

TECHNICAL PAPER

Are you at risk of counting the cost of poor seal selection?

This whitepaper describes the considerations equipment manufacturers (OEMs) and end users must address when sourcing food, dairy and pharma seals that are fit for purpose.

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Numerous industries and applications use elastomeric seals and gaskets in equipment such as pumps, valves and pipes that contain or transport fluids or gases. They are typically designed and manufactured to minimize leakage, and made from high-performance materials that resist dimensional changes and degradation due to thermal excursion, chemical attack, mechanical stresses and wear.

Elastomeric seals and gaskets that are used in food and dairy processing equipment, pharmaceutical manufacturing equipment and biomedical devices must adhere to more stringent requirements imposed and enforced by government agencies and industry advisory groups to ensure the safety of end products.

How do equipment manufacturers (OEMs) and end users ensure they are sourcing seals fit for purpose, with the correct approvals and certification?



Requirements and regulations

Depending on the industry and application, elastomeric seals and gaskets may need to comply with a variety of government regulations or industry guidelines. Examples include the following:

- **U.S. Food and Drug Administration (FDA)** — Ensures the safety of all food (except for meat, poultry and some egg products) and ensures the safety and effectiveness of all drugs, biological products and medical devices for human and animal use.
- **3-A Sanitary Standards** — Defines specifications and best practices for the design, manufacture, installation and use of hygienic equipment that apply to equipment used in the dairy industry, as well as some equipment used in egg processing.
- **U.S. Pharmacopeia (USP)** — Safeguards the quality of medicines and other healthcare technologies by setting standards for quality, purity, strength and consistency, which are published in the U.S. Pharmacopeia and the National Formulary (USP NF).
- **European Parliament Council (EC)** — Establishes general safety requirements for the manufacturing, processing and distribution of all possible food contact materials (FCMs).

The numerous government and industry standards, requirements and regulations have a significant effect on the design, manufacturing and testing of seals and gaskets used in production equipment for the food, dairy, water, pharmaceutical and biomedical industries. Examples include the following:

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- **Design** — The seal or gasket must be designed to withstand operational conditions that may result in degradation, such as extreme temperature, incompatible chemicals or sterilization.
- **Materials** — The materials that comprise the seal or gasket materials must be selected and demonstrated through testing to be biocompatible, and free of contamination or impurities that may be released into the end product throughout its operational lifetime.
- **Manufacturing** — The manufacturing process must also be controlled, audited and approved by the regulating agency and regularly monitored by the manufacturer to ensure that it does not introduce contamination into the product.
- **Testing** — The seal or gasket must undergo extensive testing in the laboratory and under field or operating conditions to ensure compatibility and compliance with regulations and requirements.
- **Records** — The manufacturer must maintain accurate records of all aspects of the design, materials, manufacturing process and tests performed on the seal or gasket to ensure process traceability and compliance to government and industry standards.

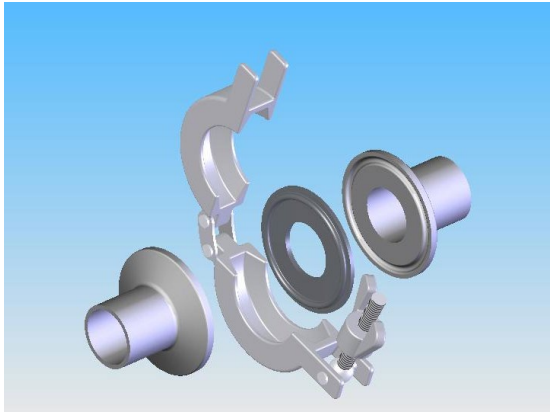
The large number of seals and gaskets produced by numerous manufacturers make it nearly impossible for government or industry regulatory organizations to audit each product and application. Many of these organizations therefore use an honor system, where gasket and seal manufacturers independently demonstrate and certify compliance with the appropriate regulations and standards. Some seal manufacturers and suppliers offer components that claim to be compliant but they are unable to prove this with documentary evidence when challenged; either because they are taking shortcuts by using lower-cost, non-compliant materials and manufacturing processes, or they are part of a supply chain where traceability has been lost.

A non-compliant seal or gasket can fail during operation, causing numerous problems for end users, such as equipment malfunctions, production downtime, higher operating costs and contamination of the product. This in turn causes problems for OEMs, such as damage to reputation, product recalls and increased maintenance and warranty costs.

It is therefore incumbent upon OEMs and end-users to ensure that their gaskets and seals are compliant with the appropriate regulations and standards by performing due diligence and obtaining certifications from seal/gasket manufacturers and suppliers. Users and OEMs must also obtain assurances that their seal suppliers do not change the seal or gasket design, substitute non-compliant materials or implement uncontrolled manufacturing processes between production batches.

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These problems underscore the need for users and OEMs to select seals and gaskets from trusted and reputable seal suppliers.



Sanitary gaskets are used in food and pharmaceutical manufacturing applications.

Precision Polymer Engineering

PPE has more than 43 years of experience producing elastomeric seals and gaskets for the food, dairy, pharmaceutical and biomedical industries. They offer the full range of technical, manufacturing and sales support to ensure that seals and gaskets are compliant with the appropriate government and industry standards and regulations.

A dedicated technical staff assists end-users and OEM customers by recommending appropriate seals and gaskets to replace non-complying products, or by developing new or custom components using advanced design and analysis techniques. State-of-the-art laboratory facilities enable PPE to test and validate materials to application requirements. All elastomer materials are externally tested in accordance with accepted industry standards and methods.

ISO audited manufacturing facilities and processes ensure traceability and production of seals and gaskets to the highest quality standards and compliance levels within the industry.

Their exemplary record of product success, quality assurance and continuous improvement make PPE's products among the most trusted by leading OEMs, food processors and pharmaceutical manufacturers.

More information on PPE and their products and services may be found on the [PPE website](http://www.prepol.com).

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