

# How to improve your company's quality management system





**The perfect QMS (Quality Management System) does not exist, but everything can and should be improved over time.**

Several examples at companies in different industries have already shown that any carelessness in processes and product quality may have catastrophic results, damaging the company's image and its reputation in the market.

The quest for regular and consistent quality improvement is a must for every Quality Management System.

Organizations that constantly improve their quality management system certainly have more efficient operations. As a result, **they have more satisfied customers, are able to better manage costs and can optimize work by quickly and effectively implementing new practices.**

Improvement can be applied in several ways, from empowering and motivating the workforce to simplifying or changing business processes if needed.

**This eBook offers some advice which can help you improve and maximize the full potential of your QMS.**



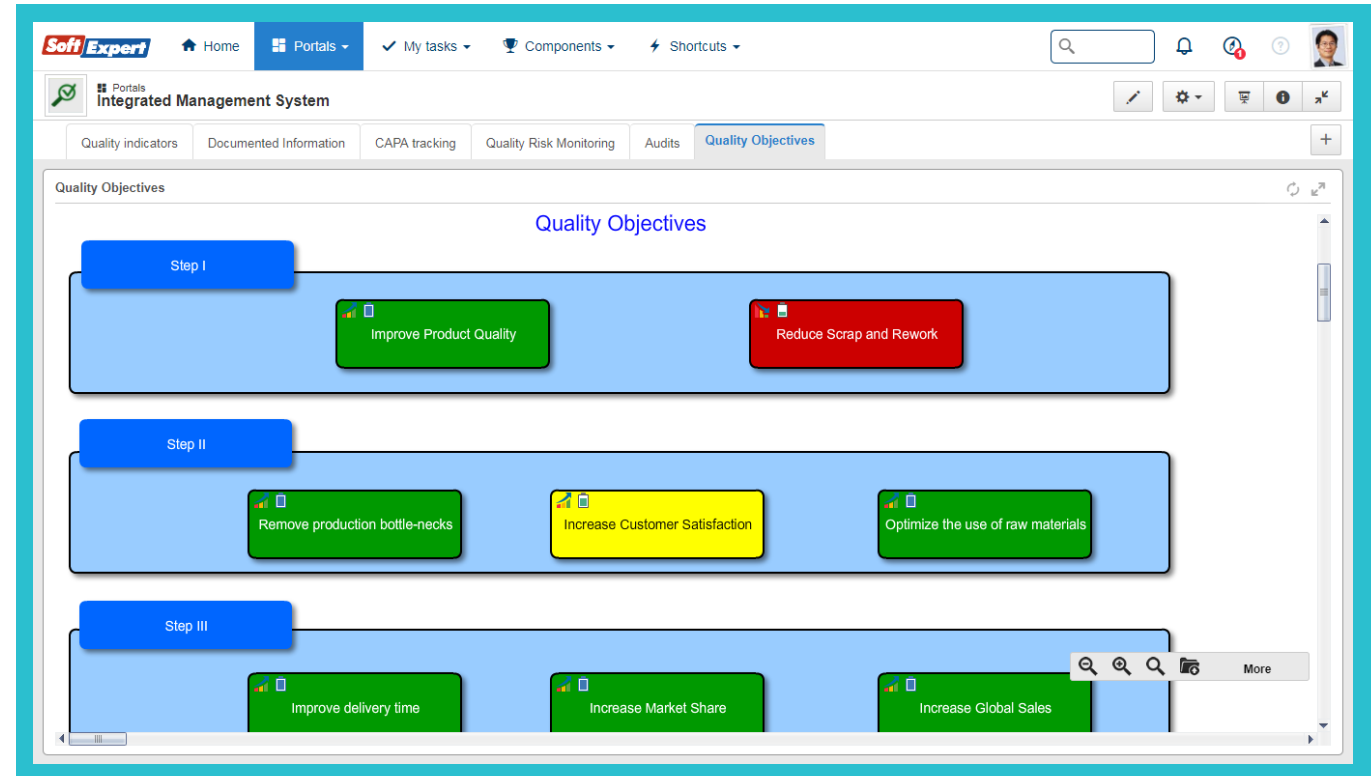
# Establish quality strategies that ensure customer satisfaction

When defining quality strategies and goals, we often see companies focused on quality but not as much on customer satisfaction.

