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**Operating elements in food processing and pharmaceutical plants**

# Hidden cost drivers in design and production?

Whitepaper
**Hygienic Design**

DESIGNED
**FOR ENGINEERING**

# Content



# **Operating elements in food processing and pharmaceutical plants** hidden cost drivers in design and production

Developing and maintaining work environments for the food and pharma industry consistently poses major challenges to designers and engineers. To prevent contamination and sources of infection, the European Union has passed a number of standards and laws for these critical hygiene areas.

The path to the coveted title of “hygienic design” is beset by many potential cost pitfalls. The additional design effort required for HD products is considerable. The challenges include a narrowly limited range of materials, specific surface roughness requirements and design conditions with regard to gap widths, lubricants and machining, just to name a few.
This applies not only to large assemblies such as machines, cabinets and accessories but alsoto small parts as well. Even operating elements like handles, hinges and latches can be subject to challenging HD requirements. Especially in areas of food and pharmaceutical production with frequently touched surfaces, these special hygiene conditions must be taken into account.

This document is intended to raise awareness of cost pitfalls in the design of machines and plants with high hygiene requirements and to offer solutions and ideas for avoiding them.

# Cost driver 1
## Requirements on the operating elements

Operating elements are small parts required for the safe handling of larger modules or complex assemblies. This makes them extremely important in the context of hygiene because they are regularly touched by various people. The manual operation of handles, levers, control knobs or hand cranks makes them a hotspot for contamination and bacteria.
The risk increases with the complexity of the operating elements. While it may be easy to clean a fixed, monolithic handle, this can be much more difficult for an adjusting or indexing lever. The interior mechanisms contain many gaps and grooves where product residue, cleaning agents and bacteria can accumulate.

**Hygienic design requirements therefore stipulate a number of conditions that apply for operating elements as well:**

- Use of materials that are easy to clean or ideally have active hygienic properties
- Avoidance of stepped contours where equipment edges are not neatly aligned
- Seals without dead space
- Hygienic sealing material
- Designs that ensure distancing from the product itself
- Defined roughness of the surfaces below 0.8 micrometers

**Brushed, non-rusting stainless steel is therefore the standard material for all components in this area. This offers a number of advantages:**

