

## ISO 13485 Internal Audit Training : 2-Day Certificate Course

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Management Support Network offers a 2-day ISO 13485:2003 Internal Auditor Training Program at your facility.

### Who Should Attend:

- Individuals managing and conducting internal audits

**Professional Fees:** \$2,400; Manual & Certificate: \$50 per person. Ideal for groups between 3-12 employees.

### Learning Objectives:

During this 2-Day Certificate Course (Option A – see below), participants will:

- Understand how each ISO 13485 requirement applies to your organization
- Create an Internal Audit Schedule
- Create an audit checklist based on your organizations procedures
- Conduct and practice an audit
- Summarize an audit in an audit report
- Raise corrective actions

This course can be conducted using one of the following two options:

**Option A – Traditional:** Using the traditional approach, about 1.0 days are spent in the classroom discussing the details of the standard, conducting classroom exercises and understanding the audit process. The other 1.0 days is spent conducting a practice audit at your facility.

**Option B – Hands-on Workshop:** Using the workshop approach, about 0.5 days are spent in the classroom discussing the audit process and reviewing the standard at a very high level. The majority of the time (about 1.5 days) is spent conducting audits at your facility.

## ISO 13485:2003 Awareness/ Transition : 1-Day Certificate Course

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### Who Should Attend:

- Individuals responsible for managing and working in an ISO 13485:2003 environment
- Individuals responsible to help their organization earn ISO 13485:2003 registration

**Professional Fees:** \$1,200; Manual & Certificate: \$25 per person. Ideal for groups between 3-12 employees.

### Learning Objectives:

During this 1-Day Certificate Course, participants will understand:

- The new requirements in the ISO 13485:2003 Standard and the requirements that have been eliminated
- Options for upgrading the Quality Manual to ISO 13485:2003
- The new evidence that will be required for ISO 13485:2003 registration

## ISO 13485:2003 Gap Analysis

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Management Support Network offers “Gap Audits” to help organizations identify and close the gaps that are preventing their organization from earning ISO 13485:2003 registration.

### Part 1 – Document Review Gap Analysis

To get the most value out of our Gap Analysis, it is best if the client provides a paper copy of all policies, procedures, work instructions and forms to Management Support Network approximately one week before the on-site audit.

When the documentation arrives, the ISO 13485 Specialist:

- reviews the documents provided
- assesses the gaps in the documentation by comparing against the ISO 13485:2003 Standard

### Part 2 – On-Site Gap Analysis

After reviewing the documents, the ISO 13485 Specialist conducts a “shop floor” and “office” assessment of the existing processes against the requirements of the ISO 13485:2003 Standard. A detailed report is written by the Specialist and includes the following information:

- The requirements of the ISO 13485:2003 Standard
- The findings for each requirement of the ISO 13485:2003 Standard & CMDCAS
- Recommended action, **with sample forms**, to satisfy the requirements in the Standard.

During the audit, the ISO 13485 Specialist works with the appropriate ISO Implementation Team member from your organization to discuss the ISO 13485:2003 requirements and the various options to meet the requirements.

### Approximate Professional Fees:

2-4 days at \$1,900 - \$4,000

## Day-by-Day Consulting Support for ISO 13485:2003

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Management Support Network helps the Quality Upgrade Team earn ISO 13485:2003 registration.

### Suitable for Organizations:

- That have the resources to lead their organization to successful ISO 13485:2003 registration but require support on an “as needed” basis
- That want some ideas from a consulting organization on how to streamline and fine-tune their quality management system, so it is done right the first time.

### Results from our clients:

- Reduced the policies, procedures and work instructions by up to 45%
- Migrated the text-based procedures to flowcharted procedures
- Reduced the number of ISO 13485 forms in use
- Simplified the maintenance of the system by moving to a more electronic system
- Removed the “Quality Jargon” to make the Manual easier to use by all employees

### Results from our clients (continued):

- Simplified and changed procedures so they better support the goals of the organization

### Work Plan:

The consultant will work with the Management Representative/ Upgrade Team through the following topics, as necessary:

- Identify areas in the quality system where there is too much paperwork/ documentation
- Identify areas in the business where there are consistent problems or frustration
- Discuss the three options to upgrade the Quality Manual to ISO 13485:2003 and select one of the options
- Mark-up the existing Quality Manual to show how it needs to be cut and pasted into an ISO 13485:2003 format
- Discuss where and how to edit the Quality Manual to make the system more helpful and user friendly
- Discuss the new ISO 13485:2003 requirements

**Professional Fees:** \$900/day + 7% for expenses.

## Guaranteed Registration Consulting & Training Support for ISO 13485:2003

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Our “front-to-finish” ISO 13485:2003 upgrade package is the same as the day-by-day package (above) but provides more training and document writing support.

### Our on-site ISO 13485 Package includes:

- Project planning and project management assistance to ensure projects are completed on-time and on-budget
- Preparing flowcharts, procedures and form templates that are in compliance to the Standard

### Our ISO 13485 Package includes (continued):

- Awareness training for all management and all employees
- Internal auditor training for the audit team
- Compliance audit and readiness training for employees.

### Professional Fee Estimate:

Typical consulting packages cost between \$3K - \$15K