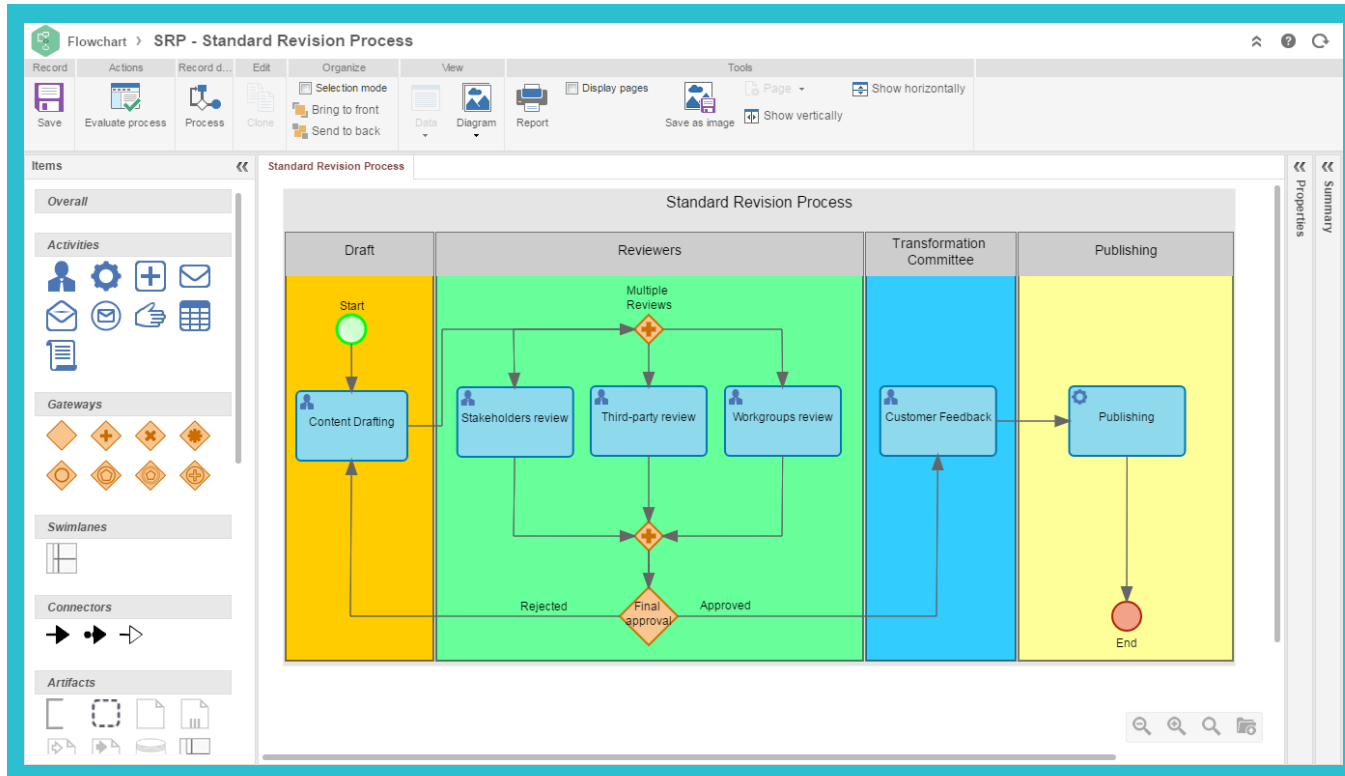
Quality management systems based on ISO 9001 were established with a focus on achieving and maintaining customer satisfaction. After all, **without customers, there is no business.**

Offering a good product / service is not enough. You have to make sure that the entire customer experience is positive. To do this, employees need to be motivated and prepared, offering a good service and effectively solving problems.

Specialized software solutions can contribute to this step. They are a good way to establish and share strategies and guidelines across the enterprise. That means everyone can easily understand which direction they need to move in to ensure customer satisfaction.



# Maximize the effectiveness of your business processes



Effective processes are essential to ensure operational efficiency. They promote transparency and positively contribute to keeping employees, customers and shareholders satisfied at the same time.

When addressing business processes, many companies only focus on results. They do not monitor their effectiveness over time.

An automated quality system provides visibility of all the details in the process. It is possible to perform analyses on how tasks are being performed or what is causing a bottleneck. This will show whether results generated by the process are meeting the expected objectives.

It is also possible to simulate execution of processes using different scenarios. **Simulation is a way of identifying inefficiencies, as well as of predicting potential impacts of modifications.** The results of the simulation show the points that need to evolve.

# Ensure accessibility and reliability of documented information

For Quality Management, documentation is one of the main methods to demonstrate the results of processes, while also providing evidence and proof of compliance, especially to auditors.

At many companies, it is not uncommon for this documentation to be managed manually through network shares, Excls, email or even paper. This contributes to making the process slower and more prone to errors.

**With a repository to centralize all documentation, you can consolidate efforts to define, approve and share standard operating procedures, quality policies, and more.**

Quick access to information increases efficiency when responding to customer expectations. The ability to quickly access information also improves decision-making processes.

By centralizing information, employees can find the right document version with ease, retrieving it whenever necessary.

The screenshot displays the Soft Expert Q View Document (DC021) interface. The top navigation bar includes links for Home, Portals, My tasks, Components, and Shortcuts. The main content area is divided into a left sidebar and a central document list/preview area.

**Left Sidebar:**

- Search filters:** A search bar with the text "quality manual".
- Saved searches:** A list of saved searches including "My documents", "Favorites", and "Documents close to due date".
- Public views:** A section for public views, currently showing "QCPW-Quality Care Pharmacy Program (Working Files)".
- Type:** A dropdown menu for document types.
- Advanced filters:** A section for advanced filtering options.
- Buttons:** "Save" and "SEARCH" buttons.

