Implementing an AS9100 Quality Management System
This guide to implementing an AS9100C Quality Management System (QMS) was prepared by ETI Group. The guide is based on our experiences assisting more than 650 small, medium and large companies through the complete ISO 9001/AS9100 implementation process from start to successful registration.
Quality management succeeds when the cost of the system is less than the cost of defects and poor service which would otherwise result.

PROFIT = INCOME - EXPENSES
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Introduction

For more and more companies, especially in the Aerospace Industry supply chain, implementing a Quality Management System (QMS) based on AS9100 is becoming a necessity! It can help win new customers as well as retain existing ones. While the goal is to achieve registration to the standard, it is not the only goal. The internal benefits of implementing an effective QMS are significant.

This e-book is intended to be a guide to implementing an AS9100 QMS in any organization. As the size and nature of organizations vary, we may not cover all of the circumstances unique to your company. We do however detail the typical process that ETI Group consultants use when assisting a company to implement an AS9100 QMS.
Introduction

Implementing an AS9100 QMS may seem daunting, especially for the smaller business, fortunately the standards are flexible and mandate requirements for your organization to follow but allow you to fulfill the requirements in a way that makes sense for your business. This allows a wide range of companies, both large and small, manufacturing and service to create a QMS that meets the specific needs of their business as well as the requirements of the AS9100C standard.

The AS9100 framework also provides an excellent and practical model from which to implement the additional requirements for an ISO 13485 or ISO/TS 16949 QMS.
Introduction

Every organization has management procedures and instructions for creating and delivering their products and services to customers. Most have evolved over the years, and are generally adequate – if they weren’t, organizations would quickly go out of business.

However poor management systems can lead to wasteful processes, poor products and services, and dissatisfied customers. An efficient organization can typically be characterized by:

- Explicit awareness of, and concern for, the needs of customers and other stakeholders (suppliers, employees, society, etc.),
- Senior and middle managers who understand and focus on business needs,
- A commitment to continuously improve products and services,
- Employee development and training programs that meet the needs of the organization,
- Processes designed to identify and reduce wasted resources,
- Complete, current, clear and relevant documentation.

Organizations are increasingly introducing formal Quality Management Systems (QMS) to gain these and other benefits.
Managing Change

The greatest resource a company has is its people, inevitably there will be resistance to changes when implementing and maintaining your QMS.

Resistance has many faces including denial, lack of motivation and questioning of the motivation behind the decision to implement a QMS. Strategies for managing change should be addressed during implementation planning.
Managing Change

The journey from a pre-QMS organization to one that operates with the quality and controls necessary for certification is not a casual task and is unlikely to succeed without the commitment and dedicated support of top management.

<table>
<thead>
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<th>For Management</th>
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<td>❖ A Solution</td>
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<td>❖ Logical</td>
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<tr>
<td>❖ Opportunistic</td>
<td>❖ Disruptive</td>
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Intentional                                                                 Disruptive

Some common forms of resistance and suggested solutions are detailed on the following page.
## Managing Change

### Common Forms of Resistance

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<th>Common Complaint</th>
<th>Root Cause</th>
<th>Proven Solution</th>
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| “This is just another ‘flavor of the month.’” | Past initiatives have been launched with high fanfare and little results    | • Demonstrate leadership belief  
• Select best people as trainers  
• Minimize fanfare                                                                  |
| “I don’t have time...cannot free up resources.” | Too many projects/activities in process                                       | • Stop other initiatives not related to current priorities or that only make a minor contribution. |
| “This can’t work in my area of the business.” | Misconception about how a Quality Management System works or lack of information about how it applies | • AS9100 has been successfully implemented in every business sector.  
• Show examples from other similar companies that are AS9100 registered. |
| “How is this different from past improvement initiatives?” | Fatigue from many improvement initiatives                                    | • Explain/show key differences.                                                  |
| “Is this incremental to my existing business plan?” | Don’t want to add to existing workload                                       | • Align AS9100 implementation work to directly support the existing business plan |
| “Does management really believe/support it?” | Lack of confidence that everyone is on board                                 | • Genuine leadership commitment to implementation is required – not just talk.    |
What is a Quality Management System?

Developed by the International Aerospace Quality Group (IAQG), AS9100 comprises a set of requirements that reflect time-proven, universally accepted good business practices, the majority of which are mandatory. AS9100C includes all of the ISO 9001:2008 requirements in their entirety plus additional Aerospace Industry specific requirements.

The aim of a QMS is to assure that an organization consistently meets customer needs by controlling the core processes that affect them such as sales orders, design, production, inspection, delivery, etc.

The requirements also go beyond these "core" processes to address support processes like purchasing, training, calibration, maintenance, and performance metrics.
What is a Quality Management System?

