ISO 9001

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UNDERSTAND,
IMPLEMENT,
SUCCEED!

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ISO 9001:2015

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Preface

In today's environment, the increased competition in the global economy has made it an absolute necessity for businesses to focus on the quality management system (QMS) as a means to increase productivity and create products and services that will yield positive customer experiences. This technique has been proven to guarantee survival in an environment marked by world-class competition and to create excellence, based on a set of philosophies, procedures, and actions that are the hallmarks of a constantly improving organization. The QMS emphasizes application of quantitative approaches, with experienced resources, to improve processes within an organization and exceed customer expectations. Today's businesses widely recognize the need for QMS to assure a disciplined approach to service and product quality, to safeguard customers from related problems, and to shelter the organization from the lawsuits that can arise as a result of inadequate quality.

The technology used by businesses has advanced in the last decade, and the enormous power of social media in shaping the reaction to business brands is widely appreciated. Owners of businesses recognize this power and know that social media can be used as a tool for marketing purposes—but only if the quality of their products and services and the level of customer satisfaction with those products and services are high. Business owners realize they must listen to the voice of the customer and concentrate on quality and defect prevention. At the same time, business proprietors are keenly aware that social media can have a negative impact on their brand if their service or product is deemed unsatisfactory.

The purpose of a QMS is to enable the company to provide a quality product or service to its customers, attain complete customer satisfaction, and gain a larger market share by following key quality management principles and regulatory requirements. Doing it right the first time—and following this philosophy every time—is the most important consideration for a successful business, as this approach will increase productivity and lower costs.

The QMS standard, ISO 9001:2015, is designed to assist product, solution, and service organizations in meeting customer expectations and delivering an overall positive customer experience. ISO 9001:2015 is published by the International Organization for Standardization (ISO), along with other industry-related standards. Adherence to the processes outlined in these standards helps to control problems related to quality and ensures that these issues are addressed at functional levels of an organization, thereby eliminating the potential for a negative impact on customers. The end result, it is hoped, will be profitability and sustainability of the business enterprise.

The authors of this book are seasoned quality assurance professionals. They have been staff members at small and large businesses in various capacities, starting from being members of line operations, to staff management, to executive management, to high-powered consulting. They have successfully implemented quality management systems, performed audits, trained auditors, and have done extensive consulting. They have been involved in the development of ISO 9001:2004 and ISO 9001:2008. They participated in authoring ISO 9001:2015 and ISO 9000:2015 ("Quality Management Systems Fundamentals and Vocabulary"). ISO 9000:2015 supports the vocabulary and terminology of ISO 9001:2015. The content of this book reveals the extensive experience both the authors have in the field of quality, in designing and implementing effective quality systems in various industry sectors.

The purposes of this book are twofold: (1) to provide individuals and organizations with an important tool to understand the newly revised ISO 9001:2015 quality management standard so that they can achieve and maintain excellence, and (2) to promote continual improvement through the implementation of this newly revised standard. The requirements of ISO 9001:2015 are clearly presented in this book as building blocks, with each block defining the value derived from the clauses of the standard. The authors offer a logical, structured process to implement ISO 9001:2015 that will improve quality in your products and services and result in higher customer satisfaction.

If you have already implemented ISO 9001:2008 in your organization, this book provides guidance on the differences between ISO 9001:2008 and the new and revised content of ISO 9001:2015. The discussions of these differences will help you determine the gaps and identify the components needed to bring your existing QMS up to par with the new requirements.

This book does not address statistical quality control or other "total quality management" principles. All of these subjects are extensively addressed by many other books and authors. Instead, this book is an in-depth guide to understanding the revised ISO 9001:2015, which provides detailed explanations to empower you to successfully implement the newly established requirements of this standard.

Throughout the book, the authors have explained each requirement of the standard in simple terms to allow you to comprehend the quality elements involved. Here is a quick guide to the book's contents:

- Chapter 1 highlights the business relevance of ISO 9001 and emphasizes the importance of operational excellence.
- Chapter 2 provides an overview of the call for the ISO 9001:2008 revision, the various activities performed to justify the need, the impact of the changes, and constraints and benefits of the revised structure. The two chapters that follow discuss various opportunities to reevaluate your QMS.
- Many readers may hear that "output matters" and wonder how to interpret this popular cliché. Chapter 3 focuses on the opportunities within ISO 9001:2008,

explaining in detail how to develop a restructuring plan and providing guidance on what it takes to address the concept of "output matters."

