NEW! Transition to ISO 13485:2016

Updated for ISO 13485:2016!
- Lead Auditor Training for ISO 13485
- Quality Systems for Medical Devices: FDA’s QSR and ISO 13485
- Implementing Design Control Requirements and Best Practices

Updated for ISO 13485:2016!
- ISO 14971: Introduction to Risk Management
- Process Validation Principles and Protocols

NEW!
- Software Verification and Validation Requirements

Updated for ISO 13485:2016!
- Optimizing CAPA Programs for the Medical Device Industry
- Root Cause Analysis for Life Science Investigations

Updated for ISO 13485:2016!
- Complaint Handling, Vigilance Reporting, and Recall Management
- Supplier Quality Management: Designing a Successful Program
- Global Product Submissions: 510(k), PMA, CE Mark
- Calibration Requirements for Medical Devices

Updated for ISO 13485:2016!
- Internal Auditor Training for ISO 13485
- Quality Systems Documentation
- Professional Certification for Medical Device RA/QA
- Applied Statistics for the Workplace
- ISO 9001 Auditor Training

NEW!
- Transition to ISO 9001:2015
- Advanced Auditing
## ACQUIRE THE SKILLS YOU NEED TO SUCCEED

1. **Begin with Foundation Training** that ensures you have a solid base in critical quality and regulatory requirements.

   - **Transition to ISO 13485:2016**
   - **Quality Systems for Medical Devices: FDA’s QSR and ISO 13485**
   - **Global Product Submissions: FDA and EU Directive Requirements [510(k), PMA, CE Mark]**

2. **From there, select Targeted Skills Training or pursue a Professional Certification Program** (see pages 12–13 for details).

   - **Implementing Design Control Requirements and Best Practices**
   - **ISO 14971: Introduction to Risk Management Across the Medical Device Product Life Cycle**
   - **Developing and Maintaining a Compliant Document Management System**

   - **Process Validation Principles and Protocols**
   - **Software Verification and Validation Requirements**
   - **Supplier Quality Management: Designing a Successful Program**

   - **Calibration Requirements and Equipment Controls for Medical Devices**
   - **Optimizing CAPA Programs for the Medical Device Industry**
   - **Root Cause Analysis for Life Science Investigations**

   - **Complaint Handling, Vigilance Reporting, and Recall Management**

3. **Continue to broaden your skill set with Performance Excellence Training** aimed at improving business performance and results.

   - **Internal Auditor Training for ISO 13485**
   - **Lead Auditor Training for ISO 13485**
   - **Advanced Lead Auditor Training**
   - **Statistics for Lead Auditors**

   - **Lean and Six Sigma**
   - **Applied Statistics in the Workplace**
ISO 13485 is evolving to keep pace with the growth of the medical device industry and align the standard with regulatory requirements. The 2016 revision provides clarifications and new requirements to improve medical device safety and performance. These are not cosmetic updates: one of the most significant changes prompts top management to consider the strategic reasons for incorporating quality objectives into their business goals. Other major changes include an increased focus on risk management throughout the product life cycle, the supply chain, as well as device usability and postmarket surveillance requirements.

In this new course, you will review the revised standard, assess its impact on your quality management system, and start working on a plan to update your ISO 13485 system to meet the new requirements.

**COURSE OBJECTIVES**
- Recognize the changes introduced in the new standard.
- Assess the impact of the changes and new requirements on your current quality management system (QMS).
- Recognize the opportunity to make quality management a strategic function within the organization – one that improves the organization’s ability to achieve compliance effectively and efficiently.
- Learn about the agreed-upon transition period for the revised standard and how it applies to your organization’s current or future certification.
- Recognize the impact of the new requirements on top management, auditors, and other relevant functions within your organization.
- Find out how to establish an Action Plan to achieve and maintain certification to ISO 13485:2016.

**TOPICS**
- Interpretation and use of ISO 13485:2016
- The audit cycle and ISO 19011
- Preaudit activities
- Auditing practices: the psychology of auditing
- Nonconformity reporting
- Process auditing
- Follow-up and corrective action

**WHO SHOULD ATTEND**
Anyone engaged in the implementation or auditing of their organization’s quality management system.

**NEXT STEPS**
- Prepare your team. Our new course Transition to ISO 13485:2016 reviews the new standard and assesses its impact on your QMS.
- Conduct a gap assessment. We will provide an objective assessment of your current ISO 13485 QMS and deliver a formal report that documents what you need to do to attain compliance to the revised standard.

Get a FREE consultation. Call 800.472.6477 or email info@orielstat.com.

**For additional dates and locations or to register — 800.472.6477 — www.orielstat.com**
Lead Auditor Training for ISO 13485

Gain a thorough understanding of how to conduct audits of quality management systems for medical devices through simulations, exercises, and workshops – now updated to use ISO 13485:2016 criteria. Workshops reinforce key topics, including audit documentation, opening and closing meetings, auditor interpretations, listening and questioning techniques, development of checklists, and nonconformance reports. Our approach preserves the teaching of the audit discipline in accordance with ISO 19011 while providing a sector-focused learning experience for those engaged in medical devices.

COURSE OBJECTIVES
Over five rigorous days, discuss background of the ISO 13485 and ISO 9001 standards and go through every phase of the audit – from planning to conducting to following up – so you will be able to lead your own audits efficiently and effectively.

• QA System Assessment – Understand the elements that comprise a quality system.
• The Requirements – Learn the relationships among ISO 9001, FDA’s Quality System Regulation, and ISO 13485 requirements.
• Quality Audit System – Using ISO 19011, work through different types of assessments.
• Preaudit Activities – Learn how to plan audit activities.
• Conducting the Audit (Assessment) – Learn how to collect objective evidence.
• Postaudit and Follow-Up Activities – Learn how to conduct closing meetings.

TOPICS
• Interpretation and use of ISO 13485:2016
• The audit cycle and ISO 19011
• Preaudit activities
• Auditing practices; the psychology of auditing
• Nonconformity reporting
• Process auditing
• Follow-up and corrective action

WHO SHOULD ATTEND
Although this course was originally designed to train third-party auditors, most of the participants lead their company’s quality system implementation and/or audit programs. Ideal for anybody involved in a supplier quality assurance program.

COURSE REQUIREMENTS
Evening study recommended. A 2-hour final exam is required.

NOTES:
• This training course is an Exemplar Global certified course. To attain registration as a QMS Auditor/ Senior Auditor/Lead Auditor, you must pass the written final examination, earn a passing grade in the course assessments, and meet prescribed professional requirements. For full details of Exemplar Global certification, please see page 19.
• Exemplar Global requires that all attendees study the current published version of ISO 13485 before attending this class.

FACULTY Spotlight

I. ROBERT MARASH (Bob) has more than 40 years of experience in auditing and implementing quality management systems for ISO 9000, ISO 14000, ISO 13485, and the US Food and Drug Administration’s (FDA’s) good manufacturing practices (GMPs). He is executive vice president of Oriel STAT A MATRIX, responsible for worldwide educational services, where he has worked with a vast array of industries ranging from nuclear to automotive to healthcare in more than 20 countries on 6 continents. Bob is an Exemplar Global certified quality system lead auditor; he has a master’s degree in engineering management.

