

UNITS AND PLANTS

SKIDS

VESSELS

DESIGN

ENGINEERING

INSTALLATION

AUTOMATION

QUALIFICATION

UNITS AND VESSELS FOR PHARMA AND BIOTECH.

RAFF + GRUND GMBH

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YOUR PARTNER FOR UNITS, SKIDS AND VESSELS

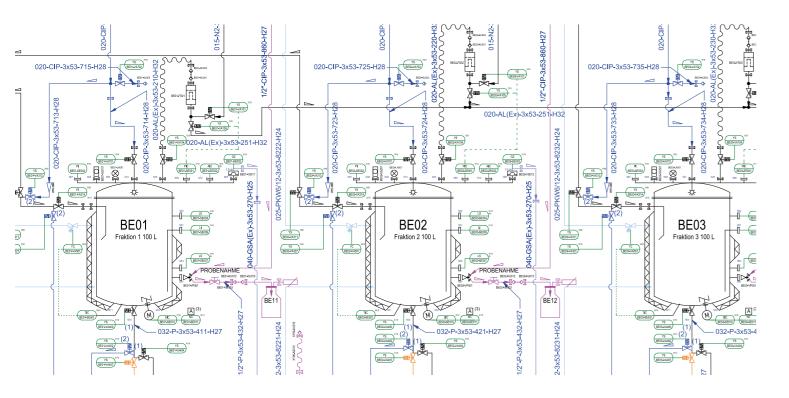
Raff + Grund is an experienced manufacturer of Raff + Grund focuses on the highest quality in all its skids, vessels and plants for the pharmaceutical and products and services. The skids, vessels and equipbiotechnology industries. The company specializes ment are manufactured under strict quality controls in the process engineering design, construction, and meet all relevant international standards. The manufacture and qualification of plants as well as company has state-of-the-art manufacturing facility vessels and has many years of experience and exper- and an experienced team of engineers and technitise in this field.

Raff + Grund's product portfolio includes a wide range of solutions designed to meet customers' specific requirements. These include skids and vessels as well as customized solutions for complex process plants.

cians to ensure that all products meet the highest requirements.



OUR SERVICES FOR PLANT AND VESSEL CONSTRUCTION



PROCESS ENGINEERING DESIGN

- Concept design
- Process engineering calculations
- P&ID

ENGINEERING

- 3D design of the units
- Strength calculations
- GMP design
- ATEX design

VESSELS

- According to PED, ASME, SELO
- Stationary, mobile, on skid
- Welding (automatic, manual)
- Grinding (automatic, manual)
- Pickling and electropolishing

PIPING

- Isometrics
- Installation on skid and on site
- Assembly
- Orbital welding
- Endoscopy

AUTOMATION

- Hardware design
- Software / FDS
- Wiring
- Connection to Scada system
- ATEX applications

FAT / SAT

- VT-/ PT testing
- Roughness test
- Riboflavin test
- Spectral analysis
- Agitator test

QUALIFICATION

- DQ
- IQ-/ OQ-FAT
- IQ-/ OQ-SAT
- PQ













PROJECT EXAMPLES: BIOTECH PLANT

PROJECT SCOPE

- P&ID
- Design and calculation
- Complete 3D planning
- Construction, installation, piping
- Qualification (DQ, IQ, OQ)

- 15 vessels on 7 skids
- Over 350 valves
- 180 measuring instruments
- Diverse pumps, heat exchangers, filters ...
- 580 meters of piping

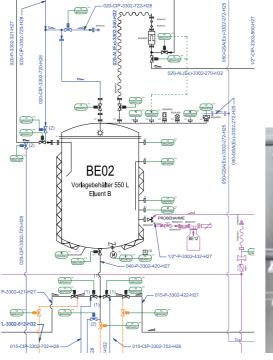






Design, engineering and construction of a pharmaceutical plant. The plant consists of 15 vessels and a CIP system. Built on 7 skids in 3 rooms including the piping of the plant on site.

Special attention was focused on the cleanability of the vessels as well as the product piping. The plant was built in compliance with the Pressure Equipment Directive (PED), the Machinery Directive (MD) and the ATEX Directive (ATEX). Including start-up and qualification of the plant.







