

## Apparatuses, pressure vessels for the pharma and biotech industry

KASAG Swiss AG has a wide range of experience in the construction of apparatuses, pressure vessels and components for the pharmaceutical and biotech industry. Pharmaceutical and biotech equipment are designed and manufactured in accordance with your requirements and made of stainless steel and special materials. Thereafter, the products are grinded and electro-polished to customer specifications. Finally, comprehensive non-destructive testing is performed. All of the materials, processes and procedures used are documented in a detailed QA documentation and traceability is given at any time. You can rely on KASAG.



### The range of services that we provide consists of:

- Apparatuses with agitator, pressure vessels, reactors
- Mobile or stationary process or batch containers
- Storage tanks, WFI (Water for Injection) or CIP (Cleaning in Place) containers
- Fermenters, bioreactors
- Bulk and transport containers
- Sheet metal and welded structures which come into contact with products

The highest manufacturing quality with optimal hygienic cleaning options (CIP cleaning-in-place/SIP sterilization-in-place) come as standard at KASAG.



### This includes:

- The correct processing of materials such as 1.4404, 1.4435 BN2 or also in special materials with tested and recorded ferrite content
- Impeccable welding seam quality and documentation
- Tested and recorded surface processing in grinded, highly polished or electro polished versions with a roughness of up to Ra 0.2  $\mu\text{m}$
- Installation of cleaning equipment within the pressure vessels for optimal cleaning processes and complete discharge in accordance with ASME-BPE
- Extensive test methodology for intermediate testing and final FAT, including: x-ray RT, dye penetrant testing PT, visual inspection VT, material testing / positive material identification PMI, helium leakage testing LT, riboflavin tests, total discharge, pressure testing up to max. 1000 bar, surface roughness testing Ra / Rz, ferrite measurement Fe, wall thickness measurements, video endoscopy and pressure loss testing (liquids)

We use automated and manual welding machinery as well as a modern orbital welding equipment to weld our components.



## Apparatuses and pressure vessels for the pharma and biotech industry for worldwide use



### Validation / Qualification

We support you with regard to the cGMP guidelines for the validation/qualification of equipment components produced by us for the manufacture of pharmaceutical and biotechnical products (DQ, IQ, OQ, PQ).

In addition to the FAT (final acceptance test) in our factory before delivery and the SAT (site acceptance test) on site, our scope of delivery includes the following areas:

#### **Design Qualification, DQ**

Verification to ensure that the quality-relevant, GMP-related requirements were taken into consideration during the design of the equipment:

- Materials
- Dimensioning / design

#### **Installation Qualification, IQ**

Documented evidence that critical equipment has been implemented and installed in compliance with customer requirements and statutory provisions:

- Calculation and documentation in accordance with regulations
- Safety equipment, risk analysis
- Accessibility for maintenance and cleaning

#### **Operational Qualification, OQ**

Documented evidence that critical equipment operates in compliance with customer requirements within the stipulated limit values throughout the entire work area:

- Leak tightness
- Mechanically moving parts
- Safety equipment
- Operating parameters

#### **Certifications, manufacturer approvals**

ISO 9001 / ISO 3834-2

PED (EN13445 / AD-2000)

ASME (U-Stamp, Code Section VIII Div. 1)

China Stamp (A1), China License

TP TC 032/2013 (EAC), Customs Union

In addition to our existing manufacturing approvals, we are able to perform the respective approval procedures for almost every country around the world (e.g. Singapore, Japan, Malaysia, Canada, etc.).

