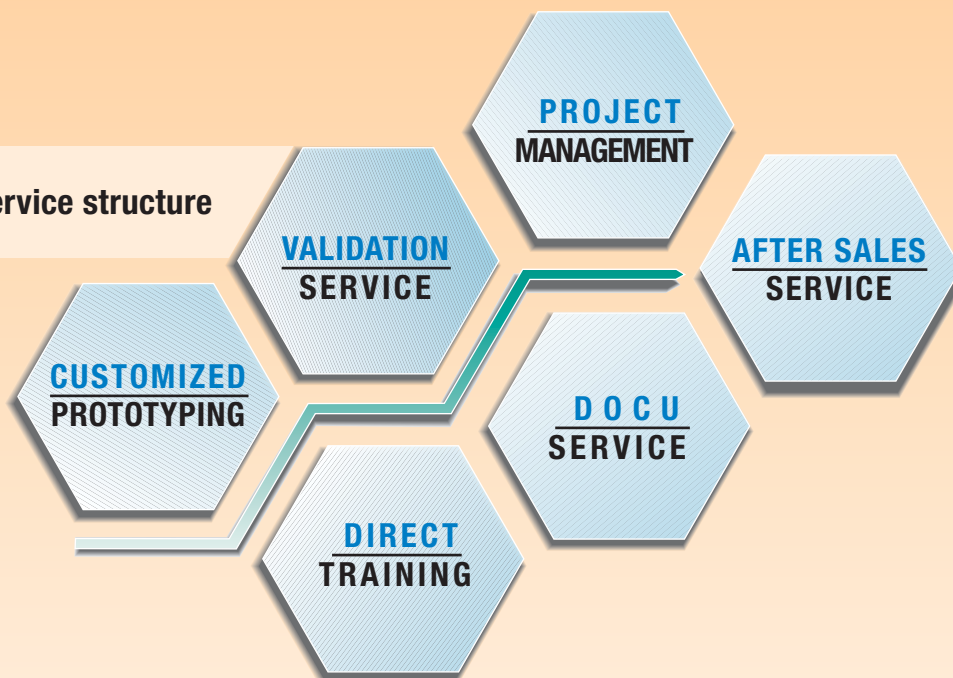


Modular service structure



Full service provided for high-tech lines.

At Höfliger the support by no means ends with the delivery of the equipment. We are ready to guarantee the overall efficiency of a production facility on a long-term basis. Therefore our service performance must be constantly organizationally and technically coordinated with our customers' requirements.

The most important criteria are:

- Fast reaction time
- Permanent reachability
- High employee competence
- Extended service standby

The service guidelines are oriented 100 % on the market's requirements. Plant operators tend to increasingly require a central partner for the coordination of all service activity. Parallel to the multitude of the different service offerings and the coordination of service, our customers are interested in a high degree of specialization.

In appropriate cases our customers would like to have the technician on-site who has detail knowledge of the machine and all of its components.

This makes a customer orientated organization possible. Preventive service, in the form of customer training courses, production monitoring, Tele-Service and maintenance contracts, is an integral component for ensuring the expected operational reliability of the equipment and the technical competence of the operators. In questions of service, we cooperate with our customers as partners in the quest for obtaining an optimal platform for maximum efficiency and availability.

With the use of internal GMP test areas we offer a completely new service sector in the framework of our Pharma-Service. Here the possibility exists of testing new production equipment under pharmaceutical conditions with original product – up to the production of stability samples.

Customized Prototyping Project Management

Project planning of new processes.

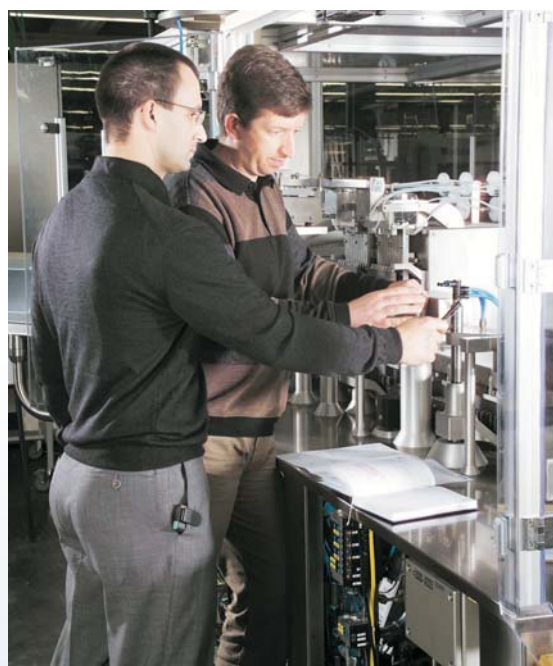
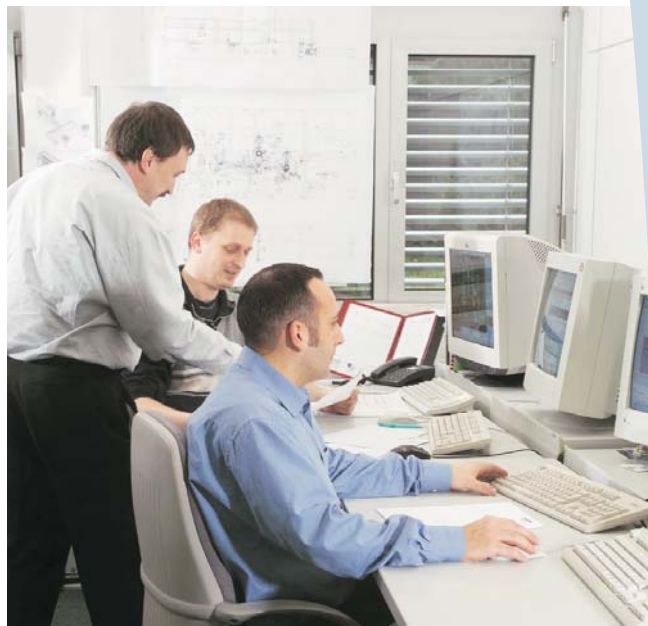
Project planning of detailed processes.

