Oriel
STAT A MATRIX

Training Catalog

Training to boost efficiency, decrease costs, and improve customer satisfaction!

Oriel STAT A MATRIX

Get the Training You Need

From the Leader in Performance Improvement and Regulatory Compliance Training and Consulting Since 1968

CONTENTS

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PHONE: 800.472.6477

EMAIL: customerservice@orielstat.com

MAIL: Checks only. See page 19 for required form and mailing information.

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Please review terms and conditions on page 19.

NEW! Advanced Lead Auditor Training

Move beyond conformance-based audits to performance-enhancing audits

> "This training has opened my eyes to a whole new level of auditing."
>
> *– Quality Engineer*

Are your audits helping your organization meet its strategic goals? Are you looking to acquire skills to make your audit program the catalyst for tangible improvements to your organization's bottom line?

The Oriel STAT A MATRIX Advanced Lead Auditor Training course has been designed to give you the skills and knowledge needed to exponentially raise your ability to determine if your organization's business management system is properly contributing to the company's financial health.

Presented primarily through hands-on workshops and exercises, this course gives auditors, audit program managers, and management representatives 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.

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.

Course Objectives

- Review fundamental concepts and statistical tools related to process performance and process control, such as data collection, data analysis, and process capability.
- Recognize the documentation that is relevant to process-focused audits.
- Command top management's attention by adding strategic value to your auditing process.
- Recognize the benefits of applying process design and process improvement methodologies that lead to continual improvement and business sustainability over the long term.
- Learn about key financial indicators and how they can be linked to process metrics.
- Understand effectiveness-focused auditing methodologies and evidence gathering.
- Explain methods for measuring the effectiveness and efficiency of the MS auditing program and its value.
- Recognize how an audit program can bring value to the organization and learn how to measure its return on the investment.

Topics

- Process performance variables and how to measure them
- Interpreting process maps and identifying opportunities for improvement
- Statistical tools that are relevant to successful process auditing (e.g., process capability and statistical process control)
- Breakthrough audit planning, including:
  - Process-focused, risk-based audit scheduling
  - Process and results data and documentation needed to plan audits and determine audit trails
- Breakthrough on-site audit activities, including:
  - Special process auditing
  - Handling adverse audit conditions
  - Measuring audit program effectiveness
  - Reporting nonconformities

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 RABQSA-certified quality system lead auditor; he has a master's degree in engineering management.

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

Oriel STAT A MATRIX
the first and the best

- Oriel STAT A MATRIX has been **training auditors since 1968**.
- Oriel STAT A MATRIX was **the first** training provider certified by the Registrar Accreditation Board (RAB, the predecessor to RABQSA) to offer lead and internal auditor training.
- Since then, we've grown into the **largest ISO 9001 and related standards training and consulting organization** in the world.
- We've **trained more than 100,000 auditors** and assisted thousands of organizations in attaining registration to ISO 9001 and related standards.

$2495 ▪ Course Code: ADV ▪ 4.0 CEUs ▪ 5 Days

APRIL 8 – 12	Dallas, TX	AUGUST 5 – 9	San Francisco, CA
MAY 6 – 10	Edison, NJ	AUGUST 26 – 30	Indianapolis, IN
JUNE 3 – 7	San Diego, CA	SEPTEMBER 16 – 20	Boston, MA
JULY 15 – 19	Chicago, IL	SEP 30 – OCT 4	Dallas, TX

Lead Auditor Training for ISO 13485

CERTIFIED QMS LEAD AUDITOR TRAINING COURSE

> "I have never come out of training and actually learned useful things like I did with this class. I will definitely be bringing knowledge back to my company of the things I learned here."
>
> *– Senior Quality Control Supervisor*

Learn how to assess conformance with ISO 13485 from the industry experts. Based on our ISO 9001 RABQSA-certified QMS lead auditor training course, this interactive course covers ISO 13485 in addition to ISO 9001 requirements for quality management systems.

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, the 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

- Overview of auditing
- Interpretation of ISO 13485
- The audit cycle and ISO 19011
- Preaudit activities
- Auditing practices; the psychology of auditing
- Nonconformity reporting
- Process auditing
- Follow-up and corrective action
- Evening sessions for the first four nights
- Final exam (2 hours)

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.

NOTE: This training course is an RABQSA-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 RABQSA certification, please see page 19.

FACULTY Spotlight*

JULIE CONGRESS has more than 15 years of experience in quality and management systems based on international standards, including ISO 9001, ISO 14001, OHSAS 18001, and ISO 13485. She provides training and support for gap assessments, documentation development, operating system implementation, auditing, and process improvement, as well as root cause analysis and problem solving. Julie holds a bachelor's degree in business administration and is certified in project management and quality improvement.

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

Did You Know ... ?

In 1978, **the US FDA chose Oriel STAT A MATRIX** to help develop regulations and train its investigators. Since then, we've been the industry leader in assisting medical device makers to achieve compliance and develop quality programs.

For Internal Auditor Training for ISO 13485, see page 9.

$1995 ▪ Course Code: LAF ▪ 4.4 CEUs ▪ 5 Days

APRIL 8 – 12	Boston, MA	JUNE 3 – 7	San Diego, CA	AUGUST 12 – 16	Irvine, CA
APRIL 15 – 19	Dallas, TX	JUNE 10 – 14	Raleigh, NC	AUGUST 19 – 23	Orlando, FL
APRIL 15 – 19	San Francisco, CA	JUNE 17 – 21	Indianapolis, IN	AUGUST 26 – 30	Minneapolis, MN
APRIL 22 – 26	Chicago, IL	JULY 8 – 12	Boston, MA	SEPTEMBER 9 – 13	San Diego, CA
APR 29 – MAY 3	Edison, NJ	JULY 15 – 19	San Francisco, CA	SEPTEMBER 16 – 20	Raleigh, NC
MAY 6 – 10	Irvine, CA	JULY 22 – 26	Dallas, TX	SEPTEMBER 23 – 27	Indianapolis, IN
MAY 13 – 17	Orlando, FL	JUL 29 – AUG 2	Chicago, IL		
MAY 13 – 17	Minneapolis, MN	AUGUST 5 – 9	Edison, NJ		

NEW! Quality Systems for Medical Devices:

A Comprehensive Overview of the FDA's QSR and ISO 13485

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

How complete is your quality system? Does your organization struggle to comply with medical device standards and regulations? Do you run parallel quality systems to meet multiple global requirements?

It's possible to create a comprehensive quality system – one that satisfies all global requirements: FDA QSR, EU Medical Device Directives, ISO 13485, and recommendations from the Global Harmonization Task Force.

A unified quality system is not only more effective, it's easier to manage. Learn how to harmonize the relevant medical device requirements to create a comprehensive quality system. Designed for both new and experienced professionals in the medical device field, this course will give you a solid understanding of the necessary components of an effective, compliant quality system for medical device manufacturing.

Course Objectives

- Understand the objectives and benefits of medical device regulations.
- Analyze the details of the 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

- Medical device regulations integral to the quality management system
- FDA requirements under 21CFR820, 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

This course is for anyone who wants to understand the requirements for a global medical device quality system. It is recommended for compliance, legal, management, quality, regulatory, and technical personnel who are responsible for the development, manufacturing, and postproduction oversight of medical devices, including R&D managers; engineering managers; management representatives; product, project, and program managers; RA/QA managers and engineers; internal auditors; and cross-functional team members.

FACULTY **Spotlight***

PAUL LANDESMAN, PHD Dr. Landesman is a results-driven global quality, regulatory, and safety professional. Currently, he is responsible for the strategic leadership and managerial oversight of Oriel STAT A MATRIX's Life Sciences practice.

