



ISO 9001: APPROACHING AND IMPLEMENTING QUALITY MANAGEMENT STANDARDS

to drive operational excellence & customer satisfaction

INTRODUCTION

ISO 9001 is a standard that sets out the requirements for a quality management system (QMS). These standards are one of ISO's most well known and most followed. It helps organizations and businesses improve products, services, customer satisfaction, environmental and organization objectives, and comply with applicable regulations while driving continuous improvement.

WHAT IS QUALITY MANAGEMENT ALL ABOUT?

ISO 9001 builds on seven quality management principles. Follow these principles to ensure organization or business value for customers. Firmly following these pillars will make implementing a quality management system much easier.

1. CUSTOMER FOCUS

Meeting and exceeding customer needs is the primary focus of quality management and contributes to long-term enterprise success.

2. LEADERSHIP

A unified direction or mission that comes from strong leadership ensures that everyone in the organization understands what you are trying to achieve.

3. ENGAGEMENT OF PEOPLE

Creating value for your customers will be easier if you have competent, empowered and engaged people at all levels of your business or organization

4. PROCESS APPROACH

Understanding activities as processes that function as a system helps achieve consistent and predictable results team wide.

5. IMPROVEMENT

Successful organizations have an ongoing focus on improvement. Reacting to changes in internal and external environments is necessary to continue to deliver value for your customers.

6. EVIDENCE-BASED DECISION MAKING

Decisions based on data analysis and evaluation is more likely to produce the desired result.

7. RELATIONSHIP MANAGEMENT

Identifying the important relationships you have with interested parties such and establishing a plan to manage them will drive sustained success.

ISO 9001 QUALITY MANAGEMENT

Key Facts & Benefits

- ISO 9001 is a generic standard, meaning the same standards apply to any size organization no matter the product or service
- 85% of certified companies report numerous benefits, such as a higher demand for products & services
- 1.1 million companies & organizations worldwide in over 178 countries are ISO 9001 certified
- ISO 9001-certified organizations are more competent & paid 7% more on average
- There are nearly 2,000 individual ISO standards



HOW TO GET STARTED

Getting ISO 9001 Certified

When a company decides to implement ISO quality standards, they often decide to become registered or certified by an accredited organization.

- **Registration vs Certification:** In North America, the term registration is most commonly used, while in the rest of the world it is usually called “certification.”
- **Certification** means that an independent, external body has audited an organization’s management system and verified that it conforms to the requirements specified in the standard.
- **Accreditation:** In order for organization to receive certification and have QMS audits performed, they need to have an audit performed by an official certification body with a license.
- **Certification is not a requirement:** ISO does not approve or carry out accreditations, but certified organizations receive several benefits.
- **Passing an Audit:** ensure ISO certification and continuous quality improvements with quality management software.



Get ISO 9001 certified with Gensuite Quality Management Software. Learn more at www.gensuite.com/quality

HOW GENSUITE CAN HELP: QUALITY MANAGEMENT MATRIX

The ISO 9001 standard is made up of several sections, each concentrating on the requirements involved in different aspects of a Quality Management System. The following matrix illustrates Gensuite QMS solutions that can be utilized to meet and maintain specific parts of ISO 9001:2015 and gain certification.

ISO 9001 Sections	ISO 9001 Requirements	Gensuite QMS Solution
Section 0-3	Introduction & scope	Doc Manager
Section 4	Context of organization	Doc Manager
Section 5	Leadership 5.1 Leadership & commitment 5.2 Policy 5.3 Organizational roles, responsibilities & authorities	Doc Manager
Section 6	Planning 6.1 Actions to address risks & opportunities 6.2 Quality objectives & plans to achieve 6.3 Planning of changes	Action Tracking System Quality Framework MOC Manager
Section 7	Support 7.1 Resources 7.2 Competence 7.3 Awareness 7.4 Communication 7.5 Documented information	Training Tracker Action Tracking System Compliance Calendar Doc Manager
Section 8	Operation 8.3 Release of products & services 8.4 Control of nonconforming outputs 8.5 Operational planning & control 8.6 Requirements for products & services 8.7 Design & development of products & services	Action Tracking System Quality Concern Reporting Quality Escapes Reporting Inspection Tool MOC Manager
Section 9	Performance evaluation 9.1 Monitoring, measurement, analysis & evaluation 9.2 Internal audit 9.3 Management review	Training Tracker Action Tracking System Compliance Calendar Doc Manager
Section 10	Improvement 10.1 General 10.2 Nonconformity & corrective action 10.3 Continuous improvement	Action Tracking System Quality Escapes Reporting Continuous Improvement

INTEGRATED QUALITY SOFTWARE

Gensuite's applications are part of an integrated quality software suite. Here are there top features.



Doc Manager

Maintain quality management system documents in a central repository and integrate SOP references via Doc Manager integration with other Gensuite applications

Action Tracking System

Manage corrective action plans, responsibility assignment, notifications and escalations with real-time status/closure tracking, trending and data mining

Quality Framework

Establish quality program expectations and an approach to achieving targets and goals to measure specific performance against program expectations across facilities

Training Tracker

Simplify the management of employee/worker training requirements using a multi-tier training matrix and automatic tracking of qualification status

Continuous Improvement

Perform detailed root cause analysis on identified issues & classify issues with failure and causal codes with corrective and preventative actions

Compliance Calendar

Schedule periodic/recurring tasks and obligations, assign responsibility with email notifications and intelligent escalations, and track and report status

Quality Concern Reporting

Enable all employees to report concerns and complaints via a simple interface and escalate key issues that require additional investigation

Quality Escapes Reporting

Report and perform follow-up of product or service commitment defects, track product and customer details and integrate with other tools for additional analysis

Inspection Tool

Conduct mobile inspections using customized inspection checklists, establish an auditing routine and assign to managers in the facility

Demo our applications:
www.gensuite.com/contact-us

PROVEN RISK & COMPLIANCE MANAGEMENT SOLUTIONS FOR FOLLOWING ISO STANDARDS

Current Gensuite Subscribers Maintaining Certification

SUBSCRIBER HIGHLIGHT

One Gensuite subscriber uses the following applications to maintain ISO 9001 certification as customized under the Audit & Compliance product software offering:

- Action Tracking System
- Compliance Calendar
- Continuous Improvement
- Training Tracker
- Quality Framework

BUSINESS PROFILE

- 700+ locations globally
- Approximately 38,000 employees serving customers in 125+ countries
- Provides broad array of power, energy and water process technologies
- Over 27 billion in revenue annually

APPLICATION HIGHLIGHT: **QUALITY FRAMEWORK**

Section 6:1 – Planning: actions to address risks & opportunities

Level 1 - 6.1.1.2

Are mitigation and contingency plans developed and enacted to address the largest risk identified during the proposal development or scoping phase?

Self-Assessment Guidance:

Regardless of project type, some project risks are identified and evaluated to determine whether mitigation and/or contingency actions are needed.

- For risks needing mitigation or contingency plans, specific actions are identified and planned with clear ownership and timeliness.

Enter validation notes

- ☐ Yes
☐ No
☐ Not Applicable
☒ Under Evaluation

BETTER TOGETHER: EHSQ



Gensuite offers proven IT solutions for Environmental, Health & Safety and quality risk management. These solutions allow companies and organizations to gain certification to both ISO 9001 and ISO 14001 – environmental management system standards.



Visit our website for a collection of
implementation guides and resources:
www.gensuite.com/solutions-resources