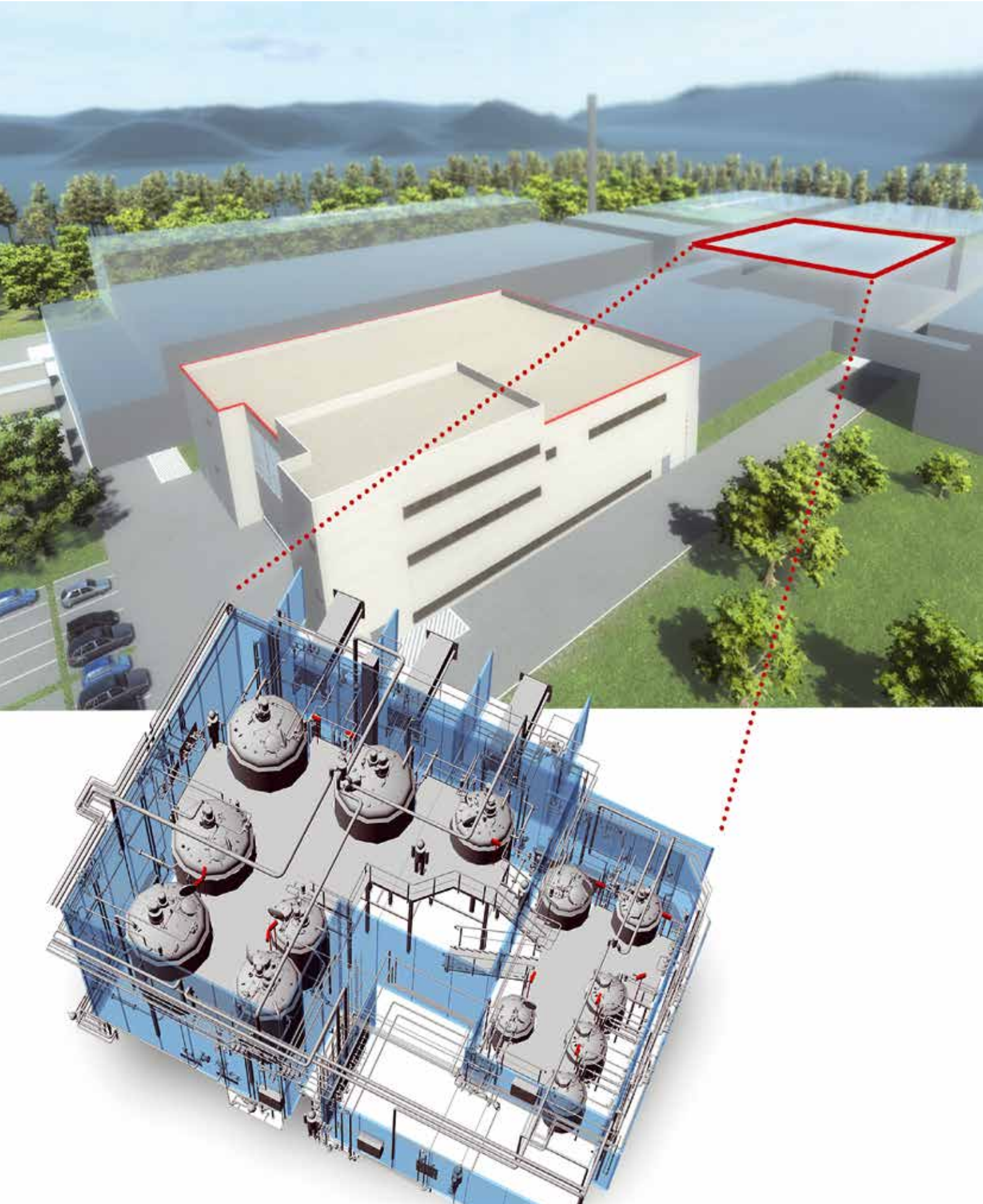


PROCESS & PLANT ENGINEERING FOR THE PHARMACEUTICAL INDUSTRY



UNIQUE TECHNOLOGY COMPETENCE

The production of pharmaceutical solids would be unimaginable if it weren't for the pioneering achievements of Glatt in the area of fluidized bed technology. But Glatt has much more to offer. In addition to the continuous perfecting of our equipment, we are developing new dosage forms, operating a subcontracting business with all the required approvals and cultivating close international contacts in the pharmaceutical research industry and with scientific institutes. At the same time, we have many years of experience in the planning, design and construction of industrial facilities. And not just in the field of solid materials.