Project planning of detailed processes is crucial for the successful facility concept, especially during new equipment development. At this time decisions are being made that can affect the further development of a customer's product.

It is the objective of project planning to develop technical solutions, jointly with the customer, for a realistic project work flow. As a result of supporting a large number of pharmaceutical customers, technologies are often asked for that fulfil the requirements of production under clean room conditions and GMP criteria.

Motion simulations are created using 3D-CAD in order to clarify the functionality of the equipment used in the project. In order to evaluate risks and feasibility the project planning department designs and builds test configurations and testing stations.

What distinguishes us when planning large facility projects is: That we are capable of supporting our customers with the realization of global production.



Support from A to Z

Project management:

With projects, which increase in complexity, a higher-level project management becomes more and more important. This project management gives transparency to all project steps. Complex procedures and the milestones aimed at by the customer can be coordinated and synchronized with each other. The dynamic controlling of the project progress replaces the rigid schedule and the immovable time window. The construction, manufacturing and installation of individual high-tech facilities require the meaningful bundling of competences for short and medium-term goals.

Production monitoring:

Beyond project management an additional service offering is available after start-up for new equipment developments. The facility is commissioned by experts, optimized and if necessary, monitored until the new production process is integrated at our customers.

Validation Service

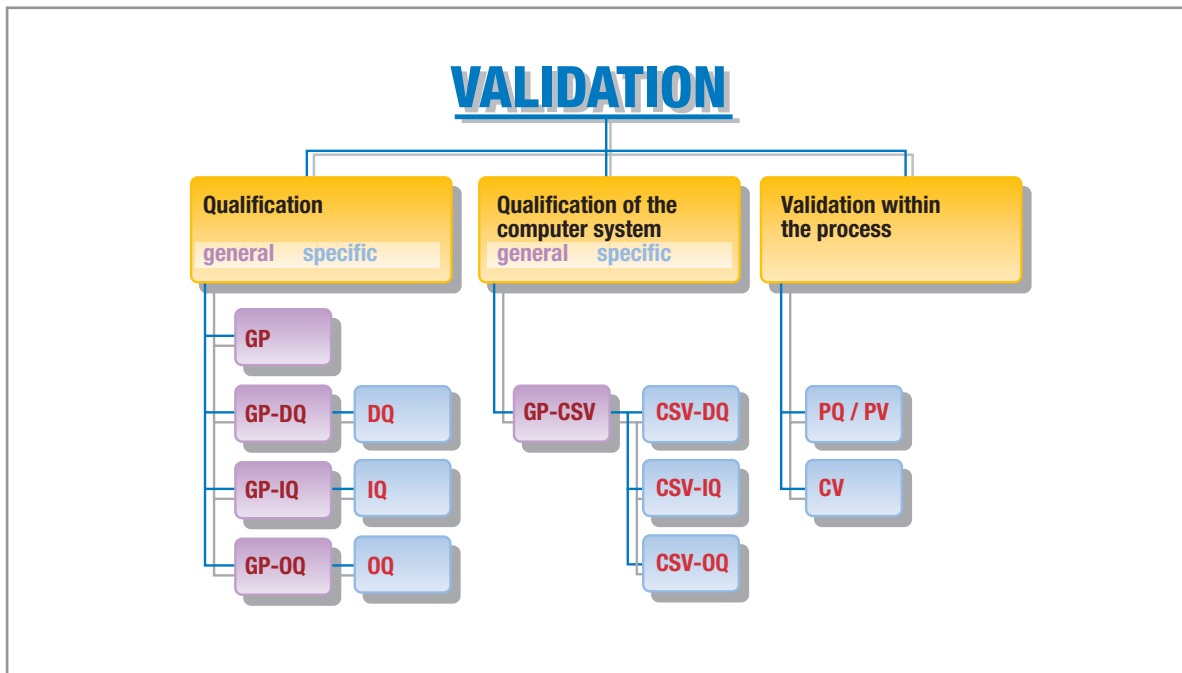
Qualification services on a modular basis.