Dr. Landesman started his professional career managing the clinical laboratories at the Ohio State University Hospitals. Prior to joining Oriel STAT A MATRIX, Dr. Landesman held various management and leadership positions at life sciences companies such as Abbott Laboratories, Amgen, Allergan, and Hospira.

Dr. Landesman has proven leadership in total-product life-cycle management for pharmaceutical, biotech, and medical device products – managing teams from system integration groups in R&D through to postmarket quality and safety organizations. He has a strong history of bringing business-centric answers to regulatory compliance issues and has provided strategic and tactical solutions throughout the organizations with which he has worked. In addition, Dr. Landesman has served on several teams working to address the creation and interpretation of global regulatory standards and legislative requirements.

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

$2195 ▪ Course Code: GRF ▪ 2.5 CEUs ▪ 3 Days

APRIL 8 – 10	Chicago, IL	MAY 6 – 8	San Diego, CA	JUNE 3 – 5	Columbus, OH
APRIL 15 – 17	Edison, NJ	MAY 13 – 15	Raleigh, NC	JUNE 10 – 12	Orlando, FL
APRIL 22 – 24	Minneapolis, MN	MAY 20 – 22	San Francisco, CA	JUNE 17 – 19	Dallas, TX
APR 29 – MAY 1	Boston, MA	MAY 20 – 22	Indianapolis, IN	JUNE 24 – 26	St. Louis, MO

NEW!

Implementing a Complaint-Handling, Safety-Reporting, and Recall Program

Over 60% of Warning Letters issued by the FDA contain a citation against the company's complaint-handling and MDR-reporting practices and/or procedures.

A poorly implemented complaint-handling process poses both regulatory compliance and business risks to an organization. Many corporate reputations have been compromised or tainted as a result of organizations' inability to determine "root cause" and take timely, effective action when a problem comes up in the field.

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. A global framework will be reviewed to help you address your organization's global requirements for complaint handling and event reporting.

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)
- 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.

$2195 ▪ Course Code: **CHF** ▪ 2.5 CEUs ▪ 3 Days

APRIL 10 – 12	Edison, NJ	JULY 23 – 25	San Francisco, CA
MAY 1 – 3	Raleigh, NC	AUGUST 20 – 22	Boston, MA
MAY 22 – 24	San Diego, CA	SEPTEMBER 10 – 12	Chicago, IL
JUNE 12 – 14	Indianapolis, IN	OCTOBER 1 – 3	Minneapolis, MN

NEW!

Supplier Quality Management: Designing and Implementing a Successful Program

Supplier quality issues account for over 50% of all product recalls, and Warning Letter citations related to purchasing controls have more than doubled in the past 5 years.

Over the past year, the FDA and ISO authorities have placed an unprecedented emphasis on supplier quality, purchasing controls, and linked processes. Companies themselves state that over 50% of their business continuation and quality issues are related to supplier quality management and purchasing controls. These issues include:

- Reactive supplier quality costs are greater than procurement costs.
- Internal communication on supplier quality management is inadequate.
- There is misalignment between supply chain and procurement personnel on managing suppliers.
- Product development, quality, and procurement personnel do not understand their roles and responsibilities within the supplier quality program.

This course will provide your organization with the knowledge and tools to design a comprehensive cross-functional supplier quality program and 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, starting with product development specifications through the maintenance of 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.

$2195 ▪ Course Code: **SQF** ▪ 2.5 CEUs ▪ 3 Days

APR 29 – MAY 1	Chicago, IL	AUGUST 13 – 15	Indianapolis, IN
MAY 20 – 22	Minneapolis, MN	SEPTEMBER 24 – 26	San Diego, CA
JUNE 10 – 12	San Francisco, CA	OCTOBER 14 – 16	Boston, MA
JULY 16 – 18	Edison, NJ		

SPECIAL OFFER

FIX PROBLEMS ONCE. A robust root cause analysis investigation provides clear solutions for an effective CAPA program. Save $200 by combining *CAPA Programs for the Medical Device Industry* with our NEW *Root Cause Analysis* course for just $3490 (COMBO COURSE CODE: ZCF)

CAPA Programs for the Medical Device Industry

In 2012, CAPA deficiencies were the number one good manufacturing practice (GMP) cited in FDA Warning Letters.

Used well, corrective and preventive action (CAPA) is a tool that goes beyond remediation and supports continuous product and business improvement. Additionally, the FDA's QSR and ISO 13485 require that a CAPA system be put into place, and CAPA is a key target of FDA and international regulator scrutiny, consistently ranking at the top of the list of 483 observations and quality system citations in warning letters. Understanding how the essentials of this system can satisfy current and future regulatory requirements and also make good business sense is the basis of our CAPA course.

Course Objectives

- Understand what is included in an effective CAPA program and where the data come from.
- Learn how to integrate 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 take.
- Understand why regulatory agencies added the "preventive action" clause to the requirements.
- Learn not only what is expected from your organization but also how you can use it to impact the bottom line.

Topics

- What is CAPA?
- CAPA application and implementation
- Sources of quality data
- Methods of data analysis
- Implementation effectiveness
- Medical device reporting and tracking
- Corrections and removals
- Communication

Who Should Attend

Recommended for top management, management representatives, and staff in:

- Compliance/regulatory affairs
- QA/QC
- Manufacturing operations
- CAPA management
- Information systems/technology
- Document management
- Distribution
- Research and development

$1495 • Course Code: CAF • 1.5 CEUs • 2 Days

APRIL 8 – 9	Indianapolis, IN
APRIL 22 – 23	Edison, NJ
MAY 20 – 21	Minneapolis, MN
JUNE 10 – 11	San Francisco, CA
JULY 22 – 23	Chicago, IL
AUGUST 19 – 20	San Diego, CA
SEP 30 – OCT 1	Boston, MA

NEW! Root Cause Analysis for Medical Device, Biotech, and Pharmaceutical Investigations

Master the *essential problem-solving methodology*

Fix it right the first time. Stop wasting resources to correct recurring problems – improve product quality instead. Root cause analysis (RCA) is the essential investigation method used by life science professionals to understand failures 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 intervention. 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
  - FMEA
  - DMAIC
  - 5 Whys
  - Tree diagrams
  - Hypothesis testing
  - Verifying effectiveness
  - 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

$2195 • Course Code: RCF • 2.5 CEUs • 3 Days

JUNE 12 – 14	San Francisco, CA
JULY 24 – 26	Chicago, IL
AUGUST 21 – 23	San Diego, CA
OCTOBER 2 – 4	Boston, MA

SPECIAL OFFER

DESIGN CONTROL IS A KEY AREA – and it works best when it is integrated with your risk management program. Learn how to accomplish this by combining our *Risk Management and Analysis for Medical Devices* and *Design Control Concepts and Implementation* courses for just $2790 (save $200) (COMBO COURSE CODE: ZCD)

Risk Management and Analysis for Medical Devices

Can your organization demonstrate an effective risk management program when your next FDA inspection occurs? Without a comprehensive risk management program, your organization is open to inspection and submission problems as well as possible enforcement action. Risk analysis has been an essential requirement of the European Union (EU) directives for medical devices. Get the latest information on risk management concepts and practices for the medical device industry.

Learn how to manage a process associated with the identification, analysis, evaluation, and control of different types of risk before production begins. Class discussions cover the use of failure mode and effects analysis (FMEA) and fault tree analysis (FTA) as methods of conducting risk analysis, including making predictions and determining approaches to reliability and safety analysis. Also covered is the application of these tools to product design and manufacturing processes.

Course Objectives

- Understand the purpose, benefits, and objectives of a detailed plan for risk management and analysis.
- Apply basic concepts of risk management and analysis.
- Identify risks and approaches to their solutions.
- Understand regulatory requirements of risk analysis.
- Use available information to analyze risk.
- Identify hazards in risk analysis.
- Estimate and evaluate risks.
- Realize what is involved in risk reduction and control.
- Interpret risk analysis reports.

