



Quality Management Systems

“

Theory of Evolution (Summary)

First, there were some amoebas. Deviant amoebas adapted better to the environment, thus becoming monkeys. Then came Total Quality Management.

Scott Adams

”

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Introduction

A quality management system (QMS) is the business processes your company uses to oversee the many tasks and procedures your company performs to ensure that your deliverables, and how they are delivered, are consistent. A good quality management system helps you reach and maintain the desired level of quality within your organization that consistently achieves customer satisfaction.

Having an effective QMS translates your organization's purpose and goals into policies and resources that help every employee implement standard operating procedures (SOPs).



Change Management

- › Design Change Management
- › QMS Change Management
- › Risk Review



Process and Production Control

- › Customer Requirements
- › Supplier Quality
- › Identification/Traceability



Design Control

- › Risk Management
- › Inputs/Outputs
- › Verification/Validation



Product Surveillance

- › Compliance Handling
- › Risk Monitoring
- › Vigilance



Corrective and Preventive Action

- › Eliminate Nonconformities
- › Quality System Improvements
- › Verify Effectiveness



Management Responsibility

- › Management Review
- › Inspection Readiness
- › Internal Process Audits



Resources

- › Employee Skill Competence
- › Infrastructure
- › Work Environment



About QMS

Quality management systems have seen a rise in use and can be traced to British Management Consultant Ken Croucher, who created a model for Total Quality Management (TQM). His model was based on quality management best practices including applying statistical sampling methods to ensure consistency. Others built upon this model, adding that everyone in the organization must be involved in the effort to make products or services that are fit for use while conforming to requirements and “building it right the first time”.

The goal of QMS is to ensure that all interested parties work together to improve your company’s processes, products, services, and culture to achieve the long-term success that stems from customer satisfaction. This is done with 8 core elements and 7 principles all on the foundation of continuous improvement.

“

Quality comes not from inspection, but from improvement of the production process.

W. Edwards Deming

”



QMS Principles

Your path to better performance through better quality starts with 7 principles to better quality, which have been adopted by the International Standard for Quality Management. Starting with great Leadership, the principles spread through your organization with employee Personal Engagement, plans and deliverables with a Customer Focus, and improved supply chains by way of Relation Management. All of this is built on a foundation of Continuous Improvement, Process Approach, and Evidence-Based Decision Making across all business units. These principles can be seen as the following:

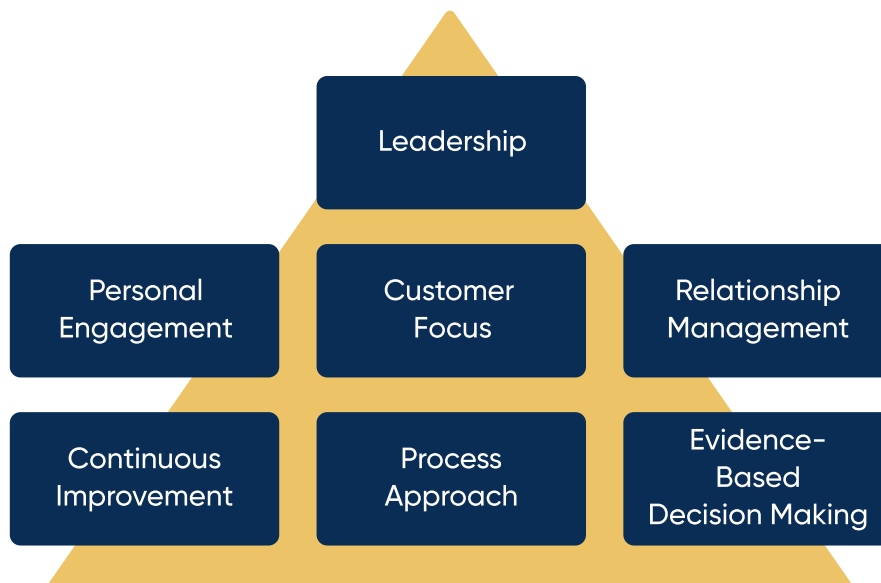


Figure 2: Principles of Quality Management



Leadership

Good leadership results in your company's success. Great leadership creates togetherness and purpose in your staff and stakeholders. This helps you create a thriving company culture that allows your staff to move toward and realize their full potential. That culture of support makes your staff want to be actively involved in achieving company objectives. As a leader, involve your employees in setting clear goals and objectives. This motivates those employees to significantly improve their productivity and loyalty.