A Process Approach

An important aspect of a QMS is its process-oriented approach. Instead of looking at departments and individual processes, it requires an organization to look at how processes interact and integrate with each other.
What is a Quality Management System?

A QMS is much more than a comprehensive set of rules. It will help you manage your business more effectively and improve the performance of your organization on an ongoing basis.

**Say what you’ll do!**

**Do what you say!**

**Prove It!**

**Improve It!**

Basically, AS9100 requirements fall under four major categories:

- Requirements that help assure that the organization’s products and/or services meet customer specifications.
- Requirements that assure the QMS is consistently implemented and verifiable.

- Requirements for measuring the effectiveness of the various components of the system.
- Requirements that support the continual improvement of the company’s ability to meet customer needs.

**Say what you’ll do** through the Quality Management System (QMS) documentation.

**Do what you say** through disciplined use of the QMS.

**Prove it** using Internal Audits (and External ones).

**Improve it** using the Corrective and Preventive Action System.
What is a Quality Management System?

The general components of a Quality Management System (QMS), as defined by ISO Technical Committee, TC176, are as follows:

**Customer Focus:** Customer’s needs and expectations need to be identified and achieved.

**Leadership:** Top Management must show their commitment to the QMS by leading, communicating and uniting everyone in the organization to achieve the company’s desired goals and by providing the resources necessary to accomplish them.

**Involvement of people:** Irrespective of their position in the company everyone is involved in the QMS.

**Process Approach:** All activities in the company are treated as a process. This will provide for a systematic definition of activities in order to meet the stated goals and identify the resources required to meet those goals.

**Systems Approach to Management:** Requires identifying all of the processes in the company and their interdependence and then managing these processes as a complete system.

**Continual Improvement:** Continual Improvement of the company is a never ending process involving establishing goals and measuring progress towards achieving those goals.

**Factual Approach to Decision Making:** This is the method of collecting and analyzing data and then using it to make sound decisions on what path to take.
What is a Quality Management System?

Quality Management System Requirements
To achieve AS9100 certification your company must establish, document and implement a QMS and maintain its effectiveness in accordance with the standard. Controlled documents are typically organized and written according to a hierarchy shown below.

AS9100 Documentation Pyramid

Quality Manual addresses each area of the standard with a statement explaining how the organization maintains compliance to requirements.

Procedures are “high-level” documents that detail how the organization’s processes are designed and controlled.

Work Instructions are very specific and detail all necessary instructions required for performing a specific task.

Records must be maintained to show compliance to quality system requirements.
What is a Quality Management System?

Documents
QMS documents detail processes and procedures to ensure they meet the needs of your business as well as the requirements of the standard. This will ensure that:

- Employees perform the same task, the same way, every time
- Information is recorded in the same way, every time
- New employees are trained to a consistent standard.

Everyone!
   Everywhere!
      Every Time!

Controlled Documents
Documents must be controlled to ensure only the current version is available to employees while performing their duties. A procedure is required to detail the management of all controlled documents.
Why Implement a Quality Management System?

Internal Benefits...

QMS registration will help you win new customers and retain existing ones. While the goal is to achieve registration, it is not the only goal. The internal benefits of an effective system include but are not limited to:

- An understanding that quality is not just the responsibility of the quality department, it’s everyone's responsibility.
- Documented procedures and work instructions form the basis for repetition and become “the way we do business.”
- Less dependency on key individuals, responsibility and accountability for key tasks are distributed across the work force.
- Monitoring and measuring of key quality performance indicators improves management oversight.
- Internal Audits help identify problems that could impact customer satisfaction and/or operational efficiency.
- A formal Corrective and Preventative Action system ensures permanent solutions to problems are developed and implemented.
- Operations transformed from detection mode to a prevention mode. Prevention takes a lot less work and is far less expensive than detection.
- Increased profitability as productivity improves and rework costs are reduced.
Why Implement a Quality Management System?

Results of a survey of Registered Companies, Quality Systems Update Magazine

Customer Satisfaction
- On-time delivery increased 20%

Improved Operations
- 89% report greater operational efficiency
- 48% report increased profitability
- 76% report marketing benefits
- 26% report improved export sales

Results of a survey of Registered Companies in The United Kingdom conducted by Lloyds Register Quality Assurance

![Bar chart showing various benefits of implementing a quality management system]
The AS9100C Standard

Goal = Develop Consistent, Reliable Processes

Model of a process-based Quality Management System

A reliable process produces a consistent, predictable outcome, and is:

- **Consciously developed**: Facts and data are collected, the method is thought about by participants, debated, and agreed to, before the method is implemented.

- **Explicitly established**: The method is carefully documented in sufficient detail for the purposes needed. Every attempt is made to make the method error-proof.

- **Consistently followed**: Everyone follows the method as documented!

