OCTOBER 2025

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Training Course Catalog.

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888- 336- 1124 | www.qualitysupportgroup.com |
319 Littleton Rd # 206. Westford, MA 01886

Training Index.

Management System Standards

APQP and CONTROL PLAN Fundamentals

8 Hour Course

The latest APQP – 3rd Edition & Control Plan- Version 1 manuals have been released by AIAG!

As you may be aware, AIAG has been working on the new APQP and Control Plan manuals for quite some time. The automotive industry OEMs and their supply base have been eagerly awaiting the new manuals, which will soon become mandatory requirements and be added to the US OEM CSR documents. Ford, GM, and Stellantis have already announced that they will accept the usage of these new manuals as soon as they are released, making way for international OEMs and a host of large Tier 1 suppliers to follow suit.

There are significant changes in both the APQP and the new Control Plan manuals, as indications have suggested. They not only address the needs of the latest ICE and hybrid vehicles but also the new electric vehicles. These developments emphasize the importance of new product development and process control more than ever before.

The QSG APQP Training course is taught in an engaging instructor-led format. The instructor will describe the best practices that have made APQP such a successful methodology for improving product quality. Participants will learn the proper course of action for each phase of APQP and will be able to identify the correct inputs and outputs to make the process work as designed.

Participants will have the opportunity to interact with all elements of the APQP process, as well as learn about the other Quality and Reliability Tools that are built into the methodology's framework. Team activities, workshops and other exercises will be used to reinforce the best practices of this methodology to ensure that each participant will be able to put APQP into action for their company's unique production needs.

Value-Add: An ever-growing number of companies must comply with Advanced Product Quality Planning (APQP) requirements. Even those that are not subject to a compliance mandate recognize the APQP process as a product development best practice that improves performance for new product introduction.

Quality system requirements are intended to develop fundamentals that provide for continuous improvement, defect prevention, and the reduction of variation. APQP is at the heart of product development/project implementation and the prime element of successful project success, as it links the special characteristics identified in the project. It then integrates all of the prime tools of IATF 16949, such as FMEA, control plans, feasibility reviews, operator instructions, process flow diagrams, etc.

This course provides valuable information and examples for the successful implementation of the APQP process at companies of all sizes and across industries. It gives the participants the opportunity to work in teams and to implement APQP using actual case studies. Training includes discussions about the use of control plan and relevant data required to construct and determine control plan parameters, as well as the importance of the control plan in the continuous improvement cycle.

VISIT OUR WEBSITE FOR MORE DETAILS

AS13100 Problem Solving Requirements for Aerospace Suppliers

16 Hour Course

This 2-day seminar covers all phases of the team approach to identifying and solving problems, based on the problem-solving requirements defined by AS13000 using the eight-discipline (8D) methodology.

AS13100 and RM13000 define the Problem-Solving standard for suppliers within the aero-engine sector, with the Eight Disciplines (8D) problem solving method as the basis for this standard. Successful application of 8D achieves robust corrective and preventive actions to reduce the risk of repeat occurrences and minimize the cost of poor quality.

This seminar covers all training requirements as specified in Appendix C of AS13000.

VISIT OUR WEBSITE FOR MORE DETAILS

AS13100 Requirements Overview Workshop

4 Hour Course

The AS13100 standard has been created by the SAE G-22 Aerospace Engine Supplier Quality (AESQ) Technical Committee to harmonize and simplify supplier quality requirements that are in addition to the requirements of AS9100 Quality Management Systems – Requirements for Aviation, Space, and Defense Organizations and AS9145 Advanced Product Quality Planning and Production Part Approval Process.

Previously the Aerospace Engine Manufacturers based their supplier quality requirements on 9100 but had differing supplemental requirements and guidance albeit with largely the same intent. These supplemental requirements originate from the need to meet Regulatory, Customer, Industry, and Business requirements that are not explicitly covered by AS9100 and AS9145.

This standard sets out to create a common set of supplemental requirements with common reference materials to improve understanding, efficiency, and performance. While significantly simplifying the businesses of suppliers with multiple customers, the primary intent of this new standard is to improve overall product quality by focusing on the key systems and processes currently deterring consistent aerospace engine product quality.

These common supplemental requirements aim to raise the bar for anticipated performance in these key areas, and therefore detailed guidance is provided to ensure clarity of expectations

*This standard establishes supplemental requirements for AS9100 and AS9145 and applies to any organization receiving it as part of a Purchase Order or other contractual document from a customer.

Participants in this overview workshop will learn the rationale for developing AS13100, management standards alignment, requirements based on organization type, as well as what an organization can do in preparation to meet these new requirements.

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AS13100:2021 Quality Management System Requirements for Aero Engine Design and Production Organizations

24 Hour Course

The AS13100 AESQ (Aerospace Engine Supplier Quality) Supplemental Quality Management System (QMS) Requirements simplifies and harmonizes the aerospace engine manufacturer requirements to its shared supply chain and includes requirements flowed-down to the engine manufacturers by regulators, customers, industry, and business specific requirements. Suppliers with multiple customers will learn how AS13100 minimizes requirements and improves overall product quality by focusing on the key quality systems and processes.

This course provides knowledge and insight for each of the AESQ supplemental requirements. Further, there are workshop activities that give practical application for the Standard requirements. Key concepts and job responsibilities are considered so that participants will gain a detailed understanding of how to understand and apply this Standard within their organization and understand the AESQ strategy to enable the supply chain to achieve Zero Defects.

Training includes the following Overview and Activities/Workshops related to the Reference Manuals:

- RM13000 Problem Solving Methods including 8D
- RM13002 Alternate Inspection Frequency Plans
- RM13003 Measurement Systems Analysis (MSA)
- RM13004 Defect Prevention Quality Tools to support Advanced Product Quality Planning (APQP) and Production
- Part Approval Process (PPAP)
- RM13005 Quality Audit Methods
- RM13006 Process Control Methods
- RM13007 Sub-tier Management
- RM13008 Design Work
- RM13009 AS13100 Compliance Matrix
- RM13010 Human Factors
- RM13011 Managing Rework and Production Repair
- RM13102 First Article Inspection Requirements (FAIR)
- RM13145 Advanced Product Quality Planning (APQP) and Production Part Approval Process (PPAP)

Training also includes practical workshops to enhance understanding and successful application of this standard:

- Identification of Standards and Handbooks that will address in more detail specifics of the AS13100 requirements such as: APQP (Advanced Product Quality Planning) and Supplemental Requirements, PPAP (Production Part Approval Process), Core Defects Prevention, Identifying and controlling Key Characteristics
- Identification and practice in Quality Core Tools such as: Design FMEA, Process Flow Diagrams, Process FMEA, Production Control Plans, Measurement Systems Analysis, and Process Capability Studies

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AS9100D Exemplar Global Certified Lead Auditor Class

40 Hour Course

Based on the current Aviation, Space and Defense requirements of AS9100D, this course engages participants in an in-depth review of the AS9100D standard and the tools to effectively conduct first, second, and third-party party audits to AS9100D. Through simulation case study activities, participants will apply and audit the requirements of AS9100D using auditing techniques as referenced by ISO 19011:2018 and AS9101F.

Upon completion of the AS9100D Lead Auditor training, participants will leave with an understanding of how to avoid, analyze and prevent future nonconformities. As well, leave with the knowledge of how to organize documentation according to AS9100D to demonstrate effective planning, operation, and control of processes.

NOTE: *Individuals desiring to perform third-party audits for a Certification Body will also need to successfully complete the 4-day IAQG-Sanctioned 9100 Aerospace Auditor Transition Training (AATT) course.*

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AS9100D Implementation Fundamentals

16 Hour Course

This AS9100D course is designed to provide training on the implementation of the requirements for a quality management system (QMS) based upon the AS9100D standard. AS9100D includes all the requirements of ISO 9001:2015 along with approximately 105 additional requirements specific to the Aviation, Space, and Defense industry.

This in-depth training course examines the requirements and intent of each clause and subclause of AS9100D, including audit evidence required to demonstrate conformity to AS9100D requirements.

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AS9100D Internal Auditing

20 Hour Course

The aerospace industry has unique requirements for quality management, which is why many companies that deliver products and services within aviation, space, and defense work to earn AS9100 certification. This standard sets quality management system requirements with the challenges of the aerospace industry in mind. AS9100D includes all the requirements of ISO 9001:2015 along with approximately 105 additional requirements specific to the Aviation, Space and Defense industry.

AS9100D Internal Auditing training is designed to provide a working understanding of a quality management system based on the requirements of AS9100D. It prepares internal auditors to perform effective process audits and helps managers and supervisors take full advantage of the internal audit process. Students will gain an understanding of the requirements of AS9100D and its interrelationship with other elements of the ISO family of standards. This course meets the training portion of the requirements for certification of individual internal auditors. Training focuses on the process approach and ensures that you maximize the benefits that implementing a quality standard can bring.

Key Session Topics:

- The Process Approach
  - "Process" definition as used in AS9100D
  - Understanding the focus on processes
  - Defining processes
  - Understanding processes versus activities
  - Explain what certification body auditors will be expecting
- The Metrics-Driven Approach
  - Discussion of the AS9101D Standard
  - Discussion of the auditing requirements cited in AS9101D
- Risk Management
  - Make risk management understandable
  - Define and give good explanations of risk management including numerous examples
  - Explain risk management approaches for different sized companies
  - Introduce several risk management tools including how apply them
- Configuration Management
  - Define configuration management and make the process understandable
  - Explain the requirements for a configuration management system
- Project Management
  - Define project management
  - Explain what is required

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AS9100D Requirements Workshop

8 Hour Course

This course covers the requirements and the application for AS9100D compliance and is designed to provide new AS9100 implementation team members and representatives from key functional groups involved in an organization's AS9100 QMS with the necessary knowledge to support their organization in achieving compliance to AS9100D.

Learn and understand the requirements of AS9100D, the process approach to managing an organization, and the risk-management requirements. This course will cover the requirements of AS9100D and demonstrate how to interpret them within an organization. Participants will gain an understanding of AS9100D,and knowledge related to the requirements for the preparation and execution of the audit process as defined in the Standard.

VISIT OUR WEBSITE FOR MORE DETAILS

AS9120 Requirements for Aviation, Space, and Defense Distributors

8 Hour Course

What is AS9120:2016/AS9120B?

What is AS9120 and who is it for?

AS9120 standardizes quality management system requirements and is used at all levels of the supply chain by organizations around the world. The use of AS9120 results in improved quality, cost, and delivery performance through the reduction or elimination of organization-unique requirements, effective implementation of the quality management system, and wider application of good practice. While primarily developed for the aviation, space, and defense industry, this standard can also be used in other industry sectors when a quality management system with additional requirements over an ISO 9001 system is needed.

The AS9120 Standard is the requirements for a Quality Management System based on AS9100 which adds 100+ additional requirements that are specific to distributors who carry aircraft components like fasteners, electronics, gaskets, etc. It helps ensure that they handle the materials properly and track the part from OEM to customer. AS9120 was developed for pass-through distributors of aerospace items and addresses chain of custody, traceability, control and availability of records.

AS9120:2016 is intended for use by organizations that procure parts, materials, and assemblies and resell these products to customers in the aviation, space, and defense industries. This includes organizations that procure products and split them into smaller quantities, including those that coordinate a customer or regulatory controlled process on the product.

This standard is not intended for organizations that maintain or repair products, or for organizations that perform work that affect or could affect product characteristics or conformity.

This standard includes ISO 9001:2015 quality management system requirements and specifies additional aviation, space, and defense industry requirements, definitions and notes.

Benefits to your organization:

- Understanding and consistency in meeting requirements
- Consideration of processes in terms of added value
- Effective process performance
- Improvement of processes based on evaluation of data and information
- Efficient handling of documentation and records
- Detecting opportunities for operational improvements and reduction of costs
- Eliminate and mitigate business risks

Below is a listing of the core requirements:

- Risk Based Thinking – The concept of risk has always been implicit in ISO 9001 but AS9120:2016 makes it more explicit and builds it into the whole management system. It ensures that risk is considered from the beginning and throughout and makes "prevention" part of strategic and operational planning.
- Clause 6.1 – is related to risks in the quality management system such as new customers, new markets, company partnerships, business localizations etc.
- Concept of Change – Provides a framework which evolves to enable organizations to adapt to their changing environments or circumstances. The benefits of a robust process to control change are that business continuity is maintained and potential consequences of change are appropriately considered.
- Organizational Knowledge – Knowledge specific to the organization is gained by experience and conveyed through lessons, identification of experts and the implementation of succession planning. AS9120:2016 can help you safeguard the organization from loss of knowledge, (e.g., through staff turnover; failure to capture and share information) and encourages your organization to acquire (e.g., learning from experience, benchmarking) and share knowledge (e.g., mentoring of newcomers).
- Product Safety – including requirements to address product safety considerations throughout the product lifecycle.
- Counterfeit Parts Prevention – Provides requirements to mitigate the effects of the growing threat of counterfeit / fraudulent product while recognizing the emerging counterfeit/fraudulent statutory/regulatory requirements on AQMS processes.
- Awareness – AS9120:2016 now requires employees to be aware of their contribution to product or service conformity, to product safety and the importance of ethical behavior.
- Human Factors – Requires the consideration of human factors in the root cause analysis for nonconformities. To do that you must understand the interactions between people, machines and each other and their impact on human performance. Human factors could include physical fitness, physiological characteristics, personality, stress and fatigue to name just a few.
- Obsolescence – In the planning process, you must consider the consequences of product obsolescence.
- Project Management – Requires that you must plan and manage product and service provision in a structured and controlled manner including scheduled events performed in a planned sequence.

- Design and Development of Products and Services – AS9120:2016 now includes a requirement that an organization is to establish, implement, and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services. An organization can determine that this (and any other requirement) is not applicable if its decision will not result in failure to achieve conformity of products and services (see AS9120 4.3 and annex A A.5).

How do we implement AS9120 rev B?
The implementation process is very similar to AS9120 or other ISO 9001 based QMS:

1. Perform a Gap Analysis to determine what your existing QMS needs.
2. Document your system with a Quality Manual and Procedures.
3. Implement the new procedures
4. Audit your system to make sure your procedures are being followed
5. Have a registrar audit your company for certification to ISO 9120

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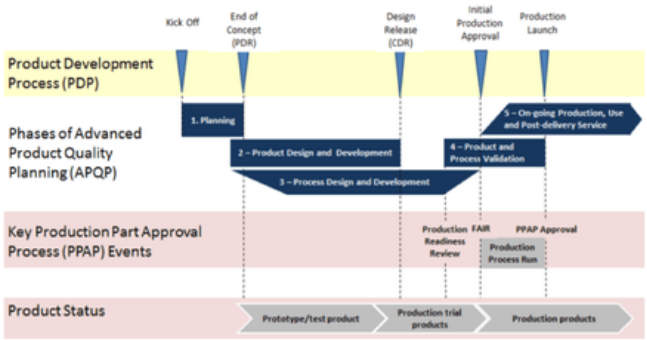
AS9145 / APQP-PPAP Workshop

16 Hour Course

The AS9145 Aerospace standard was created to define the aviation, space, and defense process requirements for Advanced Product Quality Planning (APQP) and Production Part Approval Process (PPAP). The APQP process defines a methodology for ensuring that the product development processes deployed throughout the aviation, space, and defense industries are fully integrated phased processes that extend from concept and design through manufacturing process planning and execution, and on into product use, service, and customer feedback. The PPAP is an output of APQP confirming that the production process has demonstrated the potential to produce products that consistently fulfill all requirements at the customer demand rate.

This AS9145 APQP Workshop is designed to provide participants with an understanding of how the risk management elements of APQP help ensure successful launches based on robust new product development processes and how to employ these tools to manage continual improvement in products and processes. This workshop also provides guidance on the Aerospace PPAP submission requirements and quality tools such as DFMEA, PFMEA, Control Plans, MSA, and SPC.



Aerospace Quality Core Tools

- **Advanced Product Quality Planning (APQP)** is a process that enables a manufacturer to demonstrate that it can design and manufacture a product in line with customer requirements. The main objectives of APQP are effective communication, timely completion of the tasks, reduction of quality issues, and minimization of quality-related risks during product launch. The steps in APQP are: planning, product design and development, process design and development, product and process validation, and finally, on-going production, use and post-delivery service.

- **Failure Mode and Effects Analysis (FMEA)** is a method for identification and prioritization of different modes of failure and resulting effects. The risk represents a relationship between modes of failure, their potential effects, and causes of failure. FMEA has proven itself as a valuable risk assessment tool in the design (DFMEA) and production (PFMEA) process.

- **Measurement Systems Analysis (MSA)** is a method of evaluating variability in the measurement process. It is primarily used to determine the viability of an evaluation or measuring methodology for use on a specific part characteristic. MSA looks at five distinct parameters: bias, linearity, stability, repeatability, and reproducibility, and guidelines for acceptance are "Percent Error to Tolerance" and "Percent Error to Variation."

- **Statistical Process Control (SPC)** is a statistical method applied in quality control, and it is primarily used to monitor and control processes.

- **Product Part Approval Process (PPAP)** is a process of demonstrating that the produced part meets design intent and initial requirements, and that the production process can consistently provide such products. The result of PPAP is a set of documents called the "PPAP package," which needs to be approved by the supplier and the customer to demonstrate that the client's requirements are understood, the product meets the requirements, and the production process is capable of providing conforming product.

These core tools are used during the Product and Process Development phases of New Product Introduction (NPI) and during certain events such as failure investigation or engineering changes. The training methodology from QSG harmonizes and links the inputs and outputs of the core tools to one another. Linking tools increases their value to one another and reduces overall workload.

QSG's AS9145 APQP Workshop is taught by seasoned aerospace industry professionals. It covers the requirements of each of the core quality tools and helps the student understand how to complete the necessary paperwork and forms.

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Certified Manager Of Quality (CMQ)/Organizational Excellence (OE) Certification Training

24 Hour Course

The Certified Manager of Quality (CMQ)/Organizational Excellence (OE) is a professional who leads and champions process improvement initiatives everywhere from small businesses to multinational corporations and can have regional or global focus in a variety of service and industrial settings. They facilitate and lead team efforts to establish and monitor customer/supplier relations, support strategic planning and deployment initiatives, and help develop measurement systems to determine organizational improvement. The CMQ/OE should be able to motivate and evaluate staff, manage projects and human resources, analyze financial situations, determine and evaluate risk and employ knowledge management tools and techniques in resolving organizational challenges.

Through discussion, review, and practice, attendees will become thoroughly familiar with the complete Quality Manager Certification Body of Knowledge (BoK). Class discussions include an in-depth overview of the exam process, along with rationales for correct answers. Sample test questions and answers offer participants a better understanding of the basic principles and applications that will appear on the exam.
This intensive course is designed to quickly and efficiently give students the information, skills, strategies, and techniques to successfully prepare to sit for the ASQ CMQ/OE certification exam offered 4 times a year.

*Taking this course does not constitute or imply the successful passing of the ASQ CMQ/OE certification exam. Participants will need to study the course material and practice questions outside of class.

VISIT OUR WEBSITE FOR MORE DETAILS

Certified Quality Auditor (CQA) Certification Training

21 Hour Course

The Certified Quality Auditor (CQA) is a professional who understands the standards and principles of auditing and the auditing techniques of examining, questioning, evaluating, and reporting to determine a quality system's adequacy and deficiencies. The CQA analyzes all elements of a quality system and judges its degree of adherence to the criteria of industrial management and quality evaluation and control systems.

Through discussion, review, and practice, attendees in this course will become thoroughly familiar with the complete CQA Body of Knowledge (BoK).

TClass discussions include an in-depth overview of the exam process, along with the rationales for correct answers. Sample test questions and answers offer participants a better understanding of the basic principles and applications that will appear on the exam.

This intensive course is designed to quickly and efficiently give students the information, skills, strategies, and techniques to successfully prepare to sit for the ASQ CQA exam offered 4 times a year.

*Taking this course does not constitute or imply the successful passing of the ASQ CQA exam. Participants will need to study the course material and practice questions outside of class.

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Certified Quality Engineer (CQE) Certification Training

30 Hour Course

The Certified Quality Engineer (CQE) is a professional who understands the principles of product and service quality evaluation and control. The CQE Body of Knowledge (BoK) and applied technologies include, but are not limited to, development and operation of quality control systems, application and analysis of testing and inspection procedures, the ability to use metrology and statistical methods to diagnose and correct improper quality control practices, an understanding of human factors and motivation, facility with quality cost concepts and techniques, and the knowledge and ability to develop and administer management information systems and to audit quality systems for deficiency identification and correction.

This course covers the point by point BoK and is designed to assist in preparing each student for the ASQ CQE exam. Completion of this course will not guarantee that participants pass the exam but will greatly increase the probability of success in obtaining certification. Exam applications are obtained through ASQ and must be completed and approved on or before the ASQ application deadlines. The application is not available through QSG and the associated costs of the application process are not included in this program.

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Certified Quality Improvement Associate (CQIA)

16 Hour Course

The Certified Quality Improvement Associate (CQIA) has a basic knowledge of quality tools and their uses and is involved in quality improvement projects, but doesn't necessarily come from a traditional quality area.

Through discussion, review, and practice, participants in this course will become thoroughly familiar with the complete CQIA Body of Knowledge (BoK). Class discussions include an in-depth overview of the ASQ CQIA exam process, along with the rationales for correct answers. Sample test questions and answers offer participants a better understanding of the basic principles and applications that will appear on the exam.

This intensive course is designed to quickly and efficiently give students the information, skills, strategies, and techniques to successfully prepare to sit for the ASQ CQIA certification exam offered 4 times a year.

*Taking this course does not constitute or imply the successful passing of the ASQ CQIA exam. Participants will need to study the course material and practice questions outside of class.

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Certified Quality Inspector (CQI) Certification Training

24 Hour Course

This comprehensive course prepares participants for ASQ's Certified Quality Inspector (CQI) exam with industry-relevant content, pertinent examples, and exam-style practice questions. Training includes a review of all topics in the CQI Body of Knowledge (BoK) in order to reinforce current knowledge, refresh concepts and applications not used in everyday work, and strengthen the exam preparation process.

The course begins with a pretest to identify areas of study on which to focus. Content is then covered in the order of the BoK. A post-test is included so participants can compare pretest and post-test results to verify improvement after completing the course materials.

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Certified Supplier Quality Professional (CSQP) Certification Training

21 Hour Course

The Certified Supplier Quality Professional (CSQP) is a professional who works with an organization's supply chain and suppliers to continuously improve performance of key system components (increase lifecycle, reduce scrap, improve repair processes) by implementing process controls and developing quality assurance plans. The certified supplier quality professional tracks data, identifies improvement projects, and manages cross functional implementation to improve performance of key components and suppliers.

Through discussion, review, and practice, course participants will become thoroughly familiar with the complete CSQP Body of Knowledge (BoK). Class discussions include an in-depth overview of the exam process, along with the rationales for correct answers. Sample test questions and answers offer participants a better understanding of the basic principles and applications that will appear on the exam.

This intensive course is designed to quickly and efficiently give students the information, skills, strategies, and techniques to successfully prepare to sit for the ASQ CSQP certification exam offered 4 times per year.

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Export Compliance Training Seminar for U.S. Comp.

24 Hour Course

The ability to navigate U.S. export regulations is a valuable specialty. This 3-day training program is designed for new and experienced export compliance professionals at all levels to understand the intricacies of U.S. export regulations and procedures administered by the Departments of State, Commerce and Treasury.