- Chapter 4 discusses the components that make a compelling case for leadership to implement effective governance and reviews some of the tools commonly used to achieve compliance. The content of this chapter serves as a foundation for positive results; it is intended to help you understand the needs and expectations of your customers as well as those of interested parties. Without this knowledge, regardless of how hard you try to meet customer expectations, you will fall short.
- Chapter 5 focuses on understanding the organization and its context, determining the scope of the QMS, and understanding the needs and expectations of interested parties.
- Chapter 6 outlines the commitment required from leadership; the role of the quality policy; and the importance of organizational roles, responsibilities, and authorities. The leadership in any organization is the most critical element in determining the success or failure of a QMS. Indeed, by changing the actions of management, the philosophy, values, and behaviors of an entire organization can be altered. Grass-roots efforts by line staff are certainly commendable, but without the firm support of leadership, a great idea will never take root and deliver lasting rewards. Robust quality systems require a cultural change, and the reality is that cultural change cannot survive without the constant support and encouragement of top management.
- Chapter 7 highlights the fact that no matter how well you have identified the activities and the requirements of the QMS, without a solid, well-understood, well-communicated plan, efforts to identify risks and opportunities, meet quality objectives, and plan for change will be fruitless.
- Chapter 8 elaborates on the resources, competences, awareness, communication, and documented information needed to support the QMS.
- Chapter 9 discusses operational activities such as planning, control, requirements related to products and services, design and development, control of externally provided processes, product and service provision, and nonconforming products and services.
- Lord Kelvin's quote, "To measure is to know," is a very appropriate epigraph for Chapter 10, which focuses on performance evaluation of the QMS. Such an assessment can be carried out by conducting internal audits, monitoring, measurement, analysis, and other forms of evaluation. An organization cannot begin its transformation until it is aware that the quality of its product or service must be continually monitored and improved. Chapter 10 also addresses management reviews, explaining why they are crucial to the continual improvement of the QMS.

- Chapter 11 discusses nonconformities and the actions that should be taken to analyze true root causes to prevent them from happening again in the future.
- In the concluding chapter, Chapter 12, we highlight further improvement opportunities for business excellence and emphasize the use of ISO standards as a foundation and enabler for improvement.

The appendixes provide a summary of the quality management principles that are the foundational elements for any QMS. They also list other standards relevant to the food, telecommunications, and health care industries, among others. Appendix C provides further details on documentation. Appendix D compiles various templates that can be used as is or customized depending on your needs and the size of your organization. Appendix D also offers salient examples of opening meeting agendas for external audits as well as closing meetings. These examples, along with others, are intended to assist you in understanding some of the topics that should be covered in various audit-related meetings.

In summary, this book is intended to appeal to a broad range of readers, including those who fill the following roles:

- Vice presidents/directors of corporate quality, responsible for an overall company-wide quality management system, including product quality and associated processes
- Managers in charge of TQM, managing and developing strategies for company-wide processes to increase project effectiveness and customer satisfaction
- Directors of operational excellence, responsible for overseeing defect-free, smooth running of all processes related to operations
- Quality engineers (manufacturing, service, hardware, or software), responsible for ensuring quality in their respective day-to-day jobs
- Testers, or those in charge of testing products (software, hardware, firmware), to ensure that they follow pre-established processes according to ISO 9001 requirements
- Software quality assurance managers, responsible for evaluating software quality by designing new development processes to increase the overall quality of their products and provide a positive customer experience
- Process improvement engineers, in charge of benchmarking against world-class organizations, implementing what has worked for other companies, ensuring that processes bring beneficial results, and planning new activities to improve overall product/and or service quality

There are no prerequisites required to read this book. However, you should have an orientation or context based on quality management and an awareness of industry standards for quality and regulatory requirements. Because of our experience, we understand the challenges of those who will end up implementing ISO 9001:2015. Our goal is to provide basic and understandable guidance to implementing ISO

9001:2015 by exploring necessary details and the often simple logic of quality, considering how quality excellence relates to customers, and examining the essential role of senior management.

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With a book of this breadth, it is almost impossible to acknowledge all those individuals who have made significant contributions to this collective body of knowledge.

Approximately 60-plus worldwide quality experts (including us) from more than 40 countries met regularly in international meetings, over WebEx, and in small teams around the world during the past three years to develop and finalize the contents of ISO 9001:2015. We would especially like to thank them.

Finally, we wish to acknowledge our editor, Kim Boedigheimer, and our production editor, Elizabeth Ryan, and to thank them for their patience and guidance.