**Central Document List:**

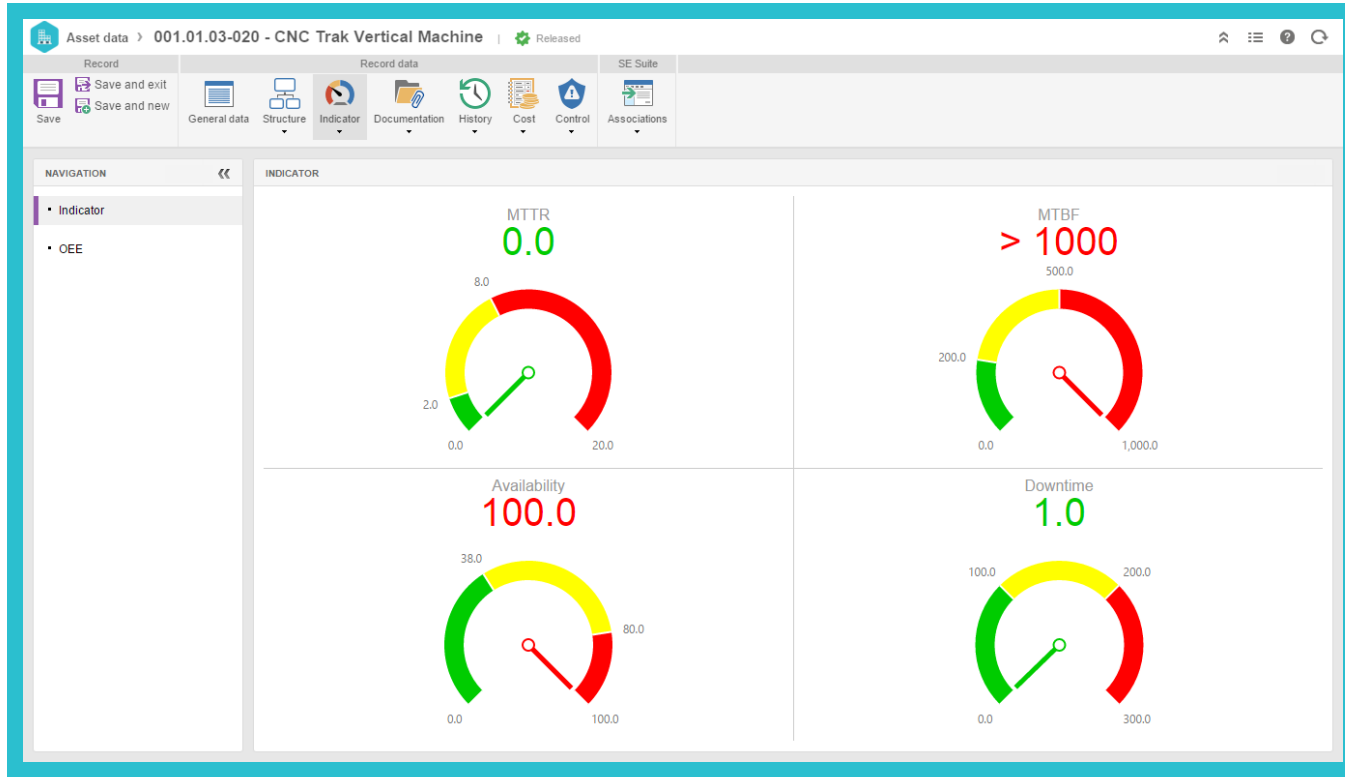
| Category | ID #      | Title                                 | Revision | Date      | Hits |
|----------|-----------|---------------------------------------|----------|-----------|------|
| MAN      | QM-000001 | Quality Manual - Standard Template    | 00       | 3/08/2010 | 16   |
| MAN      | MN000005  | Quality Manual - Ames Research Center | 00       | 3/22/2010 | 0    |
| M&M      | MN000007  | Quality Management System             | 00       | 3/22/2010 | 5    |

Total records: 16

**Document Preview:**

The preview shows a document titled "Quality Manual" with the subtitle "ISO 9001 Quality Management System". The content includes sections for "5 Leadership & Governance", "5.1 Leadership and Commitment", and "5.1.1 Quality Management". A diagram titled "Figure 3: Leadership PDCA Cycle" is visible, showing a cycle with the "Plan" stage highlighted: "Plan - Establish your organizational context and strategies. Determine regulatory and statutory".

# Preventative maintenance is key to reducing downtime



At industries and service companies, **preventative maintenance of equipment is key** to avoiding downtime and major costs to replace broken machinery.

Companies need to implement a plan to adjust and replace worn components in order to ensure equipment is working with the highest possible degree of efficiency.

All of these factors improve quality and, in terms of costs, actually save a lot of money in the long run.

# Promote improvement through audit programs

Internal auditing is a tool with great potential within the context of improvement. It helps to gauge the quality and effectiveness of processes, systems and personnel employed by the company.

**To ensure that quality is maintained throughout the enterprise, internal Audits need to be a continuous practice.** When performing audits at random, you cannot make the most of all the of tool's benefits.