PHARMALINATION FOR mRNA-DRUG SUBSTANCE PRODUCTION

PROJECT SCOPE

- 8 mobile pharmaceutical vessels with 7 L to 190 L volume
- 1 stationary preparation tank on load cells with 350 L volume
- 1 CIP system with central control
- Stationary preparation tank and CIP unit as skids
- Wall panel for docking the mobile vessels
- Touch panel in the clean room to control the system
- 1 CIP station for cleaning, several stirring stations incl. cooling
- Incl. automation, start-up and qualification



Cleanroom with preparation and mobile vessel



CIP unit

MOBILE VESSEL AND CIP UNIT FOR STERILE BATCH PRODUCTION

PROJECT SCOPE

- 4 mobile pharmaceutical vessels with 70 L and 260 L volume
- 1 CIP-/SIP plant with central control as skid in the technical room
- Cleaning (CIP) and sterilization (SIP) of the mobile vessels incl. protocol generation
- Connection of the CIP system to media supply and piping to the clean room
- Wall panel for docking the mobile vessels
- Touch panel in the clean room to control the CIP system
- 1 CIP-/SIP station for cleaning and sterilization, 2 stirring stations for batch preparation
- Incl. automation, start-up and qualification



Picture above: Mobile vessel with touch panel in the clean room

Pictures below from left to right: Mobile vessel on cleanroom floor scale

CIP system





VESSELS FOR BLOOD PLASMA-BASED MEDICATIONS

PROJECT SCOPE

- 7 stationary pharmaceutical vessels
- Preparation vessels on load cells
- 1 funnel with receptacles for a lifting unit
- Cleaning station for funnels
- Magnetic agitator with fanless stainless steel
 drive



2 RECIRCULATION TANKS 50 L WITH HEATING/COOLING

PROJECT SCOPE

- Mobile tank in GMP design
- Tank with three walls and temperature control
- Control for cooling + heating via pump and flow heater
- Magnetic stirrer, various sensors for pH, conductivity, pressure, temperature ...





MOBILE VESSELS FOR THE PHARMACEUTICAL INDUSTRY

PROJECT SCOPE

- Mobile vessel in GMP design
- Heatable/coolable via half pipe coils or double jacket/pillow plates
- Magnetic stirrer, various sensors for pH, conductivity, pressure, temperature ...
- Product contacting made of material 1.4439



PROCESS UNIT FOR THE COSMETIC INDUSTRY

PROJECT SCOPE

- Process tank with 3000 L working volume
- With coaxial agitator, homogenizer, vacuum pump
- Vessel cover with coaxial agitator can be lifted hydraulically, vessel can be turned electrically
- Design, fabrication of the vessel incl. frame and cladding, automation





RAFF + GRUND - THE SPECIALIST FOR PHARMACEUTICAL AND BIOTECH PLANTS

Our company consistently focuses on quality and attaches great importance to customer orientation during the entire order processing. With a high manufacturing depth, we can guarantee the quality of our products and flexibly implement customer requirements.

Based on the process engineering design, we construct our vessels and plants with 3D CAD systems. In our vessel manufacturing facility, the vessels are manufactured, ground, pickled, electropolished and tested. Skids piping is orbitally welded and assembled in the factory or at the customer's site.

Automation is performed by specialists including preparation of FDS (Functional Design Specification), SDS (Software Design Specification) and HDS (Hardware Design Specification). We are also able to support our customers during assembly, startup and qualification (DQ, IQ, OQ, PQ) by experienced personnel.



RAFF + GRUND MANUFACTURES THE VESSELS FOR CUREVAC'S CORONAVIRUS VACCINE

CureVac's mRNA-based COVID-19 vaccine CVnCoV comes from Tübingen, while the vessels in which the vaccine is produced come from Freiberg am Neckar. As part of the cooperation, vessel specialist Raff + Grund has now completed three more lines of vessels for the biopharmaceutical company. "Innovation in the pharmaceutical sector meets state-of-the art technology in vessel construction" - this is how the cooperation between CureVac and Raff + Grund can be described.

The mainly mobile vessels are all equipped with hygienic magnetic stirrers, modern sensor technology and controls. In addition to the mobile vessels, skids (permanently installed vessels with readypiped pumps, heat exchangers, sterile filters, etc.)

are manufactured for preparation as well as for CIP (Cleaning in Place).

"We chose Raff + Grund not only because the company is considered one of the most innovative in pharmaceutical vessel construction, but also because it provides a reliable service from the preparation of the quotation, through order support, the entire manufacturing process, to acceptance and documentation," said Heiko Klever, Head of Process Engineering at CureVac. "What is remarkable is the fast and uncomplicated cooperation, as well as the always rapid response and implementation. As a result, the delivery date of the further plants can be realized even faster than originally planned."

(Press text short version)