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About the Authors

Alka Jarvis is the first and only individual appointed as the Distinguished Quality Engineer at Cisco Systems, where she has been a staff member for the past 21 years. Ms. Jarvis has 30 years of experience in software engineering, including 19 spent in total quality management. Her background encompasses management of large-scale systems development projects, quality control, quality assurance, specification reviews, management of testing processes for large-scale companies, and teaching. She has been a frequent speaker on quality assurance issues at international as well as domestic events, and has worked in the software quality field in a variety of capacities for Fortune 500 companies such as Apple, Bank of America, AT&T and others. She is an adjunct professor at Santa Clara University in the MBA program for computer science, and is the author of five books. Ms. Jarvis is also an instructor for the software quality courses at University of California, Santa Cruz—Extension and University of California, Berkeley. She won Silicon Valley's "Corporate Woman Advocate of the Year" award for her accomplishments in the software quality field and her effectiveness in improving the environment for women in the workforce. The American Society of Quality in Milwaukee, Wisconsin, recognized Ms. Jarvis by publishing her accomplishments in its "Who's Who in Quality" article.

In her role as chair for the past nine years representing the United States on Technical Committee 176 for the International Standards Organization (ISO), Ms. Jarvis has been instrumental in the development of ISO 2000, as well as the 2004 and 2008 versions of ISO 9001 and ISO 9004. She worked in the drafting group for the revision of ISO 9001:2015. She is an ISO Lead Auditor, certified by the Exemplar Global of the United States. Ms. Jarvis has served as president of the Bay Area Quality Assurance Association (BAQAA), and has been an Applied Total Quality Advisory Board member for University of California, Berkeley—Extension, an Advisory Board member for the Certificate Program in Continuous Improvement and Quality Management at University of California, Santa Cruz–Extension, a board member of the Quality Assurance Institute, and vice president of the Indian Business and Professional Women organization. She resides in Palo Alto, California.

Paul Palmes is principal consultant with Business Systems Architects, Inc., of Fargo, North Dakota, and Prescott, Wisconsin. Working as a specialist in quality management and world-class quality systems over the past 27 years, he has enabled many organizations to attain ISO 9001 registration and many others to improve profitability and culture. He is a Certified Quality Manager and a BSI Certified Lead Auditor. He is an active podcaster who educates worldwide listeners through his "Quality 101" program series at

http://www.pdcauditing.com. His many publications include two books, *Process-Driven Comprehensive Auditing* and *The Magic of Self-Directed Work Teams*, published by ASQ Quality Press, as well as articles written for ASQ's *Quality Progress* magazine and the *Auditor Newsletter*, published by Paton Press. He is currently chairman of ISO TC 176 SC 1, responsible for the revision of ISO 9000.

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Quality Management Systems: Adding Business Value

The business case for ISO 9001 begins with its central mission—namely, enhancing world trade. ISO 9001 was developed during the same relative time frame as the European common market. Representatives from throughout the world met during the 1970s and 1980s to determine best business practices and requirements for each such practice to ensure consistent and conforming output of goods and services. The underlying principle was and remains a simple idea: Two companies operating in much the same way can expect equal treatment in managing everything from new orders to customer complaints. Of course, developing such a standard is also a rather ideal undertaking. By their very nature, all standards define an ideal state within which people—and indeed entire societies—work cooperatively, ever mindful of the best interests of all. ISO 9001, by recognizing the ideal state as rarely achievable but nonetheless a worthy aspiration, established the concept of continuous improvement to guide and motivate organizations to advance and succeed.

None of this works if you don't know who you are or where you're going. ISO 9001 therefore requires organizations to analyze their current state of affairs, define and set goals to achieve future expectations, and then monitor progress toward those goals. Top management, which is responsible for defining these goals, is therefore in need of feedback to determine how best to distribute resources. Those departments or processes that are most challenged become candidates for receiving additional resources. ISO 9001 defines all these interrelationships, some of which also require records to prove that decisions were developed and implemented based on facts, not assumptions.

Of course, this is all just "good business." Leaders decide policy and set goals to move the organization forward. Metrics are established to monitor progress. When it becomes clear that metrics are below expectations, additional resources are provided to improve performance. Finally, those same metrics are used to determine the return on investment for those additional resources. Through this activity, the company becomes an improvement engine. Assuming that the marketplace embraced and supported the outcome of all this effort, the obvious result should be sustained success—that is, a win-win scenario for both the organization and its customers.

