

ISO 9001

Quality Management
System



ISO 9001 is an internationally recognized standard that guides companies through the process of ensuring products and services meet customer and regulatory standards.

Quality management systems are leveraged by companies to ensure customer satisfaction, standardize processes to maintain consistency, streamline operations to reduce inefficiencies, and meet industry and legal requirements. A QMS involves developing and documenting procedures to meet requirements, finding innovative ways to improve quality, and coordinating and communicating within the organization.

Industries that benefit from having a QMS in place include manufacturing, consumer goods, aerospace and defense, automotive, pharmaceutical, and biotechnology.

ISO 9001 certification helps to be proactive about potential risk and quality issues, maintain regulatory compliance, and can give companies a competitive advantage in the market.

ISO 9001



Process Steps of ISO 9001

1. Assign Roles and Responsibilities

2. Develop a Quality Policy

3. Develop Process for Products & Services

4. Identify and Address Risks and Opportunities

5. Define Objectives

6. Plan Actions to Meet Objectives

7. Maintain Infrastructure and Environment to Ensure Conformity

8. Monitor Quality of Products & Services

9. Record and Share Organizational Knowledge

10. Train Employees and Develop Skills

11. Communicate with Customers

12. Determine the Requirements for Products & Services

13. Design and Develop Products & Services

14. Implement Controls to Review Outputs

15. Assess Externally Provided Products & Services

16. Obtain Customer Feedback

17. Identify and Correct Incidents of Non-Conformity

18. Review the Success of the Quality Management System

19. Improve Processes to Meet Customer Needs and Reduce Non-Conformities

EHS Insight Modules to Support ISO 9001 Compliance

Process Step	Module	Explanation
Assign Roles and Responsibilities		Administrators can create and assign roles to the employees responsible for conducting inspections, reporting incidents, and communicating with customers.
Develop a Quality Policy	Document Library	The document library stores quality policies, processes, and certifications for easy employee access, while tracking version history to ensure users have the latest updates and can review past changes.
Develop Process for Products & Services		The platform doesn't support the development of processes/procedures for developing products and services, they can be stored in the document library with version control.
Identify and Address Risks and Opportunities	Hazard & Risk Management Audit Management	The Risk Assessment form allows users to identify risks associated with processes and the development of products/services and assess their significance to produce undesirable effects. They can identify controls to help establish consistency and reduce these effects. Companies should assess the effectiveness of controls and actions identified to address risks. Users can create question sets for this assessment.
Define Objectives Plan Actions to Meet Objectives	Objectives Management	Set goals for key aspects, define actions, assign responsibilities, and allocate resources to achieve them.
Maintain Infrastructure and Environment to Ensure Conformity	Audit Management Compliance Tasks	Create question sets to inspect equipment and infrastructure; generate CAPAs when standards aren't met. Assign inspections to users, track them on a compliance calendar, and escalate if incomplete.
Monitor Quality of Products & Services	Quality Management	The Quality Inspection form allows employees to perform periodic product inspections, including part-specific checks for properties like weight, color, and size.
Record and Share Organizational Knowledge	Document Library Awareness & Accountability	Store and share organizational information, including product specs and certifications, with employees and third parties like customers or suppliers. Distribute materials for employee review and acknowledgment, including updates to processes or policies.
Train Employees and Develop Skills	Training Management Skills Management	Ensure employees have the necessary knowledge through task-specific training and skill assessments to maintain product/service conformity.

EHS Insight Modules to Support ISO 9001 Compliance

Process Step	Module	Explanation
Communicate with Customers		Upload customer communications (emails, meeting notes) and store specifications and requirements in the document library.
Determine the Requirements for Products & Services	Audit Management Compliance Tasks	Ensure products meet customer and regulatory requirements by reviewing updates with custom question sets, then assign next steps like redesigns or process updates using the compliance task module.
Design and Develop Products & Services		The platform is not built with design elements.
Implement Controls to Review Outputs	Audit Management Quality Management Management of Change	Create question sets to ensure final outputs meet requirements, including design reviews, component verifications, and final product inspections. The management of change module helps users identify, assign, and schedule updates to designs or processes.
Assess Externally Provided Products & Services	Quality Management	Use the quality inspection form to assess materials and components; if non-conformities are found, complete a quality incident form to prevent defective parts from being used.
Obtain Customer Feedback		There is currently no feature that allows users to collect customer feedback or identify post-delivery responsibilities.
Identify and Correct Incidents of Non-Conformity	Quality Management	The quality incident form helps companies identify and record quality issues, investigate causes, communicate with stakeholders, and establish corrective actions.
Review the Success of the Quality Management System	Quality Management Audit Management	Reports from inspections and incidents help management identify common non-conformities and incidents, providing insights into the effectiveness of the quality management system. Management can use question sets to review all aspects of the quality management system, including policies, processes, training, controls, feedback, and changes.
Improve Processes to Meet Customer Needs and Reduce Non-Conformities	Management of Change Objective Management	The management of change module helps identify necessary updates to controls and processes and assign responsibilities. Management can set QMS goals (e.g., customer satisfaction, product nonconformities) and define actions, resources, responsibilities, and deadlines to achieve them.