Seminar Highlights:

- **Expert Instruction:** Learn from highly respected experts with decades of experience in interpreting and navigating U.S. export controls.
- **Comprehensive Coverage:** Whether your operations involve Export Administration Regulations (EAR), International Traffic in Arms Regulations (ITAR), or Office of Foreign Assets Controls & Embargoes (OFAC), our training provides the tools you need to manage export activities more efficiently and with reduced risk.
- **Interactive Learning:** Engage in a mix of lectures, case studies, and hands-on exercises designed to solidify your understanding and application of export compliance principles.

VISIT OUR WEBSITE FOR MORE DETAILS

IATF 16949:2016 Implementation Workshop

16 Hour Course

Develop the knowledge and skills required to implement an IATF 16949:2016 Automotive Quality Management System and assess your organization's status to meet the requirements of IATF 16949:2016. This in-depth training course examines the requirements and intent of each clause and subclause of IATF 16949, including audit evidence required to demonstrate conformity to IATF 16949 requirements. Using a step-by-step approach, participants learn how to develop an implementation plan, create necessary documentation, and achieve continual quality improvement.

What is IATF 16949?
IATF 16949:2016 is the International Standard for Automotive Quality Management Systems and was developed by The International Automotive Task Force (IATF) members. IATF 16949 emphasizes the development of a process-oriented quality management system that provides for continual improvement, defect prevention and reduction of variation and waste in the supply chain. The goal is to meet customer requirements efficiently and effectively.

What are the benefits of IATF 16949?

- Fosters improved product & process quality
- Provides additional confidence for global sourcing
- Ensures a global quality system approach in the supply chain for supplier/subcontractor service consistency
- Reduces variation, waste and improves the overall efficiency in production levels
- Decreases the number of second party audits
- Provides a common platform to address worldwide quality system requirements
- Streamlines processes and better manage costs
- Provides an opportunity for integration and efficiency
- Manages risk and your supply chain

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IATF 16949:2016 Internal Auditing with Core Tools

24 Hour Course

This ISO 9001/IATF 16949 Internal Auditor with Core Tools course is designed to enhance participants' understanding of process auditing techniques. Using interactive presentations, simulated audits, and case studies, students develop practical audit skills, improve evaluation and communication skills, refine reporting skills, and sharpen their ability to implement appropriate corrective actions.
The course includes a detailed review of the technical specification IATF 16949:2016. This is a clause-by-clause review so that students understand the complete set of requirements that impact not only their audits but the organization's QMS.

This course also includes a review of the Automotive Core Tools and how they can be incorporated into your audit program. They include Advanced Product Quality Planning(APQP), Production Part Approval Process (PPAP), Failure Mode and Effects Analysis (FMEA), Statistical Process Control (SPC) and Measurement System Analysis (MSA).

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IATF 16949:2016 Requirements Workshop

8 Hour Course

IATF 16949:2016 is a technical specification for the automotive sector quality management systems. The IATF 16949:2016 standard incorporates applicable automotive customer-specific requirements and is a supplement to ISO 9001:2015 requirements for automotive production and relevant service part organizations. This ISO/IATF 16949 overview is beneficial to all levels of an organization who are interested in learning the requirements of this standard. Group exercises and case studies with examples from the automotive industry will be used to develop the required skills.

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IEC 62366-1:2015+AMD1:2020 – Applications to Usability Engineering

16 Hour Course

IEC 62366-1:2015+A1:2020 specifies a process for a manufacturer to analyze, specify, develop and evaluate the usability of a medical device as it relates to safety. This course provides a detailed presentation across 12 topics listed below and includes key check points and questions to ask as the design progresses towards the design transfer stage. A 60 Question Quiz to help practice and reinforce key concepts covered in the session.

This course includes extensive hands-on study of the standard using application examples to reinforce learning. Depending on the duration a complete case study may be used to enable participants to get firsthand experience of how to apply and meet the requirements of the standard. Time permitting some customization, and application to participant's products may also be discussed.

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Internal Quality Auditing Foundations

8 Hour Course

This 8-hour course distills down best practices in conducting internal quality audits within any industry. Audit planning, execution, finding classification, and reporting are discussed, as well as the use of key auditing tools such as turtle diagrams, pareto diagrams, fishbone diagrams, 5-why process and more.

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Introduction to International Traffic in Arms Regulations (ITAR)

24 Hour Course

International Traffic in Arms Regulations (ITAR) is a set of United States government regulations under the Arms Export Control Act (AECA) that control the export and import of defense-related articles and services on the United States Munitions List (USML).

The Department of State Directorate of Defense Trade Controls (DDTC) interprets and enforces ITAR. Its goal is to safeguard U.S. national security and further U.S. foreign policy objectives.

The U.S. Department of Commerce Export Administration Regulations (EAR) are the rules by which the Bureau of Industry and Security (BIS) regulates and controls exports of goods from the United States. All goods and services that are not covered under the State Department's US Munitions (USML) list fall within the preview of the EAR, under the Commerce Control List (CCL). Now that Export Control Reform (ECR) is taking effect, attention to the EAR is even more important.

If your company deals with defense equipment, supplies, services or technologies, the ITAR regulations specify that you share these items only with U.S. persons and organizations unless you receive authorization from the DDTCor qualify for a special license exemption. If your company offers commercial or dual-use items under the control of the Commerce Control List (CCL) of the EAR, similar restrictions are applicable. Companies and individuals may face potentially heavy fines or penalties for providing foreign persons with access to ITAR or EAR-protected and restricted items.

What makes an effective compliance program?

- Registration with DDTC (if required)
- Active and documented compliance policy and procedures
- Training for all employees involved with exporting
- Denied parties watch list screening
- Internal audits and continuous improvement discipline
- Third-Party Audits – Annual

If you are part of a large corporation with ITAR or EAR compliance related employees or a small company with a part-time compliance person, QSG has the compliance and training expertise to fit your exact needs.

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ISO 13485:2016 Internal Auditing

20 Hour Course

ISO 13485:2016 is the quality management system that governs medical devices upon which compliance with regulatory and customer compliance can be built. It embodies an agreed upon, repeatable way of managing design, production, validation, quality, and risk management. At the heart of ISO 13485:2016 is a comprehensive risk management process meant to be implemented in all medical device-related quality management processes within an organization, including processes that occur after the medical devices are placed on the market.

QSG's ISO 13485:2016 Internal Auditor workshop teaches the fundamental concepts of ISO 13485:2016 and will explain in detail how to integrate the requirements into a quality management system. In addition, this class will teach the principles and practices of effective internal audits in accordance with ISO 19011:2018, "Guidelines on Auditing Management Systems". Experienced instructors explain the clauses of ISO 13485:2016 in detail and guide students through internal audits to assure value to their business and regulatory authorities. Students gain the necessary auditing skills through a balance of formal classroom tutorials, practical role-playing, group workshops, and open forum discussions.

The emphasis of ISO 13485:2016 focuses on process effectiveness, efficacy, and safety and thus requires a different approach to auditing. A "value-add" perspective for audits is needed!

Auditing is a cost-effective means of improving the organization. To be useful, audits must be performed and presented in a meaningful approach. To change practices for the better, audit results must be in business terms and appeal to the interests of the various stakeholders.

This course is designed to enhance your understanding of process auditing techniques. Using interactive workshops, simulated audits and case studies, you will develop practical audit skills, improve evaluation and communication skills, refine reporting skills and sharpen your ability to implement corrective action programs.

VISIT OUR WEBSITE FOR MORE DETAILS

ISO 13485:2016 Lead Auditor, Exemplar Global Certified

32 Hour Course

This course prepares you to perform effective audits of Medical Device Quality Management Systems. You'll learn how to interpret the verbiage of the 13485 Standard and apply it to your own organization. We also cover the requirements of 21 CFR 820, the federal regulations governing medical device management systems. We'll take you through the full audit process, including: audit planning and preparation, opening meetings, document review, interviewing auditees, closing meetings and reporting as defined in ISO 19011. Training includes easy-to-use tools to simplify the auditing process.

This is a practical, how-to course that is not bogged down in academic discussions. We use case studies, role-plays, and other real-life practice exercises to keep the training active and build competence.

This is a four-day, instructor-led, course. There are written tests on each of the competency units on days 2, 3, and 4. Days 1 and 2 will cover medical device auditing along with a corresponding competency exam (MD). Day 3 will cover management systems auditing (AU) along with a corresponding competency exam. Day 4 will cover lead auditor requirements with a competency exam (TL).

VISIT OUR WEBSITE FOR MORE DETAILS

ISO 13485:2016 Requirements Workshop

4 Hour Course

ISO 13485 is the most common medical device QMS regulatory standard in the world. It is focused on maintaining QMS effectiveness and meeting regulatory and customer requirements. Since different countries often have different standards, ISO 13485 is intended to provide a globally harmonized model of QMS requirements for international markets.

The guidelines for maintaining effective quality management processes outlined in ISO 13485 are all geared toward the safe design, manufacture and distribution of effective medical devices. In addition to being a regulatory requirement, an ISO 13485-compliant QMS makes good business sense because it helps device manufacturers minimize variation. This in turn provides economic benefits in the form of reduced scrap and general process efficiencies.

The FDA's QSR is structured differently than ISO 13485 but they have no conflicting requirements. And because the QSR is a regulation, it is often more specific than ISO 13485.

For instance, the QSR has more detailed requirements in the areas of complaint handling and reporting requirements. Therefore, conformity to ISO 13485 does not sufficiently demonstrate to the FDA that a manufacturer is in full compliance with the QSR.

The FDA is in the process of harmonizing U.S. quality system requirements with ISO 13485, and plans to issue a notice of proposed rulemaking in 2021. For the time being, separate guidance remains in effect. Until the QSR's shift to ISO 13485 requirements is fully completed, compliance with the QSR is required for manufacturers planning to distribute medical devices in the U.S. Additionally, if a device maker based in the U.S. wishes to market its products internationally, it must comply with both the QSR and ISO 13485 manufacturing standards.

Key requirements of ISO 13485:2016 include:

- Alignment of global regulatory requirements
- Inclusion of risk management and risk-based decision making throughout the quality management system
- Requirements and clarity with validation, verification, and design activities
- Supplier control processes
- Focus regarding feedback mechanisms
- Explicit requirements for software validation for different applications
- Alignment of global regulatory requirements
- Validation using pre-clinical and clinical evaluations
- Validation of packaging and distribution requirements
- A feedback section, including a new complaint-handling section and other guidance for customer communications
- Additional improvement measures: adding the use of post-market surveillance, risk-based decisions, and timelines

QSG's ISO 13485:2016 Requirements Workshop provides a comprehensive review/explanation of this standard. ISO 13485:2016 is explained clause-by-clause with examples from various industries to illustrate individual concepts. This workshop provides a general understanding of the necessary concepts of the standard and its impact on day-to-day operations of organizations in the medical devices industry

VISIT OUR WEBSITE FOR MORE DETAILS

ISO 14971:2019 Risk Management Requirements Workshop

8 Hour Course

ISO 14971:2019 "Medical devices — Application of risk management to medical devices" defines a standard process for identifying risks associated with medical devices at all stages in a device's life cycle, from product design to production and post-production use. The goal of ISO 14971 training is to develop a risk management plan that prioritizes that **an effective quality system should systematically identify, analyze, evaluate, control, and monitor risk throughout the product life cycle** to ensure that the devices are safe and effective.

To help understand ISO 14971:2019, the course will use ISO 24971:2020 "Medical devices—Guidance on the application of ISO 14971" which is a companion document. Tools and techniques described in ISO 24971:2020 will be used to demonstrate how risks can be assessed and evaluated.

Risk management is a key focus of the new QMSR regulation, with an emphasis on integrating risk management principles throughout the QMS. Manufacturers need to fully understand the relationship between ISO 13485 and ISO 14971, with a focus on life cycle risk management starting from design to post-market to ensure full compliance with the new regulation that goes live in 2026. In alignment with this regulatory advancement, FDA is proactively training pre-market and post-market CDRH personnel on both ISO 13485 and ISO 14971. **If you work in medical devices, this is your call to action: get trained on ISO 13485:2016 and ISO 14971:2019.**

What does this mean practically for industry? Compliance with every part of ISO 13485:2016 that explicitly discusses risk management is required and could be subject to regulatory inspection and consequences for noncompliance. The totality of the risk management system that wraps around and enhances all the risk-related clauses in ISO 13485 is highly suggested (by FDA) to be designed to comply with ISO 14971.

VISIT OUR WEBSITE FOR MORE DETAILS

ISO 26262:2018 Automotive Functional Safety Certification

40 Hour Course

ISO 26262 is the Functional Safety standard that is applied to Safety Related Systems that include electric/electronic systems installed in production passenger vehicles, trucks & busses, and motorcycles. This ISO 26262 certification course is designed to help participants become Functional Safety Certified Automotive Engineers.

Training covers all 12 parts of the ISO 26262 standard and includes the information necessary to understand the standard and move their organizations toward conformance. There is an optional ISO 26262 Certification exam at the end of the class for those wanting to demonstrate and document their knowledge.

Training combines presentations, along with in-class group exercises to put what you are learning into practice. Concepts are reinforced by a running case study of an air bag system. Forms are used to complete the exercises as a part of the integrated workshops that include Item Definition, Hazard Analysis and Risk Assessment (HARA), Safety Goals, ASIL levels, Functional Safety Concept, Technical Safety Concept, and Hardware/Software Interface.

VISIT OUR WEBSITE FOR MORE DETAILS

ISO 31000 – Risk Management

8 Hour Course

Product risk management can be approached in different ways and this class presents a framework for evaluating product risk based on the product life cycle. The cycle begins when a product or service is conceptualized and ends when the institution stops offering it or the consumer stops using it (voluntarily or involuntarily). Each stage of the cycle can be subject to its own risks and challenges. This class covers various approaches to managing risk at each product stage using ISO 31000 as a process to assess both risks and challenges.

VISIT OUR WEBSITE FOR MORE DETAILS

ISO 45001 Internal Auditing

16 Hour Course

ISO 45001 is an Occupational Health and Safety (OHS) international standard that provides a framework for an organization to proactively manage the risks and opportunities associated with workplace hazards in order to prevent work-related injury and ill health to workers. This management system framework is based on the Plan-Do-Check-Act model, augmented with requirements for visible support and commitment by top management, and the engagement and involvement of workers. The intended outcome is to provide a safe and healthy workplace.

This standard has been designed to be integrated into an organization's overall Management System (MS) and implemented seamlessly with its Quality and/or Environmental Management System, such as ISO 9001 and ISO 14001.

This highly interactive course takes students through all stages of an internal OHS MS audit, using realistic case studies and exercises to emphasize the business value gained from conducting effective audits. Through workshops, discussions, and role-plays, participants will learn to develop an effective audit program, and how to plan, conduct, and report results in accordance with ISO 19011, Management System Auditing Guidelines. This course will help students learn to accurately interpret and audit against the ISO 45001:2018 requirements. Participants can use these skills to establish or enhance an existing internal audit program and perform internal OHS MS audits in a manner that provides the greatest business benefit.

VISIT OUR WEBSITE FOR MORE DETAILS

ISO 45001 Overview

ISO 45001 is an Occupational Health and Safety (OHS) international standard that provides a framework for an organization to proactively manage the risks and opportunities associated with workplace hazards in order to prevent work-related injury and ill health to workers. This management system framework is based on the Plan-Do-Check-Act model, augmented with requirements for visible support and commitment by top management, and the engagement and involvement of workers. The intended outcome is to provide a safe and healthy workplace.

This standard has been designed to be integrated into an organization's overall Management System (MS) and implemented seamlessly with its Quality and/or Environmental Management System, such as ISO 9001 and ISO 14001.

This interactive course takes students through each of the clauses of ISO 45001, providing an overview of the key requirements. Through discussions and team exercises, participants will understand the underlying concepts of:

- Organizational Context,
- Hazard identification & Risk Assessment,
- Worker participation and consultation,
- Leadership and Commitment, and
- Improvement of OHSMS and OHS performance

This course will help students learn to accurately interpret the ISO 45001:2018 requirements. Participants can use these skills to establish or enhance an existing Occupational Health and Safety program in a manner that provides the greatest business benefit.

VISIT OUR WEBSITE FOR MORE DETAILS

ISO 45001:2018 Lead Auditor, Exemplar Global Certified

32 Hour Course

ISO 45001 is a milestone! As the world's first International Standard dealing with health and safety at work, ISO 45001, Occupational health and safety management systems – Requirements with guidance for use, offers a single, clear framework for all organizations wishing to improve their OH&S performance. Directed at the top management of an organization, it aims to provide a safe and healthy workplace for employees and visitors. To achieve this, it is crucial to control all factors that might result in illness, injury, and in extreme cases death, by mitigating adverse effects on the physical, mental and cognitive condition of a person – and ISO 45001 Lead Auditor training covers all those aspects.

While ISO 45001 draws on OHSAS 18001 – the former benchmark for OH&S – it is a new and distinct standard, not a revision or update, and is due to be phased in gradually over the next three years. Organizations will therefore need to revise their current thinking and work practices to maintain organizational compliance.

Are you involved in or responsible for the planning, implementation or maintenance of the Occupational Health and Safety (OHS) management system? If so, the QSG's ISO 45001 Lead Auditor training course is suitable for you.

This course is designed to help participants understand the requirements of ISO 45001:2018 to conduct a successful audit. Training includes hands-on workshops to prepare for real-life auditing situations, and participants will learn to manage the audit process and complete reporting.

This is a four-day, instructor-led classroom course. There are written tests on each of the competency units on days 2, 3, and 4. Days 1 and 2 will cover ISO 45001 along with a corresponding competency exam (OH). Day 3 will cover management systems auditing (AU) along with a corresponding competency exam. Day 4 will cover leading management systems audit teams (TL) along with a corresponding competency exam.

VISIT OUR WEBSITE FOR MORE DETAILS

ISO 9001:2015 Implementation

16 Hour Course

This course is designed to provide an overview of the requirements for a quality management system based on ISO 9001:2015. Participants will gain an understanding of the requirements of ISO 9001:2015 and learn how to successfully implement.

This course gives you a complete review of the ISO 9001:2015 standard that includes the process approach to business, risk-based thinking, and the 14 implementation steps.

You'll learn how to identify business processes and quality metrics, create level I policy documents and level II procedures, and examine the audit program management process with a case study. You'll also learn the stage 1 and stage 2 registration process as well as the upgrading requirements.

VISIT OUR WEBSITE FOR MORE DETAILS

ISO 9001:2015 Internal Auditing

20 Hour Course

This ISO 9001 Internal Auditor Training course employs a metrics-driven, process-based approach to the theory and practice of conducting value-added audits of the ISO 9001:2015 quality management system. It prepares internal auditors to perform effective process audits and helps managers and supervisors take full advantage of the internal audit process. Training includes a detailed review of all elements of ISO 9001:2015 its effective implementation, and the benefits of quality management systems. This course meets the training portion of the requirements for certification of individual internal auditors. Training also addresses the requirements of ISO 19011 Auditing Standard.

VISIT OUR WEBSITE FOR MORE DETAILS

ISO 9001:2015 Lead Auditor, Exemplar Global Certified

40 Hour Course

ISO 9001 is the international standard for a quality management system (QMS). To be certified to the ISO 9001 standard, a company must follow the requirements set forth in the ISO 9001 Standard. The standard is used by organizations to demonstrate their ability to consistently provide products and services that meet customer and regulatory requirements and to demonstrate continuous improvement.

This course is designed to help participants understand the requirements of ISO 9001:2015 in order to conduct a successful audit. Training includes hands-on workshops to prepare for real-life auditing situations, and participants will learn to manage the audit process and complete reporting.

VISIT OUR WEBSITE FOR MORE DETAILS

ISO 9001:2015 Leadership Workshop

2 Hour Course

This workshop is focused on your leadership team and how the ISO 9001:2015 Standard will affect your business. The ISO 9001:2015 International Standard encourages more internal and external stakeholder focus as part of a risk-based and process-based approach to quality management. It also emphasizes that adopting a Quality Management System (QMS) is a strategic decision for the organization.

VISIT OUR WEBSITE FOR MORE DETAILS

ISO 9001:2015 Requirements Workshop

4 Hour Course

This workshop will provide participants with insight into the content and intent of the ISO 9001:2015 Standard. Instructors have had extensive experience in and responsibility for developing and deploying ISO 9001 compliant quality management systems in the United States and around the world. There will be ample opportunity to ask questions of these experts, which will facilitate efficient and effective ISO 9001:2015 implementation.

VISIT OUR WEBSITE FOR MORE DETAILS

ISO 9001:2015 Risk and Opportunity Based Thinking

8 Hour Course

During this course participants will learn to implement both Risk Based and Opportunity Based Thinking found in the ISO 9001:2015 Standard. Instruction includes lectures and hands-on activities that demonstrate how to effectively implement both, with a focus on how both Context of the Organization and the Process Approach facilitate the identification of both Risks and Opportunities.

The Context of the Organization focuses on both the external and internal environments of an organization that influence both risk and opportunities. The Process Approach applies to the management of processes and their interactions that can result in both risks and opportunities.

VISIT OUR WEBSITE FOR MORE DETAILS

ISO 9001:2015/IATF 16949:2016 Exemplar Global Lead Auditor Training

40 Hour Course

This five-day course was developed to cover all requirements of both the ISO 9001:2015 and IATF 16949:2016 standards, including the new IATF 16949 requirements for Internal and Second Party Auditors (clauses 7.2.3 and 7.2.4) regarding Core Tools and Customer-Specific Requirements. Group exercises and case studies with examples from the automotive industry will be used to develop the required auditing skills. The auditing guidelines of ISO 19011—including the auditing process and methodologies, e. g., planning and conducting an audit, writing nonconformity statements, preparing an audit summary and report, and verifying corrective actions—and their application in the automotive process approach are covered. Auditing case studies from the automotive industry to develop skills for identifying nonconformities will be used. Techniques for leading audit teams will also be discussed.

VISIT OUR WEBSITE FOR MORE DETAILS

ISO/IEC 17025:2017 Implementation Workshop

16 Hour Course

ISO/IEC 17025 specifies the general requirements for the competence to conduct tests and/or calibrations, including sampling. It covers testing and calibration quality systems using standard methods, non-standard methods, and laboratory-developed methods.

ISO/IEC 17025:2017 consists of five elements: Scope, Normative References, Terms and Definitions, Management Requirements, and Technical Requirements. The two main sections are Management Requirements and Technical Requirements. Management Requirements are primarily related to the operation and effectiveness of the laboratory's quality management system. Technical Requirements includes factors that determine the correctness and reliability of the tests and calibrations performed by the laboratory.

VISIT OUR WEBSITE FOR MORE DETAILS

ISO/IEC 17025:2017 Internal Auditing

16 Hour Course

ISO/IEC 17025 specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration quality systems using standard methods, non-standard methods, and laboratory-developed methods.

ISO/IEC 17025:2017 consists of five elements: Scope, Normative References, Terms and Definitions, Management Requirements, and Technical Requirements. The two main sections are Management Requirements and Technical Requirements. Management Requirements are primarily related to the operation and effectiveness of the laboratory's quality management system. Technical Requirements includes factors that determine the correctness and reliability of the tests and calibrations performed by the laboratory.

In this course participants will be introduced to the principles of auditing, will be provided with an approach for developing, implementing, and managing an audit program, will learn the audit process and several audit methods for collecting, verifying, and recording objective evidence, and will discuss audit risks. Numerous hands-on audit activities, including developing and using checklists, are incorporated throughout the course to allow participants to begin to leverage their knowledge gained during the course.

VISIT OUR WEBSITE FOR MORE DETAILS

ISO/IEC 17025:2017 Requirements Workshop

8 Hour Course

ISO/IEC 17025 specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration quality systems using standard methods, non-standard methods, and laboratory-developed methods.

