Pharma & Biopharma

Requirements profile for WFI pumps
GMP- / FDA-compliant water systems

GEA engineering for a better world

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GMP- / FDA-compliant water systems

1. The media

Covering nearly two thirds of the earth's surface and occupying 75% of the human body; it is a crucial molecule for life; essential to the functioning of most known life-forms. Its multiple chemical properties make it both useful and versatile. Not only can water dissolve nearly anything, but it is also one of few materials that can exist as a solid, liquid and gas within a relatively narrow range of temperatures.

Water in its natural state is far from being pure; contaminated with bacteria, viruses, inorganic materials and even potentially deadly chemicals; our potable water must be prepared with extreme caution. In many processes highly-purified water is needed, especially for pharmaceutical solutions, bio and medical technology - e.g. dialysis, parenteral medicines and infusion solutions. This highly pure water per DAB 10 (aqua ad injectabilia) or water for injection (WFI) must be free of pyrogens and sterile with a germ threshold of <10 KBE/ml. In order to obtain this quality of purity several process steps must be taken. Selection of the materials and components such as pipes, fittings and pumps, line routing and control technology, sterilization and CIP capacity are crucial to creating the proper environment.

2. WFI Pump Standards

DIN EN 12462 Biotechnology and QHD

Pumps for use in high-purity water facilities (WFI) are subject to different regulations and higher safety standards than most other environments. In addition to being simple to operate, they must offer the highest biological safety, without harming the sensitive products.

One specified performance for such pumps is the European "DIN EN 12462 Biotechnology". It defines cleaning and sterilization capacity, leakage tightness, materials and their surfaces, with a special emphasis on surface roughness and treatment, as well as constructional details regarding the CIP-/SIP capacity of pumps. This standard also names the test to be applied to certify the cleanability of plant components for sterile processes. These are largely in compliance with the test method created by EHEDG.

Another test system for hygienic design and cleanability is "QHD" - Qualified Hygienic Design; developed by the specialist department "Sterile Process Engineering in VDMA" with the Chair of Apparatus and Plant Design of the TU Munich/Freising Weihenstephan. This test system - is broken down into two test stages. Stage 1 comprises the theoretical proof of hygiene-compatible design and stage 2 is verified by a standard test developed by the chair. This test method is based on the ATP test, with bioluminescence serving as an indicator for impurities of surfaces.

3. Understanding Hygienic design

The main criteria for cleanability of pumps include a cleaning-compatible construction, gap-free design of all inner parts and avoidance of dead spaces. The length-to-width ratio of gaps are defined at < 1.5 and the ratio of length to diameter for dead spaces is indicated at < 2. This applies, among others, to the sealing space of the slide ring packing and the arrangement, application and sizing of the residual emptying by diaphragm valve. The surface topography of the materials used is also integrated into the criteria for cleanability in terms of the physical properties and possible habitats for germs.

4. Hilge Pump Series Unique Design Concepts

The stainless steel centrifugal pumps of the GEA Hilge HYGIA and GEA Hilge CONTRA series meet the above Hygienic requirements in full, in terms of cleanability (cleaning-in-place), sterilizability (SIP) and design. This also applies to the materials used and their surface properties as defined by the DIN EN 12462. Each pump incorporates additional, unique design offerings, to enhance their hygienic design above and beyond the standard.

I. Designing the Single Stage Centrifugal

The Unique Hilge Shaft Seal

CIP-capable and sterilizable; freely placed in the product space as opposed to recessed into the shaft, with an O-ring seal against the housing cover and the impeller. This sterile sealing construction is available in single-acting and double-acting tandem arrangement, flushed pressure-free.

Slide Ring

In addition, GEA has developed a special solution for particularly sensitive applications: A double-acting slide ring packing in tandem design that can be operated with an overlaid pressure. This gasket, particularly innovative, combines the benefits of “real” back to back-slide ring packing with the requirements that sterile applications pose in particular to slide ring packing: Cleanability, sterilizability and no dead spaces. The housing gasket is inserted gap-free according to the criteria of sterile technology.

The Power of Delivery

The stainless steel pumps of the GEA Hilge HYGIA series range up to 500 gpm and delivery heads of up to 250ft.according to the criteria of sterile technology.

