Hygienic design and seals – An overview

Giving consideration to rules, form and material

Stricter regulations and more demanding production conditions pose a challenge to sealing experts. They must therefore possess extensive material expertise and industry knowledge. When it comes to hygienic design, coordination with the customer is crucial. Only when compliance, material and design are individually matched do seals become beneficial to the customer.

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Food and pharmaceutical safety requires trustworthy partners. When it comes to seals, competent advice and close cooperation involving the seal supplier, customer and end user are important. Three topics become crucial: Material, compliance and hygienic design. Like a stool on three legs, these factors interlock to maintain a balance: If each leg is equal, the stool is stable. If one is neglected, a dangerous situation develops. A good seal supplier understands the specific applications and requirements of its customers - be they small quantities or prompt availability. Customer and industry understanding, knowledge of materials and regulations and application-related expertise are essential to designing seals that allow customers to become more efficient and improve product quality and safety.

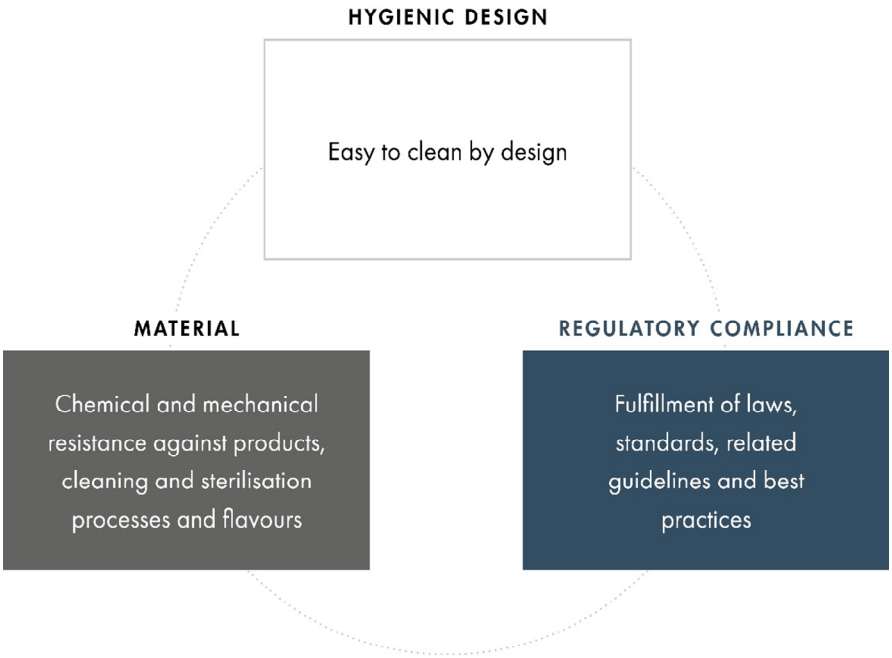

Figure 1: The three pillars of hygienic design for seals in the process industry must be individually coordinated.

Two trends can be identified in the market: Increasingly stringent regulations are restricting the choice of materials. At the same time, intensive process conditions place ever greater demand on seals: These are stressed by long maintenance intervals involving highly efficient cleaning cycles and aggressive chemicals applied at higher temperatures. The importance of material and durability was explained by Reto Müller in the August issue of *Pharma+Food*: With increasing frequency, supposedly expensive high-performance elastomers emerge as the more economical solution. For example, PERTEC® seals from Angst+Pfister have substantially extended maintenance intervals of production equipment. In the end, thorough cleaning of the installed seals must be an option. For this reason, smooth interaction with the customer is essential in hygienic design.

Compliance - avoiding restrictions through capability
Regulations must be observed at the plant site and in countries where the manufactured products are sold. This requirement has resulted in the globalization of laws and standards for materials, including seals. In the beginning were the “ambiguous paragraphs” of the U.S. Code of Federal Regulation (see Figure 2) – for which the Food and Drug Administration (FDA) is responsible. FDA-compliant seals are now seen as the minimum state of the technology: An approved list determines which ingredients may be used for material development. Maximum extrusion values define the amount of allowable discharge from the vulcanized product under certain conditions. In Europe, regulatory precursors were collected in an overarching regulation in 2004: Since then, “Regulation (EC) No. 1935/2004” has become the basic regulation for all materials coming into contact with food. Individual directives were then issued for different materials - but not for elastomers. For this reason, national laws with varying provisions apply. In anticipation of a European regulation, many of these laws were not amended over time.

Perception and implementation of regulations have changed significantly in recent years. Anyone electing not to comply with these is left exposed to increased risks: Damaged reputations, claims for compensation, reduced profits, fines or even imprisonment. Customer audits are on the rise. However, detailed knowledge concerning elastomer regulations varies across the industry. Some customers have specific toxicological and chemical expertise. Others are unpleasantly surprised by such demands. Non-compliant seals unfortunately still appear in the market - for example, when manufacturers are unaware of the regulatory consequences of a new application. This is where an attentive and competent sealing partner can help.

