



# ISO 13485 Internal Auditor Training

## ***Training Course Overview***

To successfully implement and maintain a quality management system a company must have an Internal Audit process and use trained auditors to perform the audits. Internal auditors are also a key element in quality system improvement. This course teaches auditing to the ISO 13485 standards and places a strong emphasis on promoting employee participation in the improvement process. Participants in this course will learn how to:

- Describe the goals and benefits of an internal audit
- Determine the requirements of an internal audit
- Explain how ISO 13485 differs from ISO 9001 and the areas of focus for Medical Devices.
- Plan an internal audit, and develop a guide list
- Perform an internal audit
- Identify nonconformity to requirements during an audit
- Report on an audit and follow up on corrective actions taken in response to audit findings
- Describe the actions necessary for maintaining a successful audit program

## ***Course Duration***

This course will take 2-days (16-hours) to complete

## ***Course Instructor***

Bethany Quillinan has 20 years experience in Process Management and Improvement and currently specializes in statistical methods and ISO 9001-based Quality Management Systems. Bethany has provided numerous ISO 13485 Internal Auditor training workshops for members of Oregon Bioscience Association and her other clients include Biotronik, Precision Wire Components, Silicon Forest, Hewlett Packard, Ascentec Engineering, and Leupold & Stevens. An accomplished trainer and training course developer, Bethany holds a BS in Ceramic Engineering, an MA in Whole Systems Design for Organizational Systems Renewal, has passed the examination for Certified Lead Auditor and has completed Six Sigma Black Belt training.

## ***Course Fees***

ETI Group can present this training program at your facility. Your cost, including workbooks for up to twelve people and travel will be \$4,000. Additional participants in this workshop, up to a maximum of eighteen people, will cost \$75 per person to cover the cost of the additional training materials. For more information please contact ETI Group.