# EAGLE Certification Group
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# The Crucial Role of Auditing for Packaging Manufacturers

# Introduction

In a global marketplace, quality, safety and sustainability of packaging materials are the key components for success. This applies to food products, pharmaceutical products and other products that are all dependent on the integrity of their packaging materials. With customer and consumer expectations of high standards and regulatory authorities setting strict statutory requirements around compliance, the role of auditing in the packaging industry is crucial. As requirements evolve, auditing can help support conformance to standards and compliance when addressing regulations. Auditing the packaging producer will help achieve the expected quality outcome of customer satisfaction, and the expected safety and sustainability outcomes of trust, keeping products and brands trustworthy for their consumers.

# Quality Management Systems (QMS)

## ISO 9001

ISO 9001 is often regarded as the foundation for an organization's QMS and demonstrates a manufacturer's overall commitment to quality. Auditing this standard is essential for determining the effectiveness and efficiency of their management system. ISO 9001 is an international standard that helps packaging manufacturers ensure their policies, processes and procedures comply with statutory and regulatory requirements, consistently meeting both customer specifications and process capability as it relates to quality. Example requirements include:

## Customer Focus

ISO 9001 emphasizes a strong customer focus, helping packaging manufacturers meet customer requirements. This involves collecting information for customer specifications and expectations, and integrating them into the QMS. Customer focus can lead to better customer retention and a stronger brand reputation.

## Documentation

The ISO 9001 standard requires manufacturers to maintain documented information and processes including records of communications, customer needs and corrective actions based on customer feedback.

## Quality Control

ISO 9001 mandates measures are implemented so that products consistently meet customer requirements. This includes routine inspections, testing, and validation of packaging materials to ensure they conform to the standards required to deliver quality for the customers' product.

## Supplier Management

All materials sourced from suppliers are also required to meet necessary standards. ISO 9001 helps maintain conformance and compliance of the packaging manufacturer's supply chain.

## Regulatory Compliance

For packaging manufacturers, adhering to regulatory requirements is crucial. ISO 9001 audits ensure that manufacturers comply with relevant laws and regulations, reducing the risk of legal penalties and ensuring consistent operations

## Operational Efficiency and Effectiveness

Through systematic evaluation of processes, ISO 9001 audits help identify process inefficiencies and areas where resources can be better utilized. This can lead to cost savings, improved productivity, and more streamlined operations.

## Continual Improvement

By improving processes, packaging manufacturers can adapt to changing customer requirements to meet or exceed expectations. Nonconformities identified in audits help manufacturers address gaps in their processes, which leads to improvement. Click here for an example case study using the Plan–Do–Check–Act (PDCA) cycle for improvement of sustainable packaging. Click here for more information.

# Packaging Manufacturers and Good Manufacturing Practices (GMPs)

GMPs are designed to assure that packaging materials do not compromise the safety, quality, or sustainability of the products. GMP audit requirements for packaging materials may consider similar requirements to a QMS audit with a focus on manufacturing.

A GMP Program considers hygienic facility and hygienic production conditions to include selecting appropriate packaging materials that are approved for direct food contact, do not react with the product and ensure that the packaging design protects the food from contamination. Other manufacturing considerations include labeling, where accurate and clear labeling of packaging materials is essential. Labels must include all necessary information to ensure proper identification and use, such as batch numbers, expiration dates, product ingredients and storage instructions. Line clearance and identification procedures are required to ensure that packaging lines are cleared of previous products and materials before starting a new job. This prevents mixed packaging that could impact filling at the food plant. The many verifications required in a GMP program are there to ensure that the correct packaging materials are used and that they are properly applied. This includes checks for correct labeling, sealing, and overall integrity of the packaging.

# Packaging Manufacturers and Risk Management

Audits can help identify potential risks in the manufacturing process. By assessing and mitigating these risks, packaging manufacturers can prevent issues that could lead to product recalls, legal liabilities, or damage to their brand reputation.

Risk assessment is a mandatory component in ensuring the safety of packaging materials, particularly in the food and pharmaceutical industries. Risk assessments are audited to help identify potential hazards associated with packaging materials, such as chemical contamination, physical damage, or microbial growth. This allows manufacturers to identify issues before they become defects or nonconformities. By assessing the risks, manufacturers can evaluate the safety of different packaging materials. This includes understanding how materials interact with the product it carries to the market to prevent the migration of unwanted chemicals into the product, or the product's shelf life impacted due to a loss of containment characteristics. This is crucial for maintaining consumer safety and avoiding legal issues. The insights gained from risk assessments can lead to improvements in packaging design and manufacturing processes.

When identified, manufacturers can implement measures to mitigate these risks. This may include selecting safer materials and improving manufacturing processes. By systematically identifying and addressing potential risks in a management system approach, auditors can provide assurance that packaging materials maintain the highest standards of quality, safety and sustainability.

# Packaging Manufacturers and Pharmaceutical

The ISO 15378 standard specifies the requirements for a quality management system (QMS) for manufacturers of primary packaging materials for medicinal products. This applies to all manufacturers of packaging materials that come into direct contact such as glass, rubber, aluminum, and plastics.