Through quality audits, organizations can plan, gauge and improve controls and quality assurance procedures.

When incorporating effective quality management audits, organizations can achieve, sustain, and improve their quality standards. All of this results in increased customer satisfaction.

Audit criterion requirements > 000067 - ISO 9001:2015 Requirements | ISO 9001:2015 - Quality Management - ISO 9001:2015 | Execution

Record Edit Browse View Tools

Save Save and exit Add Associate Delete Previous Next Requirement basis Import Export Expand Collapse

| Requirement  | CL | Value | % C    | AO |
|--|----|-------|--------|----|
| ISO 9001:2015 - Quality Management - ISO 9001:2015                   |    | 9.46  | 89.29  |    |
| 4 - Context of the organization                                      |    | 8.75  | 75.00  |    |
| 4.1 - Understanding the organization and its context                 |    | 10.00 | 100.00 |    |
| 4.2 - Understanding the needs and expectations of interested parties |    | 10.00 | 100.00 |    |
| 4.3 - Determining the scope of the quality management system         |    | 10.00 | 100.00 |    |
| 4.4 - Quality management system                                      |    | 5.00  | 0.00   |    |
| 5 - Leadership   |    | 10.00 | 100.00 |    |
| 5.1 - Leadership and commitment                                      |    | 10.00 | 100.00 |    |
| 5.2 - Policy   |    | 10.00 | 100.00 |    |
| 5.3 - Roles, Responsibility and Authority                            |    | 10.00 | 100.00 |    |
| 6 - Planning   |    | 7.50  | 50.00  |    |
| 6.1 - Actions to address risks and opportunities                     |    | 10.00 | 100.00 |    |
| 6.2 - Objectives and Planning  |    | 5.00  | 0.00   |    |
| 7 - Support  |    | 10.00 | 100.00 |    |
| 7.1 - Resources  |    | 10.00 | 100.00 |    |
| 7.2 - Competence   |    | 10.00 | 100.00 |    |
| 7.3 - Awareness  |    | 10.00 | 100.00 |    |
| 7.4 - Communication  |    | 10.00 | 100.00 |    |
| 7.5 - Documented Information   |    | 10.00 | 100.00 |    |
| 8 - Operation  |    | 10.00 | 100.00 |    |
| 8.1 - Operational Planning and Control                               |    | 10.00 | 100.00 |    |
| 9 - Performance Evaluation   |    | 10.00 | 100.00 |    |
| 9.1 - Monitoring, measurement, analysis and evaluation               |    | 10.00 | 100.00 |    |
| 9.2 - Internal audit   |    | 10.00 | 100.00 |    |
| 9.3 - Management review  |    | 10.00 | 100.00 |    |
| 10 - Improvement   |    | 10.00 | 100.00 |    |
| 10.1 - Nonconformity and corrective action                           |    | 10.00 | 100.00 |    |
| 10.2 - Continual improvement   |    | 10.00 | 100.00 |    |

