Four Steps to Effective Implementation or Transition to ISO 9001:2015

How BPA's SharePoint QMS solution can help organizations to become compliant to ISO 9001:2015

White Paper

by

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Explanation of symbols

ISO 9001:2015 Requirements

BPA Recommendations

0. Introduction

The need to comply with customer demands and other regulations by enterprises is challenging for executives all over the world and in all industries and public sectors. It afflicts the entire enterprise chain and executives have to ensure that compliance can be achieved within the entire corporate structure, including all affiliates. Complex risk and quality management obligations must be observed on a daily basis and down to the affiliate level or sensitive setbacks or fines caused by noncompliance can hurt the bottom line and damage corporate market positions.

With the following white paper, we at BPA Solutions aim to help you as implementer of your Quality & Risk Management System into your organization to become compliant with the international recognized ISO Standard ISO 9001:2015.

STEP 1 - How to determine Strategic Quality Directions?

When planning for your quality management system, ISO 9001:2015 requirements are requesting organizations to consider the expectations of relevant interested parties and the external/internal factors that affect the ability to achieve the intended results of your quality management system. These subjects are part of the new ISO 9001:2015 clause to understand the organization and its context.

How can you ensure to cover the requirements?

According to the ISO 9001:2015 Standard, your organization shall review and analyze key internal considerations, external stakeholders' expectations and its related risk and opportunities to determine overall strategic directions.

This involves:

- Understanding your core products and/or services and scope of the management system.
- Identifying "interested parties" (stakeholders) who receive your Products and Services, or who may be impacted by them, or those parties who

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may otherwise have a significant interest in your organization.

- Understanding internal and external challenges that will impact your organization and interested parties; these challenges may be identified through an analysis of risks facing either your organization or the interested parties. These challenges should be monitored and updated as appropriate, and discussed as part of your regular management reviews.

THE SOLUTION: While keeping your quality context in view, your organization can determine all risks and opportunities that need to be addressed to:

- Give assurance that the quality management system can achieve its intended results
- Prevent or reduce undesired effects and achieve improvement
- Enhance desirable effects

There are many ways to analyze stakeholder related risks and opportunities. One of them is to perform a SWOT analysis (S=Strengths, W=Weaknesses, O=Opportunities, T=Threats).

A SWOT analysis highlights business opportunities and threats (BPA Quality example).

A collaborative quality management system will replace heterogeneous Microsoft Excel files and disconnected databases into an all-in-one effective solution. Automated workflows will help business executives to shorten process lifecycles and reduce the costs and risks related to your processes. This way, collaborators and executives can take the control back on your strategic processes.

« A QMS needs to integrate tools like SWOT analysis or competitive intelligence to better support strategic decisions and help to drive quality improvement opportunities».

Boris Lutz, CEO BPA Solutions

This information should be periodically reviewed during the required quality management reviews.

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Quality strategies can be described by analyzing competitive intelligence, stakeholders' expectations, opportunities for business improvement and potential risks. A SWOT analysis will help you defining risks and opportunities.

STEP 2 - How to identify Quality Processes and Responsibilities?

ISO 9001:2015 promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system to meet customer requirements and improve customer satisfaction.

Understanding and managing interrelated processes as a system contributes to your organization's effectiveness in achieving its intended results and makes outcomes measurable. But how can you be sure to build your QMS to be "solid proof" and in accordance with your quality policy and cascade your strategic directions down into the whole organization?

From within your electronic QMS, end users should be able to understand how processes are interrelated. A process map will help collaborators to navigate in the system. More than a descriptive system, your QMS should be based on collaborative technology. Highly connected QMS components and functionality "tailored for you" speed up identification of all dependencies within the QMS. (See BPA Quality Process Map example).

Is a 100% connected ISO 9001:2015 QMS possible?

YES, this is the main goal to reach with an all-in-one collaborative QMS solution. The core process map and their related quality processes ensure effective implementation and monitoring of all compliance documents, KPIs and risks related to each QMS core process.