Topics

- Basic concepts and process model overview
- ISO 14971
- Meeting regulatory requirements for risk
- Four elements of risk in a management plan
- Risk management file
- Acceptability of risk
- Risk planning and analysis
- Identification of hazards; estimation of risks to public safety
- Qualitative and quantitative characteristics of risk
- Risk evaluation, control, and reduction
- Postmarket information and use
- Corrective and preventive action process
- ISO 13485 and 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 in a medical device environment.

$1495 • Course Code: FMF • 1.5 CEUs • 2 Days

APRIL 8 – 9	Indianapolis, IN
APRIL 22 – 23	Edison, NJ
MAY 13 – 14	Minneapolis, MN
JUNE 3 – 4	San Francisco, CA
JULY 15 – 16	Chicago, IL
AUGUST 12 – 13	San Diego, CA
SEPTEMBER 23 – 24	Boston, MA

Design Control Concepts and Implementation

Approximately 44% of device recalls are due to faulty design.

Make sure your design process is compliant so you can avoid costly deviations. The FDA has identified design control as a key area in its QSIT top-down inspectional approach to compliance. According to the FDA, "Manufacturers must incorporate a set of checks and balances in their design processes to assure a safe, effective finished product." Learn specified requirements and how to control the design process to ensure that your organization's devices meet user needs.

In-depth discussions and workshops 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.

Course Objectives

- Understand the control of design and development and their role in the regulated medical device industry.
- Review and compare design control in the QSR and ISO 13485.
- Understand the process model approach to design control.
- Identify the individual elements of the design control process.
- Understand the phases of the product life cycle and their relation to design control.
- Learn how to structure design control using good project management techniques.
- Build a successful design control team.
- Recognize the proper use of postproduction information in design control.
- Learn the expectations of the FDA and its QSIT approach to inspection in relation to design control.

Topics

- Basic concepts and process of FDA, ISO, and design control
- Key terms and definitions
- Principles of the process model
- Overview of the design control process model
- Product life cycle and design control
- Design control, risk management, and corrective and preventive action (CAPA)
- Building the compliant design history file (DHF)

Who Should Attend

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

$1495 • Course Code: DCF • 1.5 CEUs • 2 Days

APRIL 10 – 11	Indianapolis, IN
APRIL 24 – 25	Edison, NJ
MAY 15 – 16	Minneapolis, MN
JUNE 5 – 6	San Francisco, CA
JULY 17 – 18	Chicago, IL
AUGUST 14 – 15	San Diego, CA
SEPTEMBER 25 – 26	Boston, MA

Internal Auditor Training for ISO 13485

CERTIFIED QMS INTERNAL AUDITOR TRAINING COURSE

> "Excellent explanation and interpretation of requirements in understandable language."
>
> *– Quality Manager*

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 RABQSA-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.

This training course is certified by RABQSA and satisfies the training requirement for individuals seeking certification under the RABQSA QMS Internal Auditor Certification Scheme.

$1295 ▪ Course Code: IAF ▪ 4.0 CEUs ▪ 3 Days

APRIL 8 – 10	Edison, NJ
APRIL 29 – MAY 1	San Francisco, CA
MAY 13 – 15	Chicago, IL
JUNE 10 – 12	Minneapolis, MN
JULY 8 – 10	San Diego, CA
AUGUST 5 – 7	Boston, MA
SEPTEMBER 9 – 11	Raleigh, NC
SEP 30 – OCT 2	Indianapolis, IN

UPDATED! *Now featuring a greater emphasis on document change control and change management.*

Developing and Maintaining a Compliant Document Management System

Documentation issues account for more noncompliances than any other finding.

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.

Find out how to effectively and efficiently handle the cGMP/ISO document control requirements in this workshop-based program. We'll help you understand how much information you need to document, what level of detail is required for compliance, and how to implement and maintain a sustainable change control system.

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 documented management system.

$1495 ▪ Course Code: DOF ▪ 1.5 CEUs ▪ 2 Days

APRIL 11 – 12	Edison, NJ
MAY 2 – 3	San Francisco, CA
MAY 16 – 17	Chicago, IL
JUNE 13 – 14	Minneapolis, MN
JULY 11 – 12	San Diego, CA
AUGUST 8 – 9	Boston, MA
OCTOBER 3 – 4	Indianapolis, IN

Process Validation Principles and Protocols

> "All aspects of this course will add value to my skill set. Not only were the materials of high quality, but so was the instructor's ability to share his industrial experience – something that can't be captured in an information packet."
>
> *– Quality Manager*

Are you compliant with FDA requirements for "establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality characteristics"? If not, you may be leaving your organization open to adverse FDA inspection findings and a warning letter.

This course provides interactive team workshops and class discussions that focus on typical ways manufacturers prepare for and carry out process validations. Course participants will obtain hands-on practical application experience involving planning, execution, and reporting of process validation activities as part of the integrated requirements of a quality management system that meets FDA and ISO requirements.

Course Objectives

- Understand the purpose, benefits, and objectives of process validation as it relates to product realization.
- Develop skills in the practical application of planning, executing, and reporting of design control.
- Evaluate risks, consequences, and impacts of validation activities on customers, suppliers, and other interested parties.
- Translate design requirements into process capabilities.
- Learn how to interpret and comply with FDA, ISO, and other international requirements.
- Learn to identify, select, and utilize valid statistical techniques and methods for analyzing data and information.

Topics

- Overview of process validation: purpose and scope
- Process validation requirements: regulations, standards, and guidance
- Key aspects associated with the "process" of process validation
- Process validation within a functioning quality management system
- Planning validation scope and implementation
- Identification and use of statistical methods and tools
- Risk evaluation
- FDA inspectional observations and analysis
- Marketing and postmarket responsibilities

Who Should Attend

Recommended for engineering, manufacturing, quality, regulatory, and other technical professionals with responsibilities for planning, executing, reporting, maintaining, and managing process validation activities relating to the control of design, production and process, labeling and packaging, facility and equipment, laboratory, materials, and suppliers.

$2195 ▪ Course Code: PVF ▪ 2.5 CEUs ▪ 3 Days

APRIL 22 – 24	Minneapolis, MN
MAY 13 – 15	Edison, NJ
JUNE 3 – 5	San Francisco, CA
JULY 15 – 17	Boston, MA
AUGUST 19 – 21	Indianapolis, IN
SEPTEMBER 23 – 25	San Diego, CA

510(k) Process for Medical Devices

Medical device companies must have FDA 510(k) approval to market products in the United States. Learn the best way to get your approval to market in the US, what is needed to complete the 510(k) process, and when a 510(k) must be submitted. In addition, you'll understand how to submit a successful 510(k) for a device or a device change as quickly and efficiently as possible to avoid regulatory issues and unnecessary expenses. Upon course completion, you'll have the tools to make sure your 510(k) submission can be quickly reviewed by the FDA so you can stay ahead of the competition.

Course Objectives

- **Introduction to the 510(k) Submission Process** – Understand the elements of premarket notification 510(k) submissions for medical devices.
- **Requirements** – Use hands-on workshops to compare your medical device to a substantial equivalent product and/or predicate device.
- **The Process** – Learn what is expected and when a 510(k) is needed.
- **Modifications** – Understand when a device needs to be resubmitted.
- **Marketing and Postmarket Responsibilities** – Know what your responsibilities are after your device is on the market.

