ISO 9001:2015
For Manufacturers
[Purpose & Value]

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We Believe in Better Business

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Executive Summary

At its core, ISO 9001 is intended to highlight the key business practices that are representative of successful, long-term businesses. The ISO 9001:2015 standard is a powerful tool for manufacturing organizations to ensure that critical elements of their business are in place and functional. None of the "requirements" of ISO 9001:2015 is very specific. The elements are focused on what must be accomplished, not how. ISO 9001:2008 is very similar to the 2015 revision, with additional requirements for organization context (strategy) and interested parties (stakeholders). Content change is minimal only in the explicit requirement for evidence of risk based thinking and emphasis on achieving desired results of process objectives.

 ISO 9001:2008 to the 2015 version MUST be completed by September 14, 2018.

Introduction

I love the concept of ISO 9001 and the benefits it brings for manufacturers across the globe. To be fair, I have spent my career in Quality – something I never thought I would say – but I feel that there is a very strong case for implementing, maintaining, and improving in accordance with ISO 9001 standard.

I grew up amidst a fifth generation family business. That meant I was intimately involved in everything from the ground up and worked many summers at a young age that helped define my understanding of what it takes to run a successful business. Above all else – the longevity of any business is related to the relationship & value that any organization is able to develop with their customers.

Later in life, as I progressed through quality departments, managing one greater than the last, it has become very clear to me that some of the fundamental business practices that support longevity are not always incorporated into all organizations. While I could write a book, in and of itself, related to the mistakes and poor decisions I have been witness to over the years, my understanding and respect for a process by which to run a business has only increased.

The information provided here, and in future articles, is intended to help as many individuals & organization as possible. I hope that you will see some of the advantages & value that have become clear to me AND be able to implement these concepts with a unique flair that is your business to find the most value in each initiative you implement.

Purpose

Odds are good that if you are part of a management team and sleep well at night, many of the ISO 9001 principles are already in place within your organization. At its core, ISO 9001 is intended to highlight the key business practices that are representative of successful, long-term businesses in order to increase the success of your business and the industry & customers it serves.

Many people and organizations have come to see ISO 9001 as a "necessary evil" to pacify customer requirements and maintain large accounts. I have heard it referred to as "the largest global marketing hoax", "the result of pompous Europeans", and many, many other names. Rarely do organizations fully grasp the value of this framework around which a successful and longstanding business can be built.

ISO 9001 is intended to be implemented as Business Management System (BMS). From the top to the bottom, it outlines necessary functions of an organization – based upon experience and case studies. The content is designed to ensure the following:

1. The business has a strategy [4.1]
2. The business is aware of applicable stakeholders [4.2]
3. The business is aware of its core business & value proposition [4.3]
4. The business understands that the organization is a culmination of interacting processes [4.4]
5. Leadership is responsible for success of business and is committed to customer satisfaction [5.1]
6. Leadership is able to formulate a vision for the organization [5.2]
7. Leadership is able to clearly assigns responsibility for each critical BMS element [5.3]
8. Planning occurs to ensure actions are reducing risk & maximizing opportunities [6.1]
9. Planning occurs to determine process goals & how to achieve them [6.2]
10. Planning occurs to thoughtfully incorporate necessary changes [6.3]
11. Organizational Support ensures strategically allocating resources [7.1]
12. Organizational Support ensures competence & talent of employees [7.2]
13. Organizational Support ensures employees are aware of their impact on the business [7.3]
14. Organizational Support ensures critical information is communicated [7.4]
15. Organizational Support ensures adequate documented information to be effective [7.5]
16. Operation actions include planning of all resources required [8.1]
17. Operation actions include ability to determine customer expectations & requirements [8.2]
18. Operation actions include process to develop new products & services [8.3]
19. Operation actions include evaluation of suppliers [8.4]
20. Operation actions include ability to repeatedly make, track, and preserve quality product [8.5]

21. Operation actions include method for approving products to ship to customers [8.6]
22. Operation actions include ways for dealing with nonconforming product [8.7]
23. Performance of organization is continually monitored, measured, analyzed, and evaluated [9.1]
24. Performance of organization is regularly audited for compliance [9.2]
25. Performance of organization is regularly reviewed by management for results [9.3]
26. Improvement efforts of organization target customer satisfaction [10.1]
27. Improvement efforts address nonconforming product & processes [10.2]
28. Improvement efforts are continuous [10.3]

Each element is critical in its own right, and failure to operate with any one of these elements will typically result in future problems. Wondering why the long list, this is ISO 9001:2015 in full form!