ISO/IEC 17025:2017 consists of five elements: Scope, Normative References, Terms and Definitions, Management Requirements, and Technical Requirements. The two main sections are Management Requirements and Technical Requirements. Management Requirements are primarily related to the operation and effectiveness of the laboratory's quality management system. Technical Requirements includes factors that determine the correctness and reliability of the tests and calibrations performed by the laboratory.

This comprehensive training course on the requirements of ISO/IEC 17025: 2017 will provide participants with a detailed understanding of the concepts and requirements of the standard together with an overview of the steps required to implement the standard with a view to becoming independently accredited. The course covers basic quality concepts such as customer focus, the process approach, continual improvement and risk management.

The course addresses the relationship between ISO/IEC 17025 and ISO 9001, the difference between certification and accreditation, and provides an overview of the content of ISO/IEC 17025, followed by an in-depth examination of each clause of the standard. These include impartiality, confidentiality, organization and responsibilities, personnel, facilities and environment, equipment, traceability, purchasing, subcontracting, contract review, methods, sampling, measurement uncertainty, quality control, reporting, complaints, nonconformance handling, IT systems, records, document control, risks and opportunities, corrective action, improvement, internal audit and management review.

VISIT OUR WEBSITE FOR MORE DETAILS

Lead Auditor Training Based on ISO 13485:2016 and International MDSAP Audit Model, Exemplar Global Certified

40 Hour Course

Medical device auditing requires technical knowledge as well as a deep understanding of international medical device regulations. This five-day training course is focused on international MDSAP and ISO 13485 compliant medical device requirements and auditing methods. Course participants will gain knowledge and skills to conduct audits of ISO 13485:2016 management system requirements in accordance with the new MDSAP Audit Model.

The course provides extensive practical training and hands-on exercises that will help prepare medical device auditors to identify critical nonconformities and meet international regulatory requirements. During training participants will learn to plan, conduct, report, and follow up on QMS audits in accordance with ISO 13485:2016 and MDSAP. Auditing standards include MDSAP requirements, ISO 19011, and ISO 17021 (MDSAP auditors need to follow ISO 17021).

VISIT OUR WEBSITE FOR MORE DETAILS

Managing Organizational Risk Using the Supplier Audit Program

16 Hour Course

In this new global economy, more than 50% of value creation is achieved outside of an organization's walls, or through their suppliers. In the United States, recent studies show that 100% of manufacturers' finished products include at least one element obtained from outside of their organization. This new reality, and the increased emphasis on supplier control in federal regulations, ISO 9001, and the various industry-specific quality management system standards, require that quality professionals have a thorough understanding of the supply chain management processes that control supplier selection and management. It is also necessary to understand where the quality function fits within the overall supply chain management process and how it interacts with other functions within that process.

Quality and quality audits are an important part of the supply chain management process. Conducting a successful supplier audit can be used as a means to identify, assess, and mitigate organizational risk. Audits can be combined with Lean and Six Sigma methodologies to help drive supplier improvement. Audits can also help foster communication and build relationships (and unfortunately the opposite can also be true).

This course provides a broader than usual review of the supply chain management process from the quality perspective and includes unique applications of the supplier audit process. It helps participants understand where the quality function fits within the overall supply chain management process, as well as how it interacts with other functions within that process. Most importantly, we discuss best practices in supplier auditing and how quality audits can be used beyond traditional conformance verification. The course includes training on how to implement a robust remote auditing program, and case studies are shared to demonstrate best practices in supply chain management and supplier quality auditing, and to help identify suboptimal practices to avoid.

VISIT OUR WEBSITE FOR MORE DETAILS

Production Part Approval Process (PPAP)

8 Hour Course

PPAP process training defines requirements for initial production approval (including production and bulk materials). The objective is to determine if all customer specifications and requirements are properly understood by the supplier. Also confirming that the process has the potential to produce product consistently and reliability to these requirements, under actual production run and rate conditions.

PPAP is often mandated by automotive, aerospace, and other engineering primary manufacturers as a specific requirement on their suppliers to give them assurance that the supplier understands the customer's product specifications and that the supplier's manufacturing process has the potential to produce good quality product at agreed quality levels and production rates.

VISIT OUR WEBSITE FOR MORE DETAILS

Supplier Auditing ISO 13485:2016 with MDSAP

8 Hour Course

Medical device supplier auditing requires technical knowledge as well as a deep understanding of international medical device regulations. It also requires that auditors maintain a balance between the needs of the suppliers and their customers. Students participating in this course will gain knowledge and skills to conduct supplier audits that support ISO 13485: 2016 management system requirements and the MDSAP Audit Model.

Although ISO 13485: 2016 may have recognition in many parts of the world, the Medical Device Single Audit Program (MDSAP) offers the opportunity to demonstrate compliance with the regulatory requirements of up to five participating countries: Australia, Brazil, Japan, Canada, and the United States. In this training program, participants gain insights on requirements for suppliers from both, and therefore can become better skilled auditors when it comes to dealing with suppliers. This affords the opportunity to reduce or eliminate potential nonconformances related to suppliers.

Through training participants will learn how to plan, conduct, report, and follow up on supplier audits that enable compliance with requirements from both ISO 13485:2016 and MDSAP. This 2-day course uses the principles/practices of effective supplier audits that are a combination of the deep and rich experience of the instructor blended with suitable elements from ISO 19011:2018, "Guidelines on Auditing Management Systems." The instructor has spent decades in various roles in the medical device industry, and has coached thousands of professionals in R&D, Design, Manufacturing, Supply Chain Management, Quality, and Regulatory functions.

Participants will gain much needed understanding and practice auditing skills through a balance of formal classroom tutorials, practical role-playing, group workshops, and open forum discussions. This course provides extensive practical training and hands-on exercises that will help prepare participants to identify nonconformities, write the same, and create reports that are succinct and easy to understand. These in turn facilitate proper action on the part of suppliers to eliminate / prevent nonconformances.

Upon completion of training, participants will be capable of conducting supplier audits that support ISO 13485:2016 and jurisdiction requirements of the countries participating in the MDSAP program as they apply tosuppliers in the medical device field.

VISIT OUR WEBSITE FOR MORE DETAILS

VDA 6.3 Process Auditor

16 Hour Course

VDA 6.3 was published for the first time in 1998 and was revised in 2010, 2016 as well as 2023 (present edition).
What has changed compared to the 2016 version?

- Software aspects have been taken into consideration in the questionnaire
- The content of this volume has been harmonized with further VDA methods, namely Automotive SPICE® and maturity level assurance for new parts (VDA MLA)
- Requirements regarding purchasing activities were added to P3 and P4
- Specification of the auditor qualification
- Notes on conducting remote audits were added
- Chapter 4 ("Audit process") was deleted, as its contents are included in ISO 19011
- Chapter 8 ("Process audit services") was deleted from VDA Volume 6.3

- Chapter 10 ("Best practice/lessons learned") was deleted
- The evaluation of transport and parts handling (EU7) was omitted
- In some cases, questions with special significance (*-questions) were redefined
- Some of the questions regarding the potential analysis were reallocated
- A comprehensive online glossary for all VDA volumes was established
- Editorial revision

What has remained the same?

- The classification system (A, B, C) for the overall assessment
- The structure of the questionnaire
- The evaluation model for the individual questions (10-8-6-4-0)
- The applicability of process elements P2–P7 according to Figure 2-1
- The Turtle Model
- Previous downgrading rules

During the revision, the distinction between process and system audits was once again explicitly considered. The current IATF requirements have been observed.

For products with integrated (embedded) software, the interface between hardware and software has been strengthened. However, for a detailed evaluation of the software development, the Automotive SPICE® method should be used.

Due to the changes that have been made, the results of audits conducted according to the present volume are not directly comparable to the results of audits carried out in accordance with the previous edition from 2016.

This two-day course is designed to introduce the process audit approach as it applies to the VDA 6.3 (2023) standard. This course will help you understand the process audit and offer guidance on its use. Using the process approach and the respective customer-specific requirements, this course teaches you the basics for qualification as VDA 6.3 Process Auditor.

The introduction to the basics of process auditing includes general requirements, methods, principles, assessment scheme and risk analysis.

The course will also apply to conducting a process audit to VDA 6.3 as required by many European customers to the automotive industry. VDA 6.3 is one of many documents produced by the VDA (Verband der Automobilindustrie), an interest group of the German automobile manufacturers and component suppliers. It has been adopted by German automakers as a supplier requirement.

Each participant will receive a seminar manual with case studies and a guide for conducting a process audit to VDA 6.3.

VISIT OUR WEBSITE FOR MORE DETAILS

Regulatory Standards (FDA/ISO 13485/MDSAP)

Design Controls Concepts and Implementation

8 Hour Course

The successful development of medical devices requires that the design be controlled to ensure product safety and that the device can fulfill its intended use. This course provides a practical understanding of the engineering value of design control throughout the product lifecycle as it pertains to product quality. It includes the practical implementation of the design history file, reviews and records, transfer planning, engineering requirements and project planning. You will also learn topics related to design verification and validation testing, such as process validation and packaging validation. This highly interactive course engages the learner with an in-depth discussion of industry best practices to learn how industry leaders address design control challenges. Exercises are designed to build a solid understanding of developing and applying design control requirements.

VISIT OUR WEBSITE FOR MORE DETAILS

FDA Mock Audits (QSIT Audit) Workshop

16 Hour Course

Inspections by the FDA can be challenging and there are consequences if you do not meet the requirements. This course is designed to provide pharmaceutical professionals with the information required to prepare for and understand what will happen during a mock audit and during a Pre-Approval Inspection (PAI). For the latter, it details what the FDA looks for, among other related, in-depth topics. Mock audits are useful tools that help identify non-compliance and gaps beforehand. Furthermore, they provide an understanding of where issues lie, in order to address them proactivelyand effectively, before an actual inspection occurs by the FDA.

VISIT OUR WEBSITE FOR MORE DETAILS

FDA Requirements Training

8 Hour Course

Food and Drug Administration (FDA) 510(k) clearance is a requirement to market medical device products in the United States. Consequently, medical device companies must determine the best regulatory path to bring their products to market, as well as what is needed to complete the 510(k) process, and when a 510(k) must be submitted.

This course provides participants with an overview of the FDA regulatory approval process, with a focus on avoiding regulatory issues and unnecessary expenses. Participants will also learn how to submit a successful Premarket Notification 510(k) Submission for a device or a device change as quickly and efficiently as possible and ensure a 510(k) submission can be quickly reviewed and cleared by the FDA in order to stay ahead of the competition.

VISIT OUR WEBSITE FOR MORE DETAILS

Good Manufacturing Practices (GMP) Training

8 Hour Course

In the United States, a government agency, the Food and Drug Administration (FDA), establishes regulations that govern the sale of food, drugs, biologics and medical devices. FDA requires that manufacturers in these industries establish and maintain quality systems to ensure that their products meet the usability and safety needs of their customers. Quality systems for products that are governed by the FDA are based on Good Manufacturing Practices or GMPs.

The GMP compliance requirements for medical devices are outlined in the Code of Federal Regulations (CFR), most prominently in the FDA Quality System Regulations of 21 CFR Part 820. This part establishes the requirement for quality systems in medical device companies, mandating quality procedures such as design controls, CAPA process, quality assurance and quality control activities, document controls and more.

GMP Training requirements also include other portions of the CFR. 21 CFR Part 812 deals with investigational device exemptions, allowing devices to be shipped lawfully for the purpose of clinical investigations when they would otherwise be required to comply with a performance standard or to have premarket approval. 21 CFR Part 808 addresses exemptions from Federal regulation of state and local medical device requirements.

VISIT OUR WEBSITE FOR MORE DETAILS

IEC 62366-1:2015+AMD1:2020 – Applications to Usability Engineering

16 Hour Course

IEC 62366-1:2015+A1:2020 specifies a process for a manufacturer to analyze, specify, develop and evaluate the usability of a medical device as it relates to safety. This course provides a detailed presentation across 12 topics listed below and includes key check points and questions to ask as the design progresses towards the design transfer stage. A 60 Question Quiz to help practice and reinforce key concepts covered in the session.

This course includes extensive hands-on study of the standard using application examples to reinforce learning. Depending on the duration a complete case study may be used to enable participants to get firsthand experience of how to apply and meet the requirements of the standard. Time permitting some customization, and application to participant's products may also be discussed.

VISIT OUR WEBSITE FOR MORE DETAILS

Implementing the EU's New Medical Device Regulation (MDR 2017/745) Workshop, Exemplar Global Certified

24 Hour Course

The EU Medical Device Regulation (MDR) is far more complex than the Medical Device Directive (93/43/EEC) it replaces and presents new challenges, including strict new requirements for Clinical Data, risk management, postmark surveillance, and supplier management.

QSG's three-day course on the Medical Device Regulation 2017/745, with a focus on the requirements for Medical Device Manufacturers, provides comprehensive instruction on the EU MDR. It covers every aspect of the regulation and identifies key topics and changes, including economic operators and new roles associated with EU MDR, standard requirements that must be met by all manufacturers regardless of class, and the pre- and post-market requirements of conformity assessment.
In the course, you will receive a general overview of the Medical Device Regulation, the Implementation Timelines, Paths to CE Mark, and a deep dive into the significant articles that affect medical device manufacturers.
Included in the presentation is a copy of the MDR, a gap analysis template, and a sample of the General Safety and Performance Requirements checklist with highlights of significant differences from the MDD Annex I Essential Requirements Checklist.

VISIT OUR WEBSITE FOR MORE DETAILS

ISO 13485:2016 Internal Auditing

20 Hour Course

ISO 13485:2016 is the quality management system that governs medical devices upon which compliance with regulatory and customer compliance can be built. It embodies an agreed upon, repeatable way of managing design, production, validation, quality, and risk management. At the heart of ISO 13485:2016 is a comprehensive risk management process meant to be implemented in all medical device-related quality management processes within an organization, including processes that occur after the medical devices are placed on the market.

QSG's ISO 13485:2016 Internal Auditor workshop teaches the fundamental concepts of ISO 13485:2016 and will explain in detail how to integrate the requirements into a quality management system. In addition, this class will teach the principles and practices of effective internal audits in accordance with ISO 19011:2018, "Guidelines on Auditing Management Systems". Experienced instructors explain the clauses of ISO 13485:2016 in detail and guide students through internal audits to assure value to their business and regulatory authorities. Students gain the necessary auditing skills through a balance of formal classroom tutorials, practical role-playing, group workshops, and open forum discussions.

The emphasis of ISO 13485:2016 focuses on process effectiveness, efficacy, and safety and thus requires a different approach to auditing. A "value-add" perspective for audits is needed!

Auditing is a cost-effective means of improving the organization. To be useful, audits must be performed and presented in a meaningful approach. To change practices for the better, audit results must be in business terms and appeal to the interests of the various stakeholders.

This course is designed to enhance your understanding of process auditing techniques. Using interactive workshops, simulated audits and case studies, you will develop practical audit skills, improve evaluation and communication skills, refine reporting skills and sharpen your ability to implement corrective action programs.

VISIT OUR WEBSITE FOR MORE DETAILS

ISO 13485:2016 Lead Auditor, Exemplar Global Certified

32 Hour Course

This course prepares you to perform effective audits of Medical Device Quality Management Systems. You'll learn how to interpret the verbiage of the 13485 Standard and apply it to your own organization. We also cover the requirements of 21 CFR 820, the federal regulations governing medical device management systems. We'll take you through the full audit process, including: audit planning and preparation, opening meetings, document review, interviewing auditees, closing meetings and reporting as defined in ISO 19011. Training includes easy-to-use tools to simplify the auditing process.

This is a practical, how-to course that is not bogged down in academic discussions. We use case studies, role-plays, and other real-life practice exercises to keep the training active and build competence.

This is a four-day, instructor-led, course. There are written tests on each of the competency units on days 2, 3, and 4. Days 1 and 2 will cover medical device auditing along with a corresponding competency exam (MD). Day 3 will cover management systems auditing (AU) along with a corresponding competency exam. Day 4 will cover lead auditor requirements with a competency exam (TL).

VISIT OUR WEBSITE FOR MORE DETAILS

ISO 13485:2016 Requirements Workshop

4 Hour Course

ISO 13485 is the most common medical device QMS regulatory standard in the world. It is focused on maintaining QMS effectiveness and meeting regulatory and customer requirements. Since different countries often have different standards, ISO 13485 is intended to provide a globally harmonized model of QMS requirements for international markets.

The guidelines for maintaining effective quality management processes outlined in ISO 13485 are all geared toward the safe design, manufacture and distribution of effective medical devices. In addition to being a regulatory requirement, an ISO 13485-compliant QMS makes good business sense because it helps device manufacturers minimize variation. This in turn provides economic benefits in the form of reduced scrap and general process efficiencies.

The FDA's QSR is structured differently than ISO 13485 but they have no conflicting requirements. And because the QSR is a regulation, it is often more specific than ISO 13485.

For instance, the QSR has more detailed requirements in the areas of complaint handling and reporting requirements. Therefore, conformity to ISO 13485 does not sufficiently demonstrate to the FDA that a manufacturer is in full compliance with the QSR.

The FDA is in the process of harmonizing U.S. quality system requirements with ISO 13485, and plans to issue a notice of proposed rulemaking in 2021. For the time being, separate guidance remains in effect. Until the QSR's shift to ISO 13485 requirements is fully completed, compliance with the QSR is required for manufacturers planning to distribute medical devices in the U.S. Additionally, if a device maker based in the U.S. wishes to market its products internationally, it must comply with both the QSR and ISO 13485 manufacturing standards.

Key requirements of ISO 13485:2016 include:

- Alignment of global regulatory requirements
- Inclusion of risk management and risk-based decision making throughout the quality management system
- Requirements and clarity with validation, verification, and design activities
- Supplier control processes
- Focus regarding feedback mechanisms
- Explicit requirements for software validation for different applications
- Alignment of global regulatory requirements
- Validation using pre-clinical and clinical evaluations
- Validation of packaging and distribution requirements
- A feedback section, including a new complaint-handling section and other guidance for customer communications
- Additional improvement measures: adding the use of post-market surveillance, risk-based decisions, and timelines

QSG's ISO 13485:2016 Requirements Workshop provides a comprehensive review/explanation of this standard. ISO 13485:2016 is explained clause-by-clause with examples from various industries to illustrate individual concepts. This workshop provides a general understanding of the necessary concepts of the standard and its impact on day-to-day operations of organizations in the medical devices industry

VISIT OUR WEBSITE FOR MORE DETAILS

Lead Auditor Training Based on ISO 13485:2016 and International MDSAP Audit Model, Exemplar Global Certified

40 Hour Course

Medical device auditing requires technical knowledge as well as a deep understanding of international medical device regulations. This five-day training course is focused on international MDSAP and ISO 13485 compliant medical device requirements and auditing methods. Course participants will gain knowledge and skills to conduct audits of ISO 13485:2016 management system requirements in accordance with the new MDSAP Audit Model.

The course provides extensive practical training and hands-on exercises that will help prepare medical device auditors to identify critical nonconformities and meet international regulatory requirements. During training participants will learn to plan, conduct, report, and follow up on QMS audits in accordance with ISO 13485:2016 and MDSAP. Auditing standards include MDSAP requirements, ISO 19011, and ISO 17021 (MDSAP auditors need to follow ISO 17021).

VISIT OUR WEBSITE FOR MORE DETAILS

Managing Organizational Risk Using the Supplier Audit Program

16 Hour Course

In this new global economy, more than 50% of value creation is achieved outside of an organization's walls, or through their suppliers. In the United States, recent studies show that 100% of manufacturers' finished products include at least one element obtained from outside of their organization. This new reality, and the increased emphasis on supplier control in federal regulations, ISO 9001, and the various industry-specific quality management system standards, require that quality professionals have a thorough understanding of the supply chain management processes that control supplier selection and management. It is also necessary to understand where the quality function fits within the overall supply chain management process and how it interacts with other functions within that process.

Quality and quality audits are an important part of the supply chain management process. Conducting a successful supplier audit can be used as a means to identify, assess, and mitigate organizational risk. Audits can be combined with Lean and Six Sigma methodologies to help drive supplier improvement. Audits can also help foster communication and build relationships (and unfortunately the opposite can also be true).

This course provides a broader than usual review of the supply chain management process from the quality perspective and includes unique applications of the supplier audit process. It helps participants understand where the quality function fits within the overall supply chain management process, as well as how it interacts with other functions within that process. Most importantly, we discuss best practices in supplier auditing and how quality audits can be used beyond traditional conformance verification. The course includes training on how to implement a robust remote auditing program, and case studies are shared to demonstrate best practices in supply chain management and supplier quality auditing, and to help identify suboptimal practices to avoid.

VISIT OUR WEBSITE FOR MORE DETAILS

Process and Software Validation

24 Hour Course

This three-day Process and Software Validation training course is designed for professionals in the Pharmaceutical, Medical Device, Biotech, Biopharmaceutical and Skin/Cosmetic industries who are responsible for process and/or software validation.

VISIT OUR WEBSITE FOR MORE DETAILS

Process Validation for the Medical Device and Pharmaceutical Industries

24 Hour Course

The Medical Device and Pharmaceutical industries share the common goal of bringing safe and effective products to market as quickly and efficiently as possible. Process Validation is a formal methodology that allows companies to manufacture products on approved and qualified equipment, with a defined process leading to products that consistently meet predetermined specifications and quality requirements. This course provides an understanding of the regulatory requirements for process validation and their relationship to the Medical Device QSR and the Pharmaceutical cGMPs, and prepares participants to plan and operate a compliant validation program.

VISIT OUR WEBSITE FOR MORE DETAILS

Process Validation: Principles and Protocols

24 Hour Course

The FDA defines process validation as: "The collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality products."

This process validation training course provides an interactive approach to process validation. Class discussions focus on typical strategies for completing process validations, and through hands-on exercises, course participants gain practical experience with the planning, execution, and reporting of process validation.

VISIT OUR WEBSITE FOR MORE DETAILS

Purchasing Controls Introduction

8 Hour Course

This hands-on learning opportunity covers the key aspects of supplier controls – from planning for supplier assessment and selection, to defining acceptance activities and monitoring supplier performance – and links them to the requirements found in the ISO 13485 Standard, pertinent International Medical Device Regulators' Forum (IMDRF) and Global Harmonization Task Force (GHTF) guidance. During this 1-day course, you will learn how to evaluate your organization's compliance with FDA/ISO requirements for purchasing controls and acceptance activities, consider appropriate risk mitigation strategies for supplied products and services, and implement a life cycle management approach to your organization's supply chain.

VISIT OUR WEBSITE FOR MORE DETAILS

QMSR ISO 13485 Integration – 2024 Changes to FDA 21 CFR 820

4 Hour Course

In February 2024, the FDA published the final rule for the Quality Management System Regulation (QMSR), integrating ISO 13485:2016 standards. This article details the QMSR's implications, emphasizing the strategic adjustments medical device companies must make for compliance.

The QMSR applies to manufacturers, contract sterilizers, installers, relabelers, remanufacturers, repackers, specification developers, and initial distributors of foreign manufacturers. Additionally, component manufacturers are encouraged to voluntarily comply with the QMSR.

The harmonization between QSR and ISO 13485 addresses several challenges medical device manufacturers face. Historically, navigating the differences between regulatory regimes has been complex and resource-intensive. Misalignment between QSR and international standards often led to duplicative efforts, increased compliance costs, and delayed market entry. Manufacturers looking to enter the U.S. have been unable to fully leverage their ISO 13485 compliance, while U.S. manufacturers looking to enter the E.U. have needed double compliance to align their QSR-compliant quality systems to ISO 13485.