On-Site Audit Support
An Oriel STAT A MATRIX Lead Auditor can provide one-on-one coaching to your audit team. We can also conduct an audit of your facility – providing an independent, unbiased, and objective view of your quality system and processes.

Contact us at 800.472.6477 to learn more.

$2695 • Course Code: LAF • 4.4 CEUs • 5 Days

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Quality Systems for Medical Devices: 
FDA’s QSR and ISO 13485

Includes coverage of ISO 13485:2016
See page 3 for our new course: Transition to ISO 13485:2016.

Medical device manufacturers in the global marketplace are subject to an array of regulatory and other requirements, including:
• FDA’s medical device quality system regulation (QSR)
• EU Medical Device Directives
• ISO 13485
• Recommendations from the former Global Harmonization Task Force (now maintained through efforts led by the International Medical Device Regulators Forum)

Find out how to meet these requirements while managing one integrated quality system. First, gain an understanding of what effective compliance means to your organization and its processes. Then, learn how to compare and harmonize all relevant requirements, so your organization can deploy a single comprehensive quality system.

Using dynamic group discussions, this course covers:
• The impact of global requirements on the international medical device industry
• When FDA compliance or ISO registration is required or desirable
• The potential benefits of ISO registration, such as increased productivity, cost effectiveness, higher perceived quality, enhanced internal and external communication, and competitive advantage
• How to document and design an effective quality management system
• What auditors are looking for (and finding) in their audits

COURSE OBJECTIVES
• Understand the objectives and benefits of medical device regulations.
• Analyze the details of FDA QSR and ISO 13485 requirements.
• Compare the relationship between compliance standards and guidance documents.
• Understand international harmonization efforts and their effects.
• Understand the product life cycle in the development and support of medical devices.
• Plan and prepare for FDA and notified body inspections/audits.
• Understand the medical device manufacturer’s regulatory responsibilities.

TOPICS
• ISO 13485:2016
• FDA requirements under 21 CFR 820, 803, and 806 (corrections and removals)
• EU regulatory requirements under the Medical Device Directives and MEDDev 2.12, and integration of these requirements into a global quality system
• ISO standards for medical device CE Marking and risk management, ISO 13485, CMDCAS, and ISO 14971
• FDA QSR background and subpart review compared against ISO 13485 standard clauses
• Major subsystems: management controls, design controls, production and process controls, CAPA

WHO SHOULD ATTEND
Designed for both new and experienced professionals in the medical device field, this course provides a solid understanding of the necessary components of an effective, compliant quality system for medical device manufacturing.

FACULTY Spotlight

KATE LEITH has over 20 years of experience in global quality and compliance for life sciences organizations. She is currently responsible for the strategic oversight of Oriel STAT A MATRIX’s life sciences training practice.

Prior to joining Oriel STAT A MATRIX, Kate held several leadership and managerial positions at corporations such as Beckman Coulter, Sanofi Diagnostics, Centocor, and Invitron. Her expertise spans the total product life cycle, including design development, premarket quality, operations and supplier quality, and postmarket surveillance.

In addition to her expertise in the field, Kate has significant experience designing and delivering training programs that consistently achieve outstanding customer satisfaction marks from participants across the US, Europe, and Asia. Kate has authored and published several technical articles, holds patents in the US, Europe, and India; and is an invited speaker for quality- and regulatory-themed conferences. She holds a Master of Science degree in Microbiology and CQA, CPLP, PMP, CMQ-OE, and ASCP certifications.

* This course is also taught by other Oriel STAT A MATRIX quality management system experts.

Excellent training. The instructor was very knowledgeable, and his real-world experiences really helped to illustrate the concepts being taught.”
— Quality/Regulatory Manager

For additional dates and locations or to register — 800.472.6477 — www.orielstat.com

$2495 • Course Code: GRF • 2.5 CEUs • 3 Days

| JULY 25-27  | Orlando, FL |
| AUGUST 8-10 | Austin, TX |
| AUGUST 22-24| Indianapolis, IN |
| AUG 30-SEP 1| Boston, MA |
| SEPTEMBER 12-14 | Raleigh, NC |
| SEPTEMBER 24-28 | Minneapolis, MN |
| SEPTEMBER 28-30 | San José, Costa Rica |
| OCTOBER 3-5 | San Francisco, CA |
| OCTOBER 10-12 | Chicago, IL |
| OCTOBER 24-26 | Orlando, FL |
| OCT 31-NOV 2 | San Diego, CA |
| NOVEMBER 7-9 | Edison, NJ |
| NOVEMBER 14-16 | Boston, MA |
| DECEMBER 5-7 | Austin, TX |
| DECEMBER 12-14 | Indianapolis, IN |
Implementing Design Control Requirements and Best Practices

Design control is a key area in FDA’s QSIT top-down inspectional approach to compliance. Manufacturers must have robust design control processes to comply with the FDA regulations and to ensure a safe, effective finished product.

This 3-day course covers the practical application of design control requirements and how to control the design process to ensure that your organization’s devices meet user needs.

In-depth discussions and workshops — which include real-world industry examples — cover design and development planning, sound design inputs and corresponding design outputs, design validation, control of design changes, design results, transferring the design to product manufacturing, and the design history file. Class exercises explore the interface of design control with other processes such as risk analysis and corrective and preventive action (CAPA).

**TOPICS**
- FDA, ISO, and design control
- Principles of the process model
- Product life cycle and design control
- Design control, risk management, and CAPA

**WHO SHOULD ATTEND**
Anyone managing, developing, or engaging in the design of medical devices, including direct engineering functions, QA/QC, production management, and regulatory, as well as anyone else who has a role in building a robust regulatory-compliant environment.

- **Course Code:** DBF
- **CEUs:** 2.5
- **Days:** 3
- **Registration:** $2495

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**ISO 14971: Introduction to Risk Management Across the Medical Device Product Life Cycle**

Effective risk management spans the product life cycle, from concept of design to postmarket surveillance and eventual obsolescence. Employing risk management from the start saves time and money, and reduces exposure after commercialization.

Our risk management course covers ISO 14971:2012 (and key distinctions from the 2007 version) and the application of risk management practices throughout a product’s full life cycle. The updated content also examines ISO 13485:2016’s increased focus on risk management, as well as how US, Canadian, and global regulators view risk management and what they expect to find at your organization.

Using interactive hands-on workshops and group discussions, course participants develop the knowledge and skills necessary to understand the risk management process and each of the risk management steps.

**TOPICS**
- Fundamental risk management concepts and definitions
- Global regulatory compliance requirements for risk management, including US, EU, and Canada
- How the FDA and other global regulators interpret risk management
- The evolution of ISO 14971:2012, its purpose, and the differences between the 2007 and 2012 versions, including a comprehensive review of the key clauses and annexes
- Integrating risk management into your product development life cycle and quality management system
- Elements of an effective risk management plan
- Requirements for each step of the risk management process, including risk management plan, risk analysis, risk evaluation, risk control, risk management file, and post-production analyses
- The impact of postmarket activities on risk, including postmarket design, CAPA activities, and governmental postmarket surveillance
- The major tools and methods of risk analysis and hazard analysis: estimating, evaluating, controlling, and reducing risks

**WHO SHOULD ATTEND**
This is an introductory course. It is recommended for design managers and engineers; manufacturing, service, quality assurance, reliability, research and development, and regulatory affairs professionals; and other cross-functional team members in a medical device environment.