Opportunity

The opportunity is predominantly in avoiding the risks associated with creating an organization that does not address each of these foundational elements. It is the intent of **BioSphere Analytics** to review each of the 28 sections for specific opportunities and risks in subsequent publications.

For an organization that is able to address each of these elements, the potential is unlimited. With a readily available supply of vision, goals, strategy, planning, results, and customer satisfaction that is continually evolving to better serve the customer is far more likely to succeed in future generations than one without.

It is important to note that none of these "requirements" of ISO 9001:2015 is very specific. The criteria are focused on WHAT must be accomplished, not HOW. This clear distinction allows every organization to develop a business model that works best for their customers, employees, and industry. There are countless ways in which to achieve this successfully.

BioSphere Analytics has been involved with many clients looking for guidance on an "ISO approved" process, and the truth is that the process, objectives, and focus of each must be crafted by the people it serves.

Risks

Consider each of the 28 elements above. I am sure that you have encountered at least 1 of them missing in your organization (and likely more!). From your direct experience, what was the result? What would have prevented this from occurring? Your answer would most likely meet the requirements of ISO 9001:2015.

The answers are not difficult or elusive. The only requirement is that they exist and part of a PROCESS to ensure quality product or service for your customers. Failing to include any of these elements can detract or cripple an organization from its potential.

Implementation

ISO 9001 systems can typically be implemented within a period of 6 – 12 months from scratch. While there are multiple factors affecting the rate of implementation, most organization fit within this time schedule.

General Process

Implementation typically follows general process:

1. Top Management MUST buy into the requirement of ISO 9001
2. Business operations need to be understood and defined in terms of interacting process
3. Each process must have an objective/KPI/metric to determine level of performance
4. Data must be collected and reviewed to ensure performance is being monitored
5. Actions are taken to improve processes not meeting objectives
6. Management reviews performance of business and allocates resources
7. Leadership is able to identify highest level opportunities & risks
8. Continual Improvement efforts are made to improve customer satisfaction

Typically, an ISO 9001:2015 subject matter expert is necessary for the transition to be successful. This can be accomplished by having an internal candidate with quality system experience trained at an outside agency (Intertek, ASQ, etc..) or hiring an ISO 9001 implementation expert in the industry.

Certification Process

ISO does not issue certifications and is involved solely in the development of the standards. ISO 9001 registration is completed using registrars (http://www.iqrc.com/accreditedregistrars.htm - I have personally experience BSI Inc., Intertek, and TUV Rheinland among others). The registration process is typically conducted in 3 phases:

1. Application
   Certifications are these companies business. There is no fear of rejection from any certified registrar, but there different approaches that each may take in their protocol.

2. Pre-Assessment & Document Review
   There is usually an initial review by an auditor to ensure that your Quality Management System (QMS) is appropriate and will, likely, meet the requirements of ISO 9001:2015. These reviews are often optional and can be avoided if a certification is either a) time sensitive or b) more mature and initial review is not required. In some instances, the first review can be scheduled as a Stage 1 audit and if things go poorly, be reassigned as a pre-assessment. The difference is largely in the amount of time given to the organization to correct any nonconformities.

3. Initial Program Implementation Assessment (Stage 1)
   Essentially, the ISO 9001 registration requires that a MINIMUM of 2 days is required for certification. By separating the audits, additional time is allowed between Stage 1 & Stage 2 audits to allow any necessary changes to be implemented, improving success rate of achieving certification.

4. Registration Audit (Stage 2)
   During Stage 2, all auditor findings will directly impact your chance of becoming ISO 9001 certified. If the auditor does not feel that your organization has not met the requirements of the standard, you get to start over (this is incredibly unlikely). More likely, you come out of the final audit with a recommendation to be ISO 9001:2015 registered with some level of findings (there are typically major, minor, & opportunities for improvement [OFIs]).

5. Annual Surveillance
   After becoming ISO 9001 certified, your certification is valid for 3 years. During that period, surveillance audits are completed. Typically, this means that annual visits are scheduled to review different parts of the business during each audit. After the 3 year cycle is complete, recertification is required (Steps 3 & 4 combined, and repeat).