We bundle our expertise together in our unique, integrated service concept: sustainable process and plant engineering, adapted to your specific technological requirements. We support you from the initial idea to turn-key production with our comprehensive advice and reliable project management.

Worldwide!

GLATT PHARMA ENGINEERING

This is bundled innovation, technological progress, functionality, quality, reliability, flexibility, global and regional, from the pharmaceutical service provider for the pharmaceuticals producers. Integrated solutions for your investment.

Innovative.

We supply no ready-made solutions "from the drawer". Every project is planned individually and represents the state of the art in terms of technological development.

Technological.

We develop modern dosage forms as a platform for new medications and therefore are already using today the technology of your products of tomorrow.

Functional.

We do not draw up architecture models. We design a factory, starting from the requirements of the production process, from the inside to the outside.

High-quality.

Our project solutions fulfill the same high requirements that we also apply to the development and manufacturing of pharmaceutical dosage forms and of our technological equipment.

Independent.

As a neutral planner in the compilation of the process design and the selection of equipment, we are under no obligation to any individual manufacturer.

Reliable.

Our sureties for a verifiable project success include adherence to scheduling and budgets, efficient project management and planning tools that transcend the limits of individual building trades.

Flexible.

Our project processing convinces through short decision paths, lean management, flexible thought models and project teams made up of qualified planning specialists with comprehensive experience with respect to projects and countries.

Global and regional.

Our company is represented around the world. This ensures compliance with global and regional regulations for the design and implementation of your projects.



APPLICATIONS

The array of projects designed and implemented by Glatt represents all pharmaceutical dosage forms produced in aseptic, sterile and non-sterile processes.

Products and forms.

Tablets, film tablets, pills, capsules, pellets, powder, ointments/cremes, suppositories, infusion solutions, injection solutions, vaccines, insulin, pre-filled syringes, freeze-dried preparations, X-ray contrast agents, tinctures, extracts, juices, drops, blood plasma products, e.g. albumin, immunoglobulin or Factors VIII and IX.

Special applications.

Whether it be medical products such as disposable syringes or the continuous production of refined API – we have many additional possibilities of supporting you in the implementation of your requirements.

Tailored forms from Glatt's own developments.

Glatt Pharmaceutical Services develops and produces its own solid pharmaceutical dosage forms. The emphasis here is on multiparticulate systems such as pellets, micropellets and granules. Development experts compile strategies and formulation concepts from customized release profiles and enhanced bioavailability to taste masking and chemical stabilization.



CONSULTING

The investments in new production plants require extensive expertise and personnel. But with increasing competition, producers now need to aim their focus on their core competence. Thus, the early deployment of external experts and resources is an important factor for the success of your investment project.

Project development.

In the initialization phase, we discuss your project idea in workshops, work up your data, generate decision suggestions and determine rough budgets.

Feasibility studies.

Whether it be a site master plan, a comparison of variables, technical and technological analyses of processes or product flows, project scheduling plan or economic efficiency observations – we provide you with important project information, milestones, and related information so you can properly prepare a presentation to your management for constructive discussions and decision making.

Technical due diligence.

You are looking for a new production site?
We evaluate the available building documentation. Starting with our own checklist or with one that we have specially drawn up in consultation with you, we analyze the actual on-site conditions.



For us it is important that the project team and the customer speak the same 'Language' from the beginning. It is for this reason that we listen very closely to our customers and question the conceptual formulation.



In the result you are given a precise expert opinion on the deviations from the specified requirements and indications of risk potential, e.g. with respect to site, costs or environmental conditions.