The standard integrates the requirements of ISO 9001 with Good Manufacturing Practices (GMPs), where materials are manufactured in a controlled and hygienic environment to prevent contamination and ensure product safety. By adhering to ISO 15378, packaging manufacturers can ensure that their packaging materials are safe, reliable, and meet the stringent requirements of the pharmaceutical industry.



From a regulatory perspective, the United States Food and Drug Administration (FDA) can issue warning letters to pharmaceutical companies when there are violations in their packaging and labeling processes. For example, if a company was found to have inadequate controls to prevent contamination of their packaging materials which led to a recall. This highlights the importance of quality control measures and adherence to GMPs to assure packaging material safety.

# Packaging Manufacturers and Food

Early food safety audits primarily targeted the ingredients and food product processes within food manufacturing facilities. The goal was to ensure that the food products were safe for consumption and free from contaminants. The implementation of the Hazard Analysis Critical Control Point (HACCP) system in the 1990s was a huge success. As the food industry evolved, the role of packaging had an increased focus around food safety. Packaging materials can be a source of contamination if not properly managed. Today, food safety audits consider the food supply chain from farm to fork. This includes food products, packaging, transportation, storage and retail conditions. Packaging audits include FDA Compliance for the materials used (21CFR 176), the manufacturing processes, overall equipment and facility maintenance, along with a high expectation for cleaning and sanitation.

The Global Food Safety Initiative (GFSI), with the objective of harmonization of food safety audits, benchmarks various food safety standards, including those for packaging, to ensure consistency and reliability. Examples of GFSI-recognized packaging audits include SQF Manufacture of Food Packaging, BRCGS Packaging Materials, and FSSC 22000 Packaging.

From the US regulatory perspective, in order to understand the impact of Food Safety Modernization Act (FSMA) on the packaging manufacturing industry, it is important to review some of the regulatory definitions tied to food and food contact surfaces. The New Era of Smarter Food Safety Blueprint by the FDA emphasizes tech-enabled traceability and smarter tools for prevention and outbreak response, which includes considerations for packaging safety.

# Packaging Manufacturers and Sustainability

Sustainability encompasses both environmental and social factors. While environmental sustainability focuses on preserving natural resources and reducing pollution, social sustainability addresses issues like employee safety, fair labor practices, community development, and overall wellbeing.

ISO 14001 is an international standard for Environmental Management Systems (EMS). For packaging manufacturers, adopting ISO 14001 can significantly contribute to sustainable practices and help meet the growing demand for environmentally-friendly packaging solutions. This could include the use of clean recycled materials and the use of Post-Consumer Recycled (PCR) packaging. The EMS standard offers a framework for organizations to manage their environmental responsibilities systematically and sustainably with expected outcomes that include preventing pollution, meeting applicable legal requirements, and improving overall environmental performance. Click here for more information.

ISO 45001 is an Occupational Health and Safety Management System (OHS) that helps ensure a safe working environment by identifying and mitigating risks and reducing workplace accidents and illnesses. By systematically managing health and safety risks, companies can improve operational efficiency and reduce downtime caused by accidents. For packaging manufacturers where machinery and manual handling are common, implementing ISO 45001 can significantly reduce the risk of shop floor injuries and improve overall workplace safety. Click here for more information.

# Operation Clean Sweep®

Operation Clean Sweep (OCS) is an industry-led program that supports companies in their efforts towards eliminating plastic resin loss in operations to preserve water quality, protect the environment, and strengthen worker safety. Click here for more information.

## Packaging Manufacturers and Integration with Other Standards

ISO 9001 (QMS) can be integrated with other management system standards, such as ISO 14001 (EMS) and ISO 45001 (OHS), to streamline processes and improve overall management efficiency. An Integrated Management System (IMS) is a comprehensive approach that enhances environmental, economic and social sustainability by integrating quality, environmental impact and workplace safety in a single and more cohesive system. Click here for more information.

# Conclusion

In summary, it is crucial for packaging manufacturers to consider auditing against globally-accepted quality, safety and sustainability standards. By doing so, it will be the foundation for regulatory compliance and managing risks. It ultimately leads to operational efficiency, improved customer satisfaction, increased consumer trust, and a stronger, more resilient organization. Customers of packaging companies that receive both internal and external third-party audits from industry expert auditors have the confidence that the packaging producer is committed to the quality and safety of their products, and they are actively addressing continual improvement through the audit process.

## About EAGLE Certification Group

Since 1994, EAGLE has built a reputation on providing third party auditing services that are objective and value-added. Based in Dayton Ohio, our competent, industry-experienced auditors are well-versed in helping clients ensure their quality, environmental, health and safety, or food safety management systems are robust and effective. EAGLE is ANAB-accredited and a certified, woman-owned business through the Women's Business Enterprise National Council (WBENC). EAGLE is the North American member of IQNET, a leading international association of certification bodies and fully committed to the global IAF Cert Search database, resulting in transparency and confidence that clients can trust.

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📞 800.795.3641 or +1.937.293.2000

✉️ info@eaglecertificationgroup.com

🔗 eaglecertificationgroup.com

in linkedin | eaglecertificationgroup

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