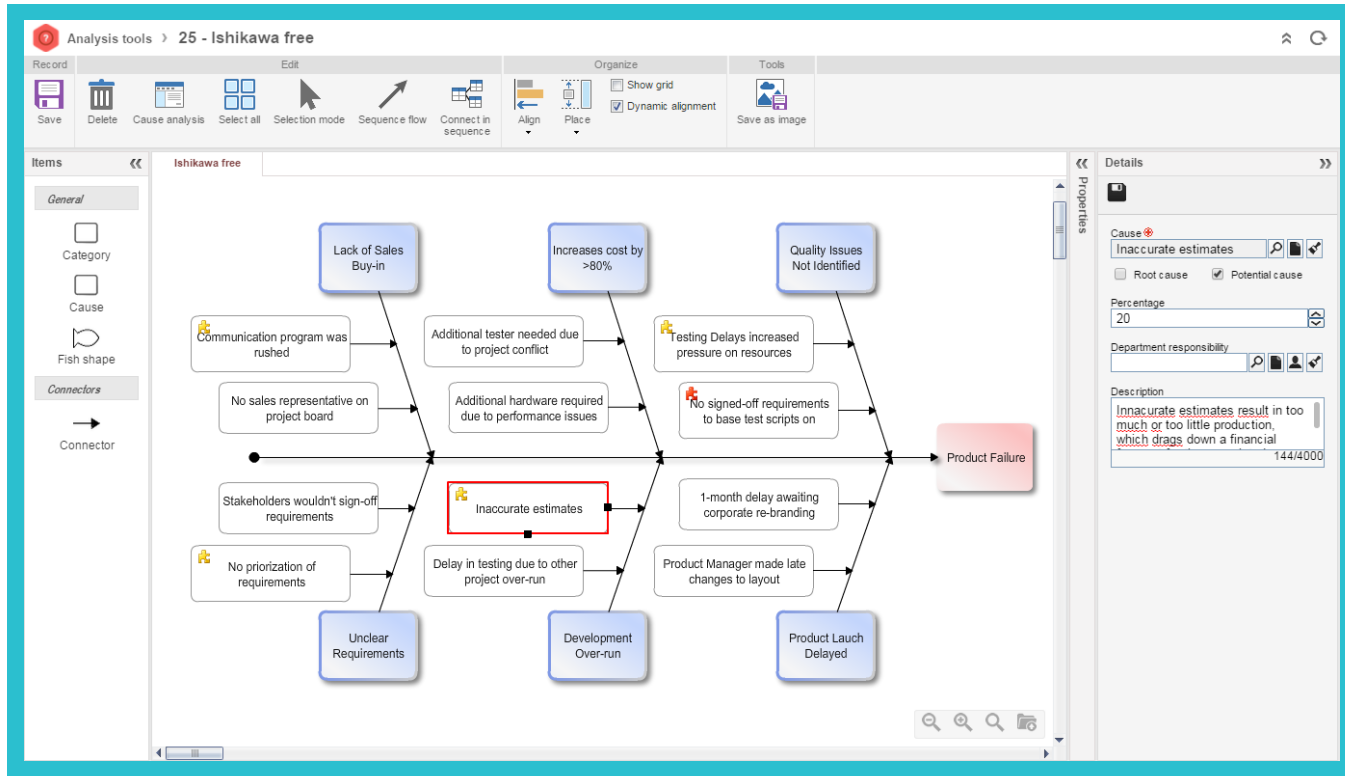
7.5 - Documented Information

| Requirement   | Evaluation | Occurrence |
|---|------------|------------|
| Requirement basis   |            |            |
| 7.5 - Documented Information  |            |            |
| ID #  |            |            |
| 7.5   |            |            |
| Name  |            |            |
| Documented Information  |            |            |
| Weight  |            |            |
| 1   |            |            |
| Description   |            |            |
| The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.<br>The organization shall:<br>a) Determine the process needed for the quality management system and their application through the organization (see 4.1) |            |            |
| Tip<br>1. Was the QMS established, documented, implemented, maintained and continually improved in accordance with this standard? Y/N<br>2. Has the organization identified process needed for the QMS and their application through the organization? Y/N<br>3. What are the process?  |            |            |

Confirm Confirm & next



# Accelerate and streamline non-conformance investigations



The customer does not always receive products and services as expected. **Customer satisfaction does not just depend on meeting expectations, but also on how the company positions itself when expectations are not met.**

Non-conformance is an important element in the success of a QMS. However, many companies find it difficult to use non-conformances to their own benefit.

Quality management software solutions provide tools that help you quickly identify the root cause. Deviations can therefore be corrected and eliminated through a plan of action.

A standardized and automated process is crucial to dealing with non-conformances. It helps you resolve the problem faster, minimizes risk and increases productivity.

# Overcome the challenge of talent development

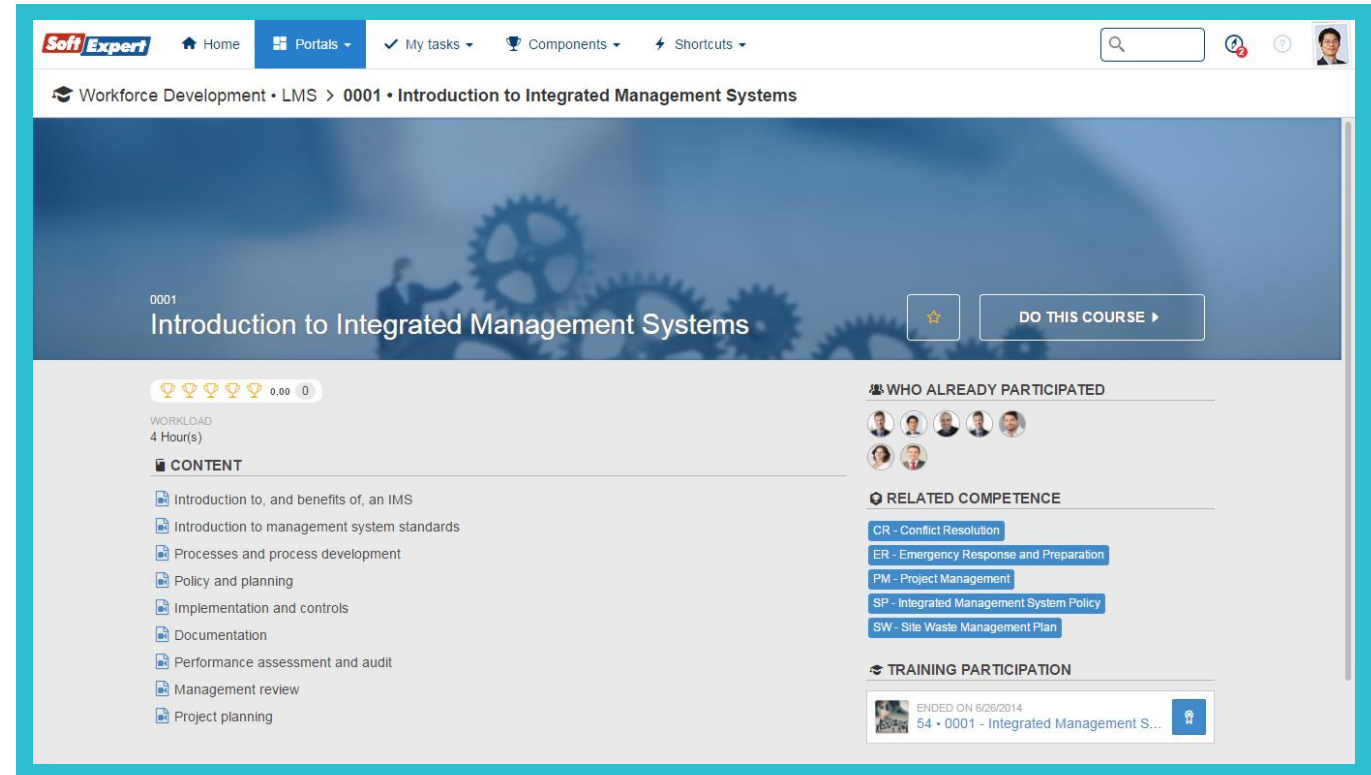
Employee engagement and motivation levels are directly related to the quality of deliveries.