“

A good leader inspires people to have confidence in the leader, a great leader inspires people to have confidence in themselves.

Eleanor Roosevelt

”

Personal Engagement

Great leadership leads to a motivated staff. Motivated staff feel ownership over their process, business unit, and company which leads to personal engagement. Regardless of their status as full-time or part-time, outsourced or in-house, engaging your staff helps them create and deliver value.

Encourage your employees to constantly improve their skills and maintain consistency. But you should also involve them in decision making and recognize their achievements. When people feel valued, they do their best and reach their best potential. Being motivated boosts their confidence and self-worth which leads them to do more. Staff that are personally engaged feel empowered and accountable for their actions, which leads to higher productivity and less errors.

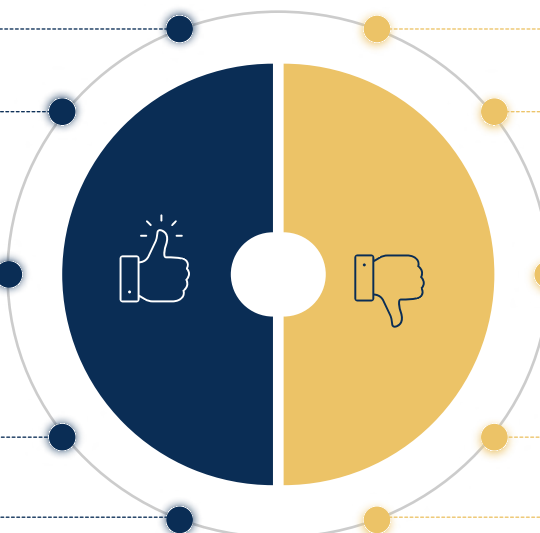


Engaged employees

- Better Health
- Increased Happiness
- Improved Job Satisfaction
- Increased Productivity
- Higher Retention

Disengaged employees

- Feel meaningless
- Increased frustration and stress
- Unhappiness with their organization
- Dissatisfaction with their employer
- Higher turnover



Customer Focus

You should always look to meet and exceed your client expectations and needs. When you understand your clients' current and future requirements, and you can cater to them, you end up with loyal clients that stay with you and increase your revenue. This also helps you find new opportunities that you can work to fulfill. Efficient and error free processes lead to higher quality, which means more satisfied customers.