Build a rigid PDCA (P=Plan, D=Do, C=Check, A=Act) process approach for your quality management system. Based on the scope of your QMS, describe key processes with their purpose, main activities, input/output information, responsibilities, related compliance documents and KPIs and make sure to cascade all within your organization. This will not only establish congruent QMS process owner responsibility, but will also help you passing successfully ISO third party audits in the future.

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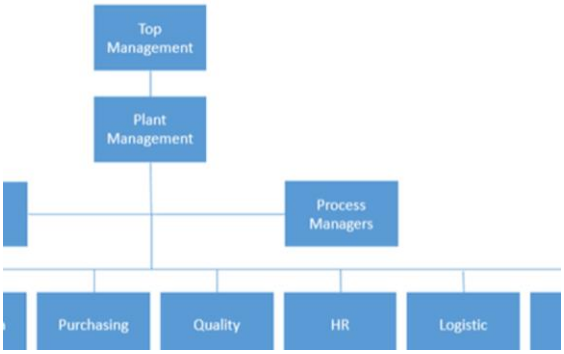
A PDCA approach will help you to determine and describe all your QMS processes with the following details:

- Process owner(s)
- Link between processes
- Applicable inputs, activities and outputs
- Applicable responsibilities and authorities
- Proposed compliance documents and indicators
- Applicable risks and KPIs
- Critical and supporting resources

As an executive you want to be sure to track all important interactions with customers, suppliers and stakeholders. Customer satisfaction should be your main objective. How can you make sure you have the right combination of organizational chart and job descriptions and how can you ensure proper communication throughout the organization?

PROCESS OWNER ROLES: To comply with ISO 9001:2015 requirements, your top management has to assign responsibilities and authorities for all relevant process roles in your organization.



The organizational chart lets you view key processes and skills needed for each executive (BPA Quality example).

Define process owners/ responsibilities (organizational chart) related with your quality processes without naming (always changing) staff members. This will help you to manage job descriptions and skills needed for your staff. Based on this information you can plan the required training for your collaborators.

STEP 3 - How to Establish Compliance of QMS Documents & Records?

ISO 9001:2015 does not make it mandatory anymore to develop a Quality Manual, but requires to establish and maintain so called "*documented information*". What is the best choice? Should your QMS documentation include both - documents and records - in hardcopy or/and electronic format?

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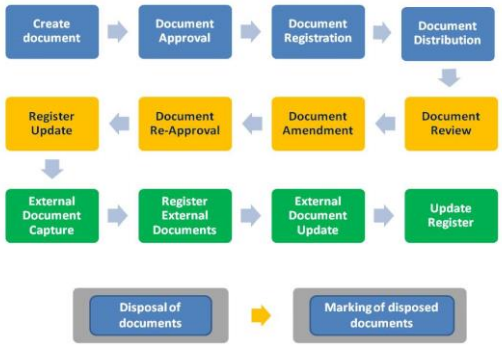
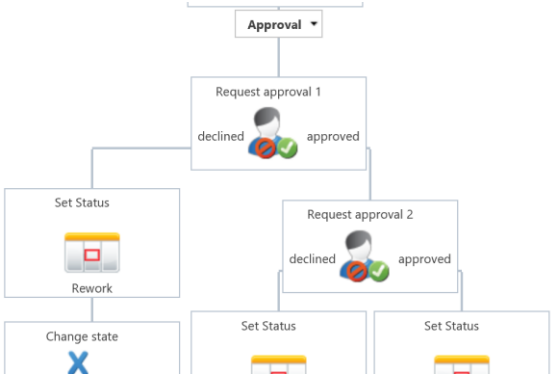
All QMS documents like procedures, policies, instructions, etc. should be established, documented, implemented and maintained either in hardcopy or electronic format and follow the document management cycle as outlined in the example below:

We all know that managing paper is complex, risky and time consuming. Fortunately, collaborative systems like SharePoint allows to manage documents and records in an electronic solution therefore avoiding a paper system.