- **Course Code:** RMF
- **CEUs:** 2.5
- **Days:** 3
- **Registration:** $2495

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OCTOBER 18–20 Boston, MA
OCTOBER 25–27 Chicago, IL
OCTOBER 25–27 Edison, NJ
OCTOBER 18–20 Boston, MA
OCTOBER 25–27 Chicago, IL
OCTOBER 25–27 Edison, NJ
DECEMBER 13–15 San Diego, CA

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San Diego, CA
OCTOBER 18–20 Boston, MA
OCTOBER 25–27 Chicago, IL
OCTOBER 25–27 Edison, NJ
DECEMBER 13–15 San Diego, CA
Process Validation Principles and Protocols

**More than IQ, OQ, and PQ!** A solid validation system includes master validation planning, effective protocol writing, and change communication.

FDA's 21 CFR 820 and ISO 13485 require process validation, but they don't offer much guidance. During this class, participants gain the knowledge and skills needed to comply with the process validation requirements of FDA's Quality System Regulation and ISO 13485, as well as information on how to implement an effective validation program.

You'll take a simple process through the entire validation cycle – writing protocols, determining key operating parameters, and identifying data analysis strategies. You will learn how to interpret the regulations, standards, and guidance documents; correctly apply the principles of risk management; create qualification protocols (IQ, OQ, PQ); and identify statistical methods and tools when implementing and maintaining process validation activities. Through interactive discussion and workshops, you'll evaluate real-world process validation examples and warning letters, and learn best practices for the practical application of process validation in medical device manufacturing.

**COURSE OBJECTIVES**
- Understand the purpose, benefits, and objectives of process validation as it relates to product realization.
- Learn the risks, consequences, and impacts of validation activities on customers, suppliers, and other interested parties.
- Apply skills to interpret and comply with FDA, ISO, and other international requirements.

**TOPICS**
- Overview of process validation: purpose and scope
- Process validation requirements: regulations, standards, and guidance
- Key aspects of the "process" of process validation
- Process validation within a functioning quality management system
- Planning validation scope and implementation
- Creation and review of qualification protocols (IQ, OQ, PQ)
- Identification of statistical methods and tools
- Risk evaluation
- FDA inspection observations and analysis

**WHO SHOULD ATTEND**
Recommended for quality, regulatory, engineering, manufacturing, and other professional workers who plan, execute, report, maintain, review, or manage process validation activities, and who have basic knowledge of statistics or statistical tools. This course is tailored to medical device companies who will also provide value to students from pharmaceutical companies.

Take your process validation skills to the next level with statistical tools training. See page 14.

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**NEW! Software Verification and Validation Requirements**

With the increasing use of software in medical devices and the expanded requirement in ISO 13485:2016, software validation is more important than ever.

Many innovative medical devices rely on software, but inadequate verification and validation of this software can lead to FDA findings, or worse yet – unexpected device failures and patient harm. As software continues to be integrated into more devices, device manufacturing, and quality management system processes, now is the time to master this crucial area.

During this course, you'll learn the US FDA and international regulatory requirements related to the validation of medical device software and how to use the Software Development Life Cycle (SDLC) to perform more effective software design validation.

The course also includes a module on qualifying quality management system software (a new ISO 13485:2016 requirement) that is used to help automate any regulated process in the design (including software development), manufacture, distribution, or support of a medical device, biological, pharmaceutical, or combination product.

**COURSE OBJECTIVES**
- Identify the typical phases, processes, and deliverables of a software development life cycle (SDLC).
- Explain how these phases, processes, and deliverables map to US and international regulatory requirements.
- Identify the benefits of a compliant SDLC, including faster time to market.

**TOPICS**
- Software development life cycle (SDLC), including examples of commonly used SDLCs
- Verification and validation, including regulatory definitions, regulatory intent, and common tasks
- Regulatory framework and the relationship of various sources of regulatory requirements
- Key regulations, standards, and guidance documents
- Integrating risk management processes
- Design control and software validation guidance
- Testing-level strategies (unit, integration, system, user)
- Describe how organizational responsibilities and interactions can affect the SDLC and an organization's ability to meet regulatory requirements.
- Evaluate how well your current SDLC meets regulatory requirements based on lessons learned.

**WHO SHOULD ATTEND**
Recommended for computer system/software users, mid-level managers, software developers/engineers/testers, product managers, regulatory personnel, and quality assurance professionals in FDA-regulated fields.

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For additional dates and locations or to register — 800.472.6477 — www.orielstat.com
Optimizing CAPA Programs for the Medical Device Industry

CAPA deficiencies are the number one reason why companies receive FDA 483 citations.

Hundreds of Form FDA 483 observations – and subsequent warning letters citing corrective and preventive action (CAPA) deficiencies – have been issued to medical device manufacturers. FDA’s QSR and ISO 13485 require that a CAPA system be in place. CAPA is also a key target of FDA and international regulatory scrutiny, consistently ranking at the top of the list of 483 observations and quality system citations in warning letters.

CAPA goes beyond remediation. It supports continuous product and business improvements. Our CAPA course will provide you with a solid understanding of the CAPA requirements, and will explain how an optimized CAPA program is essential for satisfying current and future regulatory requirements and driving performance excellence.

COURSE OBJECTIVES

- Understand the essential elements of an effective CAPA program and sources of data that must be considered.
- Learn how to improve your CAPA program to further enhance your quality system.
- Understand FDA and other regulatory officials’ expectations of “what CAPA is” and the steps required to get you there.
- Develop a risk-based approach to the CAPA process to determine the depth of investigation required, CAPA cycle time, and any immediate corrections your organization needs to make.

TOPICS

- What CAPA is and when it is required (from both FDA and ISO 13485:2016 perspectives)
- Optimizing the CAPA program: pitfalls and best practices
- Risk-based decision making for corrections and removals
- Elements of an effective CAPA system: roles, inputs, and metrics
- CAPA methodology: from problem definition to effectiveness checks
- Communication: writing for CAPA and management review

WHO SHOULD ATTEND

Recommended for top management, management representatives, and staff in:
- Compliance/regulatory affairs
- QA/QC
- Manufacturing operations
- CAPA management

Take your CAPA skills to the next level with statistical tools training. See page 14.

$1895 • Course Code: CAF • 1.5 CEUs • 2 Days

SEPTEMBER 19–20
Edison, NJ

OCT 31–NOV 1
Chicago, IL

DECEMBER 5–6
San Diego, CA

JANUARY 9–10
Boston, MA

Root Cause Analysis for Life Science Investigations

Bring this training on-site. We can tailor the content to focus on the tools you use most – and include your company’s unique examples!

Root cause analysis (RCA) is the essential investigation method used by life science professionals to understand and mitigate product failures and other issues that may occur throughout a product’s life cycle.

We will help you master the entire root cause analysis process, from accurately identifying the root cause of a problem to designing an effective long-term solution. This practical course goes beyond theory to teach you specific steps and tools so you can immediately apply what you learn.