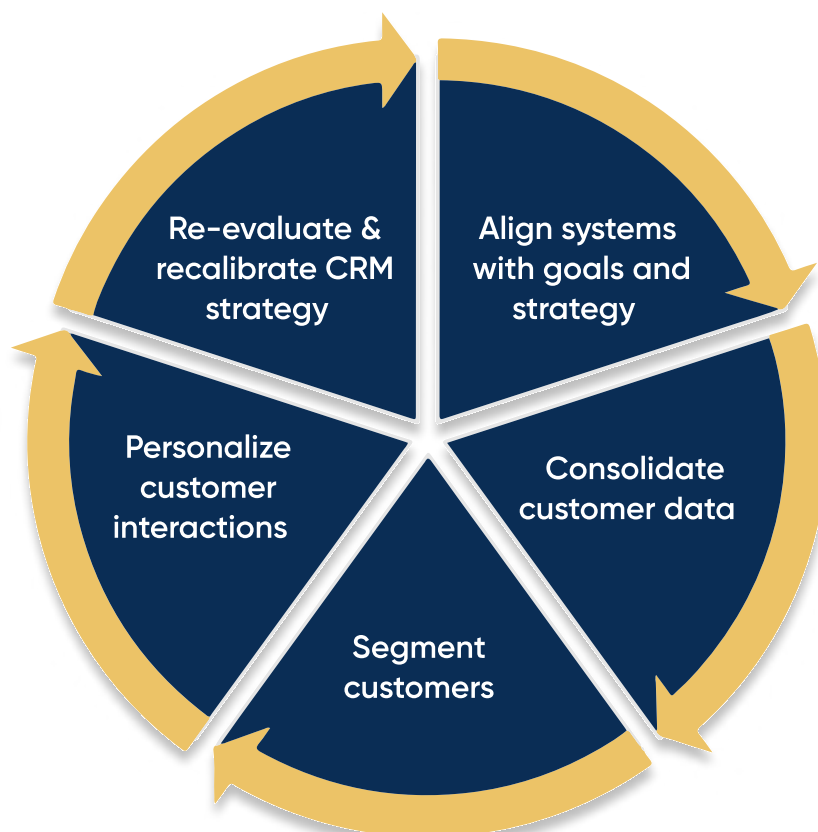


Figure 3: CRM focus cycle



Relationship Management

Just as important as good relations between staff and customers are the relations between you and your vendors. Proactively managing the supply chain process and promoting the relationship between you and your vendors creates a mutually beneficial partnership that will positively impact your company performance.

In other words, when your relationship with your suppliers is good you are more likely to achieve sustained business collaboration and success.

A good example of improved quality through vendor relations can be found in companies that share their customer specifications and quality goals with their vendors. By having the vendors know what you need to satisfy your clients (and your vendors share those needs with their vendors), you can drastically improve your overall quality and productivity.



Continuous Improvement

One of your corporate objectives is to get actively involved in continuous improvement. Businesses that take the time to look for continuously improved processes will experience improved performance, organizational flexibility, and the ability to quickly embrace new opportunities. Continuous improvement leads to a constant look at creating, implementing, and improving new processes while being able to adapt to new market situations.

“

To succeed in this world, you have to change all the time.

Sam Walton

”



Process Approach

A process approach means an organization manages their business as a system of processes – not departments or people or products.

This approach emphasizes achieving efficiency and effectiveness in your company processes. To properly manage the processes requires an understanding that good processes lead to more consistent outputs, quicker tasks, reduced costs, decreased waste, and continuous improvement.

Your organization is improved when leaders can manage and control the inputs and the outputs and every task that is done in between.



Evidence-based Decision Making

Decisions should always be made based on real, accurate, data. Businesses that make decisions based on verified and analyzed data better understand their market. This means that when they perform a task, they get the desired results and can easily justify their decisions. Making decisions based on the evidence is vital to understanding the cause-and-effect relationship of different things and also explains unintended results.

QMS Core Elements

While the principles serve as a guide to better quality, the core elements serve as a checklist of what to look for when implementing a quality management system. The eight core elements of a QMS include:

QMS Core Elements

Quality objectives	<ul style="list-style-type: none"> • Required by standard organizations • Define strategic goals • Link customer requirements with your goals
Company structure and responsibilities	<ul style="list-style-type: none"> • Clear and updated organization structure • Address the product lifecycle depicting the workflow • Responsibilities linked to standard operating procedures
Data management	<ul style="list-style-type: none"> • Real-time and accurate data • Readily available • Supports continuous improvement • Tracks relevant metrics
Processes	<ul style="list-style-type: none"> • Identify and define processes and standards • High-level view of intersecting resources • Establish success metrics • Document standardized approach and drive improvement
Customer satisfaction	<ul style="list-style-type: none"> • Establish customer requirements • Monitor customer satisfaction • Meet or exceed expectations
Continuous improvement	<ul style="list-style-type: none"> • Clear documentation of process controls • Include documents that support improvement • QMS assessment
Quality instruments	<ul style="list-style-type: none"> • Gage documentation • Calibration guides and standards • Tamper-resistant options • Maintenance scheduling and policies
Document manager	<ul style="list-style-type: none"> • All information sent or received by your organization • Centralized to keep all records automatically • Required for certification and compliance

Quality Objectives

One of the first elements of a QMS is creating quality objectives. This is often a requirement of QMS standards, including ISO 9001. Quality objectives help you define strategic goals and a purpose for the QMS. These objectives translate your vision into practice by creating a link between customer requirements and specific, measurable, and attainable goals. Well-written objectives give purpose to your QMS initiative and help in solidifying your customer-centric culture.