ISO 9001 is good business on several levels, but perhaps most importantly it offers proof of performance and therefore accountability at all operational levels. Businesses and business leaders are accountable to any number of internal and external demands. A few examples serve to illustrate this point. Shareholders want improved earnings, while the accounting department is clearly correct in submitting a costly requisition for new enterprise resource planning (ERP) software. Customers, though not willing to pay more for it, are increasingly interested in additional software functionality, even though the design team needed to accomplish the upgrade is currently cost-prohibitive. These and similar scenarios are commonplace in today's market. ISO 9001 offers a consistent set of methodologies for managing these kinds of countervailing demands. Of course, once the plan is established, the work must then be done. Performance that meets its goals becomes centermost within the organization. Expectations are defined and progress is monitored. The overall result is a new level of accountability, involvement, and visibility.

Traditional top management oversight is accomplished through analysis of monthly financial statements. If the numbers are good, especially the "bottom line," further action is less important than would be the case if profitability was reported to be under projections. But where, exactly, is the problem? Can financial statements alone provide the right answers? In many respects they can, especially if the question is directed to which losses occurred and where they happened. But financials alone do a relatively poor job of answering why and who was responsible for the loss. At best, they are the starting point for further inquiry. Without high-level objectives and department-level goals to achieve them, and without a clear and compelling vision of the future state, ailing performance often skips wildly, from month to month, from one area of the company to another.

Without mutually agreed, high-level goals, the company is a rudderless ship—and behaves like one. Although the captain may want to achieve maximum speed, the crew can, and often does, cite the weather or excessive sea conditions for poor progress. It is also clear that one function—one type of activity that's controlled by the crew—can rarely make any real difference, given the lack of a deep and solid rudder under the ship. And so it goes, month to month, swaying with each variable breeze and hoping for success. The shipping company's financials simply report that income is down, not that any particular vessel is late to unload its cargo.

ISO 9001 and Innovation

Businesses are rarely static; that is, their products and services are always adapting to a changing marketplace. Competitors are constantly eager to improve their bottom line through any number of advances within your own organization's existing customer base. Innovation is no longer an occasional threat; it is the new constant in business worldwide, announced through the Internet and the general media at the speed of light. Innovation is especially friendly to startups, which are eager to gain a toehold or to catapult their companies to mega-status through one or more new approaches to an existing model. Large firms often fall victim to smaller firms as they become comfortable with established sales volumes and less concerned with their ability to remain profitable. Market innovators often target companies such as these, applying their best designers in the quest to outperform the current players whose research and development (R&D) investments have slackened over the years. It is important to note, however, that such efforts are highly focused and deliberate.

It can't be otherwise. Smaller businesses cannot afford extended R&D projects, cost overruns, and missed launch dates. They are small in number and at the mercy of limited supplies of capital and nervous investors. Time to market is critical not only to protect their ideas, but to stay in business at all. For these nascent organizations to succeed, it becomes crucial to produce. For those individuals working in these companies, risk and reward are high, but they are also the very reason why work is exciting and fun. The atmosphere is charged, and communication is immediate as everyone works to achieve the same outcome.

ISO 9001's approach to innovation lies at the center point between the startup and the established company's approach. Remembering that fearlessness is just one step away from recklessness, ISO 9001's design requirements maintain proven risk mitigation criteria while allowing companies to move in any direction they believe to be appropriate. ISO is not restrictive in regard to innovation, but rather responsible. The key to successful design—to any innovation, for that matter—is to define new product expectations, features, and complexities. These are important to achieve focus and clarity as the work progresses. They keep the design team on track. Once the particulars are understood by the team, it is necessary to research any number of "resulting requirements" such as applicable legal issues, standards, or codes to ensure that the market can adopt the product with the assurance that it is free of any unanticipated shortcomings. Controls are defined to ensure that as the product is developed, several "go/no go" sessions are planned to assess the product's ability to provide its originally intended design features. Once things are close to completion, two types of specialized controls are employed: verification and validation. Verification seeks to determine that what's on the print is what was produced. Validation ascertains whether what was produced actually works in the marketplace. Both considerations are extremely important—and validation is especially critical

from the perspective of the consumer. A solid design program is careful to spend time researching and interacting with the market prior to launch, if only to determine whether the color is right and the consumer is not irritated by the soundtrack while waiting for an operator.