COURSE OBJECTIVES

- Create an effective problem statement.
- Understand the available RCA tools:
  - DOE – Tree diagrams
  - FMEA – Hypothesis testing
  - DMAIC – Verifying effectiveness
  - 5 Whys – Monitoring and sustaining gains
- Choose the right RCA tools for an identified problem.
- Test a cause-and-effect hypothesis to ensure that you address the failure or deviation.
- Integrate RCA findings into your quality system (e.g., in product development or CAPA).
- Minimize unintended consequences.

TOPICS

- Explication of root cause analysis
- Application and implementation of RCA tools
- Sources of quality data
- Methods of data analysis
- Effective implementation
- Medical device reporting and tracking
- Implementation of corrective and preventive actions resulting from the RCA investigations

WHO SHOULD ATTEND

Recommended for staff or top management in:
- Quality engineering
- Product development
- QA/QC
- Manufacturing operations
- CAPA management
- Research and development

Take your root cause analysis skills to the next level with statistical tools training. See page 14.

$2495 • Course Code: RCF • 2.5 CEUs • 3 Days

JULY 20–22
San Diego, CA

SEPTEMBER 14–16
Edison, NJ

OCTOBER 26–28
Chicago, IL

DECEMBER 7–9
San Diego, CA

JANUARY 11–13
Boston, MA
A poorly implemented complaint-handling process poses both regulatory compliance and business risks to an organization.

This course will help your organization establish a comprehensive process for initial intake and triage of customer complaints and any subsequent global regulatory reporting, whether for an individual case (MDR, vigilance report) or a correction/removal to ensure product quality and/or safety. The course explains the importance of complaint handling to your other quality systems, such as design control, risk management, and CAPA. It also presents a global framework for meeting international complaint-handling and event-reporting requirements.

**Course Objectives**
- Understand the medical device regulations for complaint handling and event reporting.
- Complete complaint intake documentation and triage.
- Understand requirements for reporting events to regulatory agencies.
- Conduct risk management activities associated with complaints and determination of corrections, investigation, and reporting.
- Understand how to conduct complaint investigations.
- Understand how to determine, document, and report corrections/removals to regulatory authorities.
- Develop metrics for trending/tracking, management reviews, and quality reviews.

**Topics**
- Medical device regulations for complaint handling and event reporting (21CFR820.198, 21CFR803, 21CFR806, MEDDev 2.12, and other global requirements)
- ISO 13485:2016 postmarket surveillance requirements
- The complaint-handling process: triage to closure
- Preparation and filing of medical device reports (MDRs) and vigilance reports to global agencies
- Integration of complaint investigation into CAPA and other quality systems
- Determination and documentation of corrections/removals
- Metric generation and communication for quality/compliance and management reviews
- Requirements for complaint documentation

**Who Should Attend**
Designed for those who need to understand and apply the regulatory requirements for complaint handling and event reporting, including customer-facing organizations involved with complaint intake (call centers, medical information), medical/safety personnel responsible for triage decisions concerning reportable events, personnel responsible for reporting medical events, compliance personnel responsible for field actions, quality engineers participating in complaint investigations, management representatives, sustaining engineering personnel, RA/QA managers/engineers, internal auditors, and other cross-functional team members.

**SUPPLIER QUALITY MANAGEMENT: DESIGNING A SUCCESSFUL PROGRAM**

**Supplier Quality Management: Designing a Successful Program**

**Updated to reflect ISO 13485:2016's changes in feedback and reporting.**

**FDA and EU inspections are turning up countless supplier control violations.** Poorly designed and executed supplier audits can cost your company millions—and put you at risk of 483s and warning letters. With dozens, hundreds, or even thousands of suppliers to manage, you need a proven risk-based process that meets FDA and ISO 13485:2016 enhanced requirements, as well as ensures high-quality products and protects patient safety.

This course will provide your organization with the knowledge and tools to design a comprehensive cross-functional supplier quality program. It will also help your company proactively address the development and strengthening of processes and procedures for all aspects of supplier quality management. Requirements for establishing an effective and efficient system will be detailed, from creating product development specifications through maintaining an approved supplier listing.

**Course Objectives**
- Understand the regulatory background for supplier quality.
- Develop business solutions for building a supplier quality program.
- Translate product development and manufacturing needs into supplier specifications.
- Establish a process for assessing and qualifying suppliers.
- Develop and maintain an approved supplier listing.
- Apply auditing skills when working with suppliers.
- Understand the life cycle of vendor management.
- Communicate supplier quality program status to the management team.

**Topics**
- Regulatory requirements for medical device and pharmaceutical supplier quality programs
- Business needs for and impact of a comprehensive supplier quality program
- How to assess potential vendors to meet organizational requirements
- Generation and maintenance of approved supplier lists
- Risk-based approach for vendor qualification and management
- Conducting vendor audits
- Identification and resolution of vendor issues

**Who Should Attend**
Designed for personnel involved in sourcing, securing, and maintaining suppliers and services who ensure excellent product quality and organizational reputation, including supplier quality and procurement/supply chain managers; product development engineering managers; management representatives; product, project, and program managers; RA/QA managers/engineers; auditors; and other cross-functional team members.

**$2495 • Course Code: SQF • 2.5 CEUs • 3 Days**

| $2495 • Course Code: SQF • 2.5 CEUs • 3 Days |
|---|---|---|---|
| **SEPTEMBER 7–9** | Chicago, IL |
| **OCTOBER 4–6** | Boston, MA |
| **NOVEMBER 8–10** | San Diego, CA |
| **DECEMBER 13–15** | Edison, NJ |
| **JULY 19–21** | Chicago, IL |
| **AUGUST 9–11** | Boston, MA |
| **SEPTEMBER 13–15** | San Diego, CA |
| **OCTOBER 10–12** | Edison, NJ |
| **NOVEMBER 15–17** | Chicago, IL |

For additional dates and locations or to register — 800.472.6477 — www.orielstat.com
Global Product Submissions: FDA and EU Directive Requirements [510(k), PMA, CE Mark]

No matter where you plan to market your device, you need a unified global regulatory strategy to ensure that your product is approved in your target markets. While country/region requirements for submission and approvals differ, the core documentation requirements are essentially similar. This course focuses on the required quality system elements, followed by extensive review of the FDA premarket submission processes [510(k) and PMA] and the EU Medical Device Directives submission process, as well as a guide to classification and submission requirements for other countries.

**COURSE OBJECTIVES**
- Develop regulatory strategies to meet global submission requirements, with emphasis on FDA and EU processes.
- Understand the:  
  - Global markets for medical devices.
  - FDA 510(k) classification and documentation requirements for product clearance.
  - FDA PMA process and the documentation requirements stemming from the design development and technical transfer processes.
  - European Medical Device Directives to ensure that products meet designated minimum safety standards and quality levels, as well as MDD classification and submission strategies.