Differences between ISO 9001:2008

There are numerous difference between ISO 9001:2008 and the 2015 version. Most of the changes appear more severe than the reality they represent. Most notably, there are 3 major changes to the overall presentation and appearance of the ISO 9001 standard

1. High Level Structure (HLS) Nomenclature
   All of the numbering you may have been used to has changed. ISO has consolidated the overarching programs (ISO 9001, ISO 14001, ISO 22000, & OHSAS 18001) have all transitioned to HLS to consolidate terminology, core elements, and (honestly) make it easier for companies to prescribe to all 4 ISO standards, instead of just 1.

2. Explicit requirement for RISK based thinking
   Risk has always been an implied requirement of ISO 9001 (through PARs, evaluation of requirements, etc.…). However, there has never been explicit requirements for evidence of risk analysis previously. This ubiquitous requirement will need to be documented throughout your QMS and processes to ensure that the day-to-day evaluations are documented appropriately.

3. Reduced emphasis on documentation
   As a sign of the times & the range of companies that are now adopting ISO 9001, the requirement for documentation is less specific than previous versions of the standard. Organizations can choose what file format (hardcopy, video, photos, program software, etc...) are best suited for point of use. In addition, total documentation requirements are more relaxed to allow organization to determine which documentation is critical.

4. Increased focus on Organizational Context
   Organization Context is an ISO term for strategic position of an organization. There are now requirements that the business is aware of its competitive landscape and can identify potential contributors that may affect its ability to provide quality product to customers.

5. Increased focus on Interested Parties
   Interested Parties refers to stakeholders that can influence decisions that might affect quality. While most of these parties are common knowledge, the exercise of identifying and evaluating potential contributors should provide some helpful insight into why and how decisions are made at your organization.

6. Increased leadership requirements
   Responsibility for the success of the QMS no longer resides with the quality management representative. While this person & title may continue to exist, the responsibility of the QMS is placed upon top leadership. This shift is a very clear call to

action to use the ISO 9001 standard as a Business Management System, as opposed to the historical Quality System.

7. Emphasis on achieving desired outcomes
   It has always been a requirement for each process within the organization to have an objective. It was implied that this objective should have a target and require actions be documented if this objective is not achieved. This point of closing this loophole will require more diligent documentation of efforts to correct undesirable results. In addition, it also makes the selection of process metrics much more crucial.

8. Key Terms & Definitions
   Throughout the standard, there are a number of terminology changes. There are terms that have been added, revised, and removed from the standard. In addition, the terms are no longer described in the Terms & Definitions sections, but have been moved to a supplementary ISO 9000:2015 document that should be purchased with ISO 9001 standard.

A more detailed video with explanation of the differences between ISO 9001:2008 & 2015 is available at http://biosphereanalytics.com/index.php/iso9001-2015/. This is an older presentation with some outdated contact information, but the content is still valid and useful.

Both versions continue to stress the Plan, Do, Check, Act (PDCA) model as well as focusing on a process approach to your business model. Differences between specific ISO 9001 elements will be discussed in corresponding articles.

 It is important to note that the transition from ISO 9001:2008 to the 2015 version MUST be completed by September 14, 2018. If not, organization will lose ISO 9001 registration status until it can be audited and reconfirmed. In factoring a timeframe for this transition, it is important to remember that some timing restrictions will likely be out of your control. Overall, there is a shortage of auditors at registrars and companies have decided to push out many of the audits to upgrade their compliance. Scheduling an audit in 2018 will be difficult, to say the least.

About Us

It is the goal of **BioSphere Analytics** to help US based manufacturers run more stable, effective, and efficient operations that include the essential business elements of ISO 9001:2015 as a tool to leverage the ultimate value for your organization.

We have been able to work with our clients to achieve not only ISO 9001 registration status, but significant value through cost reductions and growth initiatives alike. Every representative is focused on the needs of our client and will work 1-on-1 to ensure results are achieved.

We love helping companies grow and would love to be involved in your organization's success. We offer custom plans to meet the various demands of any manufacturing business. Please email Benjamin@BioSphereAnalytics.com or call 203-907-5646 to discuss these opportunities further!

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