Figure 2: A dynamic world: currently relevant regulations for elastomer seals

In an environment fraught with increasingly intensive production conditions and international regulatory density, sealing engineers are virtually expected to build competitive “Formula 1 cars” authorized for safe road use. Leading sealing partners must therefore have a high level of material competence. Creating rubber compounds that are resistant to chemicals, high temperatures and mechanical abrasion while complying with combined regulations is an art for material developers.

Materials selection - the experience of the sealing experts
The better and more comprehensive information the seal supplier receives, the more successful product selection and guidance will be. First, regulations restrict the choice of materials to those meeting the required certifications. Experienced customers know which markets require which certificates. But when multiple markets are being considered, the advice of elastomer developers is helpful: Which approvals can be combined - and how? Where can you kill several birds with one stone? Where do you sometimes need two material versions?

While regulatory requirements are generally known, detailed information about individual process conditions is not always available: In the supply chain, trade secrets are disclosed only to the extent necessary. The production environment has a decisive influence on the choice of materials and the resistance of seals - and thus on the economic efficiency and food safety of equipment. How is equipment cleaned and sterilized? Do the manufactured products attack seals?

Sealing experts can offer equipment operators knowledge and experience to keep maintenance intervals to a minimum. Which material lasts longest under which conditions? What prevents carryover of flavors? Which elastomers have safe extrusion values for which purposes? Which seals withstand which product changes? In the pharmaceutical industry in particular, information is often scarce. Dealing with information deficits is therefore also part of the material experts' craft: Indications such as “cosmetics,” “strong flavors,” or “greases” sometimes have to suffice to make seals last as long as possible. This is not ideal with regard to the service life of seals, but it is a characteristic of such markets. Only with a great deal of experience and the highest quality materials can these information deficits be addressed.

Figure 3: The further development of existing material portfolios to keep pace with increased demands is a constant task for leading seal manufacturers.

Hygienic design - cooperation for form and installation
Hygienic design goes beyond the construction of machines: It starts with the design of entire production facilities and their processes but ultimately also influences seals. The goal is the safe production of food or pharmaceuticals. It is the responsibility of manufacturers to protect their consumers. While the guidelines for this area are not legally binding, they are to be regarded as the current state of the art, and manufacturers should follow them. They originate with two authoritative institutions: the 3A Sanitary Standards in the U.S. and the European Hygienic Design Equipment Group - EHEDG for short. The two entities cooperate closely. They aim to make the production environment as hygienic and easy to clean as possible. While 3A primarily describes how components should be geometrically designed, the EHEDG also develops practical tests. 3A is primarily required within or for the United States. The EHEDG initially operated within the European region but has now also attained global significance. Relevant guidelines are discussed by expert groups from the industry and are further developed in a way similar to standards.

Hygienic design for seals relates primarily to form. Of course, no components of the material must be allowed to diffuse into the processed products - which is another reason why developments such as antibacterial rubber compounds have been quite unimpressive to this point. The most important question remains: What form and installation methods best facilitate cleaning? Seals are used

wherever production equipment housing must be partitioned. For these to remain hygienic, they must be as flush as possible - i.e., offering no crevices, protrusions or similar spaces where dirt can accumulate.

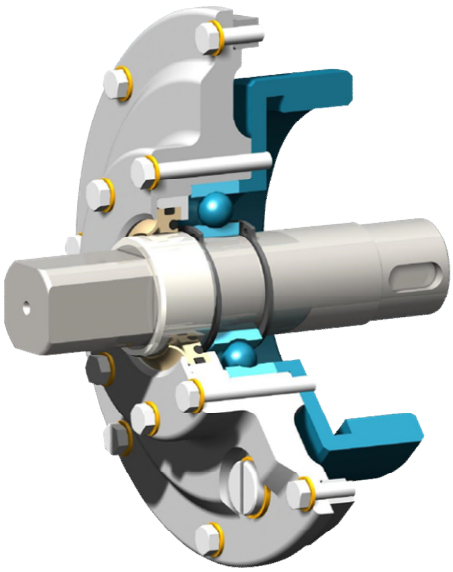

Figure 4: Shaft seal hygienically designed for minimal clearance, specifically produced by Angst+Pfister Netherlands for Van der Graaf. Van der Graaf manufactures drum motors for belt conveyors and other food industry equipment.

The most traditional form of seals are O-rings. These have limitations in hygienic design, however - especially for dynamic applications. This offers one reason why a trend towards custom-molded parts has been observed for years. They offer additional advantages and are much better suited to their application. In some cases, they can even be absolutely necessary - for example, in the case of special lips, wipers or shaft seals.
Competent seal suppliers work closely with the customer in a spirit of trust, ideally right from the outset of development. This avoids the seal having to be inserted “quickly” into an existing slot at the end. The supplier can contribute at an early stage with its knowledge of compliance, material knowledge and hygienic design. Returning to the image of the three-legged stool: These advantages help it to remain stable for a long time.