The point of this discussion of innovation and ISO 9001 is to emphasize that both the established company and the innovator are equally supported by ISO 9001's design requirements, and that neither is restricted by them. In fact, the startup may need ISO 9001 far more than the established company so that it can avoid the potential for costly omissions in its design. The established company can benefit from ISO 9001's initial design planning requirements to avoid "design creep" and cost overruns. Both types of organizations can use ISO 9001's design requirements to better plan and support their design processes, create new products that are embraced by the marketplace, and avoid excessive risk in the launch of new products and processes for managing their services.

The Business Call for ISO 9001

It was once standard practice for large organizations to help their suppliers develop ever higher levels of sophistication in quality, supplier management, and logistics. Supplier quality engineers (SQEs) were tasked with analyzing the supplier base and offering training and other direct help to targeted suppliers to improve their performance and maintain costs. Today, few offer this kind of support. As the price to do so has increased, specialists have taken the place of many former multitasking operations. In addition, the rise of ISO 9001 acceptance has largely transferred managerial oversight to ISO 9001's third-party auditor. As a result, the majority of ISO 9001–registered companies now also require ISO 9001 registration of their suppliers.

It's far less expensive to require oversight than to provide it.

Small businesses constitute the majority of organizations currently registered for ISO 9001. With more than 1 million registrations currently in place, it's also clear that many of these small organizations are registered because of requirements imposed by their larger customers. The call to be "9001 registered" by these larger clients is primarily driven by the cost of maintaining a large staff of SQEs; many have chosen to instead rely on third-party auditors to ensure compliance and related satisfactory outcomes of the audit process.

For most small businesses, the requirement to register is often perceived as a tax on business. Given that these organizations are currently successful in selling and gaining acceptance of their products, what can ISO 9001 add that isn't already in place? The answer is little more than restating the requirement that all suppliers be registered—the perception of ISO as little more than a tax, an additional fee imposed to remain or become a supplier. Indeed, the majority of registrants did so because

they had to, not because they wanted to. In turn, many approach the registration process as a "min-for-max" proposition, spending the least amount possible to gain registration and hoping that the net outcome will not excessively hinder their current practices.

This is especially true in terms of maintaining their ability to be flexible and responsive to their customers. ISO 9001 is often incorrectly perceived as a system that slows down operations with additional forms and paperwork, takes more time to develop concepts into finished products, sets up a new layer of bureaucracy through which many decisions and controls have to undergo new and confusing scrutiny, and simply costs more money than it's worth. None of these assumptions need be true, but all have the ability to become so, especially if the min-for-max approach is utilized. Unfortunately, it is easier and faster to overlay a patina of acceptability and compliance through methods that are favorable to the third-party auditor rather than addressing the improvement needs of the company seeking registration.

The min-for-max approach intensively relies on documentation, forms, and reports to provide evidence of compliance to the standard. It can be, and often is, available as a package of materials requiring some basic editing to indicate relevance to the company and its practices along with appropriate training of a select few who have been charged with developing the program. It also sets in place most of the negative perceptions of ISO 9001 as a tax on business because the goal is tactical (registration as a business requirement) rather than strategic (registration to improve business practices and performance). As a result, the company develops work instructions instead of its workforce, produces reports that satisfy specific clauses within the standard instead of specific needs, and compiles documentation structured to convey permanence and authority instead of clarity and understanding.

The call to register to the standard is strong within the marketplace. Organizations face a choice: Do they undertake study and planning for implementation that first and foremost enables and improves, or do they throw together a string of documented evidence primarily relevant to achieving registration? Even if the initial belief of top management is that ISO 9001 is a tax on business, there is much to recommend in the adage, "If all you have are lemons, make lemonade!" The strategic approach allows the company to ride atop the wave, or at least seize the opportunity to develop a clear path to doing so, while the tactical approach most often leads organizations to become consumed by it. Developing your quality management system, whether it be a new registration or an upgrade from the 2008 revision, is a strategic decision, one that will affect the working lives of everyone in your company.

We believe that there is opportunity in the making. The following chapters were developed to define the reasons, methods, and possible tools to achieve initial registration or upgrade to the 2015 revision of ISO 9001 that add value to your business. The 2015 revision is the culmination of many years of development and worldwide acceptance. Chapter 2 examines that history a bit further and explicates

the differences between the 2008 release and the 2015 revision. As you continue reading, keep in mind that the intent of the ISO 9001 standard is to enable best practices, not to restrict them. Even though you may be compelled to register by customer demands, it's infinitely better to adopt the position that the organization was instead given the opportunity to improve.