- **Currently believed to be best way**: The method is used until someone thinks of a better way.
The AS9100C Standard

How does AS9100 differ from ISO 9001?

- AS9100 emphasizes addressing customer and applicable statutory and regulatory QMS requirements and also focuses on controls that minimize error.

- Aerospace-specific requirements are added to most of the sections of the ISO 9001 Standard, with an emphasis on:
  - Conformance to customer, regulatory and statutory requirements (safety & airworthiness)
  - Flow down of requirements to suppliers and sub-tier suppliers
  - Risk management with consideration of special, critical and key characteristics
  - Configuration Management
  - Production Process Verification (First Article Inspection)
  - Change control (documents, designs, processes, equipment, tooling, etc.)

**Note 1:** AS9100 includes all of the requirements of ISO 9001 in its entirety plus additional Aerospace Industry requirements.

**Note 2:** In the overview of the AS9100 clauses that follow, ISO 9001 requirements are shown in regular type and the additional AS9100 requirements are shown in bold italic type.
The AS9100C Standard

4 – Quality Management System

4.1 General Requirements

- Describes how your QMS is to be established
- Provides “rules” for all processes in the QMS
- Gives requirements for “outsourced processes
- **AS9100 Emphasizes addressing customer and applicable regulatory requirements**

4.2 Documentation Requirements

- Describes information structure of your QMS
- Should think in terms of “information” management and control rather than “document” management
- **AS9100 emphasizes access to and awareness of relevant documentation by personnel**
- **AS9100 also requires control of records created and/or retained by suppliers**
The AS9100C Standard

5 – Management Responsibility

5.1 Management Commitment
5.2 Customer Focus
5.3 Quality Policy
5.4 Planning
5.5 Responsibility, Authority & Communication
5.6 Management Review

Implication
This system belongs to management!
Strong emphasis on responsibilities of management!

6 – Resource Management

6.1 Provision of Resources
Determine & provide resources needed
➢ Implement & maintain & ...
➢ Continually improve QMS
➢ Enhance customer satisfaction

Provide & Manage Resources Needed to Meet Customers’ Requirements

6.2 Human Resources
➢ Assignment of personnel
➢ Competence, training, and awareness

6.3 Infrastructure – buildings, utilities, equipment, transport, IT

6.4 Work Environment – temperature, humidity, lighting, cleanliness, ESD protection, etc.
The AS9100 Standard

7 – Product Realization

Sequence of processes & sub-processes needed to produce the product
Strong emphasis on sequence of processes & interactions

7.1 Planning of Product Realization

Consistent with other requirements for your QMS

Documented in a ‘suitable’ form (Quality Plan or established QMS)

Determine:

- Quality objectives for product, project or contract
- Specific resource & process needs for product
- Verification, validation, monitoring, measurement, inspection and test activities needed (including acceptance criteria)
- Record requirements

Planning must be done for each product, project or contract

*AS9100 includes resources for operation and maintenance of the product (post delivery).*
The AS9100 Standard

7.1 Planning of Product Realization (continued)

There are additional AS9100 elements that cover:

- Project Management
- Risk Management
- Configuration Management
- Control of Work Transfers

7.2 Customer Related Processes

7.2.1 Determination of requirements related to the product

7.2.2 Review of requirements – Can we do it? Is there a change?

- AS9100 adds requirement that risks are identified and special requirements determined.

7.2.3 Customer Communication – questions, orders and changes, feedback, complaints

Note: Special requirements are those which have high risks to being achieved, such as performance requirements at the limit of industry capability or the organization’s technical or process capability.
The AS9100 Standard

7.3 Design and Development

7.3.1 Planning – project plan with design stages, tasks, responsibilities
7.3.2 Inputs – the design requirements
7.3.3 Outputs – the documented design, the product specification
7.3.4 Review – checking output against input for each stage

7.3.4 Review – checking output against input for each stage
7.3.5 Verification – making sure the design will meet requirements
7.3.6 Validation – making sure the product will meet requirements
7.3.7 Control of Changes – ensure changes are identified, evaluated, controlled and recorded
The AS9100 Standard

7.3 Design and Development

**AS9100 additions emphasize:**

- Structured and thorough project planning
- Specification of critical items, including key characteristics, and specific actions to be taken
- **Definition of data required to allow product to be identified, manufactured, inspected, tested, used and maintained**
- Maintenance of configuration management throughout the design verification & validation process
- Design review authorization for progression to next stage
- Control of testing processes and records of results
- Approval of design changes by customers/regulatory authorities as required.

**Note:** Project planning must consider complexity and safety and functional objectives in accordance with customer/regulatory requirements, as well as ability to produce, inspect, test and maintain the product.