Employees that lack motivation tend to produce subpar results compared to motivated employees.

A lack of adequate employee training as well as poor training may be the cause of poor quality products or services, in addition to adversely affecting production time.

**Companies need to invest in proper training starting when the new employee is hired. By doing this, they can prevent costly mistakes and ensure that tasks are performed correctly the first time.**

With trained employees, it is possible to reduce the amount of quality control procedures. As a benefit, companies can also improve the speed of their business process.



The screenshot displays the Soft Expert Learning Management System (LMS) interface. At the top, the navigation bar includes the 'Soft Expert' logo, a 'Home' link, a 'Portals' dropdown, and user-specific options like 'My tasks', 'Components', and 'Shortcuts'. A search bar and user profile icon are also present. The main header shows the breadcrumb path: 'Workforce Development • LMS > 0001 • Introduction to Integrated Management Systems'. The course title '0001 Introduction to Integrated Management Systems' is prominently displayed with a 'DO THIS COURSE' button. Below the title, a 'WORKLOAD' section indicates '4 Hour(s)'. The 'CONTENT' section lists the course modules: 'Introduction to, and benefits of, an IMS', 'Introduction to management system standards', 'Processes and process development', 'Policy and planning', 'Implementation and controls', 'Documentation', 'Performance assessment and audit', 'Management review', and 'Project planning'. On the right, the 'WHO ALREADY PARTICIPATED' section shows a grid of user avatars. Below that, the 'RELATED COMPETENCE' section lists skills such as 'CR - Conflict Resolution', 'ER - Emergency Response and Preparation', 'PM - Project Management', 'SP - Integrated Management System Policy', and 'SW - Site Waste Management Plan'. The 'TRAINING PARTICIPATION' section at the bottom shows a completion status: 'ENDED ON 6/26/2014' and '54 • 0001 - Integrated Management S...'.

# Focus on the full risk portfolio

The screenshot displays a risk management software interface. The main window is titled 'Monitoring > MDD-RM-PL01 - New medical device development'. It features a sidebar with navigation icons for 'Structure', 'Evaluation', 'Attributes', and 'Data'. The main area is divided into two panes. The left pane, labeled 'Plan', shows a hierarchical list of risks. The right pane, labeled 'Actual', shows a detailed view of a specific risk, 'Risk: RSK-001 - Significant changes in user requirements'.

| Plan   | Actual   |
|--|----------|
| 2.2000001 - New medical device development                                   |          |
| User16715178478 - Perform device discovery and concept                       |          |
| RSK-001 - Significant changes in user requirements                           | Moderate |
| RSK-002 - Lack of commitment or ability to change current business processes | Low      |
| RSK-003 - No suitable solution found that meets all the objectives           | Moderate |
| RSK-004 - New competitor entrance  | Low      |
| User1671517927431 - Perform preclinical research-prototype                   |          |
| RSK-007 - Non-approved suppliers   | Low      |
| RSK-006 - Inadequate raw materials   | High     |
| RSK-005 - Projects that are not validated                                    | Moderate |
| User1671517104826 - Submit to approval                                       |          |
| RSK-008 - Lack of change management process                                  | Low      |
| User16715171041378 - FDA Review  |          |
| RSK-010 - Poor product quality   | Low      |
| RSK-009 - Projects that are not validated                                    | Low      |

The detailed view of RSK-001 shows the following information:

- ID #: Rev 0 (07-2016)
- Evaluation: 7/18/2016
- Actual: Moderate
- Significant: ☐
- Probability matrix (Severity vs Probability):

|           | Low | Medium | High | Very High |
|-----------|-----|--------|------|-----------|
| Low       |     |        |      |           |
| Medium    |     |        |      |           |
| High      |     |        | A    |           |
| Very High |     |        |      |           |

The 'Details' section shows the following criteria and results:

| Criterion   | Result |
|-------------|--------|
| Probability | High   |
| Severity    | High   |

Many elements of Quality Management are related to risk reduction. Audits, SOPs, NC/CAPA, KPI Tracking—they all reduce risk, although it's not always outwardly apparent.