Quality objectives provide a clear vision for every member of your organization to understand the company's purpose and the value of a QMS. The objectives should provide clear metrics for measuring progress against strategic goals, including timelines and measurable parameters of improvement.

Often the quality manual, the first document for the QMS, includes these objectives. It states the motivation for adopting the QMS and the role of quality within the organization. ISO 9000 requirements for a quality manual state that this document should:

- Describe the scope of the QMS
- Detail the requirements of the QMS standard or framework
- List any elements of the QMS which are excluded from the implementation
- Reference specific quality procedures used within the organization
- Provide visual documentation of critical processes via flowchart
- Explain the organization's quality policies and objectives



Organizational Structure and Responsibilities

The QMS should include a model of your organization structure and responsibilities of all individuals within the organization that is both easy to understand and updated regularly. This model should include visual guides, like flowcharts, and clear documentation. Some of the components that need to be documented include:



- Personnel
- Equipment
- Information Systems
- Assessment Tools
- Facilities
- Purchasing & Inventory
- Process Controls
- Documents & Records

Document your entire structure to include the product lifecycle. Include visual representations using techniques such as flowcharts to depict the workflow. When documenting the responsibilities, make sure the organizational chart has clearly defined roles and reporting structure which can be linked to standard operating procedures.

Data Management

Real and accurate data is crucial in any system, including quality management. Ensuring that your data is readily available and reliable is critical to the success of your QMS framework and the drive for continuous improvement and preventive quality control activities. After all, bad data leads to bad decisions which lead to poor product quality, inefficient operations, compliance risks, poor customer satisfaction, and low profitability.

Your organization requires data as evidence of effective quality controls. To ensure compliance and adherence to good quality management principles, your data management systems should support your continuous improvement efforts and what corrective actions are taken by defining the type of data gathered. Your data management policies should address: data types, sources, collection methods, responsibilities, storage, disposal, and analysis.

Based on your organization type and size, the data types your QMS requires to demonstrate effective performance will vary. However, all data management systems should, at least, include:

- Customer Satisfaction
- Vendor Performance
- Product and Process Monitoring
- Non-Conformance Reports
- Trends
- Preventive or Corrective Action

CUSTOMER SATISFACTION



Customer Satisfaction

As a customer focused system, QMS also needs you to have a way to monitor customer satisfaction and ensure your quality objectives are achieved. There is no set global standard here, since what satisfies customer requirements and demand will vary by industry, region, and deliverable.

A successful organization looks to its clients to understand what they need and tries to exceed those requirements. Some of the ways to establish customer satisfaction and monitor that you meet or exceed them include: Customer satisfaction surveys, complaint procedures, trend analysis, and management review.

“

Get closer than ever to your customers. So close, in fact, that you tell them what they need well before they realize it themselves.

Steve Jobs

”



Processes

Quality management systems look to your processes to drive quality and continuous improvement. QMS standards require your company to identify and define any process that uses resources to transform inputs into outputs, including purchasing.

When you start defining your processes, you should get a high-level picture of how these processes serve your organization and interact with employees, tools, technology, and other resources. Once your processes are mapped out, you can define standards of practice and success metrics that help drive continual improvement.

Processes



Figure 4: Example of a process workflow



Continuous Improvement

Continuous improvement makes another appearance here, that's how crucial of an organization-wide principle and element it is. Improving and adapting are necessary to reap the benefits of customer satisfaction, better productivity, and a healthy bottom line. As mentioned under principles, leadership plays a core role in implementing a quality-driven culture by taking accountability for effectiveness.