GMP audit.

You have a concept or planning documentation but are not sure whether this is in compliance with international standards or regional regulations?

We check your documentation. Our analysis recognizes the deviations and justifies the need for changes. If you wish, we can provide alternative solution suggestions.

Licenses.

Acting on your behalf, we search for licenses or know-how in the possession of third parties for the manufacture of new products for your market, thus facilitating your access to innovative technologies. As we act as your contract partner upon request, you minimize interfaces and risk connected with the implementation of this technology. We implement the know-how both technically and technologically, and we are moderators and intermediaries between licensors and licensees.

We have successfully implemented these types of projects on multiple occasions, e.g. for tablets or capsules, infusion solutions, blood plasma or insulin.

A selection of our references:



PLANNING

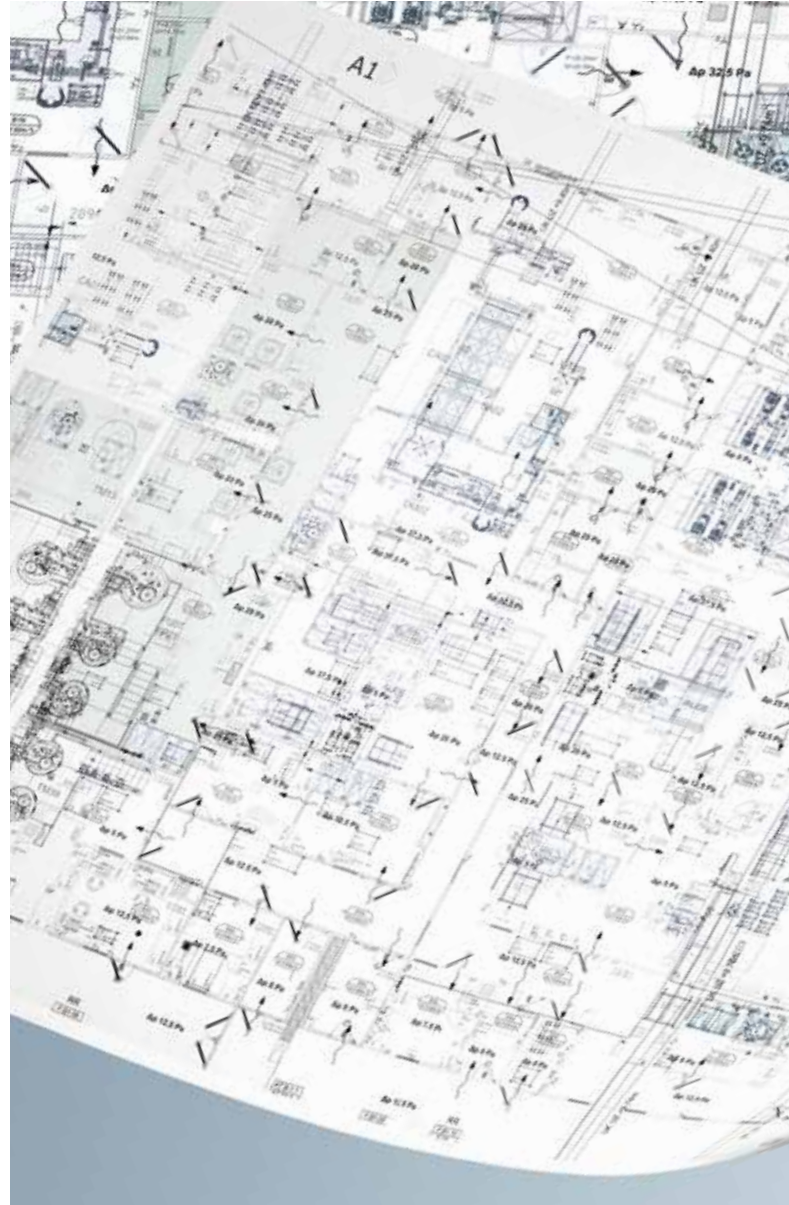
No matter whether a conversion or a new construction of your production site is involved – only an early-stage, comprehensive planning will provide you with the desired result. As a technology-oriented engineering partner, we accompany you through all planning phases. Beginning with the first concept and ranging all the way to detailed execution documents, our systematic, feasible planning ensures that all potentials are exploited to their fullest in the forefront of your investment. Custom-tailored to your production.

