

Implementing ISO9001 using BusinessPort and the AgilityBMS

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The implementation of ISO9001 consists of four main stages:

- Commitment
- Design
- Deployment
- Usage

This article will outline each of the stages and explain how BusinessPort and the AgilityBMS support and add value to implementing ISO 9001.

Commitment

The Management Team needs to fully understand why there is a need to introduce an ISO9001 - compliant Quality Management System (QMS). Is it just to gain a tick-in-the-box or is it to improve the effectiveness, efficiency and marketability of the company, as well as making it a better place to work? Without this understanding, disappointment and expense without benefit could happen.

So firstly, determine what you want to get out of ISO9001. Create a vision and set objectives. Your vision should not relate to how you will deploy the standard, but to the sort of company you wish to be as a result. What changes in behaviour do you want to see? How do you want your AgilityBMS to operate?

Once you understand where you are going, you can then start to plan the journey. However before that, the management team must commit itself to undertaking that journey, by allocating and ring-fencing the required resource. Dedicated individuals, organisation time and suitable infrastructure will be required. And this is where you must also ask the questions; do we have the experience and skills to implement ISO9001, and do we have the means to develop and deploy our processes in such a way that our vision can be achieved?

If the answer to either question is no, then this is where BusinessPort can help, by supplying experienced Project Managers, Business Analysts and our dedicated AgilityBMS software. The AgilityBMS acts as a repository for the QMS; storing processes and documents in a consistent manner which can be tracked and audited.

Design

This is where the AgilityBMS is developed in line with best practice as described in ISO9001. The standard itself mandates only 6 procedures, all of which relate to how the BMS will be used (managing documents, managing records, dealing with defective products, correcting the system, auditing the system and improving the system), but unless you have a very simple business, or a sophisticated approach, you will likely want more documented processes to support the business.

The table below identifies the key elements of ISO9001 and the way in which the AgilityBMS can assist in documentation & deployment:

Clause	Description	Agility Support
4.1 (a) & (b)	Determine process needs, sequence & interaction	Create Process Flows in Agility with linkage to supporting documentation
4.2.3, 4.2.4, 8.2.2, 8.3, 8.5.2, 8.5.3	Mandatory procedures for managing documents, managing records, auditing the system, dealing with defective products, correcting the system, and improving the system	Create as Agility Process Maps, with linkage to Process Flows and Role descriptions, accessed via navigation tree or compliance module. If needed, pre-designed templates can be supplied.
4.2.3, 4.2.4	Control of Documents, Control of Records	Agility has Documentation Management capability and can be used to create, version control and archive documentation.
5.3 & 5.4.1	Establish Quality Policy & Quality Objectives	Stored in Agility & accessed via the navigation tree or compliance module
5.6	Conduct regular Management Reviews	Meeting Terms of Reference can be stored within Agility and linked to the appropriate meetings (within Process Flows or Process Maps)
6.2	Ensure competency of Human Resources	Role descriptions can be created within Agility and linked to Organisation Charts, Process Maps and Individuals.
7.1 to 7.6	Product Realisation (planning, purchasing, developing, producing, testing, selling, service provision)	Activities and tasks can be documented as Process Maps within Agility, linked to Process Flows and role descriptions and accessed via the navigation tree. Risks can be identified and controls specified within Process Maps and summated within the Risk module
8.2.2	Planning & conducting Internal Audits	Schedules can be created and non-conformance recorded &

		actions tracked within the Audit Module
8.2.3	Monitoring & Measurement of Process	Agility can produce reports on process management statistics (process map usage, process map updates undertaken, process map feedback received)
8.5.2, 8.5.3	Corrective Action, Preventive Action	Defects, omissions and improvements can be recorded as feedback within Process Maps and managed to completion by the System Administrator. This includes the automatic issue of notifications and reminders (workflow)

Product Realisation will consume most of the Design Phase and can be approached in a number of different ways, depending on the organisation and its level of maturity. It may involve updating existing procedures, creating new procedures using 'experts' or workshops, or a combination of both. This is where BusinessPort's experienced Business Analysts can add value by creating Process Flows and Maps quickly and accurately in collaboration with the organisations work force.