Topics

- FDA's regulatory classifications and requirements
- Primary routes to market: PMA/510(k)s and exemptions
- Elements of the 510(k) and definitions
- General 510(k) principles on what to expect
- Selecting a predicate
- 510(k) structure – traditional, abbreviated, special
- Modifications to devices and resubmission
- Marketing and postmarket responsibilities

Who Should Attend

This course is designed for professionals involved with premarket notification to the FDA. Recommended for anyone heavily involved in approving the design and marketing of medical devices. Some knowledge of FDA regulations is helpful.

Who must submit an FDA 510(k)?

- Manufacturers or importers/exporters who want to introduce a new device (having a predicate device) to the US market
- Manufacturers who are introducing a new finished device to the US market
- Specification developers designing a device that is manufactured by another company for sale in the US
- Companies proposing a significantly different design or intended use for a product sold in the US
- Device repackagers or relabelers

$1495 ▪ Course Code: PMF ▪ 1.5 CEUs ▪ 2 Days

APRIL 8 – 9	Minneapolis, MN
MAY 13 – 14	San Francisco, CA
JUNE 3 – 4	Chicago, IL
JULY 9 – 10	Boston, MA
JULY 30 – 31	San Diego, CA
AUGUST 6 – 7	Indianapolis, IN
SEPTEMBER 17 – 18	Edison, NJ

Lean Six Sigma Master Black Belt Certification

> "Loved the real-world examples. There's so much I will take away from this training. I'll be able to immediately apply what I learned and make immediate improvements at my workplace."
>
> *– Business Excellence Manager*

Transform your career and be an indispensable asset to any organization by becoming a Lean Six Sigma Master Black Belt. Our intensive program focuses on increasing the ability of experienced Lean Six Sigma Black Belts to take leadership roles in achieving organizational excellence. Oriel STAT A MATRIX Master Black Belts can plan strategy with senior executives, support or act as deployment champions, and lead and coach Black Belts through complex improvement and design projects.

Tailored to trained Six Sigma Black Belts, this comprehensive workshop-based session provides a strategic view of the three Lean Six Sigma methodologies (process improvement, design and innovation, and process management).

Course Objectives

- Integrate Lean Six Sigma methodologies with business strategy to ensure that the Six Sigma program produces breakthrough return on investment.
- Plan, design, and manage complex Lean Six Sigma programs involving multiple processes, organizations, and methodologies.
- Support senior management on the effective use of Six Sigma tools for innovation and efficiency improvements.
- Mentor Black Belts on choice of methodology, statistical tools, and team support.
- Measure the financial impact of Lean Six Sigma programs.
- Use Minitab™ in support of statistical tools.

Who Should Attend

This program is for trained Six Sigma Black Belts who have demonstrated leadership, team, and statistical skills on improvement projects with documented financial benefits. Six Sigma Master Black Belts are problem solvers and motivators, leading the organization change process and coaching others to individual and team success.

Topics

- Deploying an enterprise process management system as a driver for strategic process improvements
- Voice of the Customer for innovation
- Advanced statistical topics
- Integrating Lean concepts into Six Sigma programs
- Leading successful change
- Project management for Six Sigma deployment
- Using enabling technology to effectively manage Six Sigma programs
- Fundamentals of financial management
- Decision making for process improvement
- Managing risk

This training includes Minitab™; attendees are responsible for bringing laptops with Minitab™ 16 software. Oriel STAT A MATRIX certification as a Lean Six Sigma Master Black Belt requires successful completion of the course and a passing grade on the final exam.

FACULTY Spotlight*

ERNANI PIRES has 40 years of experience facilitating quality and productivity improvement for organization-wide initiatives, working within the government, commercial, industrial, educational, and service sectors.

He is a C-level executive with subject matter expertise in the Oriel STAT A MATRIX Sustainable Performance Management methodology (including Lean Six Sigma). Ernani has extensive experience in the manufacturing and service industries, is a certified Six Sigma Master Black Belt, and holds a bachelor's degree in mechanical engineering. He has led courses in both English and Portuguese.

* *This course is also taught by other Lean Six Sigma experts.*

Did You Know…?

Since 1998 – when GE Capital asked us to develop and implement Green, Black, and Master Black Belt programs – Oriel STAT A MATRIX has coached 7,000+ performance improvement projects yielding nearly $1B in customer benefits for clients around the world.

$5995 ▪ Course Code: **MA5** ▪ 8.0 CEUs ▪ Two 5-Day Sessions		
WAVE 32 – 1, 2	JUNE 10 – 14; JULY 15 – 19	San Francisco, CA
WAVE 33 – 1, 2	SEPTEMBER 16 – 20; OCTOBER 14 – 18	Orlando, FL

LEAN SIX SIGMA ON-SITE TRAINING COURSES ARE AVAILABLE IN

Lean Practitioners Certification

> "The instructor had an excellent knowledge of the material. He shared a lot of his real-world professional experiences, which provided a great balance to the textbook discussion. All in all, this was a terrific course with a terrific instructor!"
>
> *– Vice President, Operational Improvement*

Is your organization looking for ways to improve your operations, stay competitive, increase capacity, and surpass your competition? Adopt Lean tools and techniques as a powerful methodology to achieve your strategic goals with minimal investment required. This course will develop your employees as internal experts in utilizing and applying Lean successfully. Participants will learn the full breadth of Lean approaches and how to implement Lean improvements using Lean/kaizen events under the DMAIC structure.

Upon successful completion of this program, you will have the skills and knowledge to successfully apply Lean tools and techniques in your organization.

Course Objectives

- Learn to apply the steps, approaches, tools, and techniques used to create Lean processes and a Lean organization.
- Recognize the purpose, objectives, results, and benefits that Lean can achieve.
- Clearly see the waste in your processes and identify waste's drivers (unevenness and overburden).
- Use the Lean Pathway to identify and prioritize opportunities for improvement.
- Learn the best way to plan for and implement Lean.
- Understand the improvement (kaizen) method and tools necessary to conduct a targeted Lean kaizen event.

Topics

- Lean cost model; benefits of Lean
- Lean Pathway
- Lean approaches
- Value stream mapping
- Efficiency calculations (OEE)
- Organization and safety (5S)
- Workplace arrangement
- Standardization
- Error proofing (Poka Yoke)
- Auto-stop (autonomation)
- Rapid changeover (SMED)
- Integrated maintenance (TPM)
- One-piece flow and pull (just-in-time)
- Process pulse (takt time)
- Signaling pull (kanban)
- Visual management (andon)
- Load leveling and sequencing (production leveling)
- Implement approaches using DMAIC

Who Should Attend

Quality professionals and managers; manufacturing, process, and industrial engineers; operations analysts and managers; Master Black Belts; Black Belts; Green Belts; and any manager or professional who wants to improve the efficiency of manufacturing operations, processes, and the organization.

NOTE: Unless noted otherwise, this course features the service version of the training materials. Oriel STAT A MATRIX Lean practitioners certification requires successful completion of the course, a passing grade on the final exam, and submission of a detailed report of an effective Lean improvement project or kaizen event.

$2495 • Course Code: LPM • 4.0 CEUs • 5 Days

APRIL 29 – MAY 3	Chicago, IL
JUNE 3 – 7	Dallas, TX
JULY 15 – 19	San Francisco, CA
SEPTEMBER 16 – 20	Chicago, IL
OCTOBER 7 – 11	Orlando, FL
NOVEMBER 4 – 8	San Diego, CA
JANUARY 13 – 17, 2014	Edison, NJ

Lean Six Sigma Green Belt Certification

Our unique approach to the integration of Lean and Six Sigma takes full advantage of the power of both methodologies to help team leaders and members successfully complete DMAIC and Lean DMAIC projects. The first week of training covers Lean and Lean approaches; the second and third weeks cover the DMAIC steps as well as leadership, facilitation, and change management skills.