**TOPICS**
- 510(k) and PMA processes (US FDA)
- Current EU Directives (MDD, AIMD, IVDD)
- Current medical device regulatory landscape
- IDEs as part of design validation
- Quality system certification
- Product certification
- Technical files and design dossiers
- An overview of requirements from Australia, Canada, China, Russia, Japan, Brazil, South Korea, and Mexico

**WHO SHOULD ATTEND**
This course is designed for medical device manufacturing quality and regulatory affairs professionals seeking a single global regulatory strategy, including:
- Employees responsible for product submissions
- Design development teams
- Staff responsible for product life-cycle management
- Global marketing personnel
- Management representatives
- Staff involved in change control

**Get your devices approved faster!**
Our team can help you successfully navigate the 510(k) Submission and CE Marking process so that your devices are approved more quickly, more efficiently, and with greater chances of success. Call 732.548.0600 or email info@orielstat.com to learn more.

**Calibration Requirements and Equipment Controls for Medical Devices**

The need for medical device manufacturers to calibrate equipment is a fundamental requirement of both FDA and ISO 13485. From initial design and development to the shipment of medical devices that can be characterized as safe and effective, accuracy of testing and inspection results depends on the use of measuring and monitoring equipment that is properly calibrated. In addition, materials used in the manufacture of medical devices must be tested to ensure that they are appropriate for the specific product. Design and process validation activities, the assessment of material biocompatibility, packaging studies, sterilization validation, and electrical performance testing must be all performed to a high degree of reliability.

This practical course will help you understand and interpret applicable calibration requirements and equipment controls for medical device manufacturers, and to understand what compliance means for your organization.

**COURSE OBJECTIVES**
- Understand the applicable calibration standards for medical devices, including FDA’s Quality System Regulation (QSR), ISO 13485, ISO 9001, and ISO 17025.
- Identify and interpret the relationship and differences between the applicable calibration standards and guidance.
- Interpret and apply the technical requirements to your organization.
- Understand the importance of an effective calibration program and industry best practices for medical device manufacturers.

**TOPICS**
- Overview of FDA’s QSR, ISO 13485, ISO 17025, and ISO 9001
- Importance of an effective calibration program
- Warning letter/483 issues related to calibration program deficiencies
- Terminology
- Calibration requirements
- Inspection, measuring, and test equipment controls
- Protection and maintenance of measuring equipment and instruments
- Equipment controls
- Integration of measurements into the quality system
- Audit of the calibration program and assessment of audit readiness

**WHO SHOULD ATTEND**
Recommended for team members who need an in-depth understanding of calibration requirements and equipment controls for medical devices, including quality assurance, quality control, quality engineering, QMS auditors, manufacturing engineering, production engineering, research and development engineering, calibration, and technical support professionals.

**Bring this training on-site. We can tailor the content to focus on your equipment and processes!**

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Internal Auditor Training for ISO 13485

Learn the process to audit an internal quality system that efficiently and effectively meets the requirements of ISO 13485 and ISO 9001. Understand how to prepare, conduct, and follow up on internal audits for ISO 9001 and ISO 13485. Based on our ISO 9001 Exemplar Global certified internal auditor course, this course includes workshops tailored to the changing medical device industry and discussions of ISO 9001 and ISO 13485.

COURSE OBJECTIVES
• Internal Quality Systems Assessment — Understand the quality system; interpret ISO 9001 and ISO 13485; discuss what third-party assessment agencies look for.
• The Three Audit Phases — Closely examine planning, execution, and follow-up using concepts in ISO 19011.
• Planning and Auditing — Prepare for an audit and manage resources effectively.
• Conducting the Audit — Learn how to collect audit evidence and document observations, including techniques for effective questioning and listening.
• Follow-Up Activities — Learn how to verify effectiveness and adequacy of corrective action, close out an audit, and conduct follow-up surveillances.

TOPICS
• Analysis and interpretation of ISO 13485
• The quality system
• The quality audit cycle
• Preaudit activities
• On-site audit activities
• Report writing – nonconformity reports
• Corrective action
• Final examination (1 hour)

WHO SHOULD ATTEND
This is a perfect fit if you will be conducting, managing, or participating in internal (first-party) audits or helping to develop an ISO 13485 quality system. Also great if you are involved in developing, implementing, and/or maintaining an internal audit system that meets the requirements of ISO 13485.

NOTES:
• This training course is certified by Exemplar Global and satisfies the training requirement for individuals seeking certification under the Exemplar Global QMS Internal Auditor Registration Scheme.
• Exemplar Global requires that all attendees study the current published version of ISO 13485 before attending this class.

Developing and Maintaining a Compliant Document Management System

In a regulated environment, an effective document management system is vital. To stay compliant, your organization must control all quality documentation, such as SOPs, policies, quality manuals, CAD files, and engineering change orders. However, many organizations find it difficult to manage these documents and prevent document changes from impacting other processes.

COURSE OBJECTIVES
• Understand the basic structure of a document management system.
• Interpret the relevant FDA and ISO 13485 regulations and standards.
• Recognize how document changes impact design control and risk management processes.
• Understand the potential regulatory impact of a document change and when to communicate with regulatory agencies.
• Identify the necessary documents for your quality management system.
• Plan a documentation management system.
• Use basic processes to understand flowcharting and process maps.
• Analyze procedural requirements.
• Prepare procedures using recommended formats.
• Plan and write effective job instructions.
• Develop a robust change control system linked to your design and risk control activities.

TOPICS
• Documentation requirements
• Flowcharting processes and process mapping
• Standard operating procedures (SOPs)/system-level procedures (SLPs): formats, requirements, and evaluation
• Work instructions: planning, task analysis, and readability
• Change control requirements

WHO SHOULD ATTEND
Recommended for staff members involved in preparing plans, procedures, and instructions as part of a document management system.

$1695 • Course Code: IAF • 2.5 CEUs • 3 Days
SEPTEMBER 12–14 Edison, NJ
OCTOBER 24–26 Chicago, IL
NOVEMBER 14–16 Boston, MA
DECEMBER 7–9 San Diego, CA

$1895 • Course Code: DOF • 1.5 CEUs • 2 Days
JULY 28–29 San Diego, CA
SEPTEMBER 15–16 Edison, NJ
OCTOBER 27–28 Chicago, IL
NOVEMBER 17–18 Boston, MA
Certification from Oriel STAT A MATRIX provides RA/QA professionals with the skills and knowledge they need to stay ahead of industry trends and master critical regulatory and compliance requirements. Certification also demonstrates employee competencies to regulators and notified bodies.

FDA’s QSR and ISO 13485 both emphasize the need for RA/QA employees to demonstrate they have the skills to perform their jobs.

**How It Works**

1. **TRAIN:** First, we work with you to identify the required competencies and training objectives. Then, we recommend the most appropriate Certification Program(s) for your needs. Programs consist of a series of training classes, all of which feature hands-on exercises and workshops that make them engaging and support acquisition of the required skills. Employees may sign up for public sessions or we can deliver the training at your company.

2. **EVALUATE:** Your employees will demonstrate their mastery of the topics taught with course examinations. The Leader Certification Programs go a step deeper by requiring the candidate to complete a discipline-related project. Oriel STAT A MATRIX reviews the project report and conducts an interview to verify the candidate’s understanding of the tools taught in the Certification Program.

3. **CERTIFY THE COMPETENCIES:** Upon successful completion of the program requirements, the employee is awarded a Certification from the STAT A MATRIX Institute, an industry leader in professional certification since 1974.

