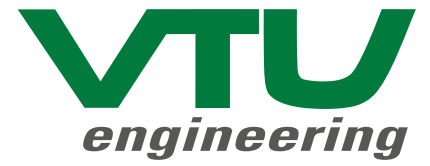


Experience
responsibility



Engineering

for Pharmaceuticals
& Biotechnology

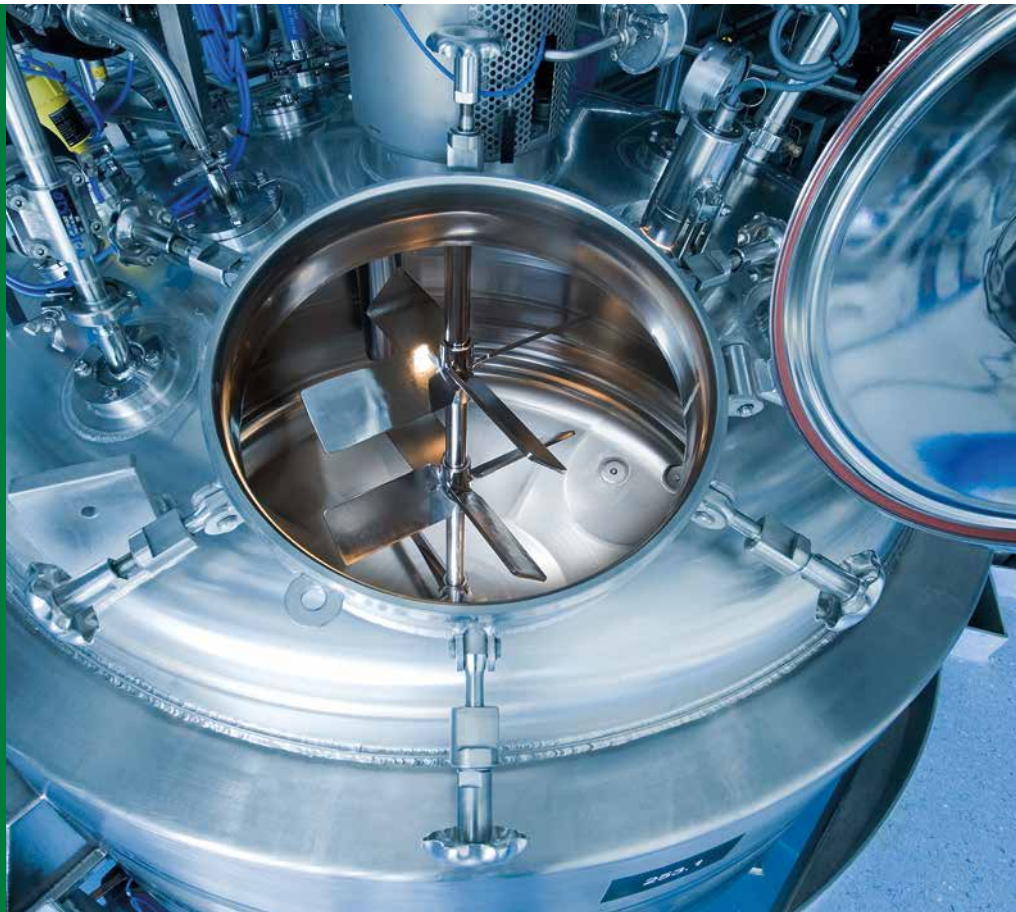


Pharmaceuticals
Biotechnology
Life Sciences



Our technical know-how and project management accompany you from the scale-up of the laboratory systems up to the start-up of the industry scale plant in all areas of the pharmaceuticals industry, especially for:

- active ingredient syntheses
- fermentation with micro-organisms or cells
- downstream processing
- blood plasma fractioning
- liquids and solids production
- sterile filling and lyophilising
- ultra-pure media and CIP systems
- clean room facilities
- recycling of solvents
- treatment of exhaust air and wastewater
- systems with explosion protection requirements



Company Portrait

VTU Engineering plans process plants for industry in the pharmaceutical, biotechnology, chemical, metallurgy, oil and gas and mineral sectors.

Their work focuses on process engineering and project management from the conceptual design to a successful start-up. Furthermore, VTU Engineering delivers turn-key, customised solutions, e.g. for solvent recovery or industrial wastewater treatment.

The process engineers, chemical engineers and biotechnologists of VTU Engineering apply their extensive knowledge in a many different process plants. You too can benefit from our high level of technical competence and know-how in project management.

VTU Engineering's sustained success since it was established in 1990 rests on two pillars.

High qualified engineers

In addition to their technical know-how, VTU engineers excel through high capability for teamwork in many different project environments. Permanent training and a proven knowledge management system are a guarantee that our customers receive best expertise.