Upon completion of the training, participants will understand Lean Six Sigma, know how to work on a project team, be able to use DMAIC on identified improvement projects, and help Lean Six Sigma leaders direct targeted Lean events and improvement projects by using the DMAIC process.

Course Objectives

- Define Lean, the Lean Pathway, and associated approaches.
- Lead a group through the Lean Pathway, including tools for seeing the waste and Lean approaches.
- Apply Lean approaches and the Lean improvement methodology to a process simulation.
- Plan for and/or coach others on planning for an event (roles, Lean charters, logistics, etc.).
- Select Lean approaches applicable to a given Lean charter.
- Select and train others on specific tools and techniques.
- Explain in general terms what "Six Sigma" refers to and why it is relevant to process improvement.
- Identify the DMAIC steps of DEFINE, MEASURE, ANALYZE, IMPROVE, and CONTROL and their sequence, along with the outputs of and tools in each step.

Topics

- Types of work (VA, NVA, waste)
- Drivers of waste (overburden, unevenness)
- Methodology for implementing Lean
- Definition of waste; eight categories of waste
- Targeted Lean events (kaizen)
- DMAIC – the process improvement method
- Voice of the Customer
- Data collection and analysis
- Identifying and verifying causes
- Generating, selecting, and implementing solutions
- Evaluating results; standardization solutions that address root causes; using data to evaluate

Who Should Attend

Anyone participating in Lean Six Sigma or process improvement; applicable to staff, line, supervisors, managers, and directors in such areas as healthcare, finance, operations, customer service, engineering, electronics, communications, logistics, sales, quality, and purchasing.

NOTE: Unless noted otherwise, this course features the service version of the training materials and meets the minimum training requirements for Lean Six Sigma Green Belt certification. Oriel STAT A MATRIX certification as a Six Sigma Green Belt requires successful completion of the course and a passing grade on the final exam.

Six Sigma (non-Lean) candidates do not need to take the first week of training for this course. Call 800.472.6477 for more information.

$7495 • Course Code: GL1 • 12.0 CEUs • Three 5-Day Sessions

WAVE 93 – 1, 2, 3	APRIL 29 – MAY 3; MAY 20 – MAY 24; JUNE 17 – JUNE 21	Chicago, IL
WAVE 94 – 1, 2, 3	JULY 15 – JULY 19; AUGUST 12 – AUGUST 16; SEPTEMBER 9 – SEPTEMBER 13	San Francisco, CA
WAVE 95 – 1, 2, 3	OCTOBER 7 – 11; NOVEMBER 4 – 8; DECEMBER 9 – 13	Orlando, FL
WAVE 96 – 1, 2, 3	JANUARY 13 – 17, 2014; FEBRUARY 24 – 28, 2014; MARCH 24 – 28, 2014	Edison, NJ

3 VERSIONS: **SERVICE • MANUFACTURING • HEALTHCARE**

Six Sigma Green Belt Upgrade to Black Belt Certification

Have you earned your Green Belt? Then you're already halfway there! Take your Green Belt to the next level – become a certified Lean Six Sigma Black Belt.

Build on your existing Lean Six Sigma skills so you can lead your team to operational excellence and improve your professional standing.

Through this program, you will learn to:

- Use advanced statistical tools that are indispensible for complex improvement projects.
- Handle projects of greater complexity that will lead to significant financial benefits for your organization.

Training consists of two interactive one-week sessions covering the Black Belt curriculum and responsibilities. There is a break of several weeks between each training session for project work.

Course Objectives

- Add value to both your career and your organization by enhancing your process improvement skills.
- Learn advanced statistical tools that can be applied across the various phases of the DMAIC methodology.
- Recognize (through exercises and workshop) the practical value of these advanced statistical tools.
- Accomplish more in the areas of data collection and data analysis.
- Improve the way you approach root cause analysis.
- Learn and apply Minitab™ in support of statistical tools.

Topics

- Introduction to Minitab™ (statistical software)
- Dealing with normal and nonnormal distributions
- Process capability
- Hypothesis testing
- Regression analysis
- Design of Experiments
- Measurement system analysis
  - Gage R&R
  - Attribute agreement analysis
- Sampling and determination of sample size

Who Should Attend

Individuals who have successfully gone through Green Belt training and wish to enhance their skills in the area of process improvement. Experience in leading the application of the DMAIC methodology is a must for a successful learning experience.

This training includes Minitab™; attendees are responsible for bringing laptops with Minitab™ 16 software. Oriel STAT A MATRIX certification as a Lean Six Sigma Black Belt requires successful completion of the course, passing grades on the quizzes and final exam, and submission of a detailed report of an effective Six Sigma project.

$4995 • Course Code: GBB • 10.5 CEUs • Two 5-Day Sessions

WAVE 92 – 1, 2	APRIL 22 – 26; JUNE 3 – 7	Edison, NJ
WAVE 93 – 1, 2	JULY 22 – 26; AUGUST 26 – 30	Chicago, IL
WAVE 94 – 1, 2	OCTOBER 14 – 18; NOVEMBER 11 – 15	San Francisco, CA
WAVE 95 – 1, 2	JANUARY 13 – 17, 2014; FEBRUARY 10 – 14, 2014	Orlando, FL
WAVE 96 – 1, 2	APRIL 21 – 25, 2014; MAY 19 – 23, 2014	Edison, NJ

Lean Six Sigma Black Belt Certification

Don't let your competition pass you by – enhance your professional credentials by becoming a certified Lean Six Sigma Black Belt.

Lean Six Sigma Black Belts direct significant product and process improvements linked to increased productivity and profitability. Our innovative program combines Lean's focus on the elimination of waste with Six Sigma's pursuit of breakthrough improvement. It also focuses on Lean Six Sigma integration and the infrastructure needed to achieve organizational excellence. Candidates learn leadership skills, team building and facilitation, coaching and mentoring, Lean DMAIC steps and outputs, and advanced statistical tools.

Led by Oriel STAT A MATRIX Master Black Belts, this workshop-based program includes five weeks of training with project application scheduled between training weeks. Upon course completion, you'll have the skills to lead Lean DMAIC projects and train team members on each step of the process.

Course Objectives

- Define the Lean Pathway in terms of Lean and Six Sigma integration.
- Lead a team through the Lean DMAIC steps and train team members on the steps, tools, and approaches.
- Use meeting skills and tools, decision making, intervention, and group dynamics for team building and facilitation.
- Prepare storyboards and presentations; give and receive feedback.
- Use Minitab™ in support of statistical tools.
- Successfully implement Lean Six Sigma projects while integrating results into the business system and culture.

Topics

- The Lean Pathway
- Benefits of implementing Lean Six Sigma
- Tools for seeing and eliminating the waste
- Key roles and responsibilities
- Problem statements and team charters
- Critical-to-quality characteristics (CTQs) from your customers' perspective
- Data collection and analysis
- Root cause identification and analysis
- Controlling the process and maintaining the gains
- Advanced statistical tools

Who Should Attend

Lean Six Sigma Black Belt candidates should be leaders and respected team members with excellent communication skills. Experience in solving problems and motivating others is essential, as is a demonstrated commitment to organizational excellence.

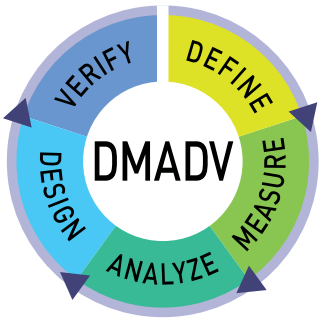
This training includes Minitab™; attendees are responsible for bringing laptops with Minitab™ 16 software. Oriel STAT A MATRIX certification as a Lean Six Sigma Black Belt requires successful completion of the course, passing grades on the quizzes and final exam, and submission of a detailed report of an effective Six Sigma project.