Our qualification and validation service provides our customers at the very beginning of a project with the possibility of performing and documenting the appropriate validation steps parallel to the development process and the construction of the line.

Contrary to normal practice our qualification package is not just an extension of the documentation, but a real qualification service, the objective of which is to keep the allocation of the resources of our customers for the qualification package as small as possible. So we not only draw up the test documentation of the individual qualification phases



(DQ, IQ, OQ and CSV), but we also integrate these into a GMP-compliant overall framework. This enables our customers to pass a GMP inspection without any additional documentation expenditure. Taking the relevant requirement of our customer as the starting point, the scope of the qualification measures that we are to perform is defined in advance.



The entire service package comprises the following elements, which can be individually structured and combined with one another:

- Risk analyses (FMEA) and risk assessments.
- Design Qualification (DQ).
- Installation Qualification (IQ).
- Operational Qualification (OQ).
- Computer System Validation (CSV) including 21 CFR Part 11.
- Customer-specific qualification packages for specialized machines (optionally on customer templates).
- Practical advice provided by our validation manager, who is experienced in the pharmaceutical industry.
- Design specification, separate for hardware and software.
- Training of the responsible validation personnel in advance of the installation of a new line.
- Holding of GMP training courses for Höfliger employees and interested customers.

Direct Training Documentation Service

Direct Training Know-How Transfer.

The organization and performance of individual customer training courses at Höfliger or at the customer's plant is a service that is in great demand. Experienced and very well instructed trainers impart the technical machine know-how to the customer's operating personnel and technicians.

This makes possible the optimal transfer of know-how from our development personnel to the customer's maintenance and operating personnel. Detailed training documentation, specially drafted for the customer's line, is handed out to each training participant upon completion of the training course.

As we address various target groups in the training course, we subdivide the training content into basic and advanced training. Seminar participants in the basic training course are trained in operation-related matters pertaining to the machine functions and receive a basic overview of the machine control system.

Documentation Service Quality and product security.

The technical documentation is part of the standard scope of supply of each machine. It informs the plant operator about the correct handling of its line and is therefore a module of our line-related service program.

The instructions are generally structured in accordance with the current machinery directives. As an external symbol our lines are provided with the CE symbol in connection with a conformity declaration or, if required, a manufacturer's declaration. Our technical editors are trained and inform themselves for each and every line about the individual functions and the main procedures. This process involves close collaboration between the technical editor, designer and installation technician.



Topics are dealt with that cover the daily handling of the machine, size changeovers and the treatment of error messages.

In contrast, advanced training is a special training course for technicians who are responsible for the routine servicing and maintenance. Accordingly the instruction on the software and hardware components and the relevant subassemblies goes into more detail.

It is our endeavor, to place at the disposal of the customer detailed knowledge about the basis necessary to draft its operating instructions.

The overall scope of the technical documentation includes:

- Structured operating and servicing instructions in German and in the relevant national language.
- The conformity declaration and manufacturer's declaration.
- Instructions and specification sheets of bought-in components, sensors and electrical components.
- A set of electrical plans, pneumatic plans, hydraulic plans, as well as cam and lifter plans.
- A printout of the PLC program.
- A list of all fault messages with information on troubleshooting.
- Information about the danger points.
- Documents on size-changing including size setting plans.

After Sales Service

After Sales Service – for integral processes:

After sales service is gaining in importance not only from the standpoint of the customer. The main task in this case is to present the customer with a quotation tailored to meet its needs over the entire life cycle of its line. The wishes of our business partners are already recorded at the initial stage of a project and are realized in accordance with an agreed time schedule.



Transparency and logic through Spare Parts Management.

When operating production lines all moving components are subject to a certain service life – measured by way of the dynamic load imposed on the parts. This inevitably causes wear and the replacement of the corresponding parts. This is a plannable process, which can be taken into consideration in advance.

The importance of the supply of spare parts in connection with installation deployments is an important factor in the field of service. An individualized service program is already drawn up at the time of delivery of our lines on the basis of the bill of materials and our empirical values.

If a spare part is required that goes beyond the scope of routine supply, we provide fast and unbureaucratic help.

- **Service contract:**
maintains the productivity of the machine.
- **Service hotline:**
guarantees constant availability on service matters.
- **System telediagnosis:**
for remote access to the control system.



All the services relating to our spare parts service:

- Experienced and technically qualified spare parts advisors.
- A central contact person.
- Fast availability of service technicians on site.
- Systematic stocking of the customer's own spare parts stores by supplying it with spare part packages.
- Parts production with modern equipment in our own company.
- A dense network of suppliers, due to which there is access within an extremely short time period to commonly required bought-in parts.
- An extensive parts warehouse for the supply of standard components.
- Advising of our customers regarding a rationally structured, in-house spare parts warehouse that is individually tailored to the customer.
- Local US service with its own suppliers and parts production.