

## How to Develop a Quality Management System

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### Introduction

In today's highly competitive business environment, forward-thinking organizations are more committed than ever to continually refining their processes and procedures to improve their products and services. The development and implementation of a quality management system (QMS) is perhaps the best way to demonstrate this commitment.

A quality management system provides organizations with the opportunity to increase their competitive position by focusing improvement efforts on those operational areas in the most need of change. This in turn streamlines operations, increases efficiency and enables organizations to provide higher quality products and more effective services to their customers.

So why doesn't every organization implement a QMS? Very often, organizations shy away from implementing a quality management system because the process is viewed as daunting. Not only does it compel an organization to take a critical look at its current business practices, analyze how well these are functioning and develop an organization-wide documentation and monitoring process, but such a system also comes with the expectation of immediate and long-term cultural change. Despite the significant commitment needed to develop, implement and maintain a QMS, the long-term benefits to an organization make such a system a worthwhile endeavor and an essential element in ensuring the organization's long-term viability.

### Development Strategy

Once an organization has committed to the development and implementation of a QMS, sound planning becomes a crucial element to the project's success. In fact, poor planning and inadequate resource allocation are often the primary causes of implementation failures. Organizations can avoid these potential pitfalls by following these key steps: establish a project plan; assemble a project team; conduct a "gap analysis"; develop and implement the system; and monitor implementation.

### Project Planning

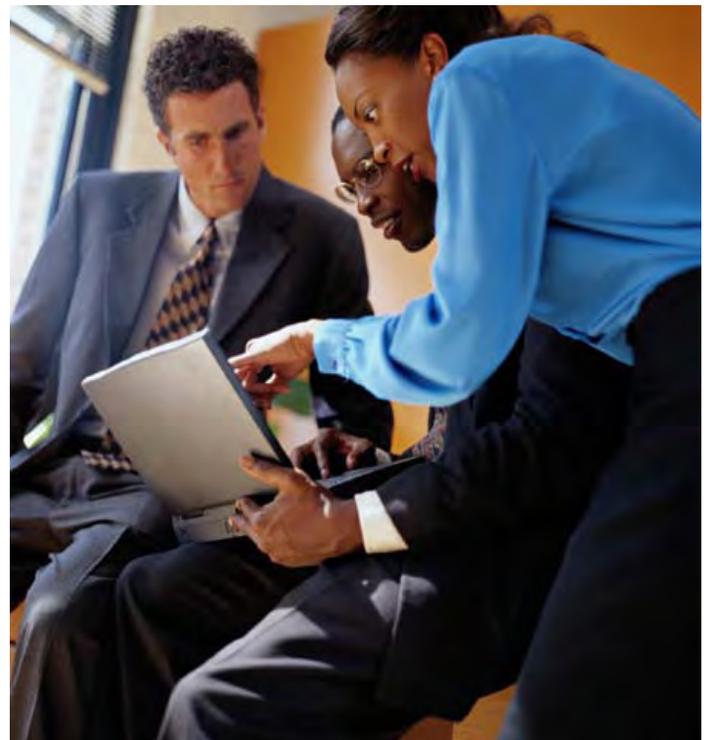
Careful planning and efficient management of the implementation are vital to the success of any QMS project, as this helps to control costs and avoid extended timelines and the loss of key personnel and general dissatisfaction with the outcome. The following steps should be considered when developing a QMS project plan:

- Identify project tasks
- Define milestones
- Establish timelines
- Develop a budget
- Assign resources
- Develop a strategy for monitoring progress

### Assemble Project Team

The scope of the work that is required to develop and implement a QMS will vary among organizations, but all will require the right mix of people to get the job done. Appointing a credible and capable leader for the project (let's call this person the "quality champion") is an essential part of the process. An organization's quality champion is responsible for guiding the quality team throughout the life of the project. It is important to select an individual who:

- Has a sound understanding of the organization, particularly of its culture and values
- Understands the rationale behind any new system implementation
- Is able to undertake a comprehensive review of all business processes and begin to develop and introduce new policies and procedures
- Can train staff to understand and help implement the system and to continuously identify areas of improvement.



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## Gap Analysis

Before implementing a QMS, a thorough analysis should be completed to profile the organization's existing business practices. Based on the findings, the organization can determine what is already in place and what needs to be created. Basic elements of a QMS, which should be taken into consideration when conducting the gap analysis, include:

- A quality manual, inclusive of the organization's mission and vision, quality policy, and structure
- Standard Operating Procedures (SOPs) for every area of operation, which address, at a minimum, vendor management, documents and records control, benchmarking, corrective and preventive action and the monitoring of customer satisfaction
- Metrics that are designed to assess the effectiveness of each major organizational function and process
- Regular internal audits that assess adherence to organizational procedures and determine the effectiveness of business operations

## System Development and Implementation

The involvement of all personnel in the development and implementation of the QMS, from the project's onset, is essential to its ultimate success. This involvement creates buy-in, helps to ensure a better understanding of the system and guarantees all major phases and facets of organizational activities are captured. Working with departmental managers and their staff, the quality team should follow the development and implementation steps below:

- Identify major functions
- List related processes
- Name related records
- Develop SOPs
- Create metrics
- Assign responsibility
- Create and/or collect records
- Conduct a procedures review with staff  
(Process requirements and related documentation are clarified and expectations established)
- Gain review and approval by executive management
- Train staff
- Formally release the system documentation

Once these steps have been taken, the organization is ready to "go live" with its QMS. When that happens, little to no disruption of the day-to-day business activities should be experienced. Of course, there will always be some minor issues that will need to be addressed, but these should be minimal and entirely manageable.



## Monitoring

To ensure the strength and effectiveness of the QMS, ongoing internal audits are critical. It is only through such mechanisms that inefficiencies are identified and addressed. When conducting QMS monitoring it is important to recognize that the system in and of itself is not a silver bullet.

Having a team of trained internal auditors who objectively review each area, document instances of noncompliance with established procedures and make sound recommendations for corrective actions is paramount to the system's ongoing success.

## Conclusion

While all of the steps noted above might seem like a lot of work, they are the only means to assure that a QMS will not become merely a document-generating system. Once a QMS is deployed, periodic health checks in the form of internal audits should become a part of the organization's routine. There is an old adage that says the only constant is change. This is particularly true in today's business environment. Therefore, organizations must constantly reassess the ability of their QMS to capture key performance and industry trends and guide efficiency improvements at all levels of the organization.