Six Sigma (non-Lean) candidates do not need to take the first week of training for this course. Call 800.472.6477 for more information.

$12,495 • Course Code: BL1 • 20.0 CEUs • Five 5-Day Sessions

WAVE 93 – 1, 2, 3, 4, 5	APRIL 29 – MAY 3; MAY 20 – 24; JUNE 17 – 21; JULY 22 – 26; AUGUST 26 – 30	Chicago, IL
WAVE 94 – 1, 2, 3, 4, 5	JULY 15 – 19; AUGUST 12 – 16; SEPTEMBER 9 – 13; OCTOBER 14 – 18; NOVEMBER 11 – 15	San Francisco, CA
WAVE 95 – 1, 2, 3, 4, 5	OCTOBER 7 – 11; NOVEMBER 4 – 8; DECEMBER 9 – 13; JANUARY 13 – 17, 2014; FEBRUARY 10 – 14, 2014	Orlando, FL
WAVE 96 – 1, 2, 3, 4, 5	JANUARY 13 – 17, 2014; FEBRUARY 24 – 28, 2014; MARCH 24 – 28, 2014; APRIL 21 –25, 2014; MAY 19 – 23, 2014	Edison, NJ

Design for Six Sigma



Is your organization having product development issues? Are these adversely affecting your business? Design for Six Sigma (DFSS) methodologies focus on preventing and removing defects before and during design, resulting in improved business performance and profitability.

Learn how to apply Design for Six Sigma's DMADV (DEFINE-MEASURE- ANALYZE-DESIGN-VERIFY) model to the design or redesign of your products, services, and processes to increase speed to market, reduce cycle time, and improve customer and employee satisfaction. Design projects deliver substantial improvement in overall organizational performance, particularly in the area of customer satisfaction.

Course Objectives

- Understand why Six Sigma is vital to design.
- Understand and apply the DMADV model.
- Translate Voice of the Customer (VOC) data into key quality characteristics (KQCs) using quality function deployment (QFD).
- Create conceptual designs using creativity tools.
- Perform risk analyses using FMEA and fault trees.
- Use propagation of variance and tolerance stacking.
- Use designed experiments to identify key variables and build predictive models.
- Analyze designs for reliability and sigma performance.

Topics

- Introduction to Six Sigma
- Defining the project
- Charters and project plans
- Change plans
- Risk analysis
- Measurement requirements
- Analyzing and verifying design
- Creativity tools
- Designing product
- Design of Experiments (DOE)
- Tolerance stacking for sums, differences, products, and quotients
- Propagation of variances for variables that are functions of other variables
- Reliability statistics

Who Should Attend

This is a fast-moving, interactive, toolkit-based course for Six Sigma design team members who need to understand how to apply the DMADV method. Six Sigma Black Belts and Green Belts who have completed a Six Sigma project are excellent candidates. Attendees should bring a potential design project to work on in class.

$2495 ▪ Course Code: **D15** ▪ 4.0 CEUs ▪ 5 Days	
JUNE 17 – 21	Chicago, IL
SEPTEMBER 16 – 20	Edison, NJ
DECEMBER 9 – 13	San Francisco, CA

Planning and Leading Lean Kaizen Events

Looking for ways to improve your operations, stay competitive, increase capacity, or surpass your competition? Learn how to apply two critical Lean concepts to your organization to help you meet those goals – value stream mapping and leading Lean kaizen events. Value stream maps document your key value-creating processes from the customer's perspective and help to identify the types and drivers of waste in your processes. Lean kaizen events are the method by which you make continual improvements to those processes to eliminate waste and its drivers.

This course will teach you how to identify value streams in your organization, map the critical value streams, analyze value streams for waste and its drivers, and execute Lean kaizen events using the DMAIC framework to implement continuous improvement. These techniques will help you get closer to the fundamental goal of Lean – to produce and deliver the highest quality products and services at the lowest possible cost.

Course Objectives

- Understand the definition of value stream and the benefits of value stream mapping.
- Describe other forms of process mapping to identify non-value-added work steps.
- Learn how to select and construct a value stream map.
- Understand the definition of Lean, types of waste, and drivers of waste.
- Describe how to select a topic for the Lean kaizen event using a value stream map or the categories of waste.
- Understand how to plan follow-up activities after a Lean kaizen event.

Topics

- Lean, the Lean Pathway, and associated approaches
- Value stream maps and their use
- Critical success factors that support value stream mapping
- Selecting appropriate team members to create value stream maps and carry out Lean kaizen events
- The eight categories of waste
- Lean kaizen events and what they can do
- Lean kaizen event charters
- Lean kaizen event planning
- Lean kaizen events within the DEFINE, MEASURE, ANALYZE, and IMPROVE steps of DMAIC
- Key roles and responsibilities involved in a Lean kaizen event
- Issues to be addressed in implementing Lean kaizen events
- Follow-up activities after a Lean kaizen event

Who Should Attend

Professionals, managers, directors, executives, Black Belts, and Green Belts with responsibility for implementing continuous improvement within your organization, whether in manufacturing, service, or administrative functions.

$995 ▪ Course Code: **VKL** ▪ 1.5 CEUs ▪ 2 Days	
APRIL 15 – 16	Chicago, IL
MAY 13 – 14	Los Angeles, CA
JUNE 10 – 11	Boston, MA
JULY 8 – 9	Edison, NJ
AUGUST 12 – 13	Dallas, TX
SEPTEMBER 16 – 17	San Francisco, CA

Focused Improvement Tools (FIT) allow you to quickly master the specific process improvement tools you need *now* by breaking down big, bold objectives into smaller, more achievable components. This more focused approach allows you to learn (or refresh) targeted skills that can be applied quickly to solve your most pressing process issues and help you see a faster return on investment.

Basic Problem Solving

Possessing the skills to solve problems within your organization is essential to professional and organizational improvement. A systematic approach to troubleshooting and problem solving is indispensible to continuous and successful process improvement.

Our three-phase, nine-step basic problem-solving strategy combines the insights of many experienced practitioners to foster the skills necessary in identifying problems, diagnosing root causes, and implementing remedies.

For each step in the problem-solving process you will learn fundamental tools and tactics, applying them in a variety of simulations and workshops throughout the course. Concepts and tactics are reinforced through challenging case studies and detailed examples. No prior statistical experience or prerequisites are necessary.

Course Objectives

- Understand the concepts of problem solving, including the structured approach, common pitfalls, and strategies for different sorts of problems.
- Employ proven tactics to identify and diagnose problems.
- Create teams to address specific problems.
- Define the scope of a problem.
- Learn strategies for data collection and root cause analysis.
- Apply a structured strategy to implementing and measuring the effectiveness of the solutions and other decisions.
- Develop strategies for documenting problem investigations and preventing recurrence.

Topics

- Principles of troubleshooting
- Teamwork and communications
- Identify the problem
- Prioritize and select
- Describe the symptoms
- Diagnose the cause
- Test and verify the cause
- Choose a remedy
- Verify the remedy
- Transfer to operations
- Hold the gains

Who Should Attend

Individuals participating in process improvement at any level, whether in manufacturing, support, or administrative functions. This includes staff, supervisors, managers, and directors in such areas as manufacturing, service, engineering, planning, human relations, quality, purchasing, etc.

$1095 ▪ Course Code: BPS ▪ 1.5 CEUs ▪ 2 Days

APRIL 10 – 11	Edison, NJ
MAY 22 – 23	San Diego, CA
JUNE 12 – 13	Chicago, IL
JULY 10 – 11	San Francisco, CA
AUGUST 7 – 8	Orlando, FL
SEPTEMBER 11 – 12	Dallas, TX

Data Collection and Gage R&R

Are you unsure what data you need to make informed, intelligent decisions about your organization's processes? Having reliable data is vital for properly measuring processes. Understanding and correctly applying key data collection concepts will ensure that you implement cost-effective data collection practices within your organization.