FOLLOW THE RULE: Your ISO 9001:2015 QMS information system must be managed. Use automated electronic workflows to control documents and processes and save time.



Import your compliance documents from a file server into a collaborative QMS solution. This will facilitate your administration work to manage and share QMS documents with your collaborators. Documents can be categorized in many virtual folders, using metadata. Select a system that provides a native integration with Microsoft Office. Your selected system needs to track document versions and document approval workflows. For industry sectors like pharmaceuticals, an electronic signature module should be available (CFR 21/11 compliance).



Example of an automatic document approval workflow (example of a workflow module with BPA Quality).

STEP 4 – How to Evaluate Performance & Drive Continuous Improvement?

To comply with ISO 9001:2015 requirements, your organization must use the quality management system to improve its processes, products or/and services. Such improvements aim to address the needs and expectations of customers as well as other interested parties, to the extent possible.

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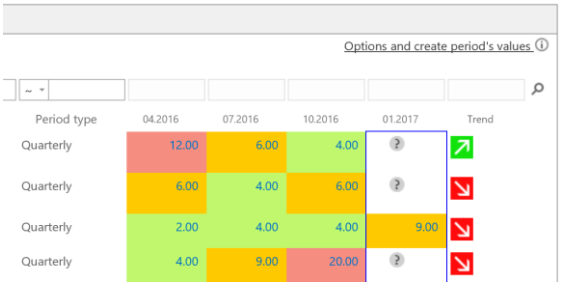
KEEP IT TO THE FACTS: Create a data-driven quality improvement plan. Data analysis results can be used to evaluate:

- Performance of QMS objectives
- Conformity of products and services
- The degree of customer satisfaction
- QMS performance and effectiveness
- The effectiveness of actions taken to address risks and opportunities
- The performance of external providers
- Other improvements to your QMS

Risk Management



INITIATE 360° RISK RADARS: Periodically prioritize and assess organizational risks based on impact & probability (BPA Quality example).

To comply with ISO 9001:2015 requirements, your organizations must consider ALL risks and improvement opportunities when taking actions within your quality management system, as well as when implementing or improving the QMS. How can you ensure to cover these new requirements?

Once identified, you need to prioritize and periodically assess all major risks based on QMS impact and probability. Define your own formulas to track the cost impact of your risks. Define mitigation strategies and if needed, treat all priority risks with corrective actions. Monitor all identified risks for your QMS with heat maps and set periodical controls to keep a great "holistic" overview of your risk management.

Customer Focus

To comply with ISO 9001:2015 requirements, your executive management must adopt a customer-first approach to ensure that customer needs and expectations are determined, converted into requirements and are met with the aim of enhancing customer satisfaction.

The question is how to best break down customer satisfaction management into "manageable" pieces? The answer is that your QMS needs to transform into a quality relationship management system where customers (and stakeholders) are at the center and where customer satisfaction is the measured output.

This is normally accomplished by assuring:

- Customer and applicable statutory and regulatory requirements are

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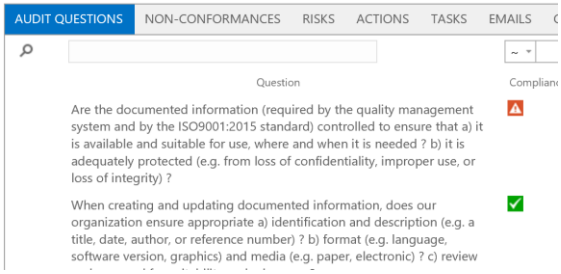
determined, understood and consistently met.

- The risks and opportunities that can affect conformity of products and/or services and the ability to enhance customer satisfaction are determined and addressed.
- The focus on enhancing customer satisfaction is maintained.

Track important stakeholders' interactions and satisfaction (BPA Quality example).

Audit Management

Does your organization have to conduct internal audits at planned intervals to comply with ISO 9001:2015 requirements? YES, internal audits can help to determine whether the management system conforms to contractual/regulatory/statutory ISO 9001 requirements and to all quality management system requirements.