*Critical items* may result from the special requirements identified during the risk assessment mentioned previously. They are items that have a significant effect on the product realization and use of the product, including safety, performance, form, fit, function, producibility, service life, etc. They require specific actions to ensure they are adequately managed.

A *key characteristic* is an attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life or producibility, that requires specific actions for the purpose of controlling variation. A critical item may be further classified as a key characteristic if its variation needs to be controlled.
The AS9100 Standard

7.4 Purchasing

7.4.1 Purchasing Process – Select & manage suppliers

- AS9100 states that the organization is responsible for product quality, including customer-designated sources
- AS9100 has specific requirements regarding supplier management

7.4.2 Purchasing Information

- Specify requirements for what you want to buy

AS9100 adds specifics regarding:

- Identification
- Data, inspections, tests, test specimens
- Notification of changes/nonconformity
- Rights of access by organization, customer, regulatory authorities to supplier facility & records as applicable to order
- Requirements for supplier to flow down requirements to sub-tier suppliers
The AS9100 Standard

7.4.3 Verification of Purchased Product – To inspect or not to inspect?

**AS9100 additions are:**

- Examples of verification
- Positive recall
- Delegation of verification to supplier

**Note:** AS9100 notes that customer verification activities (as in source inspection at the organization’s supplier) should not be used as evidence of effective control of quality by either the organization or its supplier, and does not absolve the organization of responsibility for compliance with requirements and product conformance.

7.5 **Production and Service Provision**

7.5.1 Control of Production and Service Provision

- Info that describes the product
- Work Instructions as needed
- Suitable equipment
- Availability and use of monitoring & measuring equipment
- Inspections and tests
- Release, delivery and post-delivery activities
The AS9100 Standard

7.5.1 Control of Production and Service Provision (continued)

*AS9100 adds specific requirements for:*

- Accountability for all product during production
- In-process verification considerations, evidence of completion of all production and inspection/verification operations
- Provision for tooling, utilities, removal of foreign objects,
- Workmanship criteria
- Production Process Verification (formerly called First Article Inspection)
- Control of process changes
- Control of equipment, tooling, software programs
- Planning for critical items and process control of key characteristics
- Post-delivery support

7.5.2 Validation of Processes for Production and Service Provision – “special processes”
7.5.3 Identification and Traceability – ID, pass/fail status, unique ID as required

**AS9100 additions for:**

- **Configuration identification**
- **Acceptance authority media**
- **Examples of traceability requirements**

7.5.4 Customer Property – safeguard customer supplied product, equipment, software, intellectual property, personal data

7.5.5 Preservation of Product – protect product from start to finish

**AS9100 includes considerations for:**

- **Cleaning, foreign objects**
- **Special handling for sensitive products/hazardous materials**
- **Marking and labeling including safety warnings**
- **Shelf life control and stock rotation**
7.6 Control of Monitoring and Measurement Equipment

- A.K.A. Calibration
- Calibrated or verified at specified intervals, or prior to use, against traceable measurement standards
- Identified to enable status to be determined
- Record calibration/verification results
- Assess & record validity of prior results if devices are found to not conform to requirements – take corrective action on equipment and affected product

- **AS9100 adds some specifics for methods**

8 - Measurement, Analysis and Improvement

8.1 General – Plan & determine methods (statistical techniques) and extent of use

8.2 Monitoring & Measurement

8.3 Control of Nonconforming Product

8.4 Analysis of Data

8.5 Improvement
The AS9100 Standard

8.2 Monitoring & Measurement

8.2.1 Customer Satisfaction – monitor perception of quality

*AS9100 Additions:*

- Monitoring of product conformity,
- on-time delivery and
- customer complaints & CA requests.
- Requirement to develop & implement improvement plans to address deficiencies & assess effectiveness of results.

8.2.2 Internal Audit – a *tool* for evaluating internal compliance

- Audits must be planned and recorded,
- objective and impartial, with
- timely Corrective Action taken by Management and follow-up to verify actions taken.
- Results must be reported.
- *AS9100 clarifies that customer contractual requirements are part of the “planned arrangements” to be audited for conformance*

**Note:** The purpose of an Internal Audit is not to “pass the test.” The goal is to surface issues and opportunities and address them through the Corrective and Preventive Action System.