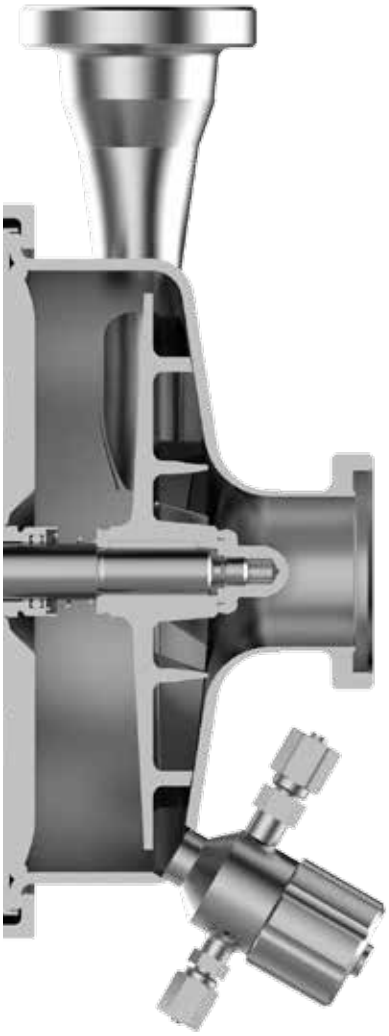

Figure 1: GEA Hilge - Unique Shaft Seal

II. Designing the Multi Stage Centrifugal

Unique Multi-Stage Impellers of the Contra

The housings and impellers in the multi-stage pumps are sealed, among others, by an O-ring seal in accordance with the criteria of Hygienic Design, gap-free with defined application pressure and with a metal stop. This ensures absolute cleaning capacity and sterilization in CIP-/SIP-processes and, as a result, safety for the user and operator of a system with sterile process control. Figure 2: Section of the Contra (4-stage) In accordance with the high quality standard, the forged impellers have milled contours for optimal efficiencies as well as very good NPSH values and smooth running. The entire construction, including the inner sterile GLRD is exclusively according to the criteria of Qualified Hygienic Design (QHD, GMP, FDA).

Figure 3: The CONTRA series with Adapta bearing support

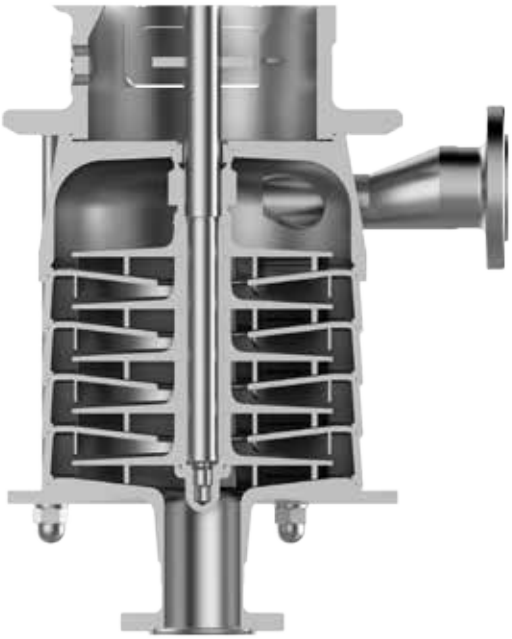

Figure 2: Cross section of a Contra (5-Stage)

Figure 4: The CONTRA series in the vertical Adapta design, fully drainable

The Power of Delivery

The stainless steel pumps of the GEA Hilge CONTRA series range up to 240 gpm and delivery heads of up to 525 ft.

III. An Adaption that Fits

In addition to the classical block design GEA Hilge Hygia and CONTRA series come with the Adapta® block option. This Adapta®-block (Figure 3) connects the pump to any IEC standard motor or Nema motor for the US market without use of a stub shaft, but with an elastic, short serial coupling. This ensures simple maintenance and permits removal of the motor without disassembly of the pump. Subsequent costs are minimized and the wet part of the pump can be left in the system (validation). This is particularly beneficial for any additional sterilization cycles and validations that may become necessary if the pump is opened or dismantled.

