Hygienic design in the life science industry: strict implementation of hygienic design requirements described by way of stainless steel furniture

A hygienic manufacturing environment is a prerequisite in life science and food & nutrition industries in order to maintain product sterility and minimise reject rates due to contamination. Product quality is primarily impaired by microorganisms, but also by other forms of contamination such as particles and chemical residues. To minimise the risk of product contamination during the manufacture, operating utilities used in the production environment should not represent a source of contamination. The hygienic design of equipment and the types of materials used for housings, shelves and joints require special consideration. The EHEDG design recommendations as well as other guidelines for hygienically designed utilities used in the food industry can be directly applied to the life science industry and are being implemented more frequently. The fundamentals of the recommendations are described in detail in this paper based on a qualification and optimisation "tested device" project on a stainless steel utility.

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In order for equipment materials to be suitable for use in life science, they must be resistant to the chemical cleaning and sterilising agents implemented. Materials used in the construction of equipment or utilities used in sensitive production environments may not allow microorganisms to colonise, present a food source for bacteria, or allow substances to migrate from materials into products. It must be possible to optimally clean material surfaces.

In general, well-known materials that have been tested and declared to be food-compatible, such as stainless steel and a range of elastomers, plastics and lubricants, are used in the construction of equipment used in the food production environment. Appropriately qualified new materials will significantly increase the current range of materials available to manufacturing operations. The selection of materials for manufacturing facilities with regard to minimal contamination is a highly relevant industrial issue, but for which there has been little research information available. The European Hygienic Engineering & Design Group (EHEDG) design Document 8 (Doc. 8) recommendations, as well as other guidelines for hygienically designed utilities used in the food industry, can be used to guide decisions about material selection and can be directly applied to the life science industry. The fundamentals of these recommendations are described in detail in this paper using an example of a qualification and optimisation "tested device" project on a stainless steel utility. The main material used in the example, a hygienically designed sink unit (Figure 1), is stainless steel-grade 1.4301 (USA AISI Type 304; Japan JIS SUS 305). It is an austenitic, acid-resistant 18/10 Cr-Ni-steel that is sufficiently resistant to atmospheric corrosion. The steel is highly polishable and can be easily shaped through deep-drawing, bending, roll-forming, etc. It is resistant to water, water vapour, humidity, food acids and weak organic and inorganic acids. This material is used in the manufacture and construction of equipment that operate in a wide variety of manufacturing sectors, including the food and beverage, pharmaceutical and cosmetics, and life science industries, as well as in plants that make chemical apparatus, household objects and appliances, surgical instruments, and bar and kitchen equipment.

Figure 1. Hygienically designed sink unit.

Design details

A. Doors and hinges

The implementation described fulfils the requirement that a utility must be completely emptied, as stated in EHEDG Doc. 8, and "to avoid the collection of liquids," as stated in DIN EN ISO 14159-1. The doors are made of double-walled, seamlessly-welded stainless steel elements, with sloping edges angled at 45° at the top and bottom (Figure 2). This enables any liquid present to drain away entirely.

The three-dimensional adjustable door hinges are of special interest: By integrating the slope as a feature into the hinge and minimising it to a small movable pin inserted into a bushing open at the base, liquids are able to drain away completely and cannot collect in the hinge. Each hinge is attached seamlessly to the door and sealed appropriately, thus preventing liquid from penetrating the connecting gap of the hinge. Therefore, the hinges do not represent a contamination risk. The sealing itself is also made of a U.S. Food and Drug Administration (FDA)-approved silicone sealant.

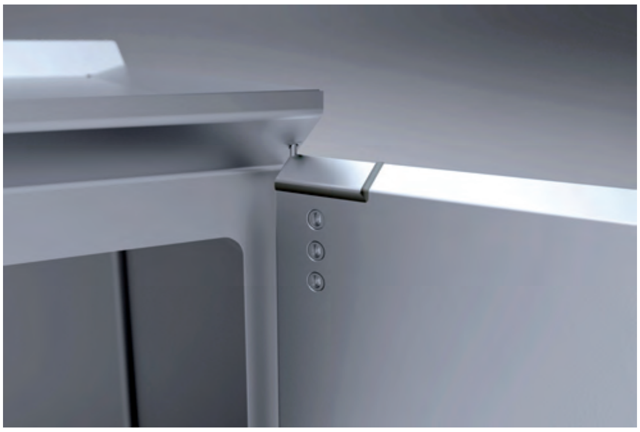

Figure 2. A close-up view of the sink unit's door and hinges shows how hinges are seamlessly attached to prevent liquid from penetrating the connecting gap of the hinge.

B. Sink and plughole

The sink is rounded with a radius of r >3 mm and thus fulfils EHEDG Doc 8 requirements. The plughole has been lasered directly into the sink to avoid any seams. The edges of the sink also are appropriately sloped to enable liquids to drain directly into the sink, minimising the amount of horizontal surface area. This fulfils the EHEDG Doc. 8 hygienic design requirement regarding the ability to empty a utility completely.

C. Opening and closing the doors

The novel Push2Open concept needs further improvement as the tiny gap between the cylinder and the housing walls is very difficult to clean (Figure 3). The markings drawn by electrolysis in the doors are completely planar and have a surface roughness of <0.8 µm, facilitating cleaning throughout the unit. When pressed lightly on the marked "push" area, the doors open gently. The Push2Open fitting also serves as a lock when the doors are closed. Avoiding the movement of the cylinder and using a fixed magnetic connection will improve cleanability extensively.

Figure 3. Push2Open concept.

D. Design of the interior

The interior of the hygienic utility is constructed without any seams (Figure 4). All rounded areas have a radius of r = 15 mm, equating to the hygienic class H3 (DIN 18865-9) and enabling all surfaces to be easily cleaned.

Figure 4. Design of the sink unit's interior allows construction without seams

E. Hygienically designed canopy

Hygienic cupboards generally have a slanted canopy or protruding edge with a 30° slope. Particles and liquids are unable to collect on it. A drip edge prevents liquids from penetrating into the interior.

Figure 5. A sloped canopy helps prevent particles and liquids from collecting on the surface.

F. Shelves

The shelves of the sink unit are also double-walled and seamlessly welded. The welded seams have been subsequently polished to ensure a uniform surface quality. Bearing pins are inserted into cut-outs in the shelves and have a rounding radius of >3 mm, thus fulfilling EHEDG Doc. 8 requirements (Figures 6 and 7). The stainless steel pins can be thoroughly cleaned, and because they can be unscrewed easily if required, the surface to which the pins are attached also are accessible for cleaning.

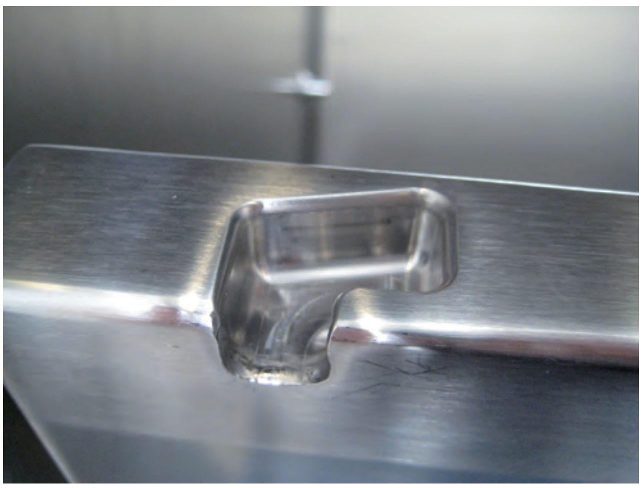

Figure 6. Cut-outs in the shelves fulfil EHEDG Doc. 8 requirements.

G. Glazing

As standard configuration, the stainless steel doors are not fitted with glazing; however, for better control of the interior, glazing can be realised using safety glass. These optional safety glass elements are planar with the surface and are sealed all the way round with an FDA-approved sealant material.

Figure 7. Glazing utilises safety glass elements that are planar, thus enhancing cleanability of the sink unit

Summary

As a result of these construction features, the stainless steel utility has been declared suitable for use in clean and hygienic manufacturing areas by Fraunhofer IPA. The assessment is based on a high-level ability to effectively clean and disinfect the representative stainless steel sink unit, which is reported in the corresponding tested device documentation.

Acknowledgement

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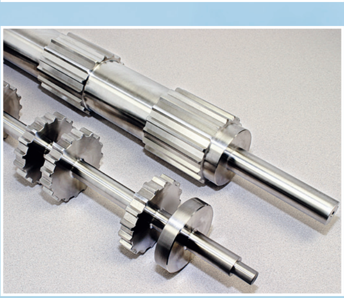



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