Often these elements are disconnected, resulting in a fragmented risk approach. Redundant controls hamper the understanding of the risk portfolio of the organization as a whole.

Organizations need to establish a single risk management process, connecting all elements of the QMS.

Software solutions specializing in quality management allow you to evaluate, quantify, prioritize and mitigate risks in a centralized and integrated manner.

**With unified efforts, you can increase visibility and also understand the big picture about risk management.**

# Track your QMS performance

Concerns about control and detailed monitoring of processes cause some organizations to establish a vast number of indicators.

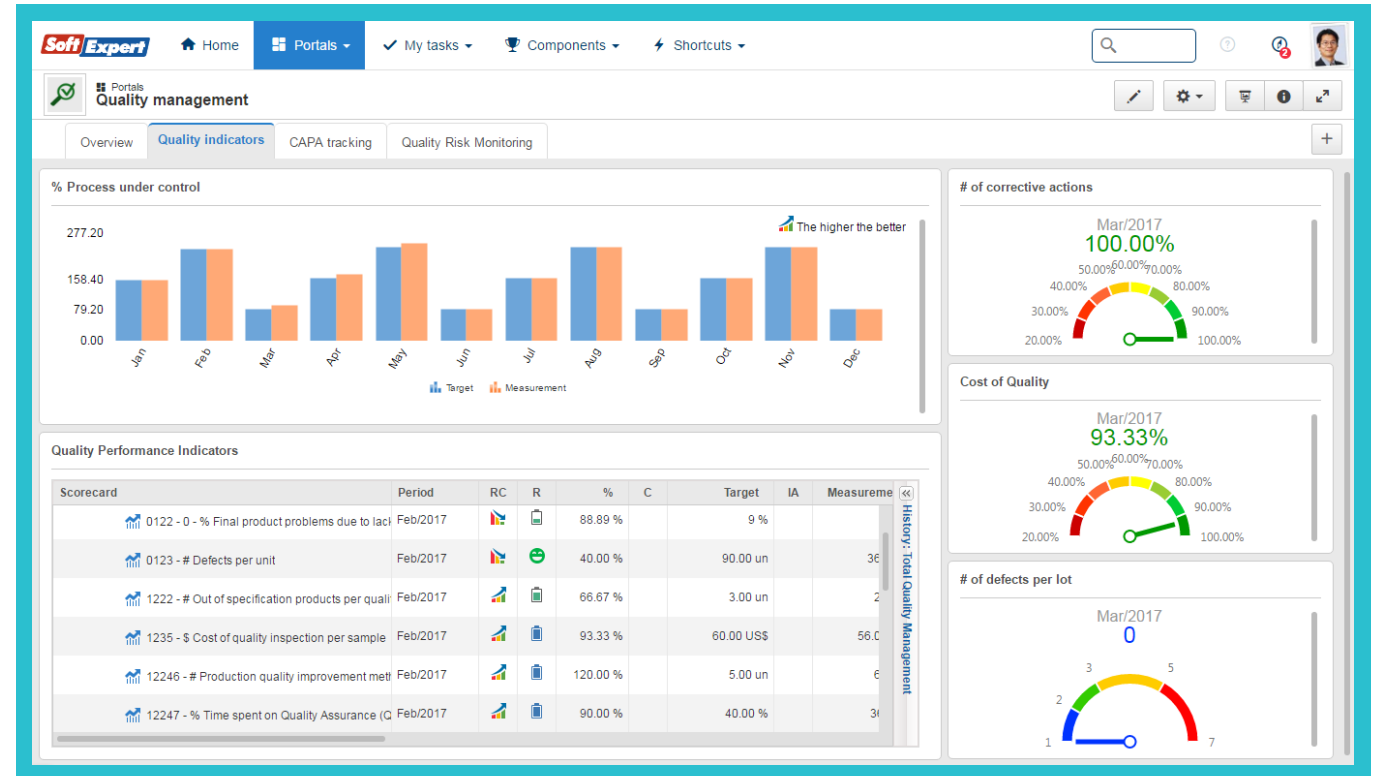
However, this usually leads to an uncontrollable situation and ends up being inconvenient because information is missing or the data is not reliable.

**It is necessary to focus on indicators that truly demonstrate the results of QMS processes and objectives.**

In addition, it is very common to use spreadsheets and manually update information. A history of what happened in the past is not as valuable to leaders, since it does not reflect the current situation.

Today's Enterprise Quality Management software solutions delivers rich reports fed by real-time information. This benefits managers, who can act proactively.

With a precise understanding of what's happening, they can make better decisions, as expensive problems are prevented more quickly.



Now that you already know **How to improve your company's quality management system**, learn more about SoftExpert EQM (Enterprise Quality Management), the most complete and innovative solution on the market for process automation and improvement, regulatory compliance and excellence in quality management.