IV. Integrated VFD Options for Total Control

Using frequency converters between the pump and the supply grid adjusts the speed and therefore the performance of the pump, permitting free definition of the delivery head H and the displacement volume Q. Recent developments in the power electronics sector make it possible to merge the components frequency converter and electric motor. Without any change to the procurement costs for frequency converters, integrated versions are preferable due to the lower connection effort and space requirement. The relocation of intelligence from the control cabinet into the field is described in the chapter on „decentralized peripherals“. Field bus systems connect individual subscribers and permit access to functions and data from one control level. The pump with integrated frequency converter is prepared for decentralized use and becomes a transparent actuator in the WFI loop. It determines a comfortable and economically efficient process.

Figure 5: GEA Hilge HYGIA series with integrated variable frequency drive (VFD)

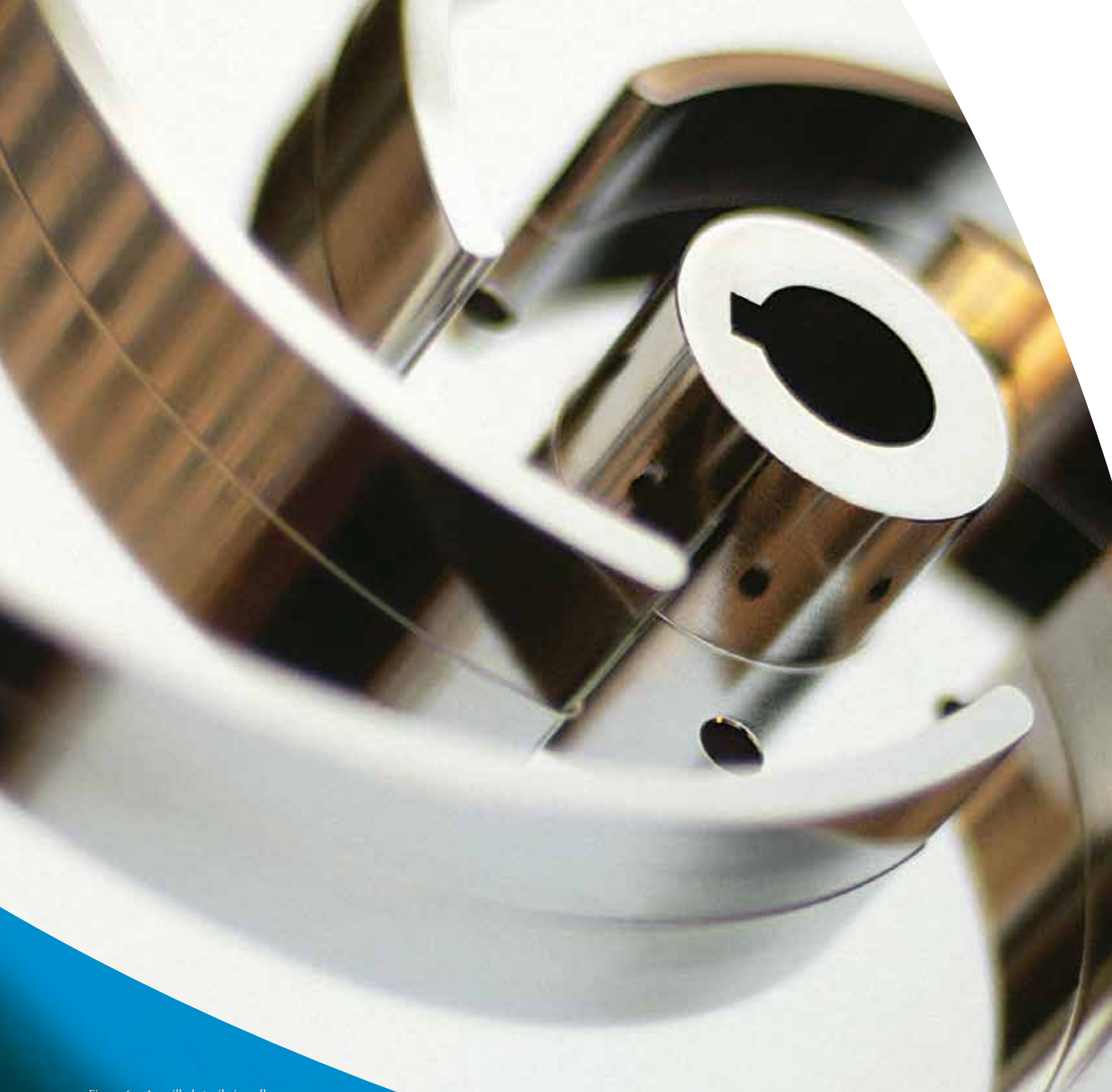

Figure 6: 3A3 milled sterile impeller

5. Meeting Hygienic Design

Fully CIP-able EHEDG

Tested and accepted for their cleaning capacity according to the provisions of the European Hygienic Equipment Design Group (EHEDG) by the internationally renowned research center Weihenstephan of TU Munich, GEA also has the right to use the QHD-sign of the specialist department for sterile process engineering in the VDMA. These tests not only confirmed that the pumps can be cleaned without residue by cleaning-in-place, but that, in contrast to the reference tube, no residual contamination could be documented anymore either. This draining capacity is largely achieved with a diaphragm valve at the bottom-most location of the housing. This perfectly ensures safety of a sterile process control. Since this option is not a perfect technical solution in multiple-stage pumps, the GEA Hilge CONTRA is also offered in the vertical position. The vertical installation guarantees absolute emptying via the suction socket. To ensure residue-free discharge of the liquid from the pump, all product-contacting components have been applied with the corresponding radii and inclinations, including the eccentric pressure piece. The vertical installation additionally saves space within a system.

DESIGN AND STERILE STANDARD

Surface roughness R_a	Material	Impeller, weldseams
≤ 0.8µm	1.4404/1.4435	Impeller casted
≤ 0.8µm	1.4404/1.4435	Weldseams ground, impeller milled