Learn about different types of data. Become adept at assessing processes to determine the most appropriate and cost-effective ways to collect data. Pinpointed data collection will help you identify areas of improvement in order to lower costs and achieve higher efficiency in your organization.

Course Objectives

- Appreciate the importance of reliable data in examining process performance.
- Recognize the different types of data and their characteristics.
- Understand the importance of operational definitions when dealing with data.
- Learn how to determine sample size in order to get the necessary data at the lowest possible cost.
- Learn how to conduct an analysis of your measurement system to ensure reliability of your data.

Topics

- The data collection process
- Data stratification
- Operational definitions
- Sampling approaches
- Determining sample size
- Population vs. process sampling
- Validating the measurement system
- Gage R&R studies
- Attribute agreement analysis
- How process measurements impact financial performance

Who Should Attend

Managers and professionals engaged in collecting and analyzing process data in order to improve the effectiveness and efficiency of their organization's processes, as well as associated quality, laboratory, and inspection professionals, and manufacturing, process, and industrial personnel. Also valuable for anyone involved in a Lean and/or Six Sigma deployment.

This course requires the use of Minitab™ statistical software; attendees are responsible for bringing laptops with Minitab™ 16 to the class.

$1595 ▪ Course Code: DAC ▪ 2.5 CEUs ▪ 3 Days

APR 29 – MAY 1	Orlando, FL
JUNE 24 – 26	San Francisco, CA
JULY 16 – 18	Edison, NJ
AUGUST 19 – 21	Dallas, TX
SEPTEMBER 16 – 18	Chicago, IL

SEE A FULL LISTING OF OUR FIT COURSES AT WWW.ORIELSTAT.COM

Potential Failure Mode and Effects Analysis

Preserve your bottom line – use FMEA to identify potential failures before they happen

Now more than ever, it's vital to prevent failures and the excessive costs involved in fixing them. By identifying potential risks long before they're actually encountered, you can preserve the health of your organization's bottom line.

In this course, learn how to reduce the risk of failure before design and manufacturing by studying the potential for product/process failure and initiating early preventive action. This workshop-intensive course is designed to provide hands-on training in conducting reliability and safety analyses for product design.

Participants are introduced to the guidelines for use of failure mode and effects analysis (FMEA) and fault tree analysis (FTA), two analytical tools that are used to examine processes and pinpoint areas where problems are likely to occur. Workshops cover how to use FMEA and FTA in order to conduct risk analyses, assess design improvements, and control engineering changes.

Course Objectives

- Explain FMEA, "the right way."
- Describe the hazard analysis process.
- Understand hazard analysis at the system level.
- Apply FMEA at the system level.
- Perform safety analysis at the subsystem level.
- Perform reliability analysis at the subsystem level.
- Describe process FMEA.
- Conduct fault tree analysis (FTA).
- Understand FMEA for serviceability.
- Describe how to control engineering changes.
- Explain how to control unresolved hazards.
- Implement FMEA and hazard analysis.

Topics

- Introduction to FMEA
- Design FMEA
- Severity ratings and special characteristics
- Product design occurrence and detection rating determination
- Process FMEA
- Severity rating adjustments for process characteristics
- Identification of special characteristics related to process parameters
- Process design occurrence and detection rating determination

Who Should Attend

Recommended for engineers and managers in design, manufacturing, service, quality assurance, reliability, and research and development. Also recommended for project managers, field service managers, and those in regulatory affairs.

$1095 ▪ Course Code: FME ▪ 1.5 CEUs ▪ 2 Days

APRIL 8 – 9	Edison, NJ
MAY 20 – 21	San Diego, CA
JUNE 10 – 11	Chicago, IL
JULY 8 – 9	San Francisco, CA
AUGUST 5 – 6	Orlando, FL
SEPTEMBER 9 – 10	Dallas, TX
SEP 30 – OCT 1	Edison, NJ

Understanding and Conducting Data Analysis

Variation can (and does) occur anywhere, and professionals who are unaware of this are at a disadvantage when it comes to monitoring and measuring process performance. Precious time can be spent searching for causes of variation that are inherent to the process. Likewise, variation caused by assigned deviations from established performance criteria may remain undetected for a long time, resulting in costly repair and rework. This course is designed to help you avoid these common pitfalls of data analysis.

Course Objectives

- Recognize the difference between common cause variation (inherent to any process) and special cause variation (that can be assigned to a specific root cause).
- Learn the appropriate business strategy to deal with common cause and special cause variation.
- Understand how plotting data helps to determine whether or not special cause variation is present in the process.
- Learn to distinguish between data patterns established over time and data patterns unrelated to time.
- Learn how to study the relationship between two variables through the use of scatter plots.
- Use Minitab™ in support of statistical tools.

Topics

- Understanding variation
- Types of variation and appropriate reaction
- Creating and interpreting plots of variation
  - Time plots
  - Individuals control charts
- Control limits and specification limits
- Studying the distribution of numerical data
  - Frequency distribution (histograms, dot plots, and box plots)
- Pareto principle and Pareto analysis
- Time plots and histograms
- Scatter plots

Who Should Attend

Managers and professionals who are engaged in analyzing process data in order to improve the effectiveness and efficiency of their organization's processes, as well as associated quality, engineering, manufacturing, process, and industrial personnel. Also valuable for anyone involved in a Lean and/or Six Sigma deployment.

This course requires the use of Minitab™ statistical software; attendees are responsible for bringing laptops with Minitab™ 16 to the class.

$1595 ▪ Course Code: DAN ▪ 2.5 CEUs ▪ 3 Days

APRIL 24 – 26	Orlando, FL
MAY 22 – 24	San Diego, CA
JUNE 19 – 21	Chicago, IL
JULY 17 – 19	San Francisco, CA
AUGUST 14 – 16	Edison, NJ
SEPTEMBER 11 – 13	Dallas, TX
OCTOBER 16 – 18	Orlando, FL

Lead Auditor Training for ISO 9001

CERTIFIED QMS LEAD AUDITOR TRAINING COURSE

> "This is an excellent course for any quality professional. The case studies and discussions were helpful. I was able to see things that I might have missed otherwise. Being able to apply the material I was learning really helped me to understand the class."
>
> *– Director of Quality Assurance*

Learn how to assess compliance with ISO 9001 from the industry experts. This course, presented largely through hands-on workshops, teaches you the skills you need to plan, conduct, and follow up on ISO 9001 compliance audits.

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.

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
- Evening sessions for the first four nights
- Final exam (2 hours)

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.

NOTE: This training course is an RABQSA-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 RABQSA certification, please see page 19.

$1795 • Course Code: LAI • 4.4 CEUs • 5 Days

APRIL 8 – 12	Houston, TX	JULY 22 – 26	Denver, CO
APRIL 22 – 26	St. Louis, MO	AUGUST 5 – 9	Orlando, FL
MAY 6 – 10	Los Angeles, CA	AUGUST 19 – 23	Chicago, IL
MAY 20 – 24	Charlotte, NC	SEPTEMBER 9 – 13	Edison, NJ
JUNE 3 – 7	Indianapolis, IN	SEPTEMBER 23 – 27	New Orleans, LA
JUNE 17 – 21	San Francisco, CA	OCTOBER 7 – 11	Houston, TX
JULY 15 – 19	Atlanta, GA		

Internal Auditor Training for ISO 9001

CERTIFIED QMS INTERNAL AUDITOR TRAINING COURSE

> "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*

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 RABQSA-certified internal auditor course includes interactive workshops and discussions so you can return to work and apply what you've just learned.

