Complete Guide to Saving Time and Money with ISO 9001

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In today's complex global business environment, more customers than ever before are insisting that suppliers comply with established standards for quality, security, sustainability, and other key priorities. Large corporate buyers want to know that the vendors from whom they source products and services can deliver consistently high quality, and that their business practices are aligned to globally recognized standards.

Perhaps the most recognizable of these is the ISO 9001 standard for quality management systems. Quality certification is more important today than it has ever been, – yet many companies hesitate to make the commitment due to costs, time, and an unwillingness to change familiar habits when conducting business.

In fact, companies that implement ISO 9001 properly stand to benefit greatly from the structure and discipline that it brings to their quality management processes. Though change is inevitable, executives who have gone through the certification process attest that implementing the standard has significantly increased the value of the company.

There are also some proven methods for reducing the time and effort required to comply with ISO 9001, and for doing it cost-effectively. Implementing flexible, configurable software is just one example. In this guide, we will describe the basic requirements for ISO 9001 compliance and describe what makes a good ISO Quality Management System (QMS). Then we'll provide some best practices and recommendations for reducing the time, effort, and expense associated with ISO 9001 compliance.

Although ISO and other organizations have developed several industry specific standards as well, the 9000 family of standards (which includes ISO 9001) are the most broadly applicable across virtually all industries. While this guide will reference ISO 9001 specifically, the principles outlined here apply equally well to various industries that implement quality management programs.

What is ISO 9001?

There are numerous organizations that work together both domestically and internationally to define and curate standards. Perhaps the best-known is the International Standards Organization (ISO), which is a consortium of national standards organizations representing more than 145 countries around the world, including the US-based American National Standards Institute (ANSI) and the Standards Council of Canada (SCC).

ISO defines a wide range of different standards that affect a multitude of products and services, – from the film speed settings on your camera, to the unique ISBN number associated with each published edition of a book, to the technical features of credit cards that make it possible for consumers to use them virtually anywhere the world.

The ISO standards that apply to organizational practices are divided into so-called 'families'. For example, the ISO 14000 family addresses environmental management, whereas ISO 22000 is concerned with food safety.

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The ISO 9000 family of standards is concerned with quality management. The primary governing document within this family is ISO 9001, and the most recent revision is ISO 9001:2015. Although ISO oversees the management of this family of standards, the American Society for Quality also plays a prominent role in shaping it.

ISO 9001 is a roadmap to success and is built around the eight quality management principles: customer focus, leadership, people involvement, process approach, a systematic approach to management, continuous improvement, a factual approach to decision-making, and mutually beneficial supplier relationships.

What are the ISO 9001 Requirements?

In his seminal book The Seven Habits of Highly Effective People, author and business guru Steven Covey outlined the behaviors that he believes are essential to the achievement of meaningful goals. Covey's book isn't just about the mechanics of getting things done; it's about living a purpose-driven life, honoring the humanity in others, and achieving excellence.

In many respects, the ISO 9001 standard has a similar framework to Covey's seven habits but in terms of quality. In fact, ISO 9001 is divided into ten sections, the first three of which are about setting the stage while the remaining seven encourage organizations to define the context in which they operate, establish a powerful management commitment to quality, and to plan and execute QMS activities and processes that help them achieve their goals.

What exactly are those goals? It's simple - to meet and preferably exceed the customer's expectations, which brings us back to the core definition of quality. According to ASQ, quality is the degree to which a product or service satisfies stated or implied needs. When organizations can deliver this on a consistent basis, – and when they follow well-defined processes for handling any instances of nonconformance, they have achieved quality excellence.

ISO 9001 includes both mandatory and non-mandatory requirements. The former are actual requirements, strictly speaking, insofar as they are necessary in order for a company to be in compliance. The latter (non-mandatory) are optional but may be submitted by companies wishing to offer additional supporting materials.