≤ 0.8µm	1.4435	Weldseams ground, impeller milled
≤ 0.8µm	1.4435 Fe < 1 %	Weldseams ground, impeller milled
≤ 0.4µm	1.4404/1.4435	Weldseams ground, impeller milled
≤ 0.4µm	1.4435	Weldseams ground, impeller milled
≤ 0.4µm	1.4435 Fe < 1 %	Weldseams ground, impeller milled

The Right Materials

The sterile pumps of the GEA Hilge HYGIA and GEA Hilge CONTRA series use only stainless Cr-Ni-Mo special steels in the low carbon rolled steel quality 316L. This material is specifically picked and selected to prevent any possibility of rouging. The product-contacting surfaces are mechanically ground, polished and electrochemically finished to the surface standard of the defined sterile class. This process of electro polishing is imperative for sterile technology since a surface that has only been mechanically polished is predestined to hiding contaminants and corrosion. Electro polishing levels out any peaks and valleys left behind by mechanical polishing, resulting in a much smoother, more corrosion resistant and low-particle surface. All static and dynamic gaskets are FDA compliant and have been chosen according to the requirements of their hygienic fitting and design, as well as their resilience, and ability to meet CIP and SIP-capacities. Static gaskets: are standard EPDM with options of PTFE, FEPS and Kalrez. Dynamic gaskets are also FDA compliant. The standard connections are TriClamp but aseptic/Sterile connections are available.

Documentation

Documentation is an important part for validation and FDA approval of a pharmaceutical system. GEA supplies the following option for the sterile pumps of the GEA Hilge HYGIA and GEA Hilge CONTRA series as a certified operation specified standards:

- Test report/acceptance minutes according to DIN EN 10204, 2.2
- Material certificate according to DIN EN 10204, 3.1
- FDA declaration of conformity for the gasket materials and other materials used
- Measuring surface roughness
- Measuring ferrite content
- EHEDG test certificate
- QHD certification
- Further inspections and certificates are available on request.

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a better world

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GEA Group is a global engineering company with multi-billion euro sales and operations in more than 50 countries. Founded in 1881, the company is one of the largest providers of innovative equipment and process technology. GEA Group is listed in the STOXX® Europe 600 Index.

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