Course Objectives

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
- Final exam (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 9001-compliant quality system.

This training course is certified by RABQSA and satisfies the training requirement for individuals seeking certification under the RABQSA QMS Internal Auditor Registration Scheme.

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

APRIL 15 – 17	Seattle, WA	JUNE 24 – 26	Washington, DC
APR 29 – MAY 1	New Orleans, LA	JULY 9 – 11	Houston, TX
MAY 13 – 15	Chicago, IL	JULY 22 – 24	Raleigh, NC
MAY 29 – 31	Edison, NJ	AUGUST 5 – 7	St. Louis, MO
JUNE 3 – 5	Indianapolis, IN	AUGUST 12 – 14	Los Angeles, CA
JUNE 17 – 19	San Francisco, CA	AUGUST 26 – 28	Hartford, CT

Lead Auditor Training for AS9100

CERTIFIED QMS LEAD AUDITOR TRAINING COURSE

Learn how to assess conformance from the industry experts. Our AS9100 lead auditor training course uses AS9100C requirements and reflects the revolutionary auditing process described in AS9101D. This course provides auditors with a thorough understanding of the revised standards and the new auditing process. In addition, this course gives a preview of what organization auditors can expect from their certification body (CB) AS9100C audits.

Over five rigorous days, class discussions and workshops cover every phase of the aerospace auditing process so you will be able to lead your own aerospace audits efficiently and effectively.

Course Objectives

Learn the background of the ISO 9000 standards and go through the audit process so you are ready to lead your own audits.

- **QA System Assessment** – Understand the elements of an AS9100C quality management system.
- **The Requirements** – Discuss the implications of the AS9100C requirements.
- **Aerospace Industry Expectations** – Understand the industry requirements for auditor competency specified in AS9104/3; learn how to use the AS9101D assessment process, methodologies, tools, and reports; and discern the impact of regulatory requirements.
- **The Audit** – Become familiar with aerospace auditing activities and responsibilities as reflected in AS9101D.

Topics

- Standards required for the audit
- Preaudit activities, including audit planning necessary to ensure QMS and process effectiveness
- Audit activities, including collecting audit evidence, identifying and documenting nonconformities, analyzing process effectiveness, documenting process effectiveness on Process Effectiveness Analysis Reports (PEARs), and conducting opening and closing meetings
- Postaudit and follow-up activities, including developing audit reports, requesting corrective action, and evaluating effectiveness of actions
- Evening sessions for the first four nights
- Final exam (2 hours)

Who Should Attend

Designed for both internal and external auditors who will be leading auditor teams and for professionals leading corporate AS9100C conformance activities. Perfect if you are involved with your organization's internal auditing process and wish to broaden your understanding of the total audit process. Recommended for anyone heavily involved in supplier quality assurance (SQA) activities.

NOTE: This training course is an RABQSA-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 RABQSA certification, please see page 19.

$1995 ▪ Course Code: LAD ▪ 4.4 CEUs ▪ 5 Days

APRIL 15 – 19	Orlando, FL
MAY 6 – 10	Cleveland, OH
MAY 20 – 24	Wichita, KS
JUNE 10 – 14	Hartford, CT
JULY 15 – 19	Raleigh, NC
JUL 29 – AUG 2	Chicago, IL
AUGUST 19 – 23	Los Angeles, CA
SEPTEMBER 9 – 13	Seattle, WA
SEP 30 – OCT 4	Edison, NJ

Internal Auditor Training for AS9100

Make sure your organization knows how to keep up with the requirements of the aerospace industry. Be a more effective member of your team by gaining the skills to perform an internal audit on an AS9100 quality management system that meets the requirements of AS9100 and AS9101 in the most effective, efficient way.

Take your training from the industry leader – Oriel STAT A MATRIX has been training auditors longer than any other training organization in the world.

This course is modeled after our RABQSA-accredited internal auditor training and includes workshops, case studies, and in-class activities tailored to the evolving aerospace industry, discussions of AS9100 and the AS9101 aerospace auditing process, and pertinent regulations.

Course Objectives

- **Internal Quality Systems Assessment** – Understand the elements of a quality system and AS9100; discuss what third-party assessment agencies look for.
- **The Three Audit Phases** – Understand the requirements for aerospace auditing; become familiar with the auditing process and methodologies; and learn the requirements for planning, on-site, reporting, and follow-up as described in AS9101 and ISO 19011.
- **Planning an Audit** – Understand how to conduct the activities related to documentation and performance results, audit review, and audit plan; use the AS9101 auditing methodologies, tools, and reports.
- **Conducting the Audit** – Apply process-focused auditing techniques and audit the effectiveness of the QMS and its associated processes as required by AS9101 (including use and development of process effectiveness assessment reports, or PEARs); learn to collect objective evidence and document nonconformities and other observations, including techniques for effective questioning and listening.
- **Follow-Up Activities** – Verify effectiveness and adequacy of corrective action, close out an audit, and conduct follow-on surveillances.

Topics

- Overview and interpretation of AS9100
- The quality system
- Preaudit activities, including audit planning, review of documentation and performance results, application of AS9101 audit methodologies and audit trails, and preparation of auditor working documents
- On-site audit activities, including auditing for both conformity and effectiveness and understanding the three process approaches to auditing
- Report writing – audit reports, nonconformity reports (NCRs), and process effectiveness assessment reports (PEARs)
- Corrective action and audit follow-up
- 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 AS9100 quality system. Also great if you are involved in developing, implementing, and/or maintaining an internal audit system that meets the requirements of AS9100 and AS9101.

$1195 ▪ Course Code: IAD ▪ 2.5 CEUs ▪ 3 Days

APRIL 2 – 4	Hartford, CT
APRIL 22 – 24	Los Angeles, CA
MAY 13 – 15	Chicago, IL
MAY 27 – 29	Edison, NJ
JUNE 24 – 26	Dallas, TX
JULY 22 – 24	Orlando, FL
AUGUST 19 – 21	Cleveland, OH
SEPTEMBER 16 – 18	Hartford, CT

Registration Details

Registration Fees

Registration fees are due prior to the start of the course and include all course materials, breakfast, 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

If you register and later find that you can't attend, you may send an alternate in your place or you may select another date based on course and date availability. You must notify us in writing of your alternate's name, the new date, and/or the course replacement.

Substitutions may be made at any time. There is no additional charge for such substitutions.

You may transfer to a different session based on course and date availability. However, if we receive notification of a transfer fewer than 15 business days prior to the start of the course, you will be assessed a service charge equal to 25% of the total tuition.

Cancellations received fewer than 15 business days prior to the course start date will be charged 50% of the entire tuition.

A $25 service charge will be applied for returned checks. Please send written confirmation of cancellations, transfers, or substitutions via email to customerservice@orielstat.com. If you did not attend a course for which you registered and did not cancel 15 business days before the start of that course, your monies will not be refunded.

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.

RABQSA-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 RABQSA-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 accrediting bodies such as IRCA, RABQSA, JAB, and CRBA.

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.

FAX: 732.626.6084, attn: Registration Dept.

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

EMAIL: customerservice@orielstat.com

ONLINE: www.orielstat.com, click on Courses & Registration

Customer Information *(please print)*

Name _____ Title _____

Company _____

Address _____

City _____ State _____ Zip _____

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

Course Code	City	Date(s)	Course Fee
		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 _____

Corrections/Deletions: To make corrections or delete your name, fax entire page to 732.626.6084. We can only correct/delete names that appear on our house mailing list.

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- Supplier Quality
- Quality Systems Documentation

> Hands down, Oriel STAT A MATRIX offers **the best** quality-related business training in the industry.
>
> *– Senior Quality Engineer*