Companies seeking ISO 9001 certification must develop and maintain the following mandatory documents:

- Scope of the Quality Management System (clause 4.3)
- Quality policy (clause 5.2.2)
- Quality objectives and how these will be achieved (clause 6.2)

(Clauses referenced in parentheses designate the section within the ISO 9001:2015 standard that contains each of these requirements.)

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In addition, companies must maintain the following mandatory records:

- Monitoring and measuring resources (clause 7.1.5.1)
- Calibration records for monitoring and measuring equipment (clause 7.1.5.2)
- Records of staff competency (clause 7.2)
- Product/service requirements review records (clause 8.2.3.2)
- Design and development inputs record (clause 8.3.3)
- Records of design and development controls (clause 8.3.4)
- Records of design and development outputs (clause 8.3.5)
- Record of design and development changes (clause 8.3.6)
- Criteria for evaluation and selection of suppliers (clause 8.4.1)
- Characteristics of product or service to be provided (clause 8.5.1)
- Identification and traceability records (8.5.2)
- Records about customer property including any changes (clause 8.5.3)
- Production/service provision change control records (clause 8.5.6)
- Release of products and services (clause 8.6)
- Control of nonconforming outputs (clause 8.7.2)
- Monitoring and measurement results (clause 9.1.1)
- Internal audit results (9.2.2)
- Results of the management review (clause 9.3.3)
- Results of corrective actions including opportunities for improvement (clause 10.2.2)

The so-called non-mandatory documents are frequently submitted as part of the ISO 9001 certification as well:

- Procedure for determining context of the organization and interested parties (clauses 4.1 and 4.2)
- Procedure for addressing risks and opportunities (clause 6.1)
- Procedure for competence, training, and awareness (clauses 7.1.2, 7.2 and 7.3)
- Procedure for equipment maintenance and measuring equipment (clause 7.1.5)
- Procedure for document and record control (clause 7.5)
- Sales procedure (clause 8.2)
- Procedure for design and development (clause 8.3)
- Procedure for production and service provision (clause 8.5)
- Warehousing procedure (clause 8.5.4)
- Procedure for management of nonconformities and corrective actions (clauses 8.7 and 10.2)
- Procedure for monitoring customer satisfaction (clause 9.1.2)
- Procedure for internal audit (clause 9.2)
- Procedure for management review (clause 9.3)

The list of documents and records presented here may seem overwhelming. As you consider each item on the list of mandatory requirements, you may find that many of them are already maintained by your organization. Records of staff competency, for example, are frequently kept as lists of employees who have completed specified training programs, who have achieved third-party

certifications, or who are current with professional licensing requirements.

Companies wishing to achieve ISO 9001 certification should consider whether their existing systems for maintaining these kinds of records are adequate to the task, and if the data they contain is easily searchable and retrievable in the event of an audit. Typically, the best information systems will also make it easier to aggregate and analyze this information. In other words, it provides greater transparency and supports business leaders in tracking and managing performance relative to the company's defined target metrics.

ISO Quality Management Systems (QMS)

This leads us to the topic of Quality Management Systems, or "QMS" for short. Strictly speaking, a QMS is a collection of documented business processes and procedures intended to support the company in delivering on its quality promises to the customer. The American Society for Quality (ASQ) offers this formal definition:

> *A quality management system (QMS) is defined as a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. A QMS helps coordinate and direct an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis.*

ASQ goes on to explain the distinction between a QMS and ISO 9001 standards:

> *ISO 9001:2015, the international standard specifying requirements for quality management systems, is the most prominent approach to quality management systems. While some use the term "QMS" to describe the ISO 9001 standard or the group of documents detailing the QMS, it actually refers to the entirety of the system. The documents only serve to describe the system.*

To add further to the confusion surrounding the definition of a QMS, people often use the term to refer to the software and information systems used for collecting quality data, managing documentation, tracking non-conformances and corrective action, and so on. In fact, the right technology can be immensely valuable in minimizing the effort required to collect and analyze data, organize documents and maintain effective version control, manage workflows and accountability, and more.