Harmonization offers a strategic solution to mitigate these challenges while fostering several key benefits:

- **Global Market Access:** By aligning regulatory requirements, harmonization promotes mutual recognition of standards, facilitating market access across diverse regions.
- **Enhanced Consistency:** Harmonization fosters consistency and clarity in regulatory expectations, reducing ambiguity and interpretation discrepancies.
- **Operational Efficiency:** Harmonization streamlines processes, eliminates redundancies, and optimizes resource allocation, enabling manufacturers to focus on innovation and product development.

Risk management is a requirement throughout ISO 13485:2016 and this course covers a summary for risk management in each of the elements.

This half (1/2) day training will inform you on recent FDA 21 CFR 820 changes to Quality Management System Regulations (QMSR), especially related to the integration of ISO 13485:2016.

VISIT OUR WEBSITE FOR MORE DETAILS

Software Development for Medical Device Manufacturers: FDA QSR, QMSR, ISO 13485 and IEC 62304

16 Hour Course

Developing software in compliance with FDA regulations, Guidance documents and international standards is challenging. This course helps medical device manufacturers develop software in a manner that is both compliant and practical.

Day 1 is focused on the recently announced FDA Quality Management System Regulation (QMSR). The existing Design Control Regulation (QSR) has been replaced with ISO 13485:2016. Differences and similarities between the existing QSR and the new QMSR regulations are discussed. In addition, the requirements of ISO-13485 section 7.3 are discussed from the perspective of software development. Corresponding requirements from IEC 62304 Medical Device Software Lifecycle Processes are included. Current FDA Guidance documents and international standards that pertain to software are reviewed as well as requirements for SaMD.
Day 2 is focused on Risk Management including Safety Risk Management, as defined by ISO 14971:2019, and Security Risk Management, as defined by ANSI/AAMI SW96:2023.
Day 2 also includes recommendations on Writing Requirements for Software and Software Tool Validation for software development tools and software used in Manufacturing and in QMS.

The training is presented in an interactive style with time allotted for discussions. Questions are encouraged!

VISIT OUR WEBSITE FOR MORE DETAILS

Supplier Auditing ISO 13485:2016 with MDSAP

16 Hour Course

Medical device supplier auditing requires technical knowledge as well as a deep understanding of international medical device regulations. It also requires that auditors maintain a balance between the needs of the suppliers and their customers. Students participating in this course will gain knowledge and skills to conduct supplier audits that support ISO 13485: 2016 management system requirements and the MDSAP Audit Model.

Although ISO 13485: 2016 may have recognition in many parts of the world, the Medical Device Single Audit Program (MDSAP) offers the opportunity to demonstrate compliance with the regulatory requirements of up to five participating countries: Australia, Brazil, Japan, Canada, and the United States. In this training program, participants gain insights on requirements for suppliers from both, and therefore can become better skilled auditors when it comes to dealing with suppliers. This affords the opportunity to reduce or eliminate potential nonconformances related to suppliers.

Through training participants will learn how to plan, conduct, report, and follow up on supplier audits that enable compliance with requirements from both ISO 13485:2016 and MDSAP. This 2-day course uses the principles/practices of effective supplier audits that are a combination of the deep and rich experience of the instructor blended with suitable elements from ISO 19011:2018, "Guidelines on Auditing Management Systems." The instructor has spent decades in various roles in the medical device industry, and has coached thousands of professionals in R&D, Design, Manufacturing, Supply Chain Management, Quality, and Regulatory functions.

Participants will gain much needed understanding and practice auditing skills through a balance of formal classroom tutorials, practical role-playing, group workshops, and open forum discussions. This course provides extensive practical training and hands-on exercises that will help prepare participants to identify nonconformities, write the same, and create reports that are succinct and easy to understand. These in turn facilitate proper action on the part of suppliers to eliminate / prevent nonconformances.

Upon completion of training, participants will be capable of conducting supplier audits that support ISO 13485:2016 and jurisdiction requirements of the countries participating in the MDSAP program as they apply to suppliers in the medical device field.

VISIT OUR WEBSITE FOR MORE DETAILS

Full Course Descriptions: www.qualitysupportgroup.com
Please contact Chris Scangas with inquiries:
888-336-1124 | chris@qualitysupportgroup.com

Lean Thinking

A3 Thinking/Problem Solving

16 Hour Course

A3 Thinking is part tool, part methodology, designed to help teams identify the most critical aspects of a problem using the PDCA cycle, then using that information to create a one-page story. A3s are valuable coaching tools, as they provide a window into the learner's thought process.

The goal with A3 Thinking is to develop a consistent, sustainable process for planning and problem-solving, as well as improving collaboration throughout the entire organization. While the format for an A3 Action Plan may vary depending upon the nature of the problem to be solved, the constraint placed by the "A3" paper size (approx. 11×17") creates the need to focus on the most critical aspects of the current condition, and then systematically apply countermeasures to achieve a substantially improved target condition.

The emphasis of A3 is placed on a strong visual presentation of both before and after conditions, to create a compelling argument to implement. Key measures and milestones highlight the benefits of executing the plan as well as creating a cadence for improvement.

The A3 process involves several steps, including:

Definition of the Problem
Clearly and briefly describe and state the problem and its impact on the organization.

Data Gathering
Collect data and evidence to help understand the problem and identify potential root causes.

Data Analysis
Use cause and effect diagrams, flow charts, and process maps to analyze the data and identify root causes.

Solution Development
Generate and evaluate potential solutions, selecting the most promising ones for further development.

Implementation Plan
Implement the selected solutions and verify that they effectively resolve problems.

Standardize and Institutionalize
Document the problem-solving process and share the results with the organization to encourage continuous improvement.

Download these documents as needed:

Managing to Learn — Detailed A3 Template
A3 Strategy Form

VISIT OUR WEBSITE FOR MORE DETAILS

Acceptance Sampling

8 Hour Course

Organizations must have some method for minimizing the total cost of inspecting from incoming, intermediate, and outgoing product inspections and at the same time not jeopardize quality of product reaching the production line or the customer.
One of the alternatives to 100% inspection of product is Sampling Inspection, also known as Acceptance Sampling. The purpose of Acceptance Sampling is to determine the disposition of goods or services (accept, reject, or screen). This is done by selecting the disposition that minimizes the cost of inspection to achieve a desired level of quality.

VISIT OUR WEBSITE FOR MORE DETAILS

Basic Quality Tools for Process Improvement

8 Hour Course

Basic Quality Tools for Process Improvement (sometimes included in the 7 Quality Tools) introduces participants to statistical methods that can be used by people with little formal training in statistics. Although called basic, these methods are nonetheless very powerful. Kaoru Ishikawa, awarded the Deming Prize in Japan for his many contributions to the field of quality, noted that these methods can be used to solve the vast majority of quality-related issues.

Ishikawa was influenced by a series of lectures presented by the late Dr. W. Edwards Deming in Japan in the early 1950s. In the wake of Deming's teaching, companies began training their workforces in statistical quality control. Unfortunately, the complexity of the subject matter was intimidating to many workers; so companies scaled back the training to focus on simpler – or more basic – techniques that are sufficient for most quality and process problems.

VISIT OUR WEBSITE FOR MORE DETAILS

Creating Manufacturing Cells

16 Hour Course

Cellular Manufacturing design is a reorganizational system for workplace design that is integral to Lean Manufacturing. In cellular manufacturing, work cells and equipment are arranged to support a smooth flow of materials to minimize the time it takes for a single product to flow through the entire production process. Benefits of cellular manufacturing include increased productivity and quality, and work cells can simplify management and even accounting systems, in addition to material flow.

QSG provides a structured approach to cellular manufacturing design that has proven effective in companies worldwide. It is based on fundamentals rather than imitation of other cells. QSG also provides support in how to handle emotional, political, and organizational issues.

VISIT OUR WEBSITE FOR MORE DETAILS

Data Mining – Advanced

16 Hour Course

Advanced Data Mining covers techniques able to handle vast numbers of input variables, correlated input variables, and complex relationships. These additional tools equip the user to perform exploratory data analysis, simplify problems, characterize relationships, set up advanced multivariate process control, and deal with binary response data. This course covers multivariate analysis methods which are ideally suited for today's big data environment.

Specifically, methods are discussed for multivariate testing with MANOVA, reducing complexity, detection of outliers or clusters, visualizing correlation with PCA, performing multivariate control, finding drivers for categorical responses with discriminant analysis, and handling short fat tables (more variables than rows with potentially correlated inputs) using PLS models.

VISIT OUR WEBSITE FOR MORE DETAILS

Data Mining – Basic

16 Hour Course

In today's data rich environment, vast amounts of data are routinely collected. These are termed 'happenstance', 'non-experimental', or 'observational' data. The role of statistics with such observational data is to extract all available information – often called Data Mining – and in particular to identify the Key Process Input Variables (KPIVs) for use in process improvement and process control. With a suitable sampling plan and a knowledge of how to prepare data for analysis, the engineer or researcher can then use statistical methods, much like a detective looking for clues, to release otherwise hidden information from data, providing the basis for correct decisions.

Observational data require special techniques and care in order to extract meaningful information and reach valid conclusions. Observational data are common in most process industries and can yield valuable information from normal process data without resorting to designed experimental data, which may be more costly to obtain. This course gives basic methods to compare a single input to a single output. It covers discrete or continuous inputs with continuous outputs and discrete inputs with discrete outputs. The methods introduced here are building blocks for more advanced data mining techniques as well as the basis for single factor experiments.

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Data Mining – Intermediate

16 Hour Course

Intermediate Data Mining extends upon the methods covered in the Basic Data Mining to build models containing multiple inputs simultaneously. This course covers multi-factor ANOVA, multiple regression, and introduces logistic regression.

Models with multiple inputs require special attention to build but offer a potentially more sensitive method to find key process input variables or model output performance. Included are logistic regression methods to model discrete outputs such as conforming/non-conforming which is particularly useful when quality problems are experienced. These methods can be used to troubleshoot processes, find potential root causes, characterize complex relationships between inputs and outputs, and even suggest optimums from observational data.

VISIT OUR WEBSITE FOR MORE DETAILS

Implementing a KanBan Pull System

8 Hour Course

A Kanban Pull System is a Lean technique that is used to control the flow of work by only replacing what has been consumed. This means that the trigger for work to be done is when a customer demands it. To better visualize a Pull System, take for example a vending machine. Products will only be replenished when the stocks have run out. Suppliers won't overstock the vending machine because each lane has a set capacity. If there is no demand for the product, then they won't replenish it.

In the vending machine example, the customer pulls products from the vending machine. Having an empty rack is a signal for the vending company to tap their brand partners to replenish their stocks. Therefore, the vending company also pulls products from the brand partners. All these happen because they act according to customer demand.

This Kanban workshop provides participants with a thorough understanding of the tools and techniques for the design and implementation of a Consumption Based Replenishment System. Students will gain comprehensive knowledge of the proper use and implementation techniques of a pull system utilizing Kanban and the warnings of inappropriate/ill-timed implementation.

VISIT OUR WEBSITE FOR MORE DETAILS

Lean 6S

8 Hour Course

6s is a systematic approach for productivity, quality, and safety improvement that is applicable to all types of business. Established by Toyota in the 1950s as 5S, a sixth S has been added to increase the focus on Safety. In addition to Safety, the other five S represent five Japanese disciplines for maintaining visual control at a workplace – Seiri, Seiton, Seiso, Seiketsu, and Shitsuke – that can be translated from the Japanese to *Sort, Set in Order, Shine, Standardize, and Sustain.*

The 6s methodology focuses on having visual order, organization, cleanliness, and standardization. It simplifies and organizes a work environment, and reduces waste and non-value activity, while improving quality, efficiency, and safety. *And a well- organized workplace motivates people.*

Participants in this course will gain valuable insight into the 6S methodology through theoretical training and hands-on application. Additionally, QSG offers to work with participants' organizations in the development of strategic 6S planning, execution, and tracking of a 6s program.

VISIT OUR WEBSITE FOR MORE DETAILS

Lean Fundamentals

32 Hour Course

Lean and Lean Six Sigma are methodologies that companies can apply to ALL aspects of their businesses (NOT just manufacturing and supply chain processes); tangible improvements and benefits can be realized in transactional, service, and other divergent business environments. The fundamental basis for the success of Lean and Lean Six Sigma methods in all facets of an organization is the ability to identify waste, reduce it, and aggressively eliminate non-value-added activities and improve response to customer bases, whether internal or external.

Lean Fundamentals is an in-person training course that helps develop critical skills required for participating in successful Lean projects.

VISIT OUR WEBSITE FOR MORE DETAILS

Lean Manufacturing Basics

16 Hour Course

Lean is a set of time-tested, widely implemented management practices that creates value from the perspective of the customer, improves flow, and promotes respect for people. This class will introduce the tools that contribute to a continuous improvement process that can be applied to any type of organization.

Lean's systematic approach helps to reduce process cycle time, improve delivery time (or overall efficiency), and provide an optimal setting for continuous improvement toward a desired condition state.

With Lean, businesses or organizations focus on eliminating in-house waste and activities that add no value to the customer. Lean enterprise refers to an entire supply chain or industry operating under compatible Lean systems and processes. This course from QSG covers the Lean Core Tools, what Lean is, why it matters, and how to lay the groundwork for a successful Lean journey.

What it comes down to is this: Lean removes waste. Waste is broken down into seven distinct areas:

- Transport
- Inventory
- Motion
- Waiting
- Over-Processing
- Overproduction
- Defects

All these wastes have a direct impact on your costs, they are all non-value adding operations, operations that your customer would not be happy to pay for and add no value to the product or service that you provide. Studies prove that we only add value for around 5% of the time within our operations, the remaining 95% is waste. Imagine if you could remove that 95% wasted time and effort, what would it do for your operations?

Lean manufacturing is also used to:

- Improve delivery performance
- Develop better customer satisfaction
- Improve employee morale and involvement
- Improve quality performance with fewer defects and rework
- Initiate faster development
- Operate with fewer machines and process breakdowns
- Operate with less space required

VISIT OUR WEBSITE FOR MORE DETAILS

Lean Simulation

8 Hour Course

Through an interactive simulation of a typical factory, participants in this course explore Lean concepts. The simulation begins with a mock factory in which departments operate with little coordination and poorly conceived goals. Participants apply Lean concepts to the simulation in multiple improvement cycles to arrive at an optimal factory, as defined by the Customer.

VISIT OUR WEBSITE FOR MORE DETAILS

Lean Six Sigma Green Belt

40 Hour Course

Lean Six Sigma is a powerful process improvement system that helps businesses streamline processes, reduce waste and increase productivity.

The Lean Six Sigma Green Belt Certification provides a comprehensive and thorough training that builds superior problem-solving and analytical skills.

This 5-day course combines classroom training with practical applications. Prior to training, you'll attend a webinar to identify and charter a project. During class, you'll receive training and tools that provide structure for LSS problem-solving. Individual and team exercises reinforce key concepts which you apply on your project. At the end of the course, you'll take the Green Belt examination. Minimum score of 80% to receive certification.

Participants should bring a laptop PC and a basic calculator. After your training, we'll provide 1 hour of personal project coaching and all templates.

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Manufacturing Business Simulation

8 Hour Course

Empower your employees to think like business owners!

Using a unique Celemi® board-based business simulation, teams of four participants form the incoming management team of A&O Inc., an established company that is facing tough challenges. The company is not profitable, is losing market share, and there are increasing demands from suppliers and customers. A&O Inc. needs a new, disciplined financial strategy, and participants are asked to provide one.

Participants simulate three years of business performance, making changes that triple profitably, create a lot of cash, and take Return on Assets from 9% to almost 20% and Return on Owners Equity from 5% to 16%. The highly interactive simulation is closely tied to their reality. A variety of challenges and some fun competition help participants learn by doing.

Through a series of exercises, participants also learn firsthand how to monitor cash flow, better utilize resources, and improve productivity. Participants will work with the balance sheets and Profit & Loss statements, learn how to measure results, and understand how their daily decisions impact the company financially and strategically.

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Measurement System Analysis (MSA) for Accuracy, Tool Matching, and Stability

8 Hour Course

There are generally four items of interest when developing or qualifying a measurement system: accuracy or bias, precision, linearity, and stability. The MSA for Gauge R&R is concerned with precision. This second course covers the remaining items of accuracy or bias, linearity, and stability, along with comparisons and matching of measurement tools regarding accuracy and precision.

Stability is addressed with LTS, long-term stability, monitors. A Type 1 gauge study provides a quick assessment of repeatability, bias, and stability and is suitable for a quick check of measurement performance, perhaps in R&D applications. A bias and linearity study gives guidance on calibration and accuracy issues. Finally, the course discusses measurement tool matching using a paired t-test, orthogonal regression, correlation for gauge linearity, an omnibus test for both accuracy and precision and ANOVA for repeated trial data.

VISIT OUR WEBSITE FOR MORE DETAILS

Measurement System Analysis (MSA) for Gauge R&R

12 Hour Course

Fundamental to collecting data on any process or equipment is a characterization of measurement. This includes variables data such as CMM measurements, laboratory measurements, or any measurements made on a continuous scale, as well as attribute inspection data into categories (e.g. pass/fail or defect categories). Data, which do not come from an accurate measurement system, may lead to erroneous conclusions.

This course provides the participants with an understanding of basic measurement process terminology including discrimination or resolution, bias, accuracy, precision, repeatability and reproducibility, along with measurement precision assessment. It provides the methodology to plan, conduct, analyze, and interpret measurements system capability study, which includes a gauge repeatability and reproducibility (R&R) study for variables data and attribute measurement study techniques for attribute data such as inspection processes. Questions such as operator differences, gauge drift issues, overkill, and escapes are addressed.

VISIT OUR WEBSITE FOR MORE DETAILS

Process Mapping

8 Hour Course

Dr. W. Edwards Deming defined a system as “a series of functions or activities (sub-processes, stages – hereafter components) that work together for the aim of the organization.” He added that the flow chart (or process map) is helpful toward understanding a system. Process mapping is a technique that provides a structural analysis of a process flow. It can be used to distinguish how work is actually being done from how it should be done. It’s very important to map the actual situation (“As Is” or “Current State”) to identify opportunities for improvement. Further study leads to mapping how the process “Should Be” (or Future State) once improvements are achieved.

Moving beyond basic process mapping, Value Stream Process Mapping (VSPM) can be viewed as a means to expose waste that’s hiding in the organization’s systems and processes. It is used to quantify the flow of throughputs, as well as waste, rework, wait time, and other drains on resources. It is a technique that is easily and effectively applied in any type of process: manufacturing, laboratory, health care, retail, office, school, etc.

Here a few examples of different types of process maps:

- **Flowcharts** are high-level overviews of processes that focus on events, decisions, and the steps involved in a process.
- **Swimlane diagrams** offer another level of detail, by defining the business units that undertake a specific process.
- **Value stream maps** cover the entire value chain from start to finish, mapping out roles, responsibilities, and the resources needed to complete a process.
- **SIPOC maps** diagram the supplier, input, process, output, and customer.
- **Deployment maps** offer a more general overview of processes and are intended for stakeholders.

In this dynamic workshop, participants will learn to apply powerful process mapping techniques to their own processes. They will leave with a powerful new skill set for dealing with future process problems in their organizations.

VISIT OUR WEBSITE FOR MORE DETAILS

Single Minute Exchange of Dies (SMED)

8 Hour Course

Single-Minute Exchange of Die (SMED) is a Lean production method for reducing waste in a manufacturing process. It provides a rapid and efficient way of converting a manufacturing process from one product to the next. SMED is also often referred to as Quick Changeover (QCO). Performing faster changeovers is important in manufacturing, or any process, because they make low-cost, flexible operations possible.

SMED was developed in Japan during the 1950s and 1960s by industrial engineer Shigeo Shingo, to help Toyota and other manufacturing firms reduce costly inventories and improve efficiency. At the time, almost all changeover work was performed while machines were down (i.e., not running). Shigeo Shingo made a distinction between changeover work that occurs while a machine is down, Internal Setup, and preparatory work that can occur while a machine is running, called External Setup.

The term "Single-Minute" refers to the objective of reducing startups and changeovers to single digit minutes (in other words, less than 10 minutes). The closely related yet more challenging concept of One-Touch Exchange of Die (OTED) states that changeovers can and should take less than 100 seconds.

The SMED philosophy breaks setup down further, into four stages:

1. In the preliminary stage there is no distinction between internal and external work, and all setup work is combined.
2. In the second stage, external setup and internal setup are identified and separated.

3. In the third stage, work that was previously included in the internal setup is transferred to external setup.
4. The fourth stage specifies continuous improvement of all internal and external setup work.

Shigeo Shingo's data from between 1975 and 1985 documents reductions in changeover times averaging over 90%, for a range of manufacturing companies. However, SMED provides additional improvements that stem from a systematic examination of operations, including:

- A reduction in the footprint of processes, with reduced inventory freeing floor space
- Productivity increases/reduced production time
- Increased machine work rates from reduced setup times, even when the number of changeovers increases
- Reduced defect rates due to the elimination of setup errors and trial runs
- Improved quality stemming from fully regulated operating conditions
- Increased safety due to simpler setups
- Simplified housekeeping due to fewer tools and better organization
- Reduced setup expense
- Elimination of unusable stock from model changeovers and demand estimate errors

VISIT OUR WEBSITE FOR MORE DETAILS

Six Sigma Black Belt

160 Hour Course

The training is organized around the five main phases of the Six Sigma Process Improvement Roadmap: **Define, Measure, Analyze, Improve, and Control (DMAIC).** Candidates participate in four training sessions, with at least three weeks in between, allowing them to apply the material learned to their project.

For project-based training, project reviews during each training session maintain project focus. In this case, it is the responsibility of the Champion to ensure that their Belt candidates arrive at class with a proper project charter.

Optional: In between training, QSG can provide coaching and guidance to ensure that the methodology and roadmap are used appropriately. This is a separate service provided apart from this 160-hour training program.

VISIT OUR WEBSITE FOR MORE DETAILS

Six Sigma Yellow Belt (DMAIC Overview)

8 Hour Course

Yellow Belt attendees contribute to an organization by playing a supportive role in the organization's larger Six Sigma Process. These individuals will understand the concepts used to collect critical information on processes and support other Yellow Belts in gaining knowledge and experience in problem-solving processes. Everyone's understanding of the process is an integral part of the improvement methodology.

Becoming a Yellow Belt will equip you with the ability to analyze complex problems utilizing the Lean Six Sigma methodology to help eliminate waste and reduce variation across processes and serve as a basis for the Six Sigma Green Belt program. Businesses are always looking for innovative ways to do things better, faster, and cheaper. The Lean Six Sigma tool set will help you achieve those goals.

The DMAIC (Define, Measure, Analyze, Improve, and Control) method is the heart of Six Sigma. This course introduces the DMAIC Roadmap and Six Sigma key concepts.

VISIT OUR WEBSITE FOR MORE DETAILS

Standard Work Documentation

8 Hour Course

Standard Work (also called Standardized Work) is the cornerstone in the Toyota Production System (TPS) house. It is an essential building block of a Lean Enterprise. Standardized Work is different from standardization or work standards and is not yet well understood by most organizations pursuing Lean.

When properly documented, it not only provides a tool for managing Safety, Quality, Delivery and Cost (SQDC) but also a baseline for future kaizen activity. It is defined as the most effective combination of manpower, material, and machinery and it is built on the three elements of takt time, work sequence and standard work in process.

QSG's Standardized Work course will help participants:

- Simplify training of new workers
- Document processes in order to reduce variability
- Reduce safety and quality problems
- Develop a foundation for continuous improvement
- Implement process level visual management

VISIT OUR WEBSITE FOR MORE DETAILS

Training Within Industry (TWI) Job Instruction (JI)

12.5 Hour Course

The demands of developing a flexible workforce and training employees requires standardized best practices. Training Within Industry (TWI) Job Instruction training (JI) teaches participants how to effectively break down a job and deliver instruction for individual tasks. Developing and delivering training in this structured fashion fosters the conditions for process stability.
JI benefits include reduced training time, less scrap and rework, fewer accidents, and increased job satisfaction.