A QMS that is designed to help your path of continuous improvement requires clear documentation of controls across the organization. The quality management system should include modules to support, at least:

- Quality planning procedures
- Compliance requirements
- Safety design
- Risk-based thinking
- Corrective and preventive actions (CAPA)
- Gradual and breakthrough improvement
- Innovation
- Assessment of the QMS



Quality Instruments

You can't have consistent quality without a way to measure and ensure that your tools are consistently calibrated. Gages and calibrations that are used to measure and validate your output must be carefully controlled and calibrated according to industry standards, with different tools and standards requiring calibration at set intervals.

To ensure that you meet your local and international standards, your QMS must have a module that tracks your gages and calibration efforts and sets your required maintenance company policy for tools and gages. An example of the items the QMS module should track are:

- Calibration and gage intervals
- Tool calibration standard
- Tool and gage manufacturer user guides
- Tool and gage procedures for identifying and documenting calibration
- Anti-tampering gage controls
- Preventive and/or predictive maintenance policies



Document Manager

Document control encompasses almost all the documents that are moved around your corporation. This includes email chains, faxes, maintenance reports, standard conformity, and internal procedures. Effective document control and data management is a crucial component for any modern company. While the method in which the documents are retained can vary, your document control and management module should make it easy for you to capture, control, and retain any supporting documentation.

To obtain certification and regulatory compliance with ISO QMS standards, all the previously mentioned documentation (like quality objectives, quality manual, procedures, process documentation, and organizational structure) should be included, but may not be enough to accurately control your quality. Your document control module should have all of the mentioned records along with any other documents that your company feels are required to control your quality and improve your QMS performance.

When you are implementing your QMS system, the document management and control module should help your company in creating policies on what documentation your company keeps.

Continuous Improvement Cycle

The key component of a QMS is, in effect, the cycle of improvement on all aspects of your operations. The improvement cycle can be shown as:

- **Plan** or Quality Planning – Identify the quality standards and production goals of the project and decide how to meet them.
- **Do** or Quality Improvement – Train staff on the planned procedure changes and deploy the new process that will improve the output.
- **Check** or Quality Control – Review the deliverable outputs and identify areas of improvement.
- **Act** or Quality Assurance – Take action on the problem areas detected by quality control and move to plan how to meet or improve the process based on the action taken.