Concept planning.

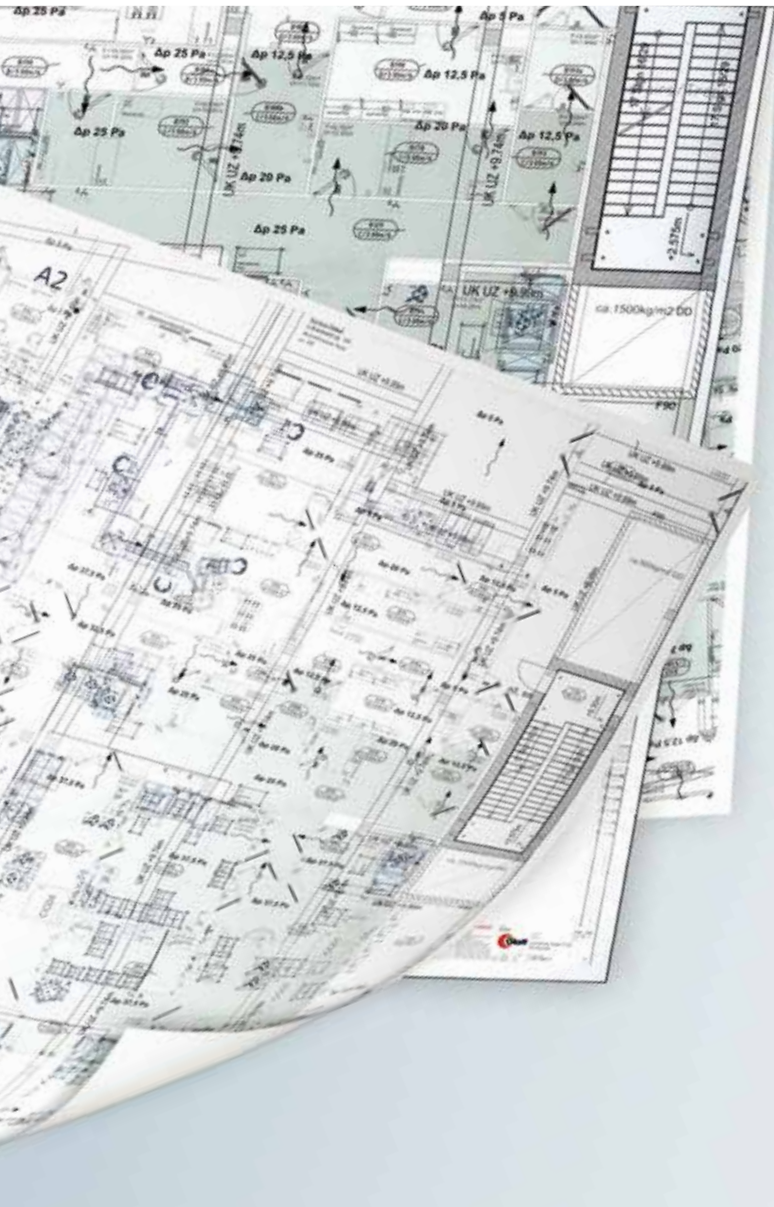
Whether it be auxiliary work for a business plan or the initial planning stage: the content of a concept sets the course for your project. Concepts that are incomplete or insufficiently thought through require a great deal of effort to correct, and may even involve increased operating costs in the worst-case scenario.

Let us coordinate your tailored package for a planning documentation. Develop with us the process layout for your factory. After a special ABC analysis of your production program and existing process data, we will dimension all the links in the technological chain, supply initial data for the required supply systems and determine the necessary spatial requirements.

Supported by our continuously updated database, we compile authoritative cost estimates, for CAPEX as well