The JI workshop consists of 5 virtual sessions that are 2.5 hour in length. Training employs a "learn by doing" model, and each active participant prepares a demonstration outside of the classroom that applies the 4-step TWI JI methodology to a task from their workplace:

4 Steps for How to Instruct	How to Get Ready to Instruct
1) Prepare the Worker	1) Make a Time Table For Training
2) Present The Operation	2) Break Down The Job (JIB)
3) Try-Out Performance	3) Get Everything Ready
4) Follow Up	4) Arrange The Workplace

VISIT OUR WEBSITE FOR MORE DETAILS

Value Stream Mapping (VSM)

16 Hour Course

Value Stream Mapping (VSM) is a Lean Manufacturing technique used to analyze and design the flow of material and/or information. It enables a company to identify and eliminate waste, in order to streamline work processes, cut lead times, reduce costs, and increase quality.

Through VSM, a team of employees maps the current state from customer back to raw material, including all steps – both value-added and non-value-added – and develops a Future State vision to act as a blueprint for Lean activities. The Future State often represents a significant change from the way the company currently operates, and during VSM, the employee team develops an implementation strategy to make the Future State a reality. The most urgent needs are addressed first and can typically be met in a short time frame when the appropriate resources are applied.

VISIT OUR WEBSITE FOR MORE DETAILS

Full Course Descriptions: www.qualitysupportgroup.com
Please contact Chris Scangas with inquiries:
888-336-1124 | chris@qualitysupportgroup.com

Six Sigma

Acceptance Sampling

8 Hour Course

Organizations must have some method for minimizing the total cost of inspecting from incoming, intermediate, and outgoing product inspections and at the same time not jeopardize quality of product reaching the production line or the customer.
One of the alternatives to 100% inspection of product is Sampling Inspection, also known as Acceptance Sampling. The purpose of Acceptance Sampling is to determine the disposition of goods or services (accept, reject, or screen). This is done by selecting the disposition that minimizes the cost of inspection to achieve a desired level of quality.

VISIT OUR WEBSITE FOR MORE DETAILS

Data Mining – Advanced

16 Hour Course

Advanced Data Mining covers techniques able to handle vast numbers of input variables, correlated input variables, and complex relationships. These additional tools equip the user to perform exploratory data analysis, simplify problems, characterize relationships, set up advanced multivariate process control, and deal with binary response data. This course covers multivariate analysis methods which are ideally suited for today's big data environment.

Specifically, methods are discussed for multivariate testing with MANOVA, reducing complexity, detection of outliers or clusters, visualizing correlation with PCA, performing multivariate control, finding drivers for categorical responses with discriminant analysis, and handling short fat tables (more variables than rows with potentially correlated inputs) using PLS models.

VISIT OUR WEBSITE FOR MORE DETAILS

Data Mining – Basic

16 Hour Course

In today's data rich environment, vast amounts of data are routinely collected. These are termed 'happenstance', 'non-experimental', or 'observational' data. The role of statistics with such observational data is to extract all available information – often called Data Mining – and in particular to identify the Key Process Input Variables (KPIVs) for use in process improvement and process control. With a suitable sampling plan and a knowledge of how to prepare data for analysis, the engineer or researcher can then use statistical methods, much like a detective looking for clues, to release otherwise hidden information from data, providing the basis for correct decisions.

Observational data require special techniques and care in order to extract meaningful information and reach valid conclusions. Observational data are common in most process industries and can yield valuable information from normal process data without resorting to designed experimental data, which may be more costly to obtain. This course gives basic methods to compare a single input to a single output. It covers discrete or continuous inputs with continuous outputs and discrete inputs with discrete outputs. The methods introduced here are building blocks for more advanced data mining techniques as well as the basis for single factor experiments.

VISIT OUR WEBSITE FOR MORE DETAILS

Data Mining – Intermediate

16 Hour Course

Intermediate Data Mining extends upon the methods covered in the Basic Data Mining to build models containing multiple inputs simultaneously. This course covers multi-factor ANOVA, multiple regression, and introduces logistic regression.

Models with multiple inputs require special attention to build but offer a potentially more sensitive method to find key process input variables or model output performance. Included are logistic regression methods to model discrete outputs such as conforming/non-conforming which is particularly useful when quality problems are experienced. These methods can be used to troubleshoot processes, find potential root causes, characterize complex relationships between inputs and outputs, and even suggest optimums from observational data.

VISIT OUR WEBSITE FOR MORE DETAILS

Design of Experiments (DOE) Advanced

16 Hour Course

This course explores how experimental design can be applied for product and process optimization of a response variable such as yield, performance, cycle time, or cost reduction. Using Response Surface Methods, second order models are created to relate process inputs to process outputs allowing settings for the inputs to be determined that will achieve optimal performance for the outputs.

Process optimization methods are given for single as well as multiple outputs considered simultaneously using desirability functions and includes a formal method for experimental confirmation.

Participants have an opportunity to practice these methods by designing, running, and analyzing a series of experiments via unique computer simulations, providing an experience as close as possible to actually running industrial experiments. A final course project lets teams compete to determine which team can find the best optimal solution.

VISIT OUR WEBSITE FOR MORE DETAILS

Design of Experiments (DOE) Basic

24 Hour Course

Design of Experiments is an off-line quality improvement technique that can be employed to dramatically improve industrial products and processes, shorten development time, and provide a structured method for improved decision making. Through its use, it is possible to isolate the cause and effect linkages between product/process variables and the resulting output measures of function, quality, cost, and performance.

This course provides participants with an in-depth understanding of the basic principles of experimental designs for screening and characterizing processes, including planning a DOE, simple comparative experiments, main effects, interactions, and detection of curvature. Experimental design includes one-factor optimization, general full factorials, two level factorials, and fractional factorials.
Actual industrial examples are emphasized along with a unique group learning technique of solving problems incorporating simulated noise allowing the full thinking process to be internalized. By solving these problems within the resource constraints given, participants learn to apply DOE economically, identify factors, set factor levels, define experimental goals, select the appropriate experimental design, and develop analysis skills for interpretation and action planning.

VISIT OUR WEBSITE FOR MORE DETAILS

Design of Experiments (DOE) for Non-Standard Situations

10 Hour Course

Most DOE courses give text book cases as examples. However, there are complexities that arise in real experiments across many industries which require special care or methods. This course attempts to address this gap to allow the practitioner to know when a special case arises and what remedies may be available.
Examples of some of the complexities in real-world experimentation include:

- Hard-to-vary factors (e.g. temperature)
- Several variables at different process steps
- Certain design level combinations that are not feasible
- Higher order models
- More factors than can comfortably be dealt with with standard methods
- Factors at more than 2 levels
- Botched experimental runs
- Discrete responses
- Covariates that can adjust outcomes or missing data in an experiment
- How to maintain an optimum value

VISIT OUR WEBSITE FOR MORE DETAILS

Forecasting and Time Series Analysis

8 Hour Course

Of fundamental importance in business planning is the ability to generate a usable forecast. Although time series is most often applied to economic sequences of events, the methodology can be applied to any manufacturing, engineering, or research data that are collected over time with a stable input pattern. This course will provide participants with a working knowledge of the applications of forecasting and time series analysis along with a general understanding of the underlying theory. This course combines both theory and application and focuses on the analysis and modeling of a series of events with the object of generating meaningful forecasts.

VISIT OUR WEBSITE FOR MORE DETAILS

Lean Fundamentals

32 Hour Course

Lean and Lean Six Sigma are methodologies that companies can apply to ALL aspects of their businesses (NOT just manufacturing and supply chain processes); tangible improvements and benefits can be realized in transactional, service, and other divergent business environments. The fundamental basis for the success of Lean and Lean Six Sigma methods in all facets of an organization is the ability to identify waste, reduce it, and aggressively eliminate non-value-added activities and improve response to customer bases, whether internal or external.
Lean Fundamentals is an in-person training course that helps develop critical skills required for participating in successful Lean projects.

VISIT OUR WEBSITE FOR MORE DETAILS

Lean Six Sigma Green Belt

40 Hour Course

Lean Six Sigma is a powerful process improvement system that helps businesses streamline processes, reduce waste and increase productivity.
The Lean Six Sigma Green Belt Certification provides a comprehensive and thorough training that builds superior problem-solving and analytical skills.

This 5-day course combines classroom training with practical applications. Prior to training, you'll attend a webinar to identify and charter a project. During class, you'll receive training and tools that provide structure for LSS problem-solving. Individual and team exercises reinforce key concepts which you apply on your project. At the end of the course, you'll take the Green Belt examination. Minimum score of 80% to receive certification.

Participants should bring a laptop PC and a basic calculator. After your training, we'll provide 1 hour of personal project coaching and all templates.
Upco

VISIT OUR WEBSITE FOR MORE DETAILS

Measurement System Analysis (MSA) for Accuracy, Tool Matching, and Stability

8 Hour Course

There are generally four items of interest when developing or qualifying a measurement system: accuracy or bias, precision, linearity, and stability. The MSA for Gauge R&R is concerned with precision. This second course covers the remaining items of accuracy or bias, linearity, and stability, along with comparisons and matching of measurement tools regarding accuracy and precision.

Stability is addressed with LTS, long-term stability, monitors. A Type 1 gauge study provides a quick assessment of repeatability, bias, and stability and is suitable for a quick check of measurement performance, perhaps in R&D applications. A bias and linearity study gives guidance on calibration and accuracy issues. Finally, the course discusses measurement tool matching using a paired t-test, orthogonal regression, correlation for gauge linearity, an omnibus test for both accuracy and precision and ANOVA for repeated trial data.

VISIT OUR WEBSITE FOR MORE DETAILS

Measurement System Analysis (MSA) for Gauge R&R

12 Hour Course

Fundamental to collecting data on any process or equipment is a characterization of measurement. This includes variables data such as CMM measurements, laboratory measurements, or any measurements made on a continuous scale, as well as attribute inspection data into categories (e.g. pass/fail or defect categories). Data, which do not come from an accurate measurement system, may lead to erroneous conclusions.

This course provides the participants with an understanding of basic measurement process terminology including discrimination or resolution, bias, accuracy, precision, repeatability and reproducibility, along with measurement precision assessment. It provides the methodology to plan, conduct, analyze, and interpret measurements system capability study, which includes a gauge repeatability and reproducibility (R&R) study for variables data and attribute measurement study techniques for attribute data such as inspection processes. Questions such as operator differences, gauge drift issues, overkill, and escapes are addressed.

VISIT OUR WEBSITE FOR MORE DETAILS

Mixture Experiments for Formulations

8 Hour Course

When formulations are developed there is one fact that can change the way standard DOEs are performed. This fact is the simple statement that the sum of the component proportions equals 100%. Because of this built-in dependency of the components, the design space will need to change, the model forms will need to change, and the analysis methods will need to reflect these new realities in design space and model forms.

Participants are prepared to understand the concept of a mixture and basic statistical models for fitting and analyzing mixture experiments. The focus is on application of mixture experiments to manufacturing or research operations involving chemical processes, powders, or other types of mixtures. Methods are developed for screening, characterizing, and optimizing mixture experiments involving basic designs such as simplex centroids, simplex lattice, and extreme vertices, along with process constraints.

VISIT OUR WEBSITE FOR MORE DETAILS

Product/Process Capability Analysis

6 Hour Course

Capability analysis is a statistical method for judging the performance of a product or process and is often part of a product or process verification. Both those who create capability studies and those who review capability studies need to understand not only the benefits of the study, but also the pitfalls and the key elements to look for when critiquing a capability study. When pitfalls are present, a capability study could be misleading and pass on a product to the customer which is potentially at risk, allow a product to proceed to production that will require massive amounts of improvement in order to be economical to produce, or at the other extreme, deny the introduction of a product to market which is perfectly suitable for that market.

This course will span the planning, execution, analysis, reporting, and actions recommended for a capability study.

VISIT OUR WEBSITE FOR MORE DETAILS

Reliability

16 Hour Course

Weibull analysis models the relationship between product failures and product reliability. These models can be used to predict future performance and to improve product reliability. A practitioner selects a relatively small number of units for test and makes predictions about a population of such units concerning important life characteristics such as the reliability function, mean time to fail or probability of failure at a certain time. The statistical software used allows for easy distribution fitting for reliability data that may be censored and also to build models that describe and predict reliability performance.

Reliability has aspects that touch many aspects of business and industry from product development to process design to equipment design to maintenance to customer data sheets to warranty analysis. This course will cover basic reliability theory and applications so that the participant will be able to perform standard reliability analyses.

The first part of the course introduces basic reliability concepts and terminology, then selected applications are covered. Topics include:

- Reliability functions
- Cumulative failure functions
- Hazard rate functions
- MTTF, bathtub curve
- Design life
- Reporting reliability
- G and T charts

- Weibull model and analysis
- Spare part analysis
- No/few failures analysis
- Reliability comparisons
- PM (Planned Maintenance) frequency
- Frequency of sampling
- Reliability demonstration tests for qualifications or verifications
- Accelerated test methods
- Reliability life regression

VISIT OUR WEBSITE FOR MORE DETAILS

Robust Design for Manufacturability

8 Hour Course

Most experimental design projects tend to stop after screening, characterizing, or optimizing. However, once a process is optimized, it may need to be implemented in manufacturing. To make the process manufacturable, the process noise variables (e.g. raw material batches, various machines, various operators, etc.) need to be considered. Robust design provides a method to leverage controllable factors to mitigate the transmission of variation from noise variables to process outputs. A dual response model is considered to keep the process mean on target, while reducing noise as much as possible.

In addition, before release of a process to manufacturing, the effects of noise can be quantified via a ruggedness test to ensure that noise variables are not drivers of the process. Both robustness and ruggedness are practical methods to help to make processes more manufacturable.

VISIT OUR WEBSITE FOR MORE DETAILS

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160 Hour Course

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The DMAIC (Define, Measure, Analyze, Improve, and Control) method is the heart of Six Sigma. This course introduces the DMAIC Roadmap and Six Sigma key concepts.

VISIT OUR WEBSITE FOR MORE DETAILS

Statistical Methods for Setting Specifications

16 Hour Course

Sometimes specifications are given by the customer or marketplace. But when these are not specified externally, a common task for engineers or designers is to set either product or process specifications. One typical case is to set process windows on inputs so as to achieve a given performance on some outputs. Unfortunately, there is very little guidance about best methods for setting these specifications. This course presents statistical approaches to certain specification problems such as setting specs for standardization, determining statistically valid process windows for inputs, setting specs to achieve a given Cpk, using correlation to set specifications, setting rework limits, or determining statistical guardbands for testing. Notice that the specification problems here are distinct and different from geometrical tolerancing which would usually be covered in a drafting or machinist curriculum.

This information is not widely seen together in one place and will give the participant the ability to improve controls on processes with statistically valid limits. The creation of specifications defines processes. It is critical that these process boundaries be set accurately based on data and sound analysis. This course provides proven techniques to set statistically valid process specification limits or to reexamine current process specifications for validity. This is vital knowledge that every engineer, manager, R&D member, or researcher should know.

VISIT OUR WEBSITE FOR MORE DETAILS

Statistical Process Control (SPC)

16 Hour Course

SPC is an effective method to control processes but also the foundation for continuous improvement. This course provides participants with the basic statistical techniques and strategies for process control and improvement. Participants will gain knowledge of the fundamentals of process improvement, concept of variation, and statistical control, be introduced to statistical software, and learn other simple but powerful statistical techniques.

This course emphasizes the concepts that motivate and underlie the techniques along with practical advice for implementation so that the participant can effectively use these techniques on their own processes. In addition to on-line SPC, this course points out the use of off-line SPC as the foundation for more advanced data analysis methods.

VISIT OUR WEBSITE FOR MORE DETAILS

Statistical Process Control (SPC) – Advanced

16 Hour Course

This second course in SPC fills a void left by many, if not virtually all, textbooks on SPC. Found among the standard assumptions for SPC are 1) no between subgroup variation, 2) normally distributed data, 3) uncorrelated data in time (no serial or autocorrelation), and 4) homogeneous subgroups. However, these so-called standard assumptions in textbooks seem to be more the exception than the rule for real industrial processes. Thus, this course presents the practical side of SPC implementation, including SPC chart design for number of subgroups, frequency of subgroups, number of out-of-control (OOC) rules, how to handle multilevel batched processes, non-normal data, serially correlated data, fixed effects within subgroups, as well as special SPC techniques such as zero-inflated models for detection limit censored data and normalized charts.

This is the practical side of SPC that is usually not taught in textbooks but is essential to meet the practical demands of industry. By following techniques from this course, SPC charts will better be able to separate common from special cause and be truly effective for making the correct process decisions. These methods are a "must" for anyone who has struggled with making SPC effective in real industrial situations.

VISIT OUR WEBSITE FOR MORE DETAILS

Statistical Strategies for Managers

16 Hour Course

A weak link in the sustainability of training for engineers is the role of management to use statistical strategies, when appropriate, to direct data collection and require data analyses for decisions. Managers should have an understanding of statistical strategies for business objectives, managers should know what their engineers, researchers, and scientists are being taught, and managers should be able to leverage data to set the right priorities, direct the right actions, and make the right decisions. This course will acquaint managers with the statistical strategies and methods necessary to characterize, improve, and control processes and products.

This course is organized into bite-sized modules that can fit into a manager's busy schedule, to acquaint management with the necessary thinking skills to understand how data, with the right statistical strategies, can be used to achieve specific business goals. Although managers are not taught here to use statistical software, they do learn what a method or strategy does, the correct assumptions for use, how to interpret software output, as well as how to check the validity of an analysis by knowing the right questions to ask and how to avoid common pitfalls. For example, managers are taught the important skill of knowing what sample size is required since this determines the time and resources necessary to reach a stated objective.

VISIT OUR WEBSITE FOR MORE DETAILS

Full Course Descriptions: www.qualitysupportgroup.com
Please contact Chris Scangas with inquiries:
888-336-1124 | chris@qualitysupportgroup.com

Process Improvement Tools & Techniques

AI for Quality & Compliance in Manufacturing

8 Hour Course

TThis virtual workshop helps manufacturing professionals learn how to use AI tools to improve quality processes, prepare for audits, reduce paperwork, and stay compliant with ISO and industry standards. No tech background required—just a desire to improve how things get done.

Bonus:
Free 1-on-1 consultation after the session (valued $2,500)
Ready-to-use AI checklist templates

VISIT OUR WEBSITE FOR MORE DETAILS

APQP and CONTROL PLAN Fundamentals

8 Hour Course

The latest APQP – 3rd Edition & Control Plan- Version 1 manuals have been released by AIAG!

As you may be aware, AIAG has been working on the new APQP and Control Plan manuals for quite some time. The automotive industry OEMs and their supply base have been eagerly awaiting the new manuals, which will soon become mandatory requirements and be added to the US OEM CSR documents. Ford, GM, and Stellantis have already announced that they will accept the usage of these new manuals as soon as they are released, making way for international OEMs and a host of large Tier 1 suppliers to follow suit.

There are significant changes in both the APQP and the new Control Plan manuals, as indications have suggested. They not only address the needs of the latest ICE and hybrid vehicles but also the new electric vehicles. These developments emphasize the importance of new product development and process control more than ever before.

The QSG APQP Training course is taught in an engaging instructor-led format. The instructor will describe the best practices that have made APQP such a successful methodology for improving product quality. Participants will learn the proper course of action for each phase of APQP and will be able to identify the correct inputs and outputs to make the process work as designed.

Participants will have the opportunity to interact with all elements of the APQP process, as well as learn about the other Quality and Reliability Tools that are built into the methodology's framework. Team activities, workshops and other exercises will be used to reinforce the best practices of this methodology to ensure that each participant will be able to put APQP into action for their company's unique production needs.

Value-Add: An ever-growing number of companies must comply with Advanced Product Quality Planning (APQP) requirements. Even those that are not subject to a compliance mandate recognize the APQP process as a product development best practice that improves performance for new product introduction. To implement APQP effectively, companies must account for a series of key considerations that will determine the success of the initiative and ultimately the performance of future product launches.

Quality system requirements are intended to develop fundamentals that provide for continuous improvement, defect prevention, and the reduction of variation. APQP is at the heart of product development/project implementation and the prime element of successful project success, as it links the special characteristics identified in the project. It then integrates all of the prime tools of IATF 16949, such as FMEA, control plans, feasibility reviews, operator instructions, process flow diagrams, etc.

This course provides valuable information and examples for the successful implementation of the APQP process at companies of all sizes and across industries. It gives the participants the opportunity to work in teams and to implement APQP using actual case studies. Training includes discussions about the use of control plan and relevant data required to construct and determine control plan parameters, as well as the importance of the control plan in the continuous improvement cycle.

VISIT OUR WEBSITE FOR MORE DETAILS

Basic Inspection Workshop

4 Hour Course

Understanding how to properly inspect, analyze, and communicate findings is essential for the success of any manufacturer. This workshop is designed for those seeking to understand best practices for capturing data using a variety of equipment such as micrometers, calipers, comparators, vision systems, and gauges. Training presents the basic elements of inspection such as types of inspection, types of inspection equipment, how to maintain consistent results, understanding the capability of your equipment, determining best methods of inspection, communicating results, and how to build risk mitigation into your inspection methods.

VISIT OUR WEBSITE FOR MORE DETAILS

Basic Problem Solving

8 Hour Course

When failure occurs, we demand a rigorous process of investigation be initiated to identify why it occurred. Problem Solving is a process that investigates and solves problems, identifies causes, takes corrective action, and prevents recurrence of the root causes. The ultimate purpose of problem solving is to ensure the problem can never be experienced again. Problem solving can be applied in many disciplines, including:

- **Manufacturing**
- **Product Design**
- **Testing Verification and Validation**
- **Distribution, Shipping, Transport and Packaging**
- **Use-Applications**

As everyone probably knows, "perfect" is a rare state. Problems pop up from time to time and people need to solve them. As a result, it is important that people become effective problem solvers. Having a workforce with well-developed problem-solving skills is a significant competitive advantage for a company.

All people can benefit from strong problem-solving skills. However, those skills don't come "built-in" to every person. And even those with a natural knack for it can always get better or learn to apply those skills more effectively in each work circumstance. As a result, it's a good idea to provide resources to help people develop and use problem-solving skills at work.

Why "Problem Solving for Employees" Matters:

- Employees should recognize the importance of being good problem solvers.
- Understanding the positive impact of employee problem solving increases workplace productivity.
- Identifying the basic steps in the problem-solving process helps employees manage problems efficiently when they do arise.
- Using effective problem-solving techniques on the job keeps problems from reoccurring.

VISIT OUR WEBSITE FOR MORE DETAILS

Blueprint Reading

16 Hour Course

How to interpret a technical drawing is an essential skill to anyone involved in the manufacturing industry. This course is designed for those seeking an overview of drawing interpretation. This course presents the basic elements of a print and introduces the concepts that students must master to successfully interpret engineering drawings.

Material covered includes: visualizing the part, finding and interpreting the drawing information needed for a task, performing shop mathematics, and reading standard symbols and notes.

VISIT OUR WEBSITE FOR MORE DETAILS

Blueprint Reading with GD&T (3-day)

24 Hour Course

How to interpret a technical drawing is an essential skill to anyone involved in the manufacturing industry. This course is designed for those seeking thorough coverage of the subject of drawing interpretation. This course presents the basic elements of a print and introduces the concepts that students must master to successfully interpret engineering drawings. Material covered includes: visualizing the part, reading standard symbols and notes, and finding and interpreting the drawing information needed for a task.