While not explicitly stated, the general expectation is that Internal Auditors receive training on auditing techniques and the Standard; sixteen hours of training are typical.
The AS9100 Standard

8.2.3 Monitoring & Measurement of Processes

- Ability to meet performance objectives
- Maintain capability and improve if needed
- *AS9100 states actions required in the event of process nonconformity*

8.2.4 Monitoring & Measurement of Product

- Verify requirements are met
- Results recorded
- Record authority responsible for release to customer

*AS9100 additional requirements:*

- *Key characteristics monitored and controlled*
- *Sampling plan specifics*
- *Positive recall consideration*
- *Documentation of Inspection plans, instructions, measuring instruments and records to provide evidence of product qualification*
- *Documents accompanying product are present at delivery*
Control of Nonconforming Product

- Identification and control of any defective material/product to prevent its use
- Determination of actions to take
- Re-verification after rework/repair
- Evaluation of need for recall of shipped product

**AS9100 additional requirements:**

- Applies to customer returns
- Process for approval of personnel who disposition product
- Restrictions on use-as-is or repair dispositions
- Taking actions to contain the effect of nonconformity on other processes or products
- Requirements for scrap marking and disposal
- Timely reporting of nonconforming product to other parties
The AS9100 Standard

8.4 Analysis of Data

Determine, collect and analyze appropriate data, Purpose:

- Demonstrate suitability and effectiveness of QMS
- Evaluate improvement opportunities

Include data generated by monitoring/measuring activities & other relevant sources

Analyze data for information on:

- Customer satisfaction
- Conformity to product requirements
- Characteristics & trends of processes and products

Look for Preventive Action opportunities

- Supplier performance

8.5 Improvement

8.5.1 Continual Improvement

- Continually improve organization’s performance
- Use Policy, objectives, audits, data, CAPA and Management Review to facilitate improvement

*AS9100 additions:*

- Organization must monitor implementation of improvement activities and evaluate effectiveness of results.
- Opportunities can result from lessons learned, problem resolution, benchmarking of best practice
8.5.2 Corrective Action

- Defined, documented process; comprehensive
- Eliminate cause(s) to prevent recurrence
- Appropriate to the impact

**AS9100 adds requirements for:**

- **Flow down of Corrective Action (CA) to suppliers**
- **Specific actions where timely &/or effective CA not achieved**
- **Determining whether additional nonconformities exist based on causes found, and taking appropriate action**

**Corrective Action versus Preventive Action**

8.5.3 Preventive Action

- Basically same process as Corrective Action but uses data proactively
- Detect — Analyze — Eliminate causes of potential problems
- **AS9100 notes Preventive Action (PA) examples such as risk management, error proofing, FMEA, information on product problems received from external sources**
15 Steps to Implement AS9100

Designing, documenting and implementing an AS9100 QMS is a significant undertaking. Typically, ETI Group recommends and uses a four phase approach to assist clients in implementing a system that meets the specific needs of their business.

Phase 1: Planning and Design
- Planning and Design
- Documentation Development
- Establish Quality System Structure
- Design/Document Management Processes

Phase 2: Establish Measurement Program
- Establish Measurement Program
- Design/Document Operations Processes

Phase 3: Implementation
- Implementation

Phase 4: Assessment and Registration
- Assessment and Registration

This approach has been successfully used by ETI Group to assist more than 650 organizations, both large and small, manufacturing and service to implement a QMS. A task by task overview of this approach is provided on the following pages.
15 Steps to Implement AS9100

PHASE 1: PLANNING AND DESIGN

Step 1 — Decision Making and Commitment
The first task is for top management to decide if the company should pursue AS9100 registration.

To make an informed decision, top management should have a good understanding of AS9100 from a business point of view, the concepts behind AS9100, the general process for implementation and the requirements of the standard as they apply to your company.

Top management must also demonstrate its commitment and determination to implement an AS9100 Quality System in the organization. Without top management commitment, no quality initiative can succeed.
15 Steps to Implement AS9100

1.1 Top Management Commitment

To provide evidence of commitment to the development and implementation of a QMS and continually improve its effectiveness, top management can achieve this by:

- Communicating to the organization the importance of meeting customer, statutory and regulatory requirements,
- Defining the organization's quality policy and making this known to every employee,
- Ensuring that quality objectives are established at all levels and functions,
- Ensuring the availability of resources required for the development and implementation of the quality management system, and
- Conducting the required management review meetings.

Top management should also consider actions such as:

- Leading the organization by example,
- Participating in improvement projects,
- Encouraging the involvement of all employees.
15 Steps to Implement AS9100

1.2 Top Management Commitment
Top management should identify the goals to be achieved through the Quality System. Typical goals may be:

➢ To become more efficient and profitable
➢ To produce products and services that consistently meet customers' needs and expectations
➢ Improve customers satisfaction
➢ Increase market share
➢ Reduce costs and liabilities

Step 2 — Implementation Team & Management Representative
AS9100 is implemented by people. The next step is to establish an implementation team and appoint a Management Representative (MR) as its coordinator to plan and oversee implementation. Implementation team members should include representatives of all organizational functions - Marketing, Design, Development, Planning, Production, Quality control, etc.