For most organisations, this is a large undertaking, and the design and deployment of a QMS is best run as a formal project in order to achieve the desired outcome within the timeframe and costs allocated. As with all projects, it is more effective to apply Quality Assurance (preventing problems arising) than Quality Control (fixing problems after they have occurred), so experience and good planning are vital.

Again, BusinessPort can assist by supplying Project Managers who are familiar with the requirements and pitfalls involved in implementing ISO9001.

Deployment

Having designed your QMS, the next task is to make it available to your staff. Although this would seem a simple task, it is considerably harder than the development stage. Many a well-designed QMS sits on the shelf, unused, because the staff did not buy into it. Experience has shown that for a QMS to be taken up actively, it needs to be easy to access, easy to understand, easy to use and easy to update.

QMS's fall into one of four categories:

1st Generation: Paper-based, rigid, lengthy formats, stored in binders, difficult to distribute and access, cumbersome to update. Used in the 1980s early 1990s.

2nd Generation: Word documents, still in the paper-based rigid formats, held in file-stores or Documentation Management tools, accessed on-line, cumbersome to update. State of the art in the mid to late 1990s.

3rd Generation: Semi-modelled, where the process flows are designed in a software tool, but the procedures remain in word and are 'attached' to the tool, still using a rigid format, stored as for 2nd Generation QMS's but accessed from the tool, cumbersome to update. Used 5 to 10 years ago.

4th Generation: Fully-modelled, where the process flows and procedures are an integral part of the software tooling and can be integrated with other tooling modules. Formats are simplified for electronic use, held as part of the tool, accessed from the tool and are easy to update. State-of-the-art now.

Most companies aspire to a 3rd generation QMS, as they have never seen anything different and their thinking is still mired in paper-based formats. Agility is a major leap forward in thinking, being the second iteration of a 4th generation tooling set.

Procedures are captured as process maps rather than being attached as external documents. These use an easy-to-understand swim-lane format and integrate activities with roles, risk controls and supporting documents.

The user can issue a change request from within the document itself. The QMS change process is controlled through an automated workflow, which both drives the change through amendment, review, approval and update, and identifies the status of the change as it is processed. Using this approach, it is feasible to process and publish changes within 30 minutes, depending on the availability of the reviewers and approvers. A document management history is retained automatically, and sensitive information can be user-protected.

Process maps are made accessible via a web-based interface to the tool, or via a SharePoint Portal (which brings other advantages, but is outside the scope of this article). In situations where a desk top or laptop is not accessible, the Process Map can be printed off as a paper-based document.

No matter how good the delivery means are, staff will still need awareness and detailed process training, and the Quality Manager and System Administrator will require specific Agility training. BusinessPort provide AgilityBMS training at all levels of requirement, usually as part of the overall deployment package.

Usage

Having designed an excellent QMS which has caught the imagination of the workforce on its launch, you now enter the most difficult stage of all - keeping it going. The initial commitment by the work force will be diluted over time; by those that never bought in, by middle management driven by short-term aims (deliver it now!), by new staff unfamiliar with the system or by existing staff who claim to have insufficient time to feedback any issues or better ways of working.

This effect is a 'negative feedback loop', where the changed system tends to revert to the original, and is a well-recognised phenomenon (see Malcolm Gladwell's 'The Tipping Point' or Peter Senge's 'The Fifth Discipline'). But, although staff will tend towards working the way they used to, there are a number of things that can be done to maintain the change and to make the QMS the way of working that people are used to, that elusive thing, a 'culture change'.

By using the AgilityBMS, you are well on the way to embedding that change. All the process information is easily available from one source, so there is no reason not to do the job as defined.

Feedback is simple so there is no excuse for having 'out-of-date' working practices. And individuals have their roles described in terms of processes used, so there can be no evasion of responsibility. Thus a different way of working has already become part of your staff's day-to-day activities.

But there are other things that will help maintain your AgilityBMS:

- Top management visibility to promote the AgilityBMS
- Middle Management have AgilityBMS related objectives built into their annual performance reviews
- Monthly 'events' highlight the importance of the AgilityBMS
- 'Quality Ambassadors' are nominated to 'spread the message'
- Internal audits are held on a regular basis
- A Steering Committee is established to manage the continued development of the AgilityBMS
- Staff are actively involved in improving their AgilityBMS