Designed to provide you with an understanding of Geometric Dimensioning & Tolerancing (GD&T) fundamentals, this course focuses on the basic requirements of engineering drawings, numeric dimensions and tolerances and geometric dimensions and tolerances.

VISIT OUR WEBSITE FOR MORE DETAILS

Corrective Action/Root Cause Analysis Workshop – Employing the 8D Problem Solving Methodology

16 Hour Course

When some people hear about “eight disciplines” for solving problems, they immediately think that it must be a complex or convoluted methodology. Actually, the 8D Problem Solving process is really not all that complicated. In fact, a number of common problem-solving models are quite similar to this team-based, data-driven approach to solving problems.

8D is a highly structured and effective scientific approach to solving chronic or recurring problems. It uses team synergy and provides excellent guidelines for identifying the root cause of the problem, implementing containment actions, and then developing and implementing lasting corrective and preventive action.

The 8D Problem Solving methodology is deployed to solve critical, major, chronic and recurring problems. It is most effective in addressing complex problems that exceed the ability of one person to resolve them. In this highly interactive workshop, you will learn how to solve future problems by applying a structured methodology that will yield faster and more effective solutions. The program provides opportunities to practice and apply the technique to case studies and participants' on-job problems.

In this course, participants will learn how to follow the 8D process steps while working in a cross functional team. They will also apply various problem solving tools to identify and verify a root cause and eliminate it through permanent corrective action, followed by additional action to prevent reoccurrence of the root cause(s). Participants can expect team activities and relevant exercises in a workshop format. All activities will include industry-specific examples and terminology.

VISIT OUR WEBSITE FOR MORE DETAILS

Cybersecurity Maturity Model Certification (CMMC)

16 Hour Course

When fully operational in 2025, CMMC will be mandatory for all entities doing business with the U.S. Department of Defense (DoD) at any level. You will no longer be allowed to self-report to be certified as compliant but will instead have to pass an audit by a certified third-party assessment organization (C3PAO). If you work with the DoD or DoD Defense Industrial Base (DIB), you need this training. It takes time to complete so get started now.

CMMC is a unifying standard for the implementation of cybersecurity across the DIB. The CMMC framework includes a comprehensive and scalable certification element to verify the implementation of processes and practices associated with the achievement of a cybersecurity maturity level.

QSG's CMMC Foundations Workshop enables participants to understand the fundamental concepts and principles of the CMMC model. It contains lecture sessions illustrated with graphics, examples, and discussions, and encourages interaction between participants by means of questions, suggestions, and quizzes. Training also includes quizzes that are a simulation of the questions of the final exam

VISIT OUR WEBSITE FOR MORE DETAILS

Design for Manufacturing and Assembly (DFM&A)

24 Hour Course

Design for Manufacturing and Assembly (DFM&A) is a set of overlapping principles applied to engineering design that consider requirements beyond the functional. DFA ensures a good design early in the design process by focusing on the number of parts, part handling, and ease of assembly. DFM achieves good product designs using simple manufacturing techniques and using standardized parts and materials. Together DFM&A helps organizations reach the goal of developing quality products at the lowest cost while saving time. This 3-day workshop will provide you with fundamental knowledge and hands-on practice with Design for Manufacturing and Assembly (DFM&A) principles and key tools.

VISIT OUR WEBSITE FOR MORE DETAILS

Design of Experiments (DOE) Advanced

16 Hour Course

This course explores how experimental design can be applied for product and process optimization of a response variable such as yield, performance, cycle time, or cost reduction. Using Response Surface Methods, second order models are created to relate process inputs to process outputs allowing settings for the inputs to be determined that will achieve optimal performance for the outputs.

Process optimization methods are given for single as well as multiple outputs considered simultaneously using desirability functions and includes a formal method for experimental confirmation.

Participants have an opportunity to practice these methods by designing, running, and analyzing a series of experiments via unique computer simulations, providing an experience as close as possible to actually running industrial experiments. A final course project lets teams compete to determine which team can find the best optimal solution.

VISIT OUR WEBSITE FOR MORE DETAILS

Design of Experiments (DOE) Basic

24 Hour Course

Design of Experiments is an off-line quality improvement technique that can be employed to dramatically improve industrial products and processes, shorten development time, and provide a structured method for improved decision making. Through its use, it is possible to isolate the cause and effect linkages between product/process variables and the resulting output measures of function, quality, cost, and performance.

This course provides participants with an in-depth understanding of the basic principles of experimental designs for screening and characterizing processes, including planning a DOE, simple comparative experiments, main effects, interactions, and detection of curvature. Experimental design includes one-factor optimization, general full factorials, two level factorials, and fractional factorials.
Actual industrial examples are emphasized along with a unique group learning technique of solving problems incorporating simulated noise allowing the full thinking process to be internalized. By solving these problems within the resource constraints given, participants learn to apply DOE economically, identify factors, set factor levels, define experimental goals, select the appropriate experimental design, and develop analysis skills for interpretation and action planning.

VISIT OUR WEBSITE FOR MORE DETAILS

Design of Experiments (DOE) for Non-Standard Situations

10 Hour Course

Most DOE courses give text book cases as examples. However, there are complexities that arise in real experiments across many industries which require special care or methods. This course attempts to address this gap to allow the practitioner to know when a special case arises and what remedies may be available.
Examples of some of the complexities in real-world experimentation include:

- Hard-to-vary factors (e.g. temperature)
- Several variables at different process steps
- Certain design level combinations that are not feasible
- Higher order models
- More factors than can comfortably be dealt with with standard methods
- Factors at more than 2 levels
- Botched experimental runs
- Discrete responses
- Covariates that can adjust outcomes or missing data in an experiment
- How to maintain an optimum value

VISIT OUR WEBSITE FOR MORE DETAILS

Engineering Drawings Primer

8 Hour Course

Intended for the professional or manager seeking an awareness of dimensioning and tolerancing who does not need to further their knowledge with a more in-depth course. Designed to provide you with an understanding of GD&T fundamentals, this course focuses on the basic requirements of engineering drawings, numeric dimensions and tolerances, and geometric dimensions and tolerances.

VISIT OUR WEBSITE FOR MORE DETAILS

Failure Mode and Effects Analysis (FMEA) Based on AIAG-VDA Harmonized Edition

16 Hour Course

The AIAG & VDA FMEA manual is not a revision of the previous AIAG FMEA handbook. It is the product of a collaborative effort between automotive manufacturers and tier one suppliers, along with members of AIAG (Automotive Industry Action Group) and VDA (Verband der Automobilindustrie), which is the German association for automotive manufacturers.

The AIAG & VDA manual is intended to replace both the AIAG 4th edition FMEA handbook and the VDA 2nd edition Product and Process FMEA volume 4 manual. While the manual has technically been completely re-written, there are several aspects that are familiar, and it includes tools that we have been using for years prior to this publication. However, there are some significant segments of the FMEA process that have been modified. Key differences include an increased push for prevention controls over detection.

In addition, the FMEA process has been transformed into a seven-step system that integrates the robustness tools that many FMEA facilitators utilize today into the FMEA standard process. Also the RPN has been eliminated and replaced by an “Action Priority” process that includes a set of tables used to define a priority for action to reduce risk regardless of the number of actions identified in the FMEA process.

This 2-day workshop addresses all of the elements of the Design (DFMEA) and Process Failure Mode Effects Analysis (PFMEA) process consistent with the intent and guidelines in the AIAG-VDA FMEA Handbook (1st edition, 2019) issued by AIAG and VDA. Control Plans in accordance with APQP Second Edition and IATF 16949:2016 are also addressed.

VISIT OUR WEBSITE FOR MORE DETAILS

Failure Mode and Effects Analysis (FMEA)- Workshop

16 Hour Course

FMEAs were first established in the late 1940's by the United States military to reduce sources of variation and corresponding potential of failures in the production of munitions – and it proved a highly effective tool. The use of FMEAs spread across industries and around the world over the next 70 years and they have become a cornerstone of quality and productivity improvement.

Today, FMEA is commonly used when a process, product, or service is being designed or redesigned, after quality function deployment (QFD), or when an existing process, product, or service is being applied in a new way.

Failure Mode and Effects Analysis (FMEA) is a powerful technique for avoiding process problems and preventing defects in products and services. The use of FMEA helps to anticipate and guide action to prevent failures in both design and process performance. Ideally, organizations should begin using FMEA during the earliest conceptual design stages of a process or product, and then through the design or redesign process. FMEA can also be used effectively before developing control plans for a new or modified process, and for control before and during ongoing processes.

In this intensive two-day workshop, you will learn to estimate the probability of failures and their causes in your product and process. Each participant will have the opportunity to develop all the elements of a Design and Process FMEA.
Benefits of FMEA

The following are benefits realized and reported by companies following the effective application and Design and Process FMEA:

- Addresses critical failure modes early in the design cycle
- Makes verification and validation plans more robust
- Fewer ECOs (engineering change orders)
- Faster time to market by reducing product development cycle time
- Reduced scrap and rework
- Fewer customer complaints
- Reduced warranty failures and costs
- Increased productivity
- Increased market share
- Reduction of product recalls

VISIT OUR WEBSITE FOR MORE DETAILS

GD&T ASME Y14.5-2018 Update

18 Hour Course

Though released in 2019, the most current standard defining Geometric Dimensioning & Tolerancing (GD&T) practices and their interpretation carries the ASME Y14.5-2018 designation. A revision of ASME Y14.5-2009, it contains many clarifications and improvements on the standard it replaces. Important changes include: concept of feature of size; datum references and degrees of freedom; composite position tolerances; surface boundaries and axis methods of interpretation; profile tolerances; and symbology and modifier tools. This course highlights the most significant of these changes and provides answers to your questions on the added, changed, and deleted content as compared to the previous revision. Don't be left behind following outdated standards, get current with the GD&T ASME Y14.5-2018 update.

VISIT OUR WEBSITE FOR MORE DETAILS

GD&T Part 1 (Basic)

24 Hour Course

Intended for practicing professionals who create drawing specifications or read drawings, this course helps students make sense of a topic that some find overwhelming. In this comprehensive class, the key principles of Geometric Dimensioning & Tolerancing (GD&T) are explained and brought down to the real world. The delivery includes lots of illustrations and animations to help with conveying concepts. More than simply memorizing symbols, students leave this course with a working understanding of how the system works and feel confident fully understanding drawing requirements and creating their own tolerancing schemes for parts.

This course provides lots of practical hands-on exercises to drive home the concepts and encourage questions and effective discussions. The exercises go beyond the theory to show how tolerancing works on real working parts.

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GD&T Part 2 (Advanced)

18 Hour Course

Even with an understanding of the fundamentals of Geometric Dimensioning & Tolerancing (GD&T), many professionals still lack the confidence to expertly and deliberately apply geometric tolerancing to clearly define their product designs. Like with any language, this deeper understanding is built off the fundamentals.

The Advanced course helps students apply GD&T to achieve the mating and functional requirements of their parts. This course reinforces fundamentals and provides applications-based exercises where students apply what they have learned. Application practice exercises and calculations are performed individually and in teams. The use of functional dimensioning and tolerancing schemes and its effect on assemblies is emphasized throughout the course. Students will expand their understanding of the implications of their specifications on function, manufacturing, inspection, and quality. Students will gain experience and confidence selecting the product definition strategy for an assembly by working more advanced application examples with their peers under the guidance of an expert in a classroom setting.

VISIT OUR WEBSITE FOR MORE DETAILS

GD&T Part 3 (Applications)

24 Hour Course

This course helps students apply Geometric Dimensioning & Tolerancing (GD&T) to achieve the mating and functional requirements of their parts using a series of case study problems including sheet metal, machined parts, plastic parts, castings etc. Light on lecture and heavy on participation, calculations and exercises are performed individually and in teams. This course provides realistic design problems where students apply what they have learned while reinforcing their understanding of the fundamentals.

VISIT OUR WEBSITE FOR MORE DETAILS

Kaizen Events

24 Hour Course

Kaizen Events (also known as Kaikaku, Kaizen Blitz, Kaizen Burst, Gemba Kaizen) are focused, intense and short-term projects in which a cross-functional team makes rapid improvements in a short period of time. Kaizen Events normally takes 3 to 10 days and the intensity and urgency overcomes the intellectual resistance to a new paradigm as people have little time to think of reasons for delay. It is common to completely re-engineer a process in a Kaizen Event week.

Common Kaizen topics include:

- 6S/Workplace Organization
- Direct Observation
- Process Improvement
- Process Layout
- Lean Office
- NPI Process Optimization
- Root Cause Analysis
- Set-up Reduction
- Standard Work
- Statistical Process Control (SPC)
- Supply Chain
- Systems Inventory Control
- Tool Crib Process – Root Cause Analysis
- Total Productive Maintenance (TPM)
- Value Stream Mapping
- Visual Factory
- Work Environment

Kaizen Event benefits include:

- Streamlined processes
- Reduced waste and/or non-value add activities
- Reduced cycle time
- Reduced cost of operations
- Removes bottlenecks
- Improved throughput
- Improved customer satisfaction
- Improved productivity

VISIT OUR WEBSITE FOR MORE DETAILS

Leadership Insight for People with Technical Backgrounds

16 Hour Course

Technical thinkers often prefer objectivity and verifiable truth over personal experience. This seminar offers participants practical and immediately applicable leadership insight based on research, case reviews, and credible data. Effective frontline leadership is the key to organizational success. The balancing act required to meet organizational and employee needs requires skill, self-understanding, understanding others, and a vision for the future.

VISIT OUR WEBSITE FOR MORE DETAILS

Measurement System Analysis (MSA) for Accuracy, Tool Matching, and Stability

8 Hour Course

There are generally four items of interest when developing or qualifying a measurement system: accuracy or bias, precision, linearity, and stability. The MSA for Gauge R&R is concerned with precision. This second course covers the remaining items of accuracy or bias, linearity, and stability, along with comparisons and matching of measurement tools regarding accuracy and precision.

Stability is addressed with LTS, long-term stability, monitors. A Type 1 gauge study provides a quick assessment of repeatability, bias, and stability and is suitable for a quick check of measurement performance, perhaps in R&D applications. A bias and linearity study gives guidance on calibration and accuracy issues. Finally, the course discusses measurement tool matching using a paired t-test, orthogonal regression, correlation for gauge linearity, an omnibus test for both accuracy and precision and ANOVA for repeated trial data.

VISIT OUR WEBSITE FOR MORE DETAILS

Measurement System Analysis (MSA) for Gauge R&R

12 Hour Course

Fundamental to collecting data on any process or equipment is a characterization of measurement. This includes variables data such as CMM measurements, laboratory measurements, or any measurements made on a continuous scale, as well as attribute inspection data into categories (e.g. pass/fail or defect categories). Data, which do not come from an accurate measurement system, may lead to erroneous conclusions.

This course provides the participants with an understanding of basic measurement process terminology including discrimination or resolution, bias, accuracy, precision, repeatability and reproducibility, along with measurement precision assessment. It provides the methodology to plan, conduct, analyze, and interpret measurements system capability study, which includes a gauge repeatability and reproducibility (R&R) study for variables data and attribute measurement study techniques for attribute data such as inspection processes. Questions such as operator differences, gauge drift issues, overkill, and escapes are addressed.

VISIT OUR WEBSITE FOR MORE DETAILS

Mixture Experiments for Formulations

8 Hour Course

When formulations are developed there is one fact that can change the way standard DOEs are performed. This fact is the simple statement that the sum of the component proportions equals 100%. Because of this built-in dependency of the components, the design space will need to change, the model forms will need to change, and the analysis methods will need to reflect these new realities in design space and model forms.

Participants are prepared to understand the concept of a mixture and basic statistical models for fitting and analyzing mixture experiments. The focus is on application of mixture experiments to manufacturing or research operations involving chemical processes, powders, or other types of mixtures. Methods are developed for screening, characterizing, and optimizing mixture experiments involving basic designs such as simplex centroids, simplex lattice, and extreme vertices, along with process constraints.

VISIT OUR WEBSITE FOR MORE DETAILS

Principles Of Inventory Management (PIM)

27 Hour Course

Inventory, if managed strategically, can work to establish and maintain a company's competitive advantage. Whether you are a materials manager, buyer/purchaser, inventory planner, or simply need to understand inventory, this course introduces the fundamental concepts. Learn to explain to colleagues how inventory objectives must be balanced with the needs of marketing, sales, and finance. Discover the decisions that effective inventory managers make. Gain knowledge about how inventory accuracy is maintained, and apply that knowledge to create an impact.

VISIT OUR WEBSITE FOR MORE DETAILS

Principles of Operations Management

30 Hour Course

Managing operations, and supply chains in a competitive environment requires knowledge of basic business principles, the workings of production and inventory management systems, and the leadership skills required to build a customer focused, continually improving culture. This course provides a well rounded exposure to all aspects of operations management. The material is organized into four categories:

- Background
- Customer focus
- Continuous improvement
- Culture and managing people

VISIT OUR WEBSITE FOR MORE DETAILS

Product/Process Capability Analysis

6 Hour Course

Capability analysis is a statistical method for judging the performance of a product or process and is often part of a product or process verification. Both those who create capability studies and those who review capability studies need to understand not only the benefits of the study, but also the pitfalls and the key elements to look for when critiquing a capability study. When pitfalls are present, a capability study could be misleading and pass on a product to the customer which is potentially at risk, allow a product to proceed to production that will require massive amounts of improvement in order to be economical to produce, or at the other extreme, deny the introduction of a product to market which is perfectly suitable for that market.

This course will span the planning, execution, analysis, reporting, and actions recommended for a capability study.

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Project Management

24 Hour Course

Project Management (PM) is the process by which resources are allocated, monitored, and utilized to achieve a particular objective within a specified period of time. QSG's PM course is designed to provide an intensive overview of the tools and methodologies associated with project management. It includes training on the quantitative and analytical techniques of project management (defining/designing, planning, estimating, scheduling, executing, etc.), as well as qualitative, team building, and people-management skills (leadership, communication, etc.), and the criticality of integrating these techniques and skills towards rendering the completion of a successful project.

During training, students will examine in detail the entire process of designing, implementing, and completing a project, from project definition and the evaluation of feasibility, to scheduling, financing, risk, and budgeting. Students will develop their understanding of project management principles through practical application, by participating in scenarios drawn from real world case analyses. This course also includes a review of contemporary PM techniques and current software options (Microsoft Project).

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Reliability

16 Hour Course

Weibull analysis models the relationship between product failures and product reliability. These models can be used to predict future performance and to improve product reliability. A practitioner selects a relatively small number of units for test and makes predictions about a population of such units concerning important life characteristics such as the reliability function, mean time to fail or probability of failure at a certain time. The statistical software used allows for easy distribution fitting for reliability data that may be censored and also to build models that describe and predict reliability performance.

Reliability has aspects that touch many aspects of business and industry from product development to process design to equipment design to maintenance to customer data sheets to warranty analysis. This course will cover basic reliability theory and applications so that the participant will be able to perform standard reliability analyses.

The first part of the course introduces basic reliability concepts and terminology, then selected applications are covered. Topics include:

- Reliability functions
- Cumulative failure functions
- Hazard rate functions
- MTTF, bathtub curve
- Design life
- Reporting reliability
- G and T charts
- Weibull model and analysis
- Spare part analysis
- No/few failures analysis
- Reliability comparisons
- PM (Planned Maintenance) frequency
- Frequency of sampling
- Reliability demonstration tests for qualifications or verifications
- Accelerated test methods
- Reliability life regression

VISIT OUR WEBSITE FOR MORE DETAILS

Robust Design for Manufacturability

8 Hour Course

Most experimental design projects tend to stop after screening, characterizing, or optimizing. However, once a process is optimized, it may need to be implemented in manufacturing. To make the process manufacturable, the process noise variables (e.g. raw material batches, various machines, various operators, etc.) need to be considered. Robust design provides a method to leverage controllable factors to mitigate the transmission of variation from noise variables to process outputs. A dual response model is considered to keep the process mean on target, while reducing noise as much as possible.

In addition, before release of a process to manufacturing, the effects of noise can be quantified via a ruggedness test to ensure that noise variables are not drivers of the process. Both robustness and ruggedness are practical methods to help to make processes more manufacturable.

VISIT OUR WEBSITE FOR MORE DETAILS

Software Failure Mode and Effects Analysis (FMEA)

16 Hour Course

Failure Mode and Effects Analysis (FMEA) is a powerful technique for avoiding process problems and preventing defects in products and services. The use of FMEA helps to anticipate and guide action to prevent failures in both design and process performance.

Application of FMEA to software design anticipates defects before they occur, thus allowing quality to be built into software products. Software FMEA assesses the ability of the system design, as expressed through its software component, to react in a predictable manner to ensure system safety. Thus, Software FMEA is a form of Design FMEA.

During this hands-on course, participants will perform FMEAs on their own designs, present the results of their analyses, and plan future applications of FMEA for when they return to work.

VISIT OUR WEBSITE FOR MORE DETAILS

Solidworks – Advanced

16 Hour Course

Solidworks training is an engineering software package that allows engineers and designers to create detailed three-dimensional representations of their ideas. These 3D models can then be used for virtual prototyping and simulation, blueprints or specifications, and photorealistic renders among other things. In this course, people with a basic understanding of Solidworks will learn its more advanced features and methods of increasing efficiency with the software.

VISIT OUR WEBSITE FOR MORE DETAILS

Solidworks – Introduction

16 Hour Course

Solidworks is an engineering software package that allows engineers and designers to create detailed 3-dimensional representations of their ideas. These 3d models can then be used for virtual prototyping and simulation, blueprints or specifications, and photorealistic renders among other things. In this Solidworks basic training course, you will learn the basics of how to create parts, assemblies, and drawings using the Solidworks software package.

VISIT OUR WEBSITE FOR MORE DETAILS

Statistical Methods for Setting Specifications

16 Hour Course

Sometimes specifications are given by the customer or marketplace. But when these are not specified externally, a common task for engineers or designers is to set either product or process specifications. One typical case is to set process windows on inputs so as to achieve a given performance on some outputs. Unfortunately, there is very little guidance about best methods for setting these specifications. This course presents statistical approaches to certain specification problems such as setting specs for standardization, determining statistically valid process windows for inputs, setting specs to achieve a given Cpk, using correlation to set specifications, setting rework limits, or determining statistical guardbands for testing. Notice that the specification problems here are distinct and different from geometrical tolerancing which would usually be covered in a drafting or machinist curriculum.

This information is not widely seen together in one place and will give the participant the ability to improve controls on processes with statistically valid limits. The creation of specifications defines processes. It is critical that these process boundaries be set accurately based on data and sound analysis. This course provides proven techniques to set statistically valid process specification limits or to reexamine current process specifications for validity. This is vital knowledge that every engineer, manager, R&D member, or researcher should know.

VISIT OUR WEBSITE FOR MORE DETAILS

Statistical Process Control (SPC)

16 Hour Course

SPC is an effective method to control processes but also the foundation for continuous improvement. This course provides participants with the basic statistical techniques and strategies for process control and improvement. Participants will gain knowledge of the fundamentals of process improvement, concept of variation, and statistical control, be introduced to statistical software, and learn other simple but powerful statistical techniques.

This course emphasizes the concepts that motivate and underlie the techniques along with practical advice for implementation so that the participant can effectively use these techniques on their own processes. In addition to on-line SPC, this course points out the use of off-line SPC as the foundation for more advanced data analysis methods.