**Practitioner Certification Programs**
- Design Control
- Management Control
- Production and Process Controls
- Supplier Management
- Quality System

**Leader Certification Programs**
- Corrective and Preventive Action
- Applied Statistics and Process Performance
- Performance-Based Auditing

**NEW! EIGHT PROFESSIONAL CERTIFICATION PROGRAMS FOR MEDICAL DEVICE RA/QA**

**NEW!**

**FDA Wants to Know You’ve Trained Your People**

*Demonstrate their competencies with Professional Certification*

Visit [http://www.orielstat.com/professional-certification](http://www.orielstat.com/professional-certification) or contact us at info@orielstat.com or 800.472.6477.
# Training Course Requirements by Program

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<td>Applied Statistics for the Workplace – Advanced</td>
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1 Select Lead or Internal Auditor

* You may pass an online exam to opt out of this class

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Have you already taken one or more of our training courses? You may be able to apply that training to a Certification Program! Contact us and we’ll let you know.
NEW!

Applied Statistics for the Workplace

Learn how to use statistics to make better business decisions AND maintain compliance.

Facts and data are necessary inputs for sound decision making. For FDA-regulated companies, mastery of collection and use of data is critical for staying compliant.

In the past, organizations had to rely on statistical experts to collect and interpret data about processes, performance, and results. But now the experts’ statistical techniques are available to everyone in the organization. Even novices can transform raw data into actionable information with statistical software.

DISCOVER HOW THESE POWERFUL TOOLS CAN TRANSFORM YOUR BUSINESS

We are offering three new applied statistics classes that will show employees from all functions and levels of experience how to collect and use statistics to enhance problem solving, process management, process design, and process improvement:

- Applied Statistics for the Workplace – Level 1
- Applied Statistics for the Workplace – Intermediate
- Applied Statistics for the Workplace – Advanced

Take these classes and apply them to our new Corrective and Preventive Action (CAPA) and Applied Statistics and Process Performance Leader Certification Programs. See pages 12–13 for more details or call 800.472.6477 to learn more.

COURSE OBJECTIVES

- Understand processes, learn how they behave, and recognize the variables that impact process performance.
- Understand the fundamentals of statistics, including measures of central tendency and variation, the normal distribution, the central limit theorem, and confidence intervals.
- Understand and apply the fundamentals of data collection and data analysis to assess process variation.
- Learn how to create plots of variation such as time plots, control charts, and frequency plots.
- Understand and apply concepts related to measuring process performance (process yield, defects per unit, and sigma quality level).
- Employ the concepts and tools learned with follow-along exercises using Minitab statistical software.

TOPICS

- Understanding, mapping, and measuring processes
- Basic descriptive statistics
- The normal distribution
- Central limit theorem
- Confidence intervals
- Data types and data collection
- Data analysis
- Measuring process performance

WHO SHOULD ATTEND

Professionals engaged in designing, improving, monitoring, and measuring processes in manufacturing, service, and transactional business environments. This course is a requirement for individuals who intend to achieve Corrective and Preventive Action and/or Applied Statistics and Process Performance Leader Certification within the Oriel STAT A MATRIX Certification Program (see pages 12–13 for details). This course is also of interest to those wishing to gain credits toward Six Sigma Green and Black Belt Certification.

NOTES:

- This training includes Minitab. Attendees are responsible for bringing laptops with Minitab software, as well as a scientific/statistical calculator.

LEVEL 1

Applied Statistics for the Workplace

Acquire the skills to apply foundational statistical procedures that are relevant to monitoring and measuring process performance. Beginning with a look at processes and how they behave, this course illuminates process analysis by introducing statistical tools that transform data into information that will help you make better business decisions.

The normal distribution
- Central limit theorem
- Confidence intervals
- Data types and data collection
- Data analysis
- Measuring process performance

APPLIED STATISTICS FOR THE WORKPLACE
Applied Statistics for the Workplace

Acquire the skills to apply intermediate-level statistical procedures that are relevant to assessing process stability, determining process capability, and verifying cause-and-effect relationships between variables that impact process performance. This course takes the concepts presented in the Applied Statistics for the Workplace – Level 1 course to the next level.

Participants in this class are expected to be familiar with basic descriptive statistics (i.e., measures of central tendency and measures of variation).

COURSE OBJECTIVES
- Understand and apply statistical procedures to deal with nonnormal data.
- Conduct process capability analysis for discrete and continuous data distributions.
- Understand and apply statistical process control (SPC) to monitor process performance.
- Understand the fundamentals of hypothesis testing and how they impact the interpretation of other statistical tools.
- Understand and apply regression analysis to verify cause-and-effect relationships.
- Recognize the importance of conducting measurement system analysis and applying relevant statistical tools (i.e., gage R&R and attribute agreement analysis).
- Employ the concepts and tools learned with follow-along exercises using Minitab statistical software.

TOPICS
- Transformation of nonnormal data
- Capability analysis (discrete and continuous data)
- Statistical process control (SPC)
- Hypothesis testing
- Regression analysis
- Gage R&R
- Attribute agreement analysis

WHO SHOULD ATTEND
Professionals engaged in designing, improving, monitoring, and measuring processes in manufacturing, service, and transactional business environments. This course is a requirement for individuals who intend to achieve Corrective and Preventive Action and/or Applied Statistics and Process Performance Leader Certification within the Oriel STAT A MATRIX Certification Program (see pages 12–13 for details). This course is also of interest to those wishing to gain credits toward Six Sigma Green and Black Belt Certification.

NOTES:
- This training includes Minitab statistical software. Attendees are responsible for bringing laptops with Minitab software, as well as a scientific/statistical calculator.
Lead Auditor Training for ISO 9001

**Exemplar Global**
**CERTIFIED QMS LEAD AUDITOR TRAINING COURSE**

**COURSE OBJECTIVES**
Over five intensive days, learn the background of the ISO 9000 standards and go through every phase of the audit process so you are ready to lead your own audits.

- **QA System Assessment** – Understand the elements of a total quality system.
- **The Requirements** – Understand the relationships among the ISO standards and the requirements of ISO 9001.
- **The Audit Cycle** – Use ISO 19011 to understand audit functions.
- **Preaudit Activities** – Conduct the documentation audit and plan audit activities.
- **The Audit (Assessment)** – Collect and evaluate audit evidence, including by listening and questioning; learn how to handle confrontation; determine audit findings.
- **Postaudit and Follow-Up Activities** – Understand how to write audit reports, assess corrective action, close out nonconformities, and conduct surveillance audits.
- **Auditing practices; the psychology of auditing**
- **Performing the audit; closing meeting**
- **Nonconformity reporting; report writing**
- **Follow-up and corrective action**

**TOPICS**
- Overview of auditing: process auditing
- Auditor registration
- Interpretation of ISO 9001
- Quality system documentation
- The audit cycle and ISO 19011
- Preaudit activities – opening meeting and checklists
- Auditing practices; the psychology of auditing
- Performing the audit; closing meeting
- Nonconformity reporting; report writing
- Follow-up and corrective action

**WHO SHOULD ATTEND**
Designed for first-, second-, and third-party auditors and professionals leading corporate ISO 9001 compliance activities. Perfect if you are involved with your organization’s internal audits and wish to broaden your understanding of the total audit process.