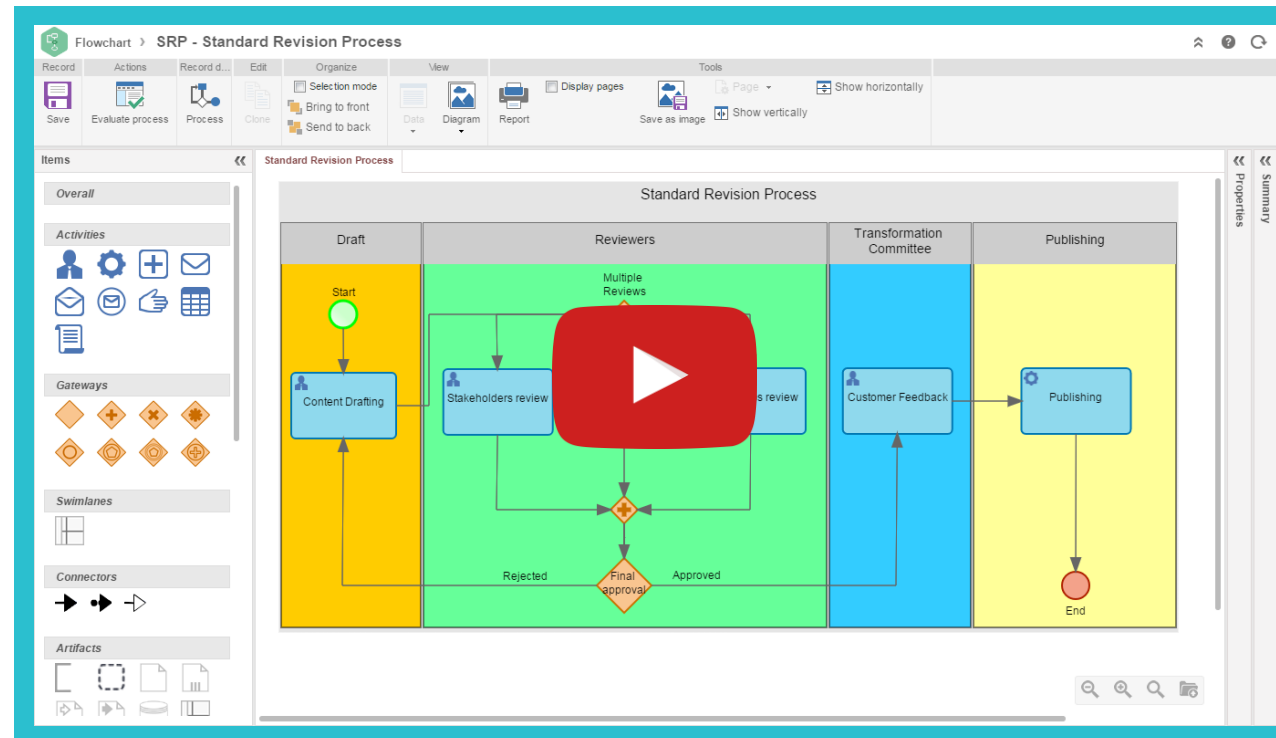
## SoftExpert EQM

**SoftExpert EQM** is the most comprehensive enterprise quality management software (EQMS) to implement and simplify enterprise-wide quality and compliance management programs, through automated, highly interactive quality processes tailored to align with each organization's specific products, operations and business practices.

SoftExpert quality management software is a modular and scalable software solution platform that integrates all key quality initiatives seamlessly, including process mapping, documented information, key performance indicators, change control, non-conformance and corrective/preventive actions (CAPA), customer complaints, compliance audits, competence and training, risk and control, incoming and outgoing inspection, statistical process control, and others.

**Automating your quality management system is a key ingredient to boosting performance and productivity rates at your business and avoiding mistakes and re-work.**

SoftExpert EQM provides all of the support needed to achieve the results you are looking for.



**Learn more about the solution**



## SoftExpert Excellence Suite



SoftExpert Excellence Suite is the most comprehensive framework of independent yet united solutions to achieve business performance excellence, streamline corporate governance, risk and compliance programs, and ensure continuous business process improvement.

Companies may not need all applications at once, or may want to deploy one application module at a time, growing gradually as the need arises. Whatever the strategy chosen, only a fully shared environment allows its applications to fit together like puzzle pieces and work seamlessly.

## About SoftExpert

SoftExpert is a market leader in software and services for enterprise-wide business process improvement and compliance management, providing the most comprehensive application suite to empower organizations to increase business performance at all levels and to maximize industry-mandated compliance and corporate governance programs.

Founded in 1995 and currently with more than 2,000 customers and 300,000 users worldwide, SoftExpert solutions are used by leading corporations in all kinds of industries, including manufacturing, automotive, life sciences, food and beverage, mining and metals, oil and gas, high-tech and IT, energy and utilities, government and public sector, financial services, transportation and logistics, healthcare, and many others.

SoftExpert, along with its extensive network of international partners, provides hosting, implementation, post-sales support and validation services for all solutions to ensure that customers get the maximum value from their investments.



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