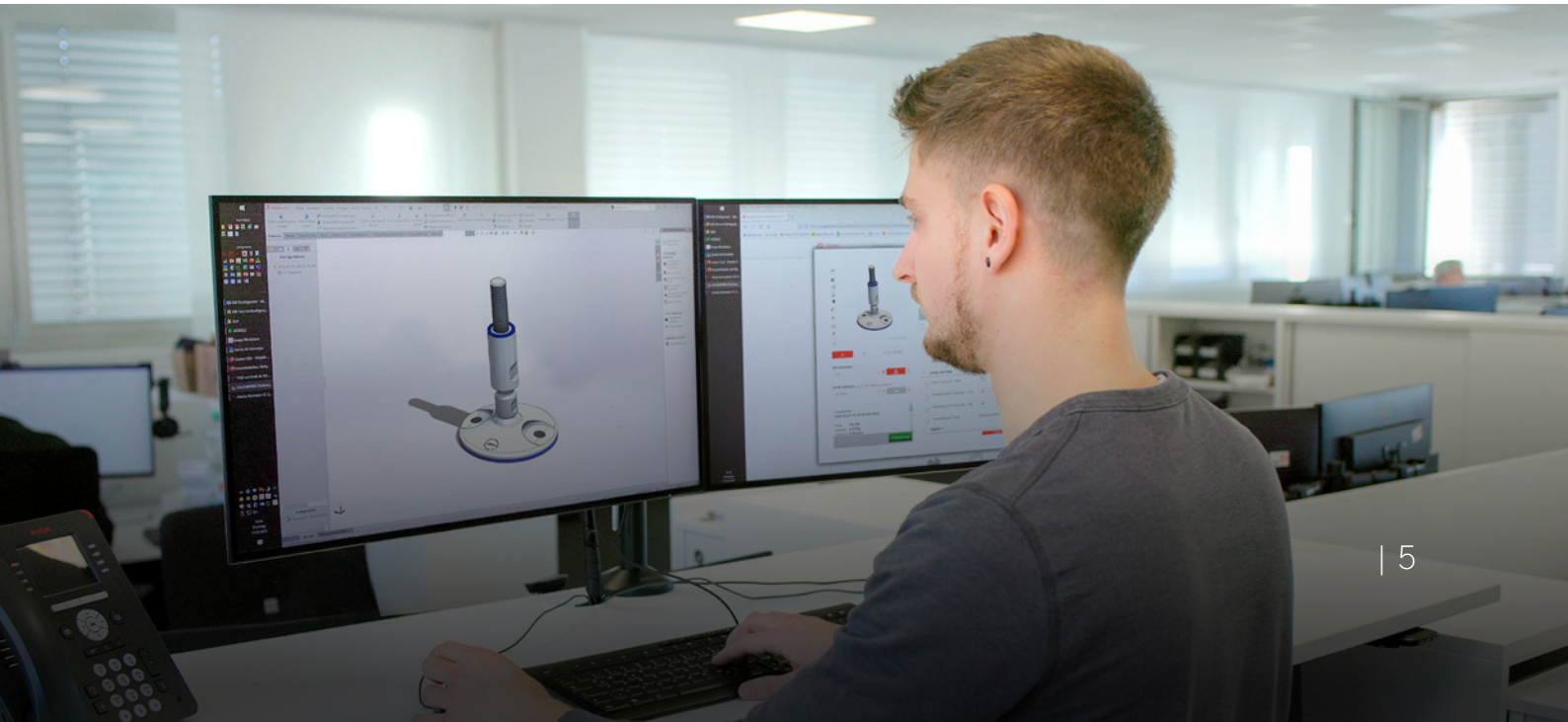
- High-precision machining for assemblies without stepped contours
- Hygienically active surface
- Manufacturing with any desired roughness
- Resistent to practically all cleaning agents

The last point is particularly important in hygienic design. Because stainless steel is equally resistant to all kinds of cleaning agents, it permits changing of the cleaning methods, which helps combat resistant strains of bacteria.

# Cost driver 2
## Challenges in hygienic design

Even simple operating elements like covers and doors can prove astonishingly labor-intensive to design in accordance with hygienic requirements. Hinges, latches and operating elements create gaps in previously smooth and easy-to-clean surfaces. In the end, it often happens that although each individual element satisfies the HD requirements, the entire assembly no longer complies with the regulations. This increases the amount of design work and therefore the costs as well.

Modern CAD systems are truly capable and deliver fast results, but the necessary expertise and extra time demands of hygienic design become major cost drivers when every little part has to be individually designed and drawn.
And the design process is far from the end. The parts must still go through manufacturing and assembly. Both stages require machines, materials and labor. In particular, the production expense can be considerable for small-scale products like operating elements. The smaller a part is, the more difficult it often is to manufacture. Slender knobs, locks and hinges with multiple parts quickly bring many companies to their limits. A number of other base materials are available for hygienic parts in addition to stainless steel. Certain types of plastic with FDA and EU certification ar e permitted as alternatives to stainless steel for manufacturing components to be used in areas with strict hygiene requirements. However, these soft and easily machined materials are still a challenge to work with when it comes to creating complex parts in hygienic design.



## Cost driver 3
HD certificates

There are also independent certificates for “hygienic design”, such as EHEDG, 3A, DGUV, and others. Unlike a conformity declaration, these can’t be issued by companies themselves. An assessment by an accredited body is required for the certification. Design certifications for series manufactured products can be obtained, but the process is expensive and can take up to a year. In Germany and Europe, this certification is granted by the EHEDG (European Hygienic Engineering & Design Group). It therefore makes sense to use as many products as possible that already have EHEDG certification. This massively lowers the scope of assessment and gets the product ready for market faster.