Customer orientation

The objective of the project is the objective of our work. Achieving our customers' goals and providing solutions of excellent quality and benefit are top priorities of our project teams. Consequently, a very high percentage of our customers cooperate with VTU since many years.

Experience and Creativity in Harmony with the Regulations

In contrast to other industries, the production of pharmaceuticals and similar products is marked by a number of particular aspects. The types of manufacturing processes used for the active ingredients diverge highly, ranging from isolation of natural products, continuing with chemical syntheses up to cell cultures. Highly complex separation steps are usually required to achieve the required purity qualities. One particular challenge for planning is the fact that many of the systems are one-of-a-kind. There is one dominating parameter that has priority over everything: GMP compliance. The qualification of plants and validation of processes determines the product development from lab testing

up to industrial scale manufacturing. This results in several unique requirements for providers of planning services.

- Detailed industry knowledge for the selection of GMP compliant equipment and suppliers that are cost-optimising: as good as necessary, as cheap as possible.
- During the planning, activities taking place parallel to the qualification must be observed.
- An industrial scale implementation of the plant is very closely tied to the tested process steps of the clinical phases. New approaches – the buzzword is PAT – allow more flexibility for an intelligent scale-up.

Process Development

We have many years of experience in planning industrial plants and we provide process development as a symbiosis of theory and practice. In the process, the know-how and experience of the customer is included in the process development. We perform tests and measurements in our technical centre as well as directly at the customer's site or in the labs of university institutes. Besides plant-related issues during process development, the process development phase also includes process characterisations which lead to the process validation later on during the course of the project.

Conceptual Design & Operator Requirements

VTU prepares the operator requirements together with the client and incorporates know-how from plant technology and qualification starting in this early, important stage. An optimum plant concept is developed based on this, supported by the use of comprehensive software tools for process simulation and process risk assessment such as, for example, REXS (VTU's own development), Aspen Plus and ChemCAD.

As a prerequisite for these activities, process-related expertise and experience with work procedures in pharmaceutical plants must come together in order to optimally design the material and personnel flow and hence the hygienic zones concept in accordance with all GMP requirements. This industry-specific know-how and a large portion of creativity lead to concepts that result in resource-optimised plant projects.



- The dictates of the time-to-market often make it necessary to start planning the plant before process or product development has been completely finished. Perfect project management is required here. Buzzwords like concurrent, fast track or flash-track engineering were coined for this.

We know these requirements very well due to years of experience and the qualification of a great variety of pharmaceutical systems.

Basic Engineering

In our view basic engineering is defined as the elaboration of all subject areas within the project in order to achieve cost certainty of +/-10%. VTU prepares the Piping and Instrumentation Diagrams (P&ID), the supply concept of the processing plants including all ultra-pure media, the automation concept, the construction and layout plans with the personnel and material flow and the HVAC concept, especially in connection with the clean room zones. Process engineering, works standards, requests from production, start-up and shut-down, unusual operating situations, safety aspects, process control, service friendliness and many other items must be taken into account. These are the core documents passed on to implementation planning (detailed engineering). The software tools are orientated around the ones that are common in the field of plant planning in order to guarantee the greatest possible compatibility.

GMP Services

VTU Engineering performs all the necessary qualification and validation services for plants and processes in the pharmaceuticals industry, including support during inspections and audits. Together we define customised risk-based solutions for your systems that span the entire development, planning, production and validation lifecycle. In like manner, we audit existing systems for GMP conformity. GMP Services: creation of qualification concepts, process characterisation, plant qualification, validation of automation systems, process validation, audit preparation and audit accompaniment, employee training, temperature mapping and much more.

EPCM Services / Project Management

The entire portfolio of our expertise is highly in demand in many projects in order to have a single responsible contact partner for the entire planning of a processing plant. VTU has the in-house knowledge to provide you with all key planning steps, and integrates approved partners as far as necessary. Our experience in project management and technical controlling ensures that the project will run smoothly. General planning with VTU means one contact person with expertise, team skills, project management and personal involvement.



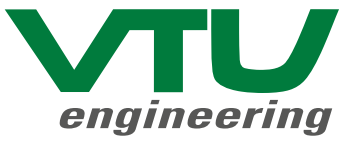
Detail Engineering

The results of the process engineering have to be detailed to be ready for construction. VTU will provide installation plans, steel construction master drawings, 3D piping models and isometric piping diagrams, detailed specifications of equipment/instruments/valves, instrumentation and control equipment planning, tenders, bid comparisons, etc.

Our technical controlling ensures optimum interaction between the various subsections.

Construction Management & Commissioning

Our experienced construction managers will prepare installation and construction schedules and control all construction site activities to ensure contract-compliant and timely completion of your plant. VTU process engineers will plan the commissioning meticulously and carry it out together with your staff and, where appropriate, with suppliers of packages.



Pharmaceuticals

Biotechnology

Life Sciences

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Engineering

for Pharmaceuticals & Biotechnology

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office@vtu.com