized by Exemplar Global as meeting the training requirements for 13485 - Medical Device Management Systems Lead Auditor personnel certification.*

While 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](http://www.QMII.com).