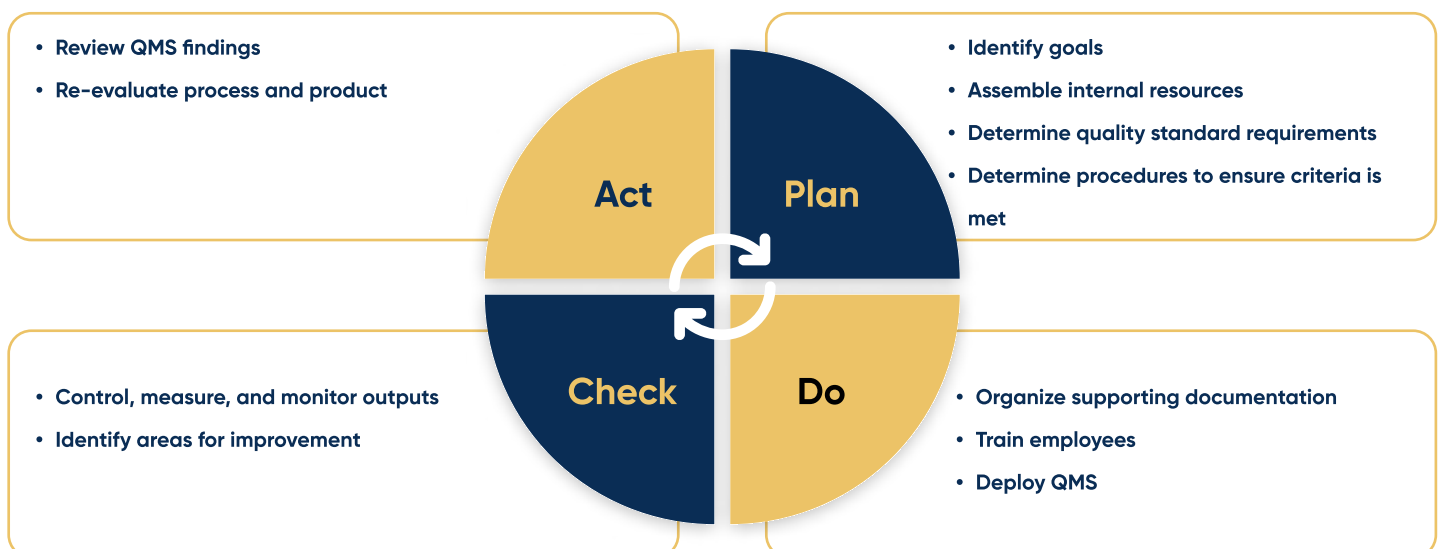


Figure 5: PDCA cycle of continuous improvement

Conclusion

Implementing QMS frameworks will guide your firm to a culture of continuous improvement with a focus on evidence-based decision making. Another benefit is helping with acquiring certification with globally recognized standards, such as ISO 9001. Implementing a quality management system affects every aspect of an organization's performance. Benefits of a documented quality management system include:

Meeting customer requirements which lead to

- Client confidence
- Repeat business
- More customers
- More sales

Meeting organization requirements which lead to

- Regulation compliance
- Deliverable compliance
- Improved efficiency
- Decreased cost and resources used
- Improved profits and growth

These benefits offer additional advantages, including:

- Defining, improving, and controlling processes
- Reducing waste
- Decreasing errors
- Better employee skill management and facilitation
- Better staff engagement
- Setting organization-wide direction

Where OnRamp Helps You

OnRamp is a single point database ERP system that was designed from the ground up to touch all your business units and improve their processes and communication with each other.

Included in the ERP is a best-in-class QMS module built from the ground up, for manufacturers by manufacturers, with the 7 principles in mind and to meet all 8 core elements. This makes your quality exceed customer expectations, your DOWNTIME waste is cut, and your bottom line is improved all while ensuring you adhere to ISO standards. All with no added IT systems, no other vendors, no messy 3rd party plug-ins, and no added costs. All your data instantly shared with all your business units. And to help you get started quickly and with your best foot forward, OnRamp's consulting team has decades of combined experience in manufacturing and implementing proven management methodologies that will improve your bottom line. Whatever you make, we can help you make it better.

**We know manufacturing.
And we want to work with you to make it better.**



Improve Customer
Service



Increase
Productivity



Reduce Costs



Increase Profits

Here are some of the things that OnRamp can help you improve:

◆ PRODUCTION FLOOR:

Warehouse management system	Storage system management	Production planning
Order policy suggestions	EOQ calculations	Inventory management
Shipment management	Work order management	5S audits
MRP	Finite scheduling	Maintenance management, including preventative maintenance management
Worker skill management	Plant issue/ suggestion tools	Detailed capacity planning
Gateway queues	Work center scheduling	Online inspection software
Task automation	Quality management system	Scrap management
Quality alerts	Shop monitors with production entry capacity	Engineering document and drawing management

◆ FRONT OFFICE:

A single database for all records	Paperless approval and sign-off	Customer request management
Easy to access files and data	Team communication tools	Paperless accounting
Lead time and inventory management	Vendor relations portal and management	Customer relation management
Project management and approval	Training and skills gap analysis	Notification systems
Server run software with a locally installed shell	Customizable reports and documents	



Head Office : 10114 ON-26 Unit 2, Collingwood, ON L9Y 3Z1

☎ **+1 (905) 901-5020**

✉ **info@onramp-solutions.com**

🌐 **www.onramp-solutions.com**

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