**COURSE REQUIREMENTS**
Evening study recommended. A 2-hour final exam is required.

**NOTES:**
- This training course is an Exemplar Global certified course. To attain registration as a QMS Auditor/Senior Auditor/Lead Auditor, you must pass the written final examination, earn a passing grade in the course assessments, and meet prescribed professional requirements. For full details of Exemplar Global certification, please see page 19.
- Exemplar Global requires that all attendees study the current published version of ISO 9001 before attending this class.

**$1895 • Course Code: LAI • 4.4 CEUs • 5 Days**

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Internal Auditor Training for ISO 9001

**Exemplar Global**
**CERTIFIED QMS INTERNAL AUDITOR TRAINING COURSE**

**COURSE OBJECTIVES**
Learn the steps to develop, implement, and evaluate an internal audit system that meets the requirements of ISO 9001 and the needs of your organization. Get the training you need from the industry’s leader – Oriel STAT A MATRIX has been training auditors longer than any other training organization in the world. Our Exemplar Global certified internal auditor course includes interactive workshops and discussions so you can return to work and apply what you’ve just learned.

**COURSE REQUIREMENTS**
Understand how to prepare, conduct, and follow up on internal audits for ISO 9001.

- **Internal Quality Systems Assessment** – Discuss the elements of a quality system, interpretation of ISO 9001, and what third-party assessment agencies look for.
- **The Three Audit Phases** – Planning, execution, and follow-up are examined closely using concepts detailed in ISO 19011.
- **Planning and Auditing** – Learn how to prepare for an audit and manage your resources effectively.
- **Conducting the Audit** – Learn how to collect audit evidence and document observations, including techniques for effective questioning and listening.
- **Follow-Up Activities** – Learn how to verify effectiveness and adequacy of corrective action, close out an audit, and conduct follow-up surveillances.

**TOPICS**
- Analysis and interpretation of ISO 9001
- The quality system
- The quality audit cycle
- Preaudit activities
- On-site audit activities
- Report writing – nonconformity reports
- Corrective action

**WHO SHOULD ATTEND**
This is a perfect fit if you will be conducting, managing, or participating in internal (first-party) audits or helping to develop an ISO 9001-compliant quality system.

**COURSE REQUIREMENT**
1-hour final exam.

**NOTES:**
- This training course is certified by Exemplar Global and satisfies the training requirement for individuals seeking certification under the Exemplar Global QMS Internal Auditor Registration Scheme.
- Exemplar Global requires that all attendees study the current published version of ISO 9001 before attending this class.

**$1195 • Course Code: IAI • 2.5 CEUs • 3 Days**

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“Excellent course for any quality professional. The case studies and discussions were particularly helpful – being able to apply the material as I was learning it really helped me to understand the class.”

– Director of Quality Assurance

“Outstanding instructor. This was the best class I’ve taken in years. The instructor’s mix of analogies, humor, and overall knowledge was superb and created an optimal learning environment.”

– Supply Chain Manager
This class was very informative. It gave me great insight into what we need to do to transition to the revised standard, and how we can use the process to drive overall improvements. Excellent class!

– Director of QA

In this course, we present the major changes introduced in the new standard, and address how organizations should consider these changes as opportunities to make their quality management system a strategic element of good performance and sustainability over time. We also explain the transition period for currently certified organizations.

**COURSE OBJECTIVES**
- Learn about the evolution of the ISO 9000 series over the years.
- Assess the overall impact the new standard will have on your current quality management system.
- Understand the new clause structure of Annex SL, the ways it impacts how standards are written, and the fundamental changes being introduced in the new ISO 9001.
- Recognize the opportunity to make quality management a strategic function within your organization and learn how it can have a positive impact on your organization's business results.
- Learn about the agreed-on period to transition to the new standard in order to maintain/expand current certification or achieve certification.
- Recognize the implications of the new requirements on management and auditors.
- Establish an action plan to achieve and maintain certification to ISO 9001:2015.

**TOPICS**
- The new ISO 9001 standard – a clause-by-clause review
- Evaluating the QMS performance
- Improving the QMS performance
- Linking process metrics to key performance indicators (KPIs)
- The transition period and a recommended action plan

**WHO SHOULD ATTEND**
Senior managers, operational managers, management representatives, quality managers, auditors, and other professionals engaged in the implementation and auditing of their organization’s quality management system.

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The concept of risk has always been implicit in ISO 9001 – the 2015 revision makes it more explicit and builds it into the whole management system.

In today’s business environment, managing risks effectively has become an essential element of sustainability over time. More than ever, risks can have devastating consequences to the organization in terms of financial performance, image in the marketplace, and ability to retain customers or develop new market segments. Risk-based thinking is not just the responsibility of management – it must become an integral part of the organizational culture.

ISO 9001:2015 uses ISO 31000:2009 (“Risk management – Principles and guidelines”) as a reference for risk management. During this course, you’ll learn the appropriate application of the principles presented in ISO 31000 and how they help organizations achieve strategic objectives by recognizing risks, assessing their impact on performance, and initiating appropriate mitigating actions.

**COURSE OBJECTIVES**
- Understand the purpose, benefits, and objectives of a risk-based approach to quality management.
- Learn how ISO 31000 and ISO 31010 can support the development of a risk management program within the context of ISO 9001:2015 implementation.
- Recognize the process for identifying, analyzing, evaluating, and treating risks in a way that is commensurate with the context of the organization.
- Recognize and apply risk assessment techniques.
- Determine approaches to treat/mitigate identified risks.
- Estimate and evaluate risks.
- Realize what is involved in risk reduction and control.

**TOPICS**
- The framework for managing risk
- The structure of ISO 31000:2009 and clause review
- The risk management process
- ISO 31010:2009 and risk assessment techniques
- Documenting risk management
- Attributes of risk management

**WHO SHOULD ATTEND**
Recommended for design managers and engineers; manufacturing, service, quality assurance, reliability, research and development, and regulatory affairs professionals; and other cross-functional team members.
Advanced Lead Auditor Training

“This training has opened my eyes to a whole new level of auditing.”

— Quality Engineer

Acquire the skills to make your audit program the catalyst for tangible improvements to your organization’s bottom line. Designed to offer experienced auditors a performance-based approach to auditing, participants gain the skills needed to:

• Shift energies from conducting clause-based audits to determining and documenting effectiveness and efficiency of processes beyond mere conformity with management system (MS) standards.
• Provide valuable information to top management and stakeholders concerning process performance.
• Achieve audit results that identify breakthrough improvements and lead to higher levels of MS capability than those attained with the traditional, segmented approach.