The “Management Representative” is your company's point-person and soon to be expert on AS9100. In the context of the standard, this person acts as the interface between your top management and the AS9100 registrar. This role is, in fact, much broader than that. The Management Representative should also act as the organization’s “Quality System Champion.”
15 Steps to Implement AS9100

2.1 Management Representative (MR) Responsibilities

The MR must be a person with:

- The total backing of the CEO,
- A genuine and passionate commitment to quality in general and the Quality Management Systems in particular,
- The respect resulting from rank and/or seniority to influence people at all levels and functions of the organization, and
- A good knowledge of quality methods in general and AS9100 in particular.

The standard makes it very clear that the Management Representative takes on the three responsibilities described below.

1. Quality System Maintenance. Ensuring that Quality Management System processes are established, implemented and maintained.

2. Reporting on Quality System performance. Reporting to top management on how well, or poorly, the Quality Management System is performing, including identifying any needs for improvement.

3. Promoting customer requirements. Ensuring all employees are aware of customer requirements. It is essential that all employees understand what the customer needs, and how they can affect how well the company satisfies these needs.
Steps to Implementing AS9100

Step 3 — Employee Awareness Training

It is important to inform employees as early as possible of your plan to become AS9100 registered. You will need to explain the concept of a QMS and how it will affect employees in order to gain their buy-in and support. Don't delay this simple step, if negative rumors and gossip develop, your implementation efforts will become much more difficult!

Since AS9100 affects all the areas and all personnel in the organization, training programs should be structured for different categories of employees - senior managers, middle-level managers, supervisors and workers. This training should cover:

- The basic concepts of quality systems and the standard,
- The overall impact on the company’s strategic goals
- The changed work processes, and the likely work culture implications of the quality system.

In addition, initial training may also be necessary on writing quality manuals, procedures and work instructions. When the in-house ability to provide this training is not available, it may be necessary to participate in external training courses run by a professional training organizations or an external training organization could provide this training in-house.
15 Steps to Implement AS9100

Step 4 — Perform a Gap Assessment

The next step in the implementation process is to compare your existing quality system with the requirements of the AS9100 standard. This is often referred to as "gap assessment" with the goal of determining:

- What existing company processes and procedures already meet AS9100 requirements
- What existing procedures and processes need to be modified to meet AS9100 requirements
- What additional procedures and processes need to be created to meet AS9100 requirements

In general, the steps to perform a gap assessment are:

1. What is the present operation/process? What already exists?
2. Analyze the relevant sections of the AS9100 standard to determine what is actually required?
3. Document the “gaps.”

The gap assessment can be performed internally if the required knowledge exists, or an experienced AS9100 consulting firm can provide this service for you.
15 Steps to Implement AS9100

**Step 5 — Implementation Planning**

After the gap assessment, you should have a clear picture of how your existing Quality System compares with the AS9100 standard.

A detailed implementation plan should be developed that identifies and describes task required to make your Quality System fully compliant with the standard. This plan should be thorough and specific, detailing:

- Quality documentation to be developed
- The relevant AS9100 standard section
- Person or team responsible
- Approvals required
- Training required
- Resources required
- Estimated completion date

These elements should be organized into a detailed chart, to be reviewed and approved by top management. The plan should define responsibilities of different departments and personnel and set target dates for the completion of tasks. Once approved, the Management Representative should control, review and update the plan as documentation and the implementation process proceeds.

A “high-level” 12-month implementation action plan is shown on the following page.
15 Steps to Implement AS9100

'High-level” 12 month implementation plan
15 Steps to Implementing AS9100

—— PHASE 2: DOCUMENTATION DEVELOPMENT ——

**Step 6 — Documentation Development**
There is no right or wrong way to document your Quality Management System. We believe that your company should start with the minimum requirements. This would include your Quality Manual and six documented procedures that are currently required to create an AS9100 QMS: Document Control; Control of Records; Internal Audit; Non-Conforming Product; Corrective Action and Preventive Action. There will be some additional documented procedures that will be helpful for your staff to follow while working on your company’s various processes. These can be determined during the planning stage and should be included in your implementation project plan.

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**The “Right-Size” Quality Management System**

- **A good start**
  - Minimum Requirements
  - Quality Manual
  - 6 Procedures
  - 20 Records
- **Just right**
  - Plus Additional Key Processes
- **Too big and too complex**
  - Overkill
15 Steps to Implementing AS9100

6.1 Organizing and Documenting Your Quality System

Documentation is typically organized and written according to a hierarchy shown below. A list of the documents to be prepared should have been drawn up and the responsibility for writing documents assigned to the persons responsible for each of the quality system processes in your company during implementation planning.