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Statistical Process Control (SPC) – Advanced

16 Hour Course

This second course in SPC fills a void left by many, if not virtually all, textbooks on SPC. Found among the standard assumptions for SPC are 1) no between subgroup variation, 2) normally distributed data, 3) uncorrelated data in time (no serial or autocorrelation), and 4) homogeneous subgroups. However, these so-called standard assumptions in textbooks seem to be more the exception than the rule for real industrial processes. Thus, this course presents the practical side of SPC implementation, including SPC chart design for number of subgroups, frequency of subgroups, number of out-of-control (OOC) rules, how to handle multilevel batched processes, non-normal data, serially correlated data, fixed effects within subgroups, as well as special SPC techniques such as zero-inflated models for detection limit censored data and normalized charts.

This is the practical side of SPC that is usually not taught in textbooks but is essential to meet the practical demands of industry. By following techniques from this course, SPC charts will better be able to separate common from special cause and be truly effective for making the correct process decisions. These methods are a “must” for anyone who has struggled with making SPC effective in real industrial situations.

VISIT OUR WEBSITE FOR MORE DETAILS

Statistical Strategies for Managers

16 Hour Course

A weak link in the sustainability of training for engineers is the role of management to use statistical strategies, when appropriate, to direct data collection and require data analyses for decisions. Managers should have an understanding of statistical strategies for business objectives, managers should know what their engineers, researchers, and scientists are being taught, and managers should be able to leverage data to set the right priorities, direct the right actions, and make the right decisions. This course will acquaint managers with the statistical strategies and methods necessary to characterize, improve, and control processes and products.

This course is organized into bite-sized modules that can fit into a manager's busy schedule, to acquaint management with the necessary thinking skills to understand how data, with the right statistical strategies, can be used to achieve specific business goals. Although managers are not taught here to use statistical software, they do learn what a method or strategy does, the correct assumptions for use, how to interpret software output, as well as how to check the validity of an analysis by knowing the right questions to ask and how to avoid common pitfalls. For example, managers are taught the important skill of knowing what sample size is required since this determines the time and resources
necessary to reach a stated objective.

VISIT OUR WEBSITE FOR MORE DETAILS

Introduction to Supply Chain Management (SCM)

12 Hour Course

Supply chains are what enable organizations to deliver value to customers and stakeholders. They are always evolving to keep pace with product developments, competitive pressures, and global dynamics. Supply chain professionals frequently find themselves scrambling to keep up with the latest set of challenges confronting their supply chains.

In order to realize the most from a supply chain, practitioners must have a solid understanding of:

1. Supply Chain design and mechanics
2. The supply chain's role in strategy execution
3. Key indicators of supply chain performance.
4. Strategies to remove waste and increase supply chain contribution.
5. Likely future demands for the management of supply chains.

The course uses a combination of lecture, discussion and hands-on simulations to give participants a working foundation in all of these imperatives.

VISIT OUR WEBSITE FOR MORE DETAILS

Train-the-Trainer: Achieving High Levels of Performance

16 Hour Course

Train-the-Trainer is an intensive 16-hour (2 day) program that prepares individuals responsible for training others to get their trainees to the desired level of competence in the shortest possible time. Participants learn how to apply a step-by-step framework to deliver on-the-job training that provides new learners with the necessary skills and knowledge to successfully execute job tasks. When using these strategies, trainers must take into consideration each trainee's readiness to learn, baseline competency, preferred learning style, and motivation to learn, as well as possible barriers to learning. The program provides a comprehensive practicum in which each participant leads a mini training session that incorporates real-life scenarios to ensure that training is relatable and actionable. Each participant will receive a critique with valuable feedback to enhance their training skills as they relate to the specific content of their current job tasks.

VISIT OUR WEBSITE FOR MORE DETAILS

Professional Development

5 Functions of Great Teams

16 Hour Course

This interactive workshop and group experience provides leaders tools and methods to enhance team performance. An in-depth analysis identifies strengths and growth areas as they apply to teams.

Teams receive learning to develop their leadership competencies. Insights are shared to develop as a team and to be mindful of areas that could impact team effectiveness. Participants learn how their unique individual strengths contribute to the team's strengths as well as challenges. Insights are shared to develop as a team and to be mindful of pitfalls that impair both the team and each other's individual effectiveness.

Using the LionsLead training materials and 5 Dysfunctions of a Team book by Patrick Lencioni as well as evaluation tools, this workshop focuses on critical team functions and the behaviors that lead to their success. This includes emphasis on Self-Leadership, to know and lead yourself first, as being critical to effectively building relationships and leading others. Including a particular focus on emotional intelligence. Other topics include building team trust, improving team accountability and achieving better results towards team objectives.

Training and Results are presented through interactive discussion, team exercises, and application of the findings. This workshop and associated evaluation methods provide concise and powerful data that reveals primary and secondary team roles critical to creating high performance teams.

VISIT OUR WEBSITE FOR MORE DETAILS

Change Management

12 Hour Course

Whether you're dealing with a planned initiative, volatile industry, or unexpected situation, change is inevitable. This course covers the Guiding Principles for Change including how to identify the organization's approach and process to change, how to develop a business case for change, determine governance for the change, how to address the people side of change, how to create a change plan, and how to influence those who will make the change and, of course, the desired result, a reality. Instruction is provided using the Adult Learning Model and can be virtual or in-person. Taking this course will increase an employee's ability to identify, create, navigate, and realize change effectively.

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Conflict Management

8 Hour Course

Conflict management is the process of limiting the negative aspects of conflict while increasing the positive. The aim of conflict management is to enhance learning and group outcomes, including effectiveness or performance in organizational settings. Properly managed conflict can improve group outcomes.

Conflict is inevitable, especially when work teams are diverse and stress levels are high. Conflict results from:

- Poor Relationships
- Externals & Moods
- Ineffective Structure
- Varying Interests
- Opposing Values
- Improper Data

During this course, the instructor leads participants through a series of exercises and facilitated discussions to develop an understanding of how to achieve better results.

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Consensus Building

8 Hour Course

There is little consensus on what critical thinking and problem solving are. Within the context of management, however, there is widespread agreement that taking on multiple perspectives about an issue leads to more effective courses of action.
This course draws upon the work of Edward DeBono's Six Thinking Hats model. The "hats" ensure that each component of an issue receives adequate consideration.

These are:

- Hard Data
- Intuition
- Downside Risks
- Upside Benefits
- Creativity
- Control

In addition, participants are introduced to a process of perspective taking or stakeholder analysis.

VISIT OUR WEBSITE FOR MORE DETAILS

Create a Culture of Performance and Accountability in Your Organization

16 Hour Course

Grow into a decisive leader using the practical skills that will transform your current methods of management, employee engagement, and productivity and performance oversight. Unlike traditional management methods, this workshop provides supervisors and managers the advanced skills needed to truly succeed in effectively managing and developing employees in a government work environment.

Through class interaction and group exercises, participants will learn the importance of creating a culture that demands excellence and productivity. You will learn powerful processes and techniques used to develop, mentor and coach employees to unleash the human potential of each individual and the organization as a whole. Participants will learn proven strategies to increase influence, conquer performance issues, and increase accountability. Attendees learn how to develop operating mechanisms and processes through hands-on exercises, so they gain the skills needed to create and sustain a culture of performance while in class.

This workshop addresses real world situations and approaches concepts from a perspective that makes implementation practical even with the most challenging personality/performance landscape. This training will pull back and remove constraints and empower people to maximize potential in relationships, profits, and purpose.

VISIT OUR WEBSITE FOR MORE DETAILS

Customer Service Excellence

12 Hour Course

Everyone SAYS it… "We pride ourselves on excellent customer service!" Those who attend Customer Service Excellence training create processes and best practices to actually LIVE it! The focus of this course is on retaining and upselling customers, relationship building, and increasing customer satisfaction ratings. Topics include: Cross-selling, Handling difficult situations, and Optimizing the customer service call process. Training uses the adult-learning model.

VISIT OUR WEBSITE FOR MORE DETAILS

Effective Communication

12 Hour Course

In what situations do you find it most difficult to communicate? Is it when giving feedback, critiquing others, or dealing with a lack of performance issue? How about when you think your manager or supervisor is wrong?

In this classroom-based, hands-on course, participants learn and practice the techniques and models of effective communications using real-world situations in a safe training environment. During training each participant will also take self-assessments to identify their strengths, weaknesses, and specific social style (Driving, Expressive, Amiable, or Analytical). Additional topics include: Active and Reflective Listening, Feedback, Team Communications, when to use technology to communicate, and the importance of face-to-face conversations.

VISIT OUR WEBSITE FOR MORE DETAILS

Effective Meetings

8 Hour Course

Research shows that the average individual in our society today will sit through 9,000 hours of meetings in their lifetime! That is over 365 days spent in meetings – not to mention the thousands of dollars spent on meetings. Meetings can be run efficiently and managed in a way that produces high impact. These techniques will allow participants to produce successful results from any meeting, whether as a participant or leader.

VISIT OUR WEBSITE FOR MORE DETAILS

Emotional Management & Wellness

4 Hour Course

At work and outside of work, employees frequently encounter situations that spark a variety of emotions. There can be disagreements over decisions, frustration of not being taken seriously, disappointment over not getting a promotion, or even total dissatisfaction with a job. It's important to know when and how to express emotions, and when to keep them in check.

Outbursts, passive-aggressive behavior, or detachment are not constructive ways to handle emotions at work. While it is not always possible to check emotions at the door, it is possible to figure out what triggers emotional responses and then learn how to respond appropriately.

Emotional Management & Wellness provides the tools needed to recognize your emotional triggers, control your emotional and physical responses, and handle other's emotions.

VISIT OUR WEBSITE FOR MORE DETAILS

Empathic Leadership

8 Hour Course

Organizations today face unprecedented disruption, uncertainty & change – AND immense opportunity. Essential to their resilience and future success is a culture of honest, authentic, human-centered leadership that prioritizes employee well-being and workplace relationships.

From multinational corporations to local teaching hospitals, savvy leaders are incorporating empathic practices and realizing benefits, including increased employee engagement & productivity, greater constructive conflict, growing customer/client loyalty and improved business results.

In this course for senior leaders, participants will learn &/or review the communication skills & behaviors foundational to empathic leadership. Employees below the senior level can experience the full eight-hour course that includes role-playing and create an action plan to implement immediately after training is complete.

Empathic Leadership introduces key principles and practices of leading experts in empathy in organizations and empathic communication including Marshall B. Rosenberg, PhD, Daniel Goleman, Marie R. Miyashiro, Simon Sinek, and Helen Reiss, MD.

According to a 2021 Workforce Empathy study* 84% of CEOs said empathy leads to better business outcomes. And yet, 7 in 10 CEOs find it difficult to implement. Even for those without a strong natural inclination, empathy can be learned.

**Source: Businessolver – theempathybusiness.com*

VISIT OUR WEBSITE FOR MORE DETAILS

Feedback and Conflict Management

8 Hour Course

High-quality feedback & conflict management is an essential element in any thriving organization. Yet few of us are taught how to do it, and even fewer are actually eager to give and receive feedback, especially when it is perceived as negative. The fear of hurting others' feelings, and risk of being shamed ourselves, often prevent us from embracing this fundamental process.

The goal of this training is to build participants' skills, willingness, and confidence in giving and receiving feedback and managing conflict, and then taking it a step further-to positive action that leads to improved outcomes.

This course leads participants to explore and practice the necessary conditions, mindset, skills and tools associated with both topics.

VISIT OUR WEBSITE FOR MORE DETAILS

Fundamentals of Technical Writing for the Life Sciences Industry

16 Hour Course

Fundamentals of Technical Writing for the Life Sciences Industry is designed for those in the Life Sciences industry who need to write about their work or submit their work to a regulatory body. Training includes an overview of Technical Writing and Regulatory Agencies and Regulations, as well as technical instruction on writing for the regulatory audience: sentences and paragraphs, word use, punctuation, readability, and the writing and review process.

VISIT OUR WEBSITE FOR MORE DETAILS

HR: New Employee Hiring, Orientation, Performance Review

12 Hour Course

It is said that you cannot motivate people. You CAN, however, provide a motivational environment. This course ensures the most effective and productive human resource environment possible from new hires to high performing teams. Participants are exposed to the Employee Commitment Curve, a phenomenon that can't be avoided that tracks an employee's commitment level in the company and how to manage it for optimal productivity.

VISIT OUR WEBSITE FOR MORE DETAILS

Leadership Insight for People with Technical Backgrounds

16 Hour Course

Technical thinkers often prefer objectivity and verifiable truth over personal experience. This seminar offers participants practical and immediately applicable leadership insight based on research, case reviews, and credible data. Effective frontline leadership is the key to organizational success. The balancing act required to meet organizational and employee needs requires skill, self-understanding, understanding others, and a vision for the future.

VISIT OUR WEBSITE FOR MORE DETAILS

Leadership: Meeting the Needs of Employees and the Company

32 Hour Course

Effective leadership is the key to organizational success. Many leaders are promoted into their roles based on knowledge and technical competency as an individual contributor. The competencies to be successful in the leadership role expand to include the ability to influence, adapt, take initiative, manage the performance of others, develop talent, and provide feedback.

Throughout this highly interactive series, participants will both learn and use skills necessary to effectively manage relationships with their direct reports, peers, and managers. Participants will leave with the ability to effectively apply the skills they learned to their day-to-day work.

VISIT OUR WEBSITE FOR MORE DETAILS

Management Skills

16 Hour Course

The success of an organization is largely dependent on its managers and leaders. Success is usually defined by tangible results, and the manager is accountable to motivate and develop the team to deliver the desired outcomes.

Management Skills is for those who are looking for higher level processes, tools, and systems to consistently deliver results to the company from those people they lead. Talent development, coaching, delegation, and accountability ideas and systems will be shared and new processes and tools created and implemented immediately following each session. Content in this course comes from many of the leading management gurus, including Ken Blanchard, Stephen Covey, and John C. Maxwell.

VISIT OUR WEBSITE FOR MORE DETAILS

Manufacturing Business Simulation

8 Hour Course

Empower your employees to think like business owners!

Using a unique Celemi® board-based business simulation, teams of four participants form the incoming management team of A&O Inc., an established company that is facing tough challenges. The company is not profitable, is losing market share, and there are increasing demands from suppliers and customers. A&O Inc. needs a new, disciplined financial strategy, and participants are asked to provide one.

Participants simulate three years of business performance, making changes that triple profitably, create a lot of cash, and take Return on Assets from 9% to almost 20% and Return on Owners Equity from 5% to 16%. The highly interactive simulation is closely tied to their reality. A variety of challenges and some fun competition help participants learn by doing.

Through a series of exercises, participants also learn firsthand how to monitor cash flow, better utilize resources, and improve productivity. Participants will work with the balance sheets and Profit & Loss statements, learn how to measure results, and understand how their daily decisions impact the company financially and strategically.

VISIT OUR WEBSITE FOR MORE DETAILS

Microsoft Excel Advanced

6 Hour Course

Microsoft Excel Advanced training is a powerful tool you can use to create and format spreadsheets and analyze and share information to make more informed decisions. This class is designed for students that want to use the full power of Excel with functions, VLookups, PivotTables and Macros.

VISIT OUR WEBSITE FOR MORE DETAILS

Microsoft Excel Intermediate

6 Hour Course

Elevate your Excel skills with this comprehensive intermediate course designed to enhance your confidence in working with spreadsheets. You'll master essential formulas, functions, and cell references, including relative and absolute references, and improve your navigation skills with quick tips. Dive into Excel essentials like conditional formatting, data validation, and date management while gaining expert tips for printing. Explore advanced workbook management with three-dimensional cell references, named ranges, and range-based functions. Unlock the power of graphing by learning various chart types, formatting, and data manipulation. Master the IF function for dynamic decision-making and explore powerful lookup functions like VLOOKUP and XLOOKUP. Finally, prepare your data with tables and discover the full potential of PivotTables and PivotCharts, including the use of slicers and timelines for interactive data analysis.

VISIT OUR WEBSITE FOR MORE DETAILS

Microsoft Excel Introduction

6 Hour Course

Microsoft Excel training is a powerful tool you can use to create and format spreadsheets and analyze and share information to make more informed decisions.

VISIT OUR WEBSITE FOR MORE DETAILS

Microsoft PowerPoint Intermediate

6 Hour Course

Meetings, instruction, training, pitches; these are all a part of our daily lives. We are often called upon to deliver presentations with little notice, at multiple venues, and with varying requirements. Microsoft PowerPoint training provides you with a variety of tools that can help you deliver content in nearly any situation, while saving time and effort.

VISIT OUR WEBSITE FOR MORE DETAILS

Negotiation Skills

16 Hour Course

People who can master the art of negotiation find they can save time, save money, develop a higher degree of satisfaction with outcomes at home and at work, and earn greater respect in the workplace.

Negotiating is a fundamental fact of life at any level. This interactive workshop ensures participants gain skills and confidence when negotiating with both internal and external clients. Training also includes techniques to promote effective communications and to turn face-to-face confrontation into side-by-side problem solving.

Two books, Getting Past No and Getting To Yes, both authored by William Ury, and educational curriculum from the Harvard University Business School,
are referenced throughout the training.

VISIT OUR WEBSITE FOR MORE DETAILS

Personal Productivity

12 Hour Course

Personal productivity is an interactive training that has participants identify and set SMART goals during the class. These goals will have the purpose of increasing sales, increasing service, increasing revenue, or decreasing expenses. The bottom line results of the goals will exceed the cost of the entire training event.

Employees often find themselves busy instead of productive and feel overwhelmed with the amount of tasks on their to-do lists. This training will introduce participants to current time management tips, processes, and tools to analyze and adjust activities, ensuring the highest priority behaviors and action steps toward pre-determined goals are scheduled, executed, and measured through completion. A time analysis tool will be conducted to understand where time is currently being spent and determine which tasks need to be done, deleted, delegated, or delayed.

The entire process of goal setting, time management, performance management, and motivation helps an individual or team create a goal achievement culture. It is also a holistic process, allowing participants to design and establish a healthy work/life balance and achieve their ultimate success, potential, and happiness in every area of life.

VISIT OUR WEBSITE FOR MORE DETAILS

Presentation Skills

16 Hour Course

Whether managing a meeting, or communicating with peers, colleagues, community, or professional groups, your single most important business tool is your ability to present ideas clearly and effectively.

Sitting or standing, in casual or formal situations, Presentations Skills teaches you how to create meaningful presentations that your audience will take note of, care about and buy into.

Presentation Skills is a highly interactive skill development workshop that takes participants beyond theory to actual practice and helps them develop their own personal delivery style.

During training participants will use their cell phones (or audio-visual capability will be provided) to record themselves using the techniques learned during all three sessions on Presentation Skills. Each participant will return to the following session with a video demonstrating mastery of the skills and techniques.

VISIT OUR WEBSITE FOR MORE DETAILS

Presentation Skills II: Organizational Storytelling

16 Hour Course

Stories are a powerful medium for creating and making meaning… Stories communicate deeply held individual and organizational values. Listening to the stories… is like reading the maps that guide our thoughts and behaviors.

Russ S. Moxley
Center for Creative Leadership

To be an effective communicator you must tell stories that nurture, comfort, and motivate internal and external stakeholders.

Organizational Storytelling helps you identify, organize, and tell the important stories about you, your department, your organization and its products and services.

It takes you beyond theory to actual practice and is an excellent team building exercise. Organizational Storytelling works with our natural affinity to listen to and tell good stories.

During training participants will use their cell phones (or audio-visual capability will be provided) during the first four hours to record themselves using the techniques learned. Each participant will then present during the second four hours with a video demonstrating mastery of the skills and techniques.

VISIT OUR WEBSITE FOR MORE DETAILS

Sales Excellence

12 Hour Course

Sales Excellence improves the skills and competencies of all sales people and ensures they are strong in every step every step of the sales process from prospecting through post-sales service and upselling opportunities. Training topics include how to identify prospects, how to analyze their needs, how to create and present a proposal, how to overcome obstacles, and how to close deals.

Attendees practice new tools and tactics in role-playing activities. Assignments are simply identifying opportunities to implement what is learned in the classroom in the real world.

VISIT OUR WEBSITE FOR MORE DETAILS

Social Styles & How To Work With Others

8 Hour Course

This course teaches SOCIAL STYLES, the world's leading Behavioral Style model used by thousands of organizations to improve communication skills and relationships. Every employee at every level of the company attends this instructor-led course, either onsite or virtually. Benefits include improving communications, reducing conflict, and increasing staff retention. Topics include understanding the four Social Styles, how to identify your predominant style, recognize the Social Style of others, strengths and potential weaknesses of each Social Style, and how to flex how you communicate to meet the needs of others. Immediate implementation makes relationships and communications much more effective with internal and external customers.

VISIT OUR WEBSITE FOR MORE DETAILS

Supervisory Skills

16 Hour Course

Far too often people are promoted into leadership positions without the proper training. Just because an employee is a good 'worker' doesn't mean he or she will automatically be a great 'leader' of others! Being a leader is an entirely different job with an entirely different set of skills and competencies.

Leaders are also not born proficient; there is a substantial amount of learning and experience that is needed to be successful. The goal of this training is to accelerate the learning curve. This course teaches participants the techniques and methodologies of supervising and leading themselves and others, which will immediately be put into action.

Participants will assess their own levels of proficiency and create a plan to improve effectiveness. They will also begin to identify and change their immediate work environment into a more healthy, positive, and professional one.

Supervisory Skills covers the key concepts of many of the leading management gurus, including Ken Blanchard, Stephen Covey, and John C Maxwell.

VISIT OUR WEBSITE FOR MORE DETAILS

Team Building

12 Hour Course

This classroom-based, adult learning training event promotes team building, morale, and team performance. Participants will learn the five stages of team performance – Forming, Storming, Norming, Performing, and Adjourning – and create action plans to optimize each one for their own team.

During training participants will take a Jung Personality assessment and learn about their personality type and potential strengths and potential weaknesses of that type. They will learn about other personality types and discuss tactics to use when working with people who are different from them.

Participants will also take the TORI Team Building Principles assessment and learn how to optimize Trust, Openness, Realization, and Interdependence in their teams.

VISIT OUR WEBSITE FOR MORE DETAILS

Train-the-Trainer: Achieving High Levels of Performance

16 Hour Course

Train-the-Trainer is an intensive 16-hour (2 day) program that prepares individuals responsible for training others to get their trainees to the desired level of competence in the shortest possible time. Participants learn how to apply a step-by-step framework to deliver on-the-job training that provides new learners with the necessary skills and knowledge to successfully execute job tasks. When using these strategies, trainers must take into consideration each trainee's readiness to learn, baseline competency, preferred learning style, and motivation to learn, as well as possible barriers to learning. The program provides a comprehensive practicum in which each participant leads a mini training session that incorporates real-life scenarios to ensure that training is relatable and actionable. Each participant will receive a critique with valuable feedback to enhance their training skills as they relate to the specific content of their current job tasks.

VISIT OUR WEBSITE FOR MORE DETAILS

Transformational Leadership

16 Hour Course

Grow into a decisive leader using the practical skills that will transform your current methods of management, employee engagement, and productivity and performance oversight. Unlike traditional management methods, this workshop provides leaders the advanced skills needed to truly succeed in effectively managing and developing employees in any work environment.

Through class interaction and group exercises, participants will learn the importance of creating a culture that demands excellence and productivity. You will learn powerful processes and techniques used to develop, mentor and coach employees to unleash the human potential of each individual and the organization as a whole. Participants will learn proven strategies to increase influence, conquer performance issues, and increase accountability. Attendees learn how to develop operating mechanisms and processes through hands-on exercises, so they gain the skills needed to create and sustain a culture of performance.

Using strategies, methods and tools of Transformational Leadership system this course provides strategics and methods to successfully navigate and address real world challenges. Participants will also enjoy access to the TL On Demand video training system to expedite learning.