An effective QMS that meets the formal definition, – that is, a formalized system for managing and achieving quality objectives, – is most effective when it is supported by the right technology.

However, it's critically important that business leaders begin with the unique needs and priorities that apply to their own organizations. All too often, we see companies that embarked on an effort to enhance their quality programs by implementing rigid, inflexible QMS software systems that are not easily adaptable to their business practices.

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Software should conform to the way your organization works, – not the other way around. In this respect, QMS as a body of practice comes first. The QMS technology needed to support those practices must follow, based on how the company wishes to operate.

Saving Time and Money on ISO 9001 Compliance

The number one mistake that most companies make as they begin to formalize QMS processes is relying too heavily on existing tools and manual processes. As they begin the ISO 9001 certification process, many attempt to get by with the desktop productivity software that they already use every day. Additionally, employees collect data using paper-based systems and enter the resulting information into spreadsheets. They rely on ordinary word processing documents, which they then exchange via e-mail or store on shared network drives. Some may even develop rudimentary databases to store larger quantities of information and run simple reports.

Over time, these methods tend to be difficult to manage. Paper forms can be misplaced, data may be entered incorrectly, and managing multiple versions of a document can be cumbersome, especially when multiple users are collaborating on the same document. Information is disjointed, making it difficult to analyze data for meaningful insights.

To achieve and maintain ISO 9001 compliance without overburdening your staff, consider adopting technology that incorporates the following features and attributes:

Document Control: Document control is an application that oversees the orderly creation, review, revision, approval, and distribution of important documents. In addition, document control aims to assure that those documents can be accessed by the right people at the right time. Since ISO 9001 emphasizes thorough documentation and effective control processes, companies can save considerable time by implementing technology that supports good document management.

We're all familiar with the problem of misaligned versions of the same document. Imagine that someone in your organization creates the first draft of an important document, then sends it to few key stakeholders for review. Several of the reviewers add up their input and e-mail it back. The original author must now contend with two or more conflicting versions that must be merged and re-shared with the remaining stakeholders. That process can quickly become unwieldy, and often leads to errors and omissions.

The problem of managing multiple versions of the document can become even more problematic after it has been placed into circulation. What happens when revisions to an existing document are required, or when a periodic review is needed to determine whether any changes must be made? As procedures change, as policies and procedures are updated, and as specifications and standards evolve, documents must be updated accordingly.

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Outdated versions of a documents (especially digital copies) should be withdrawn from use, so they are not mistaken for a current version. If document control is not managed proactively, it can lead to multiple "official" versions of the same document being in circulation. When auditors are reviewing your mandatory ISO documents for accuracy and consistency, it pays to have a strong document control system in place to make the process go smoothly.

Managing document approvals with manual systems can be a time-consuming process as well. Someone needs to see to it that approvals are happening on schedule, and that signoffs are properly recorded. Then they must ensure that approved documents are distributed or otherwise made available to the appropriate parties, and that deprecated documents are withdrawn from use. It's a lot of work, and it's why so many organizations stand to benefit from document control.

Simplified Data Collection: ISO 9001 provides a long list of mandatory recordkeeping requirements. Each of those has a purpose, but historically the process of collecting data has come at a relatively steep price. Gathering and recording data has often been regarded as a burdensome distraction from the core tasks to which employees have been assigned. With the advent of sensors, wireless connectivity, and mobile devices, processes have become substantially easier, – provided that your QMS software supports it.

Given the availability of increasingly powerful data analytics at very affordable prices, there is no reason why any organization should not avail itself of the power to better understand the factors that impact their success. Executive dashboards have grown considerably in popularity because of their ability to visually communicate what is happening in the organization, quickly and intuitively, often in real time.

Business leaders, by and large, are eager to have more information at their fingertips. They want to know how their organization is performing against key metrics, and they want the capacity to drill down into the details and explore them further when necessary.