The Quality Manual – A high-level document that typically includes:

- A statement explaining the scope of the QMS, including exclusions and details for their justification
- A description of the QMS processes and their interactions
- The company’s quality policy and quality objectives
- An company profile showing the relationships and responsibilities of persons whose work affects quality
- An overview of the system level procedures
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Quality Manual (Continued)

The Quality Manual is usually written early on in your QMS implementation. Processes and procedures may change as your organization works through the documentation process. It will be necessary to go back and revise the Quality Manual to bring it back up to date and ensure that the correct process interfaces are defined and responsibilities and authorities documented.

Procedures are “high-level” documents that detail how the organization’s processes are designed and controlled and the checks that are carried out.

Work Instructions are very specific, and detail all necessary instructions required for performing a specific task.

Lists provide information. They can also be incorporated into the back of a procedure as additional information (Appendix, Attachments, etc.).

Forms capture records for data/information required to support or confirm processes. Forms can be separately controlled documents and/or included within the appropriate procedure.

Records must be maintained to show compliance to quality system requirements.
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6.2 Record Keeping - Quality records provide objective evidence of your compliance to many of the AS9100 requirements. You must keep your records up to date to prove compliance during your registration or subsequent surveillance audits. Minimum required records include but are not limited to:

- Evidence that metrics are used to monitor and improve processes (Quality Objectives)
- Management Review Meetings
- Employee Competence, Awareness, and Training
- Product planning meets customer requirements
- Contract review and actions arising from the review
- Design and development planning, inputs, reviews, verification, validation (including changes to designs)
- Supplier evaluation and re-evaluation
- Results of monitoring and measuring
- Internal Audits
- Approval to release product for delivery
- Action taken on non-conforming product
- Corrective Action
- Preventive Action
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6. 3 Documentation – Getting Started

Your company probably already has some documented policies and/or procedures. Although they may be incomplete, lack specific detail, be out of date, or are not integrated with other business processes as required by the AS9100 standard.

Make a list of all these documents, including procedures, work instructions, forms and lists and include their current status... incomplete, lacking detail, out of date, inaccurate, not integrated with other business processes, etc.

There may also be some areas of the business which you choose not to include within the scope of your QMS, such as finance or business strategy documents.

Areas deemed out of scope must not have an impact on product quality and should not be included in your QMD documentation, although these areas should be listed in the exclusions documented in your Quality Manual.

Consider the primary audience for the document and use language and vocabulary that is appropriate for the company and for the users.
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6.4 Documentation – Map Current Processes

Map the processes used to manage the quality framework, including their sequence and interaction with each other. Ensure that all stakeholders are included in the mapping process and gaps are noted where documents are missing or where a process needs to be updated to meet a requirement of the AS9100 standard.
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6.5 Templates for Controlled Documents

Templates should be developed for all of the controlled document types you intend to use. Templates should have consistent styles and formats so that documents are easy to read and navigate.

Each template must meet controlled document requirements. Procedures and Work Instructions should have Purpose, Scope and Responsibilities sections. A company logo can also be included with the document header.

Documenting your Quality System is challenging and time-consuming but can be simplified with good pre-designed templates or the help of an experienced consulting firm. If you choose to purchase templates they should be chosen carefully as they will have a significant impact on the effort you spend on implementation, and even more importantly, on how efficient and business-friendly your company's Quality System will be.

6.6 Create a Company Quality Policy

We have all read an organization’s posted “Mission Statement” when entering their establishment. A Quality Policy is similar but addresses the specific requirements of AS9100. This is the foundation of your QMS and establishes top management’s commitment to Quality. It should also be communicated throughout your organization.
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6.7 Top Level Quality Objectives
The framework for determining your Quality Objectives is established in your organization’s Quality Policy, these objectives are present at all levels of the organization, they establish measureable processes to assure your product or service meets stated requirements.

6.8 Determining Interactions
One of the many benefits in creating your QMS is improved communications between departmental functions.
Accomplishing this requires that you clearly define these departmental functions and identify their interactions.
You can use the Quality Manual, Documented Procedures, or a Process Flow Chart to do this.

6.9 Determine Authorities
Another benefit of your QMS is the requirement to clearly define and document authorities. It is not uncommon in many organizations to make staff responsible for something without giving them a clearly defined authority to see the task through. This often leads to stress and low morale.
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6.10 Document Control
A Documentation Control System must be created to manage the creation, approval, distribution, revision, storage, and disposal of the various types of documentation that your company develops. Your document control systems should be as simple and as easy to operate as possible but sufficient to meet AS9100 requirements. It should include:

- A unique identification, usually a letter code for the type of document (e.g. SOP, WI, LST) and a sequential number.
- Revision control where each update to the document must result in an incremental increase in the revision number.
- A change history summarizing changes made to a document
- Signatures of the person preparing and the person approving the document. A verification signature is also usually required to confirm that the contents of the document are accurate.
- The date of the version or revision

The principle of AS9100 document control is that employees should have access to the documentation and records needed to fulfil their responsibilities.
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Step 7 — Review and Release Documents
Management should review all of the documentation to ensure it meets the operational needs of the business as well as As9100 requirements. Following the reviews, subsequent revisions, and final management approval, documentation is released for use.