**COURSE OBJECTIVES**

- Understand effectiveness-focused auditing methodologies and evidence gathering.
- Recognize the benefits of applying process design and process improvement methodologies that lead to continual improvement and business sustainability over the long term.
- Explain methods for measuring the effectiveness and efficiency of the MS auditing program and its value.
- Breakthrough audit planning, including:
  - Process-focused, risk-based audit scheduling
  - Process and results data and documentation needed to plan audits and determine audit trails
  - Interpreting process maps and identifying opportunities for improvement

**TOPICS**

- Process performance variables and how to measure them
- Statistical tools that are relevant to successful process auditing (e.g., process capability and statistical process control)
- Breakthrough on-site audit activities, including:
  - Handling adverse audit conditions
  - Measuring audit program effectiveness
- Basic descriptive statistics
- The normal distribution, including assessing normality and transforming to normality
- Data collection, sampling, and sampling approaches
- Process capability analysis (discrete and continuous data)
- Statistical process control (SPC)
- Measurement system analysis (gage R&R and attribute agreement analysis)
- Linear regression applied to verify cause-and-effect relationships
- Introduction to regression analysis

**SPECIAL FEATURE: TEACH-BACK SESSION**

At the end of Day 4, we assign groups a topic to prepare for a teach-back session. This approach allows students to apply what they have learned and resolve any remaining questions prior to taking the 2-hour exam.

**WHO SHOULD ATTEND**

Aimed at experienced MS auditors who have successfully completed an auditing course and performed actual audits, as well as audit program managers and QMS management representatives.

**Statistics for Lead Auditors**

**What makes a great auditor?** Most audits verify that people are following processes. An effective audit goes further by also verifying that the processes themselves are effective.

**How can you raise the level of your audits?** By using statistical knowledge to analyze process data and draw meaningful conclusions.

Whether you are a lead auditor, an internal auditor, a supplier auditor, or a certification body auditor, this hands-on course will help you understand statistical tools and how to apply them in an audit setting. You will develop the skills you need to analyze process data thoroughly and determine how effective the processes are in meeting established targets.

Your new knowledge will help you link process metrics (e.g., process capability index) to key performance indicators (e.g., customer satisfaction). Furthermore, you will be able to assist top management in determining how process effectiveness impacts the bottom line, thus increasing your value to your organization.

**COURSE OBJECTIVES**

- Understand the statistical tools relevant to auditing and the fundamental concepts behind them.
- Practice with follow-along exercises, using Minitab statistical software to apply statistical tools. Course exercises show what impact the tools have on the full range of audit activities.
- Enhance your ability to prepare for an audit, conduct an audit, and verify the effectiveness of corrective actions initiated by process owners.

**TOPICS**

- Basic descriptive statistics
- The normal distribution, including assessing normality and transforming to normality
- Data collection, sampling, and sampling approaches
- Process capability analysis (discrete and continuous data)
- Statistical process control (SPC)
- Measurement system analysis (gage R&R and attribute agreement analysis)
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**WHO SHOULD ATTEND**

This course is aimed at lead auditors, experienced internal auditors, supplier auditors, certification body auditors, audit program managers, quality managers, quality engineers, and management representatives. It will be of particular interest to those who have successfully completed the Oriel STAT A MATRIX Advanced Lead Auditor training.

**NOTE:** This training includes Minitab. Attendees are responsible for bringing laptops with Minitab software, as well as a scientific/statistical calculator.

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www.orielstat.com — 800.472.6477 — All of our courses can be delivered on-site
Registration Details

REGISTRATION FEES
Registration fees are due prior to the start of the course and include all course materials and lunch. Program schedules will be sent with the registration confirmation.

DISCOUNTS
You may qualify for one of the discounts listed below. Offers may not be combined with any other discounts.
• Group Discount: Enroll 3 students in the same course (held on the same date and at the same location) at the regular price and receive a 4th enrollment for free.
• Government Discount: 10% courtesy discount for all US government employees, as per our GSA contract.

SUBSTITUTIONS, TRANSFERS, CANCELLATIONS POLICY
Substitutions – If you cannot attend a course, you may send an alternate person to attend in your place. You can make a substitution at any time, at no additional charge. Email us (details below) and tell us the alternate’s name, the course name, and the session dates.

Transfers and Cancellations – You may transfer to a different course session (based on availability). Transfers and cancellations will be charged as follows:
• 22 or more days before the course start date: no charge
• 15–21 days before the course start date: 25% of the tuition
• 7–14 days before the course start date: 50% of the tuition
• 6 or fewer days before the course start date: 100% of the tuition

Email your requests for cancellations, transfers, or substitutions to customerservice@orielstat.com.

A $25 service charge is applied to returned checks.

MATERIALS
Course materials may be delivered in either hard-copy or electronic formats.

We reserve the right to charge a $100 expedite fee to ship additional materials for those individuals who register for a course fewer than 7 days before the start date.

NOTICE
Oriel STAT A MATRIX prohibits tape or digital recordings of any sessions. Oriel STAT A MATRIX reserves the right to rearrange course content and is not responsible for typographical errors. Courses may be cancelled and locations may be changed at the discretion of Oriel STAT A MATRIX. Oriel STAT A MATRIX is not responsible for airfare, hotel, or other costs incurred by registrants.

POLICY
Oriel STAT A MATRIX does not discriminate on the basis of race, national origin, religion, gender, age, or handicap in its policies, procedures, or practices.

HOTEL INFORMATION
Please call 800.472.6477 or check our website for hotel information.

EXEMPLAR GLOBAL CERTIFIED COURSES
To attain registration as a QMS Auditor, QMS Senior Auditor, or QMS Lead Auditor, you must pass the written final examination, earn a passing grade in the course continuous assessments, and meet prescribed professional requirements, including a number of actual audits. Training courses presented as Exemplar Global certified courses meet the training requirements for certification of individual QMS Auditors, QMS Senior Auditors, and QMS Lead Auditors. “Successful completion” satisfies the training requirements for individual auditor certification under the qualification-based system offered by Exemplar Global.

Registration Form

FIVE EASY WAYS TO ENROLL IN A COURSE

PHONE TOLL-FREE: 800.472.6477 (for US and Canada)
732.548.0600. Select option 1.

MAIL (checks only): Oriel STAT A MATRIX
One Quality Place, Edison, NJ 08820

EMAIL: customerservice@orielstat.com

ONLINE: www.orielstat.com, click on Find a Training Course

Customer Information  (please print)
Name __________________________ Title ________________________
Company __________________________
Address __________________________
City __________________________ State _________ Zip ______________
Country ________________________ Phone ____________ Ext. ____________
Fax __________________________ Email __________________________
Home phone (for emergencies only) __________________________

Dietary requirements:
☐ Vegetarian ☐ Kosher ☐ Other ________________

Is this a confirmation of a telephone registration? ☐ Yes ☐ No

Please tell us how we can best accommodate your needs.

Course Selection and Location

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Course Subtotal: ________________

Subtract discount, if applicable. Only one discount per course.
Check applicable discount and enter figure below.

☐ Group Discount
☐ Government Discount 10%

Subtract Discount: ________________

TOTAL AMOUNT DUE: ________________

☐ Check enclosed for $ ________________

Please make check payable to Oriel STAT A MATRIX.

☐ Bill my purchase order # ________________ for $ ________________

Signature __________________________ Date __________________________

☐ Bill my credit card (check one): ☐ Visa ☐ MasterCard ☐ American Express

Please enter account #: __________________________

Exp. date ________________ CVV (3- or 4-digit security code) ________________

Signature __________________________ Date __________________________

Credit card payments and purchase orders must be signed.

Zip code for credit card billing address ________________

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