## Cost driver 4
## Maintenance and upgrades under HD conditions

A design change to an EHEDG-certified product may require another assessment. To avoid this expense, it makes sense to use identical parts. As long as a worn operating element is replaced with another of the same type, there is no need to repeat the certification process. However, if the customer wishes a more far-reaching design change, another EHEDG certification will be unavoidable.

# Solutions
## for creating hygienic designs

It is possible to avoid these cost pitfalls when designing operating elements, but it does require extensive knowledge and advanced manufacturing expertise. Both factors may not always be found in every company. This poses a significant risk that an ambitious project could wind up floundering due to unforeseen complications or go way over budget.

A wide range of solutions are available to enable cost-efficient and profitable design even in the face of hygienic requirements.

- **Weighing inhouse production against an outside manufacturer**
- **Standardizing as many parts as possible**
- **Using HD-certified standard parts**
- **Consulting with an EHEDG-certified body, partner or manufacturer.**

The question of manufacturing inhouse or outsourcing must always be answered at the start of every design process. The more standard or series-produced parts from other manufacturers are used, the lower the inhouse design expense. When using third-party productsin an HD context, however, it must always be evaluated whether the purchased parts actually have an EHEDGcertification (or „3-A Sanitary Standard, Inc“ certification for the US market). These certificates are generally available for downloading directly from the manufacturer's online catalog.

Standardized processes, dimensions and production steps simplify the design and make it easier to integrate outsourced parts. This starts with adherence to the system of preferred numbers and can be continued throughout the entire design process.

The use of HD standard parts offers a wealth of advantages. Thanks to existing EHEDG or 3-A certification, much of the testing on the final product can be eliminated. The manufacturers of standard parts commonly do much to make things easier for designers. Downloadable CAD files save considerable engineering time. Instead of designing every handle, knob or lever yourself, you can easily insert precisely generated files from the manufacturer into the design files. The advantage: accidents and mistaken measurements are practically impossible.

The use of standard parts may limit the creative freedom of a designer somewhat, but this limitation also has advantages: Standard parts require an adaptation of the design to suit their requirements. For instance, many handles require a minimum sheet thickness for a secure attachment. Of course, complying with these requirements also makes it that much easier to integrate other standard parts.

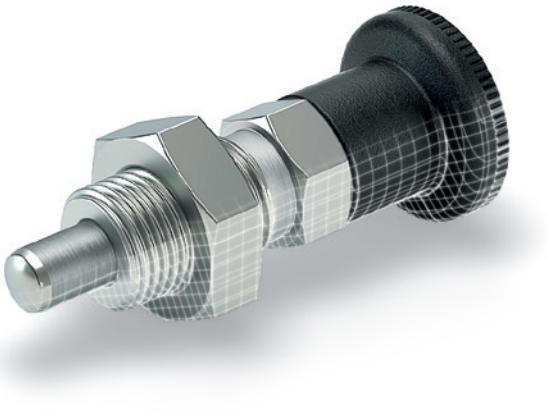
Standard parts offer particular advantages for series-produced products. Discounts are possible when purchasing high volumes, significantly reducing the cost of the final product. Manufacturers of standard parts also offer extensive advice and support. Many providers can adapt or customize their standard parts to a certain extent, even when hygiene design requirements apply.

Plus, the EHEDG itself offers direct consulting services as well. To get an idea of how challenging it can be to design and manufacture under HD conditions, download the free PDF “EHEDG Guidelines – Hygienic Design Principles”.

# HD standard parts

## lower the costs for design and production

The use of HD standard parts relieves machine builders and outfitters of the greater part of their workload. They offer tested solutions for the most important and critical hygiene aspects as well as legal cover. Extensive use of HD standard parts can considerably reduce design expenses. The end result is higher profit and productivity. Purchased standard parts do not have to be manufactured inhouse. They are immediately ready for installation. Manufacturers are aware of the need for standard parts in sensitive applications. They can provide you with parts manufactured using state-of-the-art processes that satisfy all hygiene requirements while keeping installation costs and other ancillary costs at a reasonable level.



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