VISIT OUR WEBSITE FOR MORE DETAILS

Transformational Leadership (8 Week Virtual Training)

16 Hour Course

Grow into a decisive leader using the practical skills that will transform your current methods of management, employee engagement, and productivity and performance oversight. Unlike traditional management methods, this workshop provides leaders the advanced skills needed to truly succeed in effectively managing and developing employees in any work environment.

Through class interaction and group exercises, participants will learn the importance of creating a culture that demands excellence and productivity. You will learn powerful processes and techniques used to develop, mentor and coach employees to unleash the human potential of each individual and the organization as a whole.

Participants will learn proven strategies to increase influence, conquer performance issues, and increase accountability. Attendees learn how to develop operating mechanisms and processes through hands-on exercises, so they gain the skills needed to create and sustain a culture of performance.

Using strategies, methods and tools of Transformational Leadership system this course provides strategics and methods to successfully navigate and address real world challenges. Participants will also enjoy access to the TL On Demand video training system to expedite learning.

VISIT OUR WEBSITE FOR MORE DETAILS

Workplace Harassment Prevention Training

3 Hour Course

Workplace Harassment Prevention Training is designed to help employees across your organization recognize, address, and prevent harassment, stereotyping, and bias. The goals of training are to promote cultural competency and to create a culture of respectful communication. Instruction is hands-on and will incorporate real-life scenarios to ensure that sessions are relatable and actionable.

VISIT OUR WEBSITE FOR MORE DETAILS

Full Course Descriptions: www.qualitysupportgroup.com
Please contact Chris Scangas with inquiries:
888-336-1124 | chris@qualitysupportgroup.com

Environmental Management Systems

Internal Quality Auditing Foundations

8 Hour Course

This 8-hour course distills down best practices in conducting internal quality audits within any industry. Audit planning, execution, finding classification, and reporting are discussed, as well as the use of key auditing tools such as turtle diagrams, pareto diagrams, fishbone diagrams, 5-why process and more.

VISIT OUR WEBSITE FOR MORE DETAILS

ISO 14001:2015 Internal Auditing

16 Hour Course

ISO 14000 is a series of international standards that deal with environmental issues. The first of this series, ISO 14001, specifies the requirements for an Environmental Management System (EMS) which is the part of an organization's overall management system used to manage environmental issues. ISO 14001:2015 provides organizations with a systematic methodology to understand strategic implications of environmental management, address adverse effects on the environment or the organization, satisfy compliance obligations, and leverage opportunities for improvement. Environmental issues are at the forefront of corporate priorities today. They present risks and opportunities to both the local/regional environmental conditions and to the organization's objectives. Having an EMS is important for aligning environmental priorities with business priorities, ensuring that processes for preventing and mitigating environmental impacts are effectively implemented throughout the organization, and driving continual improvement. One of the processes within an EMS that drives improvement is an internal audit.

This highly interactive course takes students through all stages of an internal EMS audit, using realistic case studies and exercises to emphasize the business value gained from conducting effective audits. Through workshops, discussions, and role-plays participants will learn to develop an effective audit program, and how to plan, conduct, and report on an EMS audit in accordance with ISO 19011, Management System Auditing Guidelines. This course will help students learn to accurately interpret and audit against the ISO 14001:2015 requirements. Participants can use these skills to establish or enhance an existing internal audit program and perform internal EMS audits in a manner that provides the greatest business benefit.

VISIT OUR WEBSITE FOR MORE DETAILS

ISO 14001:2015 Requirements Workshop

8 Hour Course

ISO 14001:2015 is a global environmental management system that has been adopted by thousands of companies all over the world. The intent of ISO 14001:2015 Training is to provide a framework for a holistic, strategic approach to an organization's environmental policy, plans, and actions. The benefits of implementing its framework include increased efficiency in the use of energy and resources as well as a reduction in waste outputs.

The 2015 revision to ISO 14001 is based on the PDCA approach, and clauses follow this structure:

1. Introduction
2. Scope
3. Normative references
4. Terms and definitions
5. Context of the organization
6. Leadership 6: Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement

Anyone familiar with ISO 14001:2015 will notice that the ISO 14001:2015 Standard represents a significant change in structure. This revised format, in addition to the adoption of Annex SL, will consist of multiple discipline-specific requirements to make it a fully functional environmental management system standard.

Join QSG as we map out the latest versions of the revisions to ISO 14001:2015. We will provide the tools and techniques to help you understand the spirit and letter of these new revisions, as well as give you the latest information available from the technical committees to help you and your organization adopt this new approach.

VISIT OUR WEBSITE FOR MORE DETAILS

ISO 45001 Internal Auditing

16 Hour Course

ISO 45001 is an Occupational Health and Safety (OHS) international standard that provides a framework for an organization to proactively manage the risks and opportunities associated with workplace hazards in order to prevent work-related injury and ill health to workers. This management system framework is based on the Plan-Do-Check-Act model, augmented with requirements for visible support and commitment by top management, and the engagement and involvement of workers. The intended outcome is to provide a safe and healthy workplace.

This standard has been designed to be integrated into an organization's overall Management System (MS) and implemented seamlessly with its Quality and/or Environmental Management System, such as ISO 9001 and ISO 14001.

This highly interactive course takes students through all stages of an internal OHS MS audit, using realistic case studies and exercises to emphasize the business value gained from conducting effective audits. Through workshops, discussions, and role-plays, participants will learn to develop an effective audit program, and how to plan, conduct, and report results in accordance with ISO 19011, Management System Auditing Guidelines. This course will help students learn to accurately interpret and audit against the ISO 45001:2018 requirements. Participants can use these skills to establish or enhance an existing internal audit program and perform internal OHS MS audits in a manner that provides the greatest business benefit.

VISIT OUR WEBSITE FOR MORE DETAILS

ISO 45001 Overview

ISO 45001 is an Occupational Health and Safety (OHS) international standard that provides a framework for an organization to proactively manage the risks and opportunities associated with workplace hazards in order to prevent work-related injury and ill health to workers. This management system framework is based on the Plan-Do-Check-Act model, augmented with requirements for visible support and commitment by top management, and the engagement and involvement of workers. The intended outcome is to provide a safe and healthy workplace.

This standard has been designed to be integrated into an organization's overall Management System (MS) and implemented seamlessly with its Quality and/or Environmental Management System, such as ISO 9001 and ISO 14001.

This interactive course takes students through each of the clauses of ISO 45001, providing an overview of the key requirements. Through discussions and team exercises, participants will understand the underlying concepts of:

- Organizational Context,
- Hazard identification & Risk Assessment,
- Worker participation and consultation,
- Leadership and Commitment, and
- Improvement of OHSMS and OHS performance

This course will help students learn to accurately interpret the ISO 45001:2018 requirements. Participants can use these skills to establish or enhance an existing Occupational Health and Safety program in a manner that provides the greatest business benefit.

VISIT OUR WEBSITE FOR MORE DETAILS

ISO 45001:2018 Lead Auditor, Exemplar Global Certified

32 Hour Course

ISO 45001 is a milestone! As the world's first International Standard dealing with health and safety at work, ISO 45001, Occupational health and safety management systems – Requirements with guidance for use, offers a single, clear framework for all organizations wishing to improve their OH&S performance. Directed at the top management of an organization, it aims to provide a safe and healthy workplace for employees and visitors. To achieve this, it is crucial to control all factors that might result in illness, injury, and in extreme cases death, by mitigating adverse effects on the physical, mental and cognitive condition of a person – and ISO 45001 Lead Auditor training covers all those aspects.

While ISO 45001 draws on OHSAS 18001 – the former benchmark for OH&S – it is a new and distinct standard, not a revision or update, and is due to be phased in gradually over the next three years. Organizations will therefore need to revise their current thinking and work practices to maintain organizational compliance.

Are you involved in or responsible for the planning, implementation or maintenance of the Occupational Health and Safety (OHS) management system? If so, the QSG's ISO 45001 Lead Auditor training course is suitable for you.

This course is designed to help participants understand the requirements of ISO 45001:2018 to conduct a successful audit. Training includes hands-on workshops to prepare for real-life auditing situations, and participants will learn to manage the audit process and complete reporting.

This is a four-day, instructor-led classroom course. There are written tests on each of the competency units on days 2, 3, and 4. Days 1 and 2 will cover ISO 45001 along with a corresponding competency exam (OH). Day 3 will cover management systems auditing (AU) along with a corresponding competency exam. Day 4 will cover leading management systems audit teams (TL) along with a corresponding competency exam.

VISIT OUR WEBSITE FOR MORE DETAILS

Managing Organizational Risk Using the Supplier Audit Program

16 Hour Course

In this new global economy, more than 50% of value creation is achieved outside of an organization's walls, or through their suppliers. In the United States, recent studies show that 100% of manufacturers' finished products include at least one element obtained from outside of their organization. This new reality, and the increased emphasis on supplier control in federal regulations, ISO 9001, and the various industry-specific quality management system standards, require that quality professionals have a thorough understanding of the supply chain management processes that control supplier selection and management. It is also necessary to understand where the quality function fits within the overall supply chain management process and how it interacts with other functions within that process.

Quality and quality audits are an important part of the supply chain management process. Conducting a successful supplier audit can be used as a means to identify, assess, and mitigate organizational risk. Audits can be combined with Lean and Six Sigma methodologies to help drive supplier improvement. Audits can also help foster communication and build relationships (and unfortunately the opposite can also be true).

This course provides a broader than usual review of the supply chain management process from the quality perspective and includes unique applications of the supplier audit process. It helps participants understand where the quality function fits within the overall supply chain management process, as well as how it interacts with other functions within that process. Most importantly, we discuss best practices in supplier auditing and how quality audits can be used beyond traditional conformance verification. The course includes training on how to implement a robust remote auditing program, and case studies are shared to demonstrate best practices in supply chain management and supplier quality auditing, and to help identify suboptimal practices to avoid.

VISIT OUR WEBSITE FOR MORE DETAILS

Full Course Descriptions: www.qualitysupportgroup.com
Please contact Chris Scangas with inquiries:
888-336-1124 | chris@qualitysupportgroup.com

Food Safety & Certification

Food Safety Preventive Control and HACCP – FDA

24 Hour Course

The Hazard-Analysis and Preventive Controls Rule of the US Food and Drug Administration indicates a Preventive Controls Qualified Individual must conduct or oversee certain aspects of the Food Safety Plan. The FSPCA Preventive Controls Course provides that training for your team.

Unfortunately, the FSPCA Preventive Controls Course does not fulfill customer and third-party audit requirements for HACCP training. QSG has the solution to meet your training needs in one course.

QSG is one of the few companies offering a combined course, under the permission of the FSPCA and the International HACCP Alliance. Participants receive all the training they need for both classes in 3 days rather than spending up to 4.5 days to achieve this goal. Two certificates are issued at the completion of the course.

VISIT OUR WEBSITE FOR MORE DETAILS

Food Safety Preventive Controls – FDA

20 Hour Course

Does your company have a Food Safety Preventive Controls Qualified Individual on site to help with FSPCA Training?

The FDA Preventive Controls Rule for Human Food has been in place since September 2016. It is imperative to understand expectations through this course to enable a functioning program.

The Hazard-Analysis and Preventive Controls Rule of the US Food and Drug Administration indicates only a qualified individual can appropriately manage a food safety preventive controls program. Does this apply to you?

If your facility is required to register with the FDA under section 415 of the Food, Drug, & Cosmetic Act, you must comply if your activities include manufacturing, processing, packing or holding human food.

Many activities required by law can only be conducted or overseen by a qualified individual. This is not the same as a HACCP-certified individual. This requires more to be in compliance with the Food Safety Modernization Act Rules. The FDA will begin enforcement of the Preventive Controls Rule for Human Food in September 2016. It is imperative to understand expectations through this course to enable a functioning program before that time.

This 2.5 day course, developed by the Food Safety Preventive Controls Alliance, uses the ONLY curriculum recognized by the FDA to meet requirements. Successful completion results in participants' qualification as a Preventive Controls Qualified Individual, who can design, implement, and maintain the company Food Safety Plan. The course will be taught by a Lead Instructor for the FSPCA Preventive Controls for Human Food Course.

Training materials include:

- A comprehensive manual with all slides,
- Explanations of key terms and concepts,
- Example model Food Safety Plans
- An exercise workbook with all sample forms
- Reference material to help you communicate requirements to your staff

Participants will receive their official FSPCA Preventive Controls Qualified Individual certificate.

VISIT OUR WEBSITE FOR MORE DETAILS

Food Safety Systems Internal Auditing

16 Hour Course

Food Safety System Internal Auditor training is designed specifically for the food and food-related industries. Founded on proven techniques, this course provides a comprehensive introduction to internal auditing for Safe Quality Food (SQF) Systems that can also be applied to other auditing schemes. Training covers essential elements of the SQF Standard, key concepts and skills necessary for internal auditing, and the development of risk-based auditing schedules. This course emphasizes clear communication of results, the effective use of corrective action, and follow-up to ensure internal auditing contributes toward successful attainment of company business and food safety objectives.

VISIT OUR WEBSITE FOR MORE DETAILS

Good Manufacturing Practice (GMP) for Food

16 Hour Course

Current food Good Manufacturing Practice for Food are published in Title 21 of the Food and Drug Administration's Code of Federal Regulations, Part 110 (21 CFR 117). GMPs describe the methods, equipment, facilities, and controls for producing processed food. As the minimum sanitary and processing requirements for producing safe and wholesome food, they are an important part of regulatory control over the safety of the nation's food supply. GMPs also serve as one basis for FDA inspections.

Good Manufacturing Practice for Food regulations are designed to be the "minimum" standards for the food industry, and because they are general in nature, the regulations use words such as "adequate," "appropriate" or "as necessary." Each firm must develop and implement procedures for each GMP requirement that will protect the food that they receive, store, or process from contamination. These procedures are specific to the individual firm since they are developed to meet the unique needs of the facility and their food products, processes, and equipment. Additionally, there may be many different strategies that are "adequate" or "appropriate" for different situations. The GMP is designed to provide this flexibility.

Different types of training are needed for individuals with different roles and responsibilities. This course is designed to accommodate individuals with overall responsibilities for developing and implementing effective procedures to meet GMP requirements and who are charged with assigning more directed tasks to production and other workers.

VISIT OUR WEBSITE FOR MORE DETAILS

HACCP Fundamentals and Implementation

16 Hour Course

Hazard Analysis and Critical Control Point (HACCP) is a practical, systematic management tool designed to ensure food and product safety. It identifies critical areas of handling and demonstrates where resources should be targeted to reduce the risk of selling an unsafe product. Benefits of HACCP include:

- Confidence that food safety is being effectively managed in your operation
- Prevention planning rather than defect control to ensure product safety
- Significant improvement in the area of product quality
- Customer confidence in the safety of your products through documentation

This course, provided by the HACCP Consulting Group, is accredited by the International HACCP Alliance and meets Global Food Safety Initiative requirements. This course is based on International CODEX Principles for HACCP and addresses the U.S. HACCP requirements based on attendees' specific needs.

VISIT OUR WEBSITE FOR MORE DETAILS

Implementing Safe Quality Food (SQF) 9.0 Systems

16 Hour Course

The Safe Quality Food (SQF) 9.0 Program is one of the world's leading globally accepted food safety and quality management systems. SQF provides independent certification that a food safety and quality system complies with international and domestic food safety regulations. It also assures consistent quality and that buyer specifications are being met. SQF certification is supported and often required by an increasing number of international retailers and foodservice providers.

When seeking certification, the SQF audit consists of two pieces:

1. The documentation audit, often completed off-site, is a review of written programs to assure the company is prepared prior to the on-site audit. This unique offering from SQF 9.0 provides the company an opportunity to improve the written program without damaging their potential for an "Excellent" audit score overall in the first year.
2. The on-site audit includes a thorough examination of facility conditions, processes and employee actions. The auditor collects evidence of how the written plan is implemented, as well as how records and training demonstrate an effective system.

The SQF 9.0 Code is a site-specific, process and product certification standard with an emphasis on the systematic application of CODEX Alimentarius Commission HACCP principles and guidelines for control of food safety and food quality hazards. When implementing SQF 9.0, many companies become overwhelmed with the number requirements. This course will help you distinguish between what must be done and what is recommended. We work to simplify the SQF 9.0 Code and ensure a solid understanding of the Code. Instruction also meets the SQFI standards for Practitioner and employee training.

VISIT OUR WEBSITE FOR MORE DETAILS

Full Course Descriptions: www.qualitysupportgroup.com
Please contact Chris Scangas with inquiries:
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MEMBERSHIP.

Where Quality Meets Community!

Over the last 30 years, Quality Support Group (QSG) has grown its membership to over 175 companies, and we continue to expand through networking and best-practice meetings, training opportunities, and word-of-mouth from satisfied members.

Your membership helps support QSG's diverse training and educational programs.
The financial support of our Members allows us to engage industry experts for our Quarterly Meetings and develop other initiatives.

Consider supporting QSG with a paid membership!

BENEFITS OF MEMBERSHIP

QSG Members gain access to an unparalleled peer network, industry-leading consulting and training solutions, and exclusive perks designed to enhance your business performance.

ALL MEMBERS RECEIVE:

- **FREE** Attendance at all Quarterly Networking Meetings
- **FREE** Grant Writing Services
- **FREE** 2-Hour Lean Assessment
- **FREE** 2-Hour Review of Your QMS
- **Discounts** on ALL Public Training Workshops
- RU **Credits** for ASQ Certifications
- **FREE** Webinars
- 1 **FREE** Seat in a Workshop
  16-Hour Workshop for Company Memberships
  8-Hour Workshop for Individual Memberships
- **Access** to a Pool of Qualified Second-Party Auditors
- **Access** to Master Black Belts for Best Practices & Benchmarking
- On-Site and Remote Training & Support Options

MEMBERSHIP OPTIONS

1	2	3	4	5
Individuals **$100**	Companies with **2 - 50** employees **$250**	Companies with **51 - 200** employees **$500**	Companies with **201 - 500** employees **$750**	Companies with **501 +** employees **$1000**

TESTIMONIALS.

Quality Support Group, Inc. has 250+ ★★★★★ Google Reviews:

Have worked with the Quality Support Group for 20+ years and we have always had a positive experience. The training services they have provided have been excellent, and they make every effort to tailor their programs to meet our specific needs.
I recommend Quality Support Group without reservation.
-- Kevin Travis, Manager of Global Quality Systems | **Velcro Companies**

★★★★★

We have done several projects and trainings with QSG in Germany, France and Japan, if you are in need of training or are seeking a partner with international experience who is well versed with global requirements and for us important, cultural differences, Quality Support Group is the partner you want! It's always a pleasure working with Quality Support Group. I have partnered with them multiple times in the last 15 years on various projects. Angelo Scangas is exceptionally knowledgeable and highly experienced in working with the various global interfaces. I am looking forward to our next project!
-- Dirk Eickmeier, Quality Manager | **Bose Corporation**

★★★★★

Worthen Industries has utilized the training services of QSG for several years. We have sent individual employees to scheduled quality training sessions with very positive feedback from them on both the training content and instructor. Additionally, within the past year we have contracted on-site training from QSG which they customized to fit our specific needs and our designated participants. We have no hesitancy to call on QSG for future training needs - their work is excellent.
-- Dennis Sasseville, Director of Corporate Sustainability & Quality Systems | **Worthen Industries**

★★★★★

Great, knowledgeable, and professional instructors! Angelo and his team worked closely with us early on to help us identify, prioritize, and plan our training needs. They also helped us with the application process to secure funding through Mass Workforce Training fund. The course offering QSG had was diverse and allowed us to cover technical topics like statistical techniques, DOE, and gauge R&R; risk management; and soft skills like project management and supervisory skills. QSG was also accommodating in terms of scheduling the courses so not to disrupt normal course of business. Content was tailored to regulated industries and relevant to our company needs. Instructors made it a point to use company examples when possible to put taught concepts to practice. I highly recommend QSG services for your company training needs.
-- Skander Limem, Product Innovation Manager | **Tepha, Inc.**

★★★★★

We have been working with QSG over the last 2 years on training topics, from ISO 17025, GMP, Lean Manufacturing, Green Belt to Internal Auditing and much more...
Every person we have had assigned for training has been extremely knowledgeable and professional.
QSG also wrote a Training Grant for our company that paid 100% of the training costs.
We are very satisfied with the support and the value we received from the relationship.
Give QSG a call! They are great to work with.
--Todd Place, Quality Manager | **AMETEK Brookfield**

Great, knowledgeable, and professional instructors!
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Further, QSG has been our training and consulting partner for over 5 years. The training and consulting they delivered was actionable and tailored to our specific needs.
I highly recommend QSG services for your company training needs!
--Skander Limem, Director of Innovation, Surgery R&D | **Becton Dickinson & Co**

Over the past 5 years I've worked with QSG on two MA Workforce Development Training Grants and several other paid seminars at several of our manufacturing sites across the US. Their grant writer worked with us every step of the way to develop a training plan and then prepare and submit the application. The entire process was a breeze!
Training topics have include Six Sigma, Advanced Problem Solving (Root Cause Analysis), Failure Modes and Effects Analysis, Statistical Process Control, Design of Experiments, The Team Process, Project Management, and Auditing.
I've had nothing but positive experiences all the way around and I consistently receive very positive feedback from trainees on the class content and instructors.
They have an extensive network of trainers with real world experience and have always been flexible to customize and even develop new training content from scratch when needed.
I highly recommend reaching out to QSG to discuss your business training needs!
--Reggie Gagnier, Director of Quality | **Entegris**

Quality Support Group provides world class training in many useful topics. Their trainers, specifically Don and Dave, are very knowledgeable and genuinely there to help you learn and understand. I took their Green Belt training and certification, and highly recommend it. They have excellent training material, software tools, and activities. They are teaching from many years of experience and have so much technical and industry knowledge that makes it easier to relate to, understand, and apply the concepts. From this experience, I will definitely be looking to get more training from them to improve my skills. I highly recommend reaching out to QSG for your training needs and more. My company, Hexagon, has trusted them for years, having them continually train our employees in regulatory standards, problem solving 8D, continuous improvement, etc.
-- Kyle Jordan, Business Operations Analyst | **Hexagon**

Full Course Descriptions: www.qualitysupportgroup.com
Please contact Chris Scangas with inquiries:
888-336-1124 | chris@qualitysupportgroup.com

LEADERSHIP TEAM & CONSULTANTS.

ANGELO SCANGAS
CEO AND CHIEF CUSTOMER OFFICER

BARBARA MACLACHLAN
PRESIDENT

CHRIS SCANGAS
OPERATIONS MANAGER

SETH DEYSHER
OPERATIONS MANAGER

ERIC DOODY
OPERATIONS MANAGER

PHIL SCANGAS
GRANT WRITER, DIGITAL CONTENT MANAGER

LEADERSHIP TEAM & CONSULTANTS

Charles A Gillis – Senior Consultant, Design Engineering
James F. Leonard – Senior Consultant, Process Improvement and Statistical Methods
Dr. Jane T. Wilson – Senior Consultant, Operational and Organizational Excellence
Peter J. Sherman – Senior Consultant, Lean Six Sigma
Dave Margil – Consultant, Lean Six Sigma
Susan Gorveatte – Consultant, Quality Management Systems / Auditing
Laura Halleck – Senior Consultant, Quality Management Systems
Paul Mullenix – Consultant, Statistical/Quality Methods and Six Sigma for Manufacturing, Research, and Service Industries
Saleha Yusof-Mullenix – Consultant, Statistical/Quality Methods and Six Sigma
Ken Campanale – Consultant, Quality and Regulatory Systems

TO MEET ALL THE PEOPLE BEHIND OUR SUCCESS ,CHECK OUT OUR **WEBSITE**!