Nowadays, almost everyone has a mobile device. Mobile apps make it possible to collect data in the field, in the warehouse, or around the shop floor; without the need to carry around a bulky device. Mobile devices enable scanning of barcodes or QR codes, and make it possible to attach photos, videos, or audio recordings to a document record.

Investing in the right technology ensures that recordkeeping processes can be implemented and maintained with minimal effort, saving considerable staff time.

Strong Integration: A key aspect of ISO 9001 is its comprehensive nature, covering everything from records of employee training and competency to corrective action with respect to non-conformances.

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Powerful integration provides a one-stop shop for documentation and records that impact quality management. Integration to your ERP system, for example, provides a clear and automated link between a customer's return of defective product and the CAPA processes that have been initiated in response to it. When data is stored in a central repository and made available to all authorized users, it can be analyzed and understood holistically. Collections of spreadsheets, in contrast, provide disjointed information that is generally difficult to connect and analyze in a meaningful way.

Ease of Use: A key barrier to effective quality management processes in many organizations is the perception that it creates a lot of additional work. User-friendly software in the long way to mitigating this problem. When the systems people use every day are intuitive, when they are visually appealing and uncluttered, without extraneous information; employees will embrace them more readily.

User-friendly software makes it easy to find the right information at the right time. "Tool tips" and similar features can anticipate potential questions and problems, automatically guiding users in the right direction. Whenever there's a question, user-friendly software makes it easy to find the right answer.

Perhaps most importantly, well-designed software guides the user through each process in a way that makes complete sense. There is an art to this; but fortunately, the tools used for developing software have evolved to help facilitate good design. Bottom line: ease-of-use is a time-saver for everyone.

Configurability: As you set out to achieve ISO 9001 compliance, chances are you will be re-evaluating many of your internal processes and modifying them. As you do, it's helpful to have QMS software systems in place that can easily adapt to the way you do business, rather than forcing your organization to change your business operations in ways that don't make sense for you.

Many QMS software products require custom programming if they are to be adapted to fit your business. That can be costly, and it takes time. Once you have communicated your needs to a programmer, it can be expensive to make any additional changes, – and it may delay the completion of the project even further.

The concept of extreme configurability, in contrast, is based on the idea that non-technical users should be able to adapt the software quickly and easily, without extensive training. Changing a business process, adding a field, modifying a workflow, or editing a screen should not be a major undertaking. It should be quick, easy, and intuitive.

Administrators should be able to hide features and fields that aren't needed, reducing clutter, and eliminating confusion. A quality manager should even be able to design and implement an entirely new process from scratch, without programming skills or any other specialized technical expertise.

Configurability can save time and effort in subtler ways as well. Many organizations, for example, have their own unique terminology, – a company-specific nomenclature that has evolved over

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time. Employees should not have to learn a new language to accommodate their new QMS software. By making it easy to adjust field names, tool tips, and instructions to fit the way your company already works, life can be made a little easier for everyone in your company. This, in turn can add up to meaningful improvements in efficiency.

As the old saying goes, “time is money”. Whenever your company saves time, it enables your team to allocate resources more efficiently, get the job done faster, and contribute more effectively to the bottom line.

Benefits of ISO Certification

ISO 9001 certification, – or certification on any of the industry-specific standards that may apply for your company, – can add tremendous value, as it establishes your company’s commitment to quality management and all-around excellence. For many, certification is a requirement mandated by key customers.

Although the process of achieving and maintaining ISO 9001 compliance may seem overwhelming at first, the right tools can ensure that the process goes smoothly and that it ultimately enhances your organization’s ability to consistently deliver quality products and services to your customers. By achieving compliance, your company stands to gain market share by qualifying as a supplier to organizations that require ISO 9001 certification.

Whether your company is already certified in one of the standards or is working to achieve certification, it helps to have strong QMS technology in place to ensure consistent and accurate data collection, visibility to performance, and a common set of tools for employees. At Intellect, we provide highly configurable software for quality management that helps you achieve your objectives. Learn more about how Intellect can work for you, contact us today to discuss your needs.

Demo Request