Phase 3: Implementation

Step 8 — Implementation and Employee Training
The newly documented Quality System is put into practice throughout the company. Management and employees are trained on the new or revised work processes, procedures and work instructions as formalized in your documentation.
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Step 9 — Quality System Registrar Selection

It is advisable to select a Registration Body that is suited to your organization early in your implementation project. The registration body is an independent organization that is officially accredited to issue Quality System certifications. The registrar will audit your company's Quality System and if the audit is successful – issue the Quality System certificate.

When choosing a certification body to carry out your As9100 registration audit, some selection criteria should be taken into account:

- Is the certification body accredited and, if so, by whom? Accreditation means that the certification body has been officially approved as competent to carry out certification by a national accreditation body.

- Is the certification body recognized by your company’s customers?

- Does the certification body auditor(s) have experience in your organization’s business sector?

- Is your organization comfortable working with your auditor(s) as both sides have to work together for a long period of time?

- Last but not least, we consider it important that your actual auditor is based geographically close to you, otherwise travel expenses for your auditor’s visit to your facility could be very high?
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Step 10 — Internal Auditor Training & Commence Internal Audits

AS9100 and related standards require that your company periodically perform an internal audit to evaluate the effectiveness of your Quality System and check that it complies with AS9100 requirements as well as your organization’s own documented work practices.

A quality audit is a: “Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.”

Internal audits are also a great help implementing your Quality System and a complete internal audit of your Quality System is required before you can pass your registration audit.

Your internal audit program should be planned, taking into consideration the status and importance of the different processes that are running in your organization.

At least two of your employees will need to be trained as internal auditors.

The criteria for the audit, scopes, frequencies and methods should also be defined. The person(s) responsible for the audit, should be objective and impartial, the only restriction is that they cannot audit their own work.
Step 11. Management Review
When your Quality Management System has been operating for three to six months and an internal audit of your Quality System has been completed a Management Review should be conducted and corrective actions implemented as necessary.

Management reviews are conducted to ensure the continuing suitability, adequacy and effectiveness of your Quality System. The review should include assessing opportunities for improvement and the need for changes to the Quality System, including the quality policy and quality objectives. The input to management review should include:

- Results of audits,
- Customer feedback
- Process performance and product conformity
- Status of preventive and corrective actions
- Follow-up actions from previous management reviews
- Changes that could affect the Quality System, and recommendations for improvements
- Management Reviews should also address pitfalls to effective Quality System implementation

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--- PHASE 4: ASSESSMENT AND REGISTRATION ---

Step 12 — Stage 1 Registration Audit

When you Quality System has been in operation for a few months and has stabilized, it is normally time to schedule your stage 1 registration audit.

Your selected registration body will first carry out an audit of your documentation and then, if your documents meet the requirements of the standard, the registrar will visit your facility and perform a stage 1 Audit to ensure all applicable AS91100 or related standard requirements have been met.

Step 13 – Corrective Actions

Following your stage 1 audit, management will review the results and make corrective actions to fix any non-conformances (activities that are not in compliance with the requirements of the standard and/or your own documented work practices) found during the stage 1 registration audit.
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Task 14 — Stage 2 Registration Audit
Your selected Registrar will perform a stage 2 Registration Audit to ensure all applicable AS9100 or related standard requirements have been met and that you have corrected any non-conformances found during the stage 1 audit.

Following the successful completion of the stage 2 audit your company will be awarded an AS9100 certificate, generally for a period of three years. During this three-year period, your registration body will carry out periodic surveillance audits to ensure that the system is continuing to operate satisfactorily.

Task 15 — Continual Improvement
Certification to AS9100 should not be an end. You should continually seek to improve the effectiveness and suitability of your Quality System through the use of your:

- Quality policy
- Quality objectives
- Audit results
- Analysis of data
- Corrective and preventive actions
- Management review
ETI Group:

To date, ETI Group has assisted more 650 companies to achieve Quality Management System (QMS) Certification...all passed their registration audits at the first attempt. Our services include. Our Quality Management System services cover the full range of ISO 9001/AS9100 and related standards:

**ISO 9001 - AS9100 - ISO/TS 16949 - ISO 13485**

Implementing a QMS can be expensive, challenging and time consuming. It can also distract key people from their regular day-to-day tasks. To minimize disruptions to your business, ETI Group offers a broad range of practical solutions to assist you in implementing a QMS that meets the specific needs of your business as well as the requirements of the appropriate standard(s).

For more information on how we can help you implement an effective Quality Management System please contact ETI Group at:

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or

visit our website at www.etigroupusa.com