A mid-sized bicycle manufacturer specializing in utility bikes (practical use bikes) has had an increased number of customer complaints about their products. Customers are mainly complaining about the handlebars and handlebar placement. They've received complaints that it's "too high" and 'feels unbalanced' and the 'grips are uncomfortable and gave me blisters'. They must follow the Consumer Product Safety Commission's Requirements for Bicycles (CFR in Title 16 Part 1512). To help reduce the number of customer complaints and ensure compliance with applicable safety standards, they are looking to improve their quality management system.

Step 1: Conduct Inspections

They are working on an order for a new model of a bike they just launched. This is their second order for the new model. They increase the number of inspections completed to try to maintain uniformity in products. While all bikes get a final check at the end, there are only "spot checks" during the assembly process. They look to increase the number of spot checks throughout the manufacturing and assembly process.

They add an inspection that relates to handlebar construction, and they develop a procedure for inspection. Materials are inspected prior to being cut and formed to ensure the correct and quality materials are used. They then inspect the following features against the design elements post construction.

Measurement	Design Value	Value
Handlebar Width	30"	34"
Clamp Diameter	31.8mm	31.8mm
Grip Diameter	22.2mm	22.2mm
Upsweep Angle	406 degrees	6 degrees
Backsweep Angle	7-10 degrees	9 degrees
Height Above Seat	16"	17.5"
Wall Thickness	2mm	2mm
Welding Seams	No Gaps, Cracks, or Defects	Pass
Surface Dents	No Scratches, Dents, Burrs, or Material Inconsistencies	Pass

Step 2: Report Nonconformities

Based on the results of their inspection, they notice that the handlebar length is longer than the design features and sits much higher above the seat. These are likely the factors contributing to customer complaints about the handlebars being too high and feeling unbalanced. While there are no limits on handlebar length, per the Consumer Safety Requirements, the handlebars cannot sit more than 16" above the seat. They must report this incident and issue a recall on this bike model.

They complete a Quality Incident form for 'Product'. They describe the details from the inspection and indicate the part number. They note the failure type as 'Design Specification Error'. Due to the regulatory non-compliance, they indicate the event as severe and worth investigating. They communicated with the Consumer Product Safety Commission to report the event and a recall was issued.

Step 3: Investigate and Correct

They investigate the cause and discover that old design specifications were being used during the production process. The cutting and molding machines were set for longer dimensions. Their initial severity was HIGH as there is a possibility of bike accidents that can have negative consequences. However, no injuries were reported but they did receive complaints about the feel of the bike, which could affect someone's riding ability. They determine the actual severity was medium. They found that document versions were not being updated appropriately by the Design Team which lead to the Engineering Team programing the machine incorrectly. This highlighted the importance of good document management and communication between teams. It also reinforced the idea that more inspections were needed, as the single final inspection does not always check all measurements, as it was assumed the spot checks would detect those errors.

They assigned a corrective action to the Design and Engineering Teams to reprogram the machines to align with the newest design specifications. They also inspected each of the first 50 handlebars made prior to further assembly as a double check.

Step 4: Improve Quality

While the measurement error was the root cause of some of the customer complaints, they still needed to address the handlebar grips, which were causing customers blisters. They decide to research and redesign the grips. They complete a management of change that will update both an asset and design document. It is assigned to the Lead Designer and Head Engineer to make updates to the design and subsequently the manufacturing machine.

Step 5: Monitor Quality and Set Goals

With the increased number of inspections, they have a lot of data that will give them insights into the quality of their products. They also consider consumer reviews and send out customer satisfaction surveys. They review data related to the number and types of quality nonconformities that are being detected, as well as classifying reviews to see what issues consumers are having the most and what they like the best. This data will help prioritize where within the manufacturing process they should focus on improving quality.

They set goals aimed at reducing the number of quality incidents and getting a customer satisfaction rate of 80%. For each type of nonconformity, they identify actions that can help prevent them. Based on customer feedback, they prioritize the design features with the most complaints and identify how to update the design to address their concerns. Responsibilities and timelines are also established.

Step 6: Train Employees

To further improve their QMS, they ramp up employee training for each role. All employees are required to review and acknowledge the company's quality policy. Each role is also assigned annual training that covers the following:

- Overview of the role, including actions and processes performed in their role
- Safety practices, including PPE requirements and incident reporting
- Inspection procedures

Step 7: Continuous Improvement

As the company aims to have high quality products, they should review progress and assess procedures for effectiveness. To do this, they conduct an audit that includes:

- Review of all incidents and corrective actions, ensuring all actions have been completed
- Review of metrics to ensure the company is working towards their goals
- Interviews with employees to understand pain points as well as successes
- Review of all compliance requirements, including recordkeeping, monitoring results, and violations
- Review of all manufacturing and inspection procedures