Manage QHSE/supplier audits and track related findings, risks, etc. (BPA Quality example).

Are Management Reviews Needed?

According to ISO 9001:2015 requirements, does your executive management have to review the QMS at planned intervals and document the review? YES, to ensure its continuing suitability and adequacy of QMS effectiveness, your top management needs to periodically review the QMS. Management review actions and meeting minutes are created as evidence for any future ISO third party audit.

Objectives and KPIs

How can relevant QMS KPIs be gathered and measured on a monthly basis for each quality process? How does executive management review, analyze and make decisions based on these KPIs during periodical management reviews?

KEEP IT SIMPLE: Adjustments of QMS objectives/KPIs can be set in order to ensure continuous quality improvement. Process owners track their relevant objectives and KPIs.

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How about Non-Conformances and Corrective Actions?

HAVE A PREVENTIVE MINDSET: To comply with ISO 9001:2015 requirements, your organization must take corrective actions to eliminate nonconformity causes in order to prevent recurrence. To comply with ISO 9001:2015 requirements, you must identify preventive risk in order to prevent nonconformity occurrence.

CAPA 8D Report

CAPA No:	5	Start Date:	12/2/2
CAPA Title:	Broken package	Initiator	Boris L
CAPA Status:	In Progress		
TEAM			
Leader:	Belinda Schoeni;	Team Members:	Belind
PROBLEM DESCRIPTION			
Broken package and products.			
CONTAINMENT ACTION & ROOT CAUSE INVESTIGATION			
Responsible:	Belinda Schoeni;	Comment:	Done.
CORRECTIVE & PREVENTIVE ACTIONS (CAPA)			
Responsible:	Belinda Schoeni	Comment:	
VERIFICATION & EFFECTIVENESS MEASUREMENT			
Responsible:		Comment:	

Example of an electronic 8D (9D) CAPA report (generated with BPA Quality).

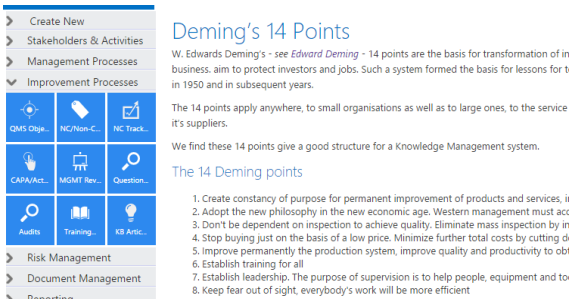
Competence Evaluation and Training

Staff members performing work affecting product or service quality must be competent on the basis of appropriate education, training, skills and experience.

Manage skills, education, experience and training accomplished for your senior staff and compare all with the required skills needed for their position in using competency matrixes with your QMS system.

Knowledge Management

When addressing changing needs and trends, your organization should consider its current knowledge and determine how to retain and develop knowledge in the company in order to support quality management related tasks.



TIP: Internal electronic based wiki systems can help to develop & maintain QMS knowledge in the company (BPA Quality example).

Conclusion

In this whitepaper we have identified four valuable steps to help you transitioning to the ISO 9001:2015 Quality Standard:

1. Determining your strategic quality direction
2. Identifying your quality processes and responsibilities
3. Establishing your compliance documents & records
4. Evaluating performance & driving continuous improvement

We provided recommendations on how an electronic system will help democratizing your QMS to all collaborators.

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About BPA Solutions

BPA Solutions is a leading global provider of innovative business software solutions based on Microsoft technologies.

BPA has developed an all-in-one QHSE + Risk management solution, built on #1 Microsoft SharePoint technologies and compliant with ISO 9001:2015. We engineered an innovative solution where super users have full control and where stakeholders are at the center of the system. We guarantee the best user experience and return on investment.

ASK FOR A FREE TRIAL: We can guide you on your continuous journey to Quality Excellence. Ask us for a free trial now!

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