CNA

Quality Management Tips for Maintaining Product and Service Integrity

Quality Management System (QMS) defines a company's all-encompassing approach to the quality of their products and services, beginning with design and planning, material selection, processes, packaging and distribution, and ending with support. Businesses known for quality aim for continuous improvement and have formal QMSs.

Quality management, quality assurance and quality control are used to pursue excellence of a product or service. In general, quality management is the overall company approach to all aspects of quality. Quality assurance may be viewed as the company's activities to maintain internal and external standards. Quality control is the written program and standards followed to achieve the desired product standard or level of service.

Design and Planning

Comprehensive product design, at its core, focuses on developing a product with minimal inherent dangers when operated by a reasonable person. Consumer products present a much wider range of exposures than a specialty product with minimal or no public exposures. For example, the potential hazards presented by a riding lawnmower far exceed the potential hazards of a metal server rack in a locked computer room.

Products are designed to fulfill a need. Risk assessments can identify potential product hazards and operator misuse in the design process. Design revisions can eliminate or reduce hazards through the addition of safety features. For example, the design of a production machine may locate the operator controls far away from the point of operation to keep the operator physically separate from the hazard, or an enclosure may physically protect the operator from the hazard. A product's design may evolve as hazards are identified and changes are implemented to reduce the exposure.

Similarly, a service offering may incorporate the substitution of a material or process, such as using a less toxic cleaning solution, to reduce a hazardous exposure to the individual providing the service. Also, modifying a service procedure may reduce a hazard once the service is complete, such as adding particles to a floor coating to reduce slip-and-fall incidents. Companies with comprehensive QMSs involve the design and engineering staff and monitor similar products in their industry to identify complaints, exposures, hazards and unexpected scenarios to be addressed during the design stage.

Material Selection

Materials used in performing a service or in the fabrication of a product are a quality factor. They become a concern when the design parameters are compromised. Materials specified in the design may range from raw materials to component parts to sub-assemblies.

Raw material selection and quality can affect a completed service or an end product. For example, a floor wax may increase the slip-and-fall potential on a highly polished floor. Wet aggregate will increase the moisture content in wet cement, which can weaken a concrete batch. A substituted O-ring of an inferior material used to seal a coupling may rapidly deteriorate, fail to seal properly and result in a fluid leak. Sub-assemblies from third-party suppliers may have multiple product applications. However, certain applications may subject the sub-assembly to harsh environmental conditions not initially contemplated in the sub-assembly design.

When multiple suppliers are used to stabilize supply chain disruptions, slight material variations may require increased quality inspections. Material substitutions may not meet design specifications, as an unknown substitution by a supplier may compromise the integrity of a completed service or finished product.

Implementing strict quality standards and conducting supplier evaluations with regular audits can reduce the overall loss potential.

Processes

Proper product fabrication steps and procedures for completing a service are foundational to a successful quality program. Following a defined set of procedures in the execution of a service ensures consistency. Skipping a step or substituting a material may compromise the end result, leading to inferior service. Fabrication work performed outside the design parameters may also result in a product quality issue. These excesses may be identified through adverse incidents such as product failure due to a manufacturing defect or inferior services such as surface coating that fails to protect the underlying material.

When production steps or provided services are subcontracted, manufacturing defects can arise, as subcontractors may not meet specifications, substitute non-approved materials, or further subcontract the work. Quality assurance steps can reduce this loss potential through inspections, audits and risk transfer mechanisms.

Packaging and Distribution

A finely crafted product can be damaged from rough handling. Therefore, the packaging is important. A precision instrument, packaged in a custom cardboard box, may be shipped by a distributor in a larger corrugated box with insufficient packing materials, resulting in damaging impacts while in transit. Packaging may also present bodily injury concerns such as lacerations from metal banding, suffocation from plastic bags, choking from small parts and exposure to toxic contents from failed containers. Re-designing the packaging to protect the people handling it, as well as its contents, may solve these concerns.

Support

Quality management support may involve customer support online or at a call center, translation of documents for non-domestic customers, follow-up services and disposal concerns. The QMS includes how a company responds to product or service complaints and internal reviews to ensure product specifications are within tolerance, to identify opportunities for design improvements, and to identify concerns with a supplier, contract manufacturer, or subcontracted service provider. An enterprise-wide supply chain QMS applies to both new and repaired products. Regular comprehensive supply chain audits and testing recall program components support the overall QMS initiative.

Exposures

A company with no formal QMS risks providing deficient services or producing inferior products, increasing its liability. An HVAC contractor that misses sealing a condensation line may be the focus of a slip-and-fall or water damage claim. A manufacturer that substitutes a substandard lithium-ion battery in their product due to supply chain issues may be the focus of a fire damage claim when the battery experiences thermal runaway.

Providing a service at a customer site may involve multiple steps, starting with cleaning a product or preparing a site by setting up barricades. Then the service needs to be conducted appropriately, such as powder coating a part or repairing equipment. Finally, the service needs to be concluded entirely, such as inspecting a part, testing repaired equipment and cleaning the work area. Failure to complete these steps can result in the product not meeting the design specifications, resulting in premature failure or a jobsite hazard such as machine oil spilled on the floor or improperly installed roofing membrane that results in water damage.

Product liability claims often cite product defect as the problem, resulting from poor design, an error during manufacturing or a marketing issue. Manufacturing defects may result from using inferior material, material substitutions, subcontracted manufacturing steps improperly performed, failure to execute a manufacturing step or performing a manufacturing process incorrectly. In addition, some marketing defects include poorly written instructions, lack of warning labels and demonstration videos portraying users without proper safety equipment.

Companies may assume all liability when products are directly imported. Additionally, responding to a claim may prove difficult when all inspections, testing and quality control documentation reside in the country of origin.

Controls

A comprehensive QMS, supported by top management, provides guidance from the design and planning stage through to the completion of a product or service, with measured documentation of key elements and follow-up for continuous improvement. System elements may include, but not be limited to, a written program, involvement from all departments, incorporation of industry regulations and standards, thorough documentation, regular updates and independent audits. When non-conforming products are identified, corrective and preventative actions (CAPA) can be implemented for quality improvement.

Thorough research and development, exceeding regulations and standards, and third-party evaluations can reduce design defects. Risk assessments of new and revised products and services support the design aspects and are critical to continuous improvement. Comprehensive inspections with detailed documentation throughout the production process can also reduce manufacturing defects. Internal and external audits and third-party testing provide regular feedback to achieve quality metrics.

Managing external exposures further supports the quality system. Auditing business partners such as material suppliers and subcontracted service providers helps maintain a high quality standard. A company that directly imports an item is often considered the product manufacturer from a liability perspective. Therefore, addressing imported product quality as if the company itself designed and manufactured the product is critical.

Documentation is a crucial element of a formal and successful QMS. Documentation ensures the company's quality goals are measured and met. From the design process to prototyping and testing, and throughout the production process, documentation may be used for internal evaluations. Response to regulatory requirements and evaluation of customer concerns are also supported with extensive documentation. Documentation examples include original designs, design revisions, test results, raw material certification, in-process inspection results, final testing, final inspections, photographs of completed work and product sample retention, as well as support materials such as instructions, website content, demonstration videos and warning labels.

Establishing your QMS may only require formalizing your processes and documenting what you are already doing, then continually monitoring products and services, identifying opportunities for improvement, and updating quality metrics in a documented and structured approach. Nevertheless, it is important to evaluate your current system to ensure it meets quality standards and to maintain a reputation for quality products and services.

Resources

American National Standards Institute

American Society of Mechanical Engineers

American Society of Quality

ASTM International

CSA Group

ECA Academy GMP Compliance

Institute of Electrical and Electronics Engineers

ISO 9001 – Quality Management Systems

ISO 16485 – Quality Management for Medical Devices

ISO/TS 16949 – Quality Management System, Automotive-Related Products

Six Sigma

Underwriters Laboratories

Underwriters Laboratories of Canada

European Commission

CNA Product Recall Planning Guide

For more information, visit cna.com/riskcontrol.