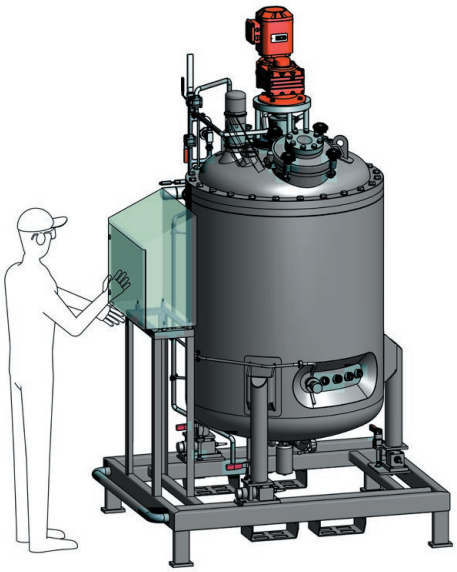
Plant, apparatus, pressure vessel construction

KASAG

Skids, modules for the pharmaceutical-biotechnological industry

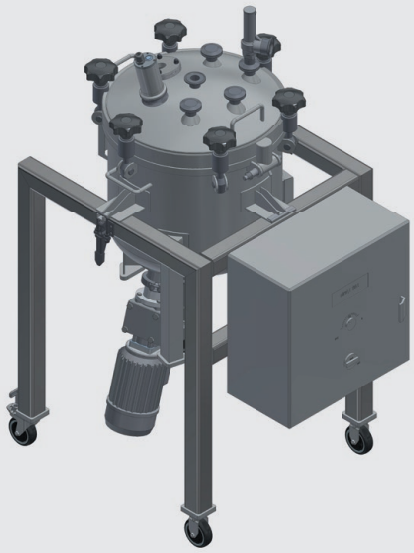
KASAG Swiss AG offers concepts, planning, manufacturing and qualification of customised process technology for the production of medicinal products in compliance with cGMP guidelines. As expert designers of process facilities, automation systems, machinery and containers, we deliver individually designed skids and modules to complement your process line. Delivery from one source, from basic engineering to the commissioning of the plant, including detailed engineering as well as production and assembly. To the perfect solution with KASAG.

Concept development and planning (basic engineering, detailed engineering)
In the concept development and planning stage, the key features of the plant are defined. Documents such as the flow and system layout, diagrams, P+I-diagram, functional descriptions, technical specifications, schedules are developed. The strength calculations for apparatuses, pressure vessels, pipes, etc. are carried out in compliance with the various regulations, and the material availability is checked. Furthermore, the optimum position of the cleaning nozzles, for example, complying with their corresponding use, is defined or a special focus is placed on the selection of the correct piping dimensions, valves, sensors, which we take into consideration for the design. In this way, each design element and each calculation is checked to ensure safe operation of the plant. In this process, we rely on our long-standing practical experience and our comprehensive expertise in this field.



Production processes
All our apparatuses, pressure vessels and the assembly of skids, modules are produced in our workshops to ensure maximum quality. Benefits of using skids, modules are the detailed pre-qualification during the FAT (final acceptance test) in our factory, the easy on-site assembly and the significantly shorter SAT (site acceptance test) and production start-up time. All this saves you valuable time.

Testing procedures
For testing the plant parts, skids, modules, we offer a wide range of testing procedures such as radiography RT, material testing / positive material identification PMI, helium leak testing LT, Riboflavin test, pressure tests up to max. 1000 bar, surface roughness Ra/Rz, ferrite measurements Fe, video endoscopy, etc.



Skids, modules for global use in the pharmaceutical-biotechnological industry.

Validation / Qualification
The skids, modules are qualified and documented as far as possible in our factory in the course of the FAT. We support you concerning the requirements from the cGMP guidelines in the validation / qualification of the plantparts manufactured by us for the production of pharmaceutical and biotechnological products. In addition to the FAT (final acceptance test) in our plant prior to delivery and the SAT (site acceptance test) on-site, our scope of supply includes the following fields:

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

Support with regard to the cleaning qualification, CQ
– Pre-qualification via Riboflavin test during the FAT
– Support with regard to the inspection of cleaning on-site

Performance Qualification, PQ
– Support regarding the technical aspects of the scope of supply

Risk analysis
– Support with regard to the risk analysis for the operating company. For example in accordance with HAZOP.
– Support with regard to the definition of the explosion-endangered areas and specification of the ATEX requirements of the corresponding plant parts

Our 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.).

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