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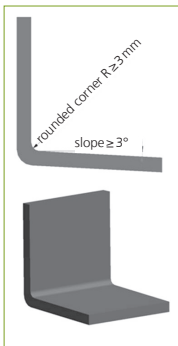
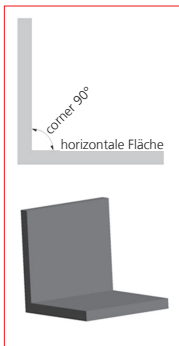
FRAUNHOFER INSTITUTE FOR
MANUFACTURING ENGINEERING AND AUTOMATION IPA

HYGIENIC DESIGN



hygienic risk

hygienic design
= OK



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Definition

Hygienic design refers to the design of parts, components and manufacturing equipment for easy cleaning.

Introduction

In manufacturing environments which have to be kept hygienically clean, a core requirement is the avoidance of microbial and particulate contamination of the end-product. The selection of appropriate materials for operating utilities and their geometric design significantly affect their suitability for use in clean manufacturing.

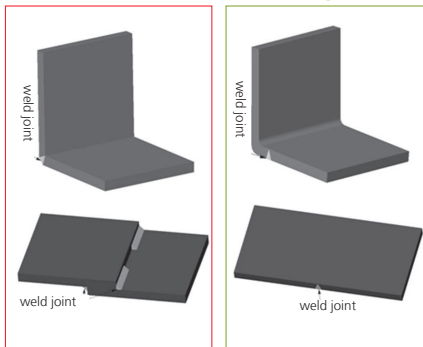
Procedure

Conformity analyses of operating utilities are carried out in the form of expert reports, in accordance with the relevant norms and guidelines applying to manufacturing under clean conditions (e. g. FDA, GMP, ISPE, ISO, EHEDG, DIN). Here, the hygienic design of an operating utility is evaluated with regard to its suitability for use in clean manufacturing areas and the respective results documented.

The following guidelines state conception and design specifications and recommendations concerned with the design, technical realization and workmanship of an operating utility.

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- EHEDG (European Hygienic Equipment Design Group)
- FDA (Federal Drug Administration)
- GMP (Good Manufacturing Practice)
- ISPE (International Society for Pharmaceutical Engineering)
- ISO (International Standards Organization)
- DIN (German Institute for Standardization)

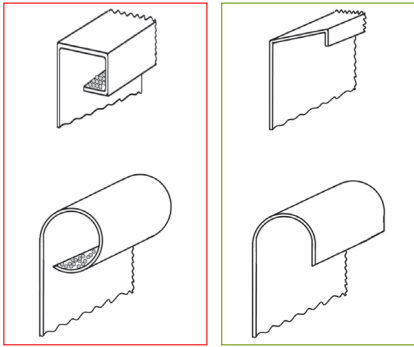
Assessment

Conformity is assessed by visually inspecting the test piece and evaluating the documentation and information supplied to the Fraunhofer IPA for qualification purposes. Among other things, the following details relevant to hygiene are examined:

- Materials implemented
- Material pairings
- Geometry
- Joining techniques
- Constructional details
- Installed components
- Surface coatings

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When examining the various hygiene details, among others, the following questions are considered:

- Are surface characteristics conform to the recommendations made in the various norms and guidelines?
- Have screws connections been correctly carried out from the point of view of hygiene and are they easy to clean?
- Are dead spaces present where liquids could accumulate?
- Can all areas be adequately treated with cleaning and disinfection agents?
- Can all liquids run off unimpeded?
- Have piping connections been correctly carried out from the point of view of hygiene?
- Have seals been designed to enable their implementation in hygienic areas?

Based on the completed assessment and with the aid of expert knowledge, the suitability of an operating utility is then determined for use in hygienic manufacturing environments and – where available – relevant potentials for optimization pointed out.

- 1 *Inner angle and edges.*
- 2 *Welded-on connections.*
- 3 *Cleanability.*
- 4 *Hygienic cable glands.*



Areas of application

Expert reports can be compiled for all manner of products and operating utilities planned for use in clean manufacturing areas. This applies especially to products and operating utilities utilized in branches of life science:

- Food manufacturing and processing industry
- Pharmaceutical industry
- Cosmetic industry
- Medical technology
- Biotechnology

Assessments can be made either during the planning or construction phases, or on existing products. An assessment can also be made as a basis for modifying an existing product or developing a hygienically-suitable product series.

TITLE *Welded-on components.*

5 *Rounded edges and angles.*

6 *Rounded body.*

Our references

- REGENT Beleuchtungskörper AG
- FRIEDRICH SAILER GmbH
- HUBL GmbH Edelstahl-Blechverarbeitung

Our range of services

- Assessing conformity to relevant norms and guidelines for manufacturing under clean conditions (e.g. FDA, GMP, ISPE, ISO, EHEDG, DIN) with regard to cleanliness and cleanroom suitability for critical hygienic processes
- Developing optimization recommendations
- Compiling an Fraunhofer IPA qualification package comprising qualification certificate, qualification document and marketable self-adhesive qualification labels
- Accompanying product optimization developments for later use in hygienically critical areas
- Advising on GMP-suitable cleanroom planning and design
- Seminars and training courses on the subject of hygienic design

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For further information about our range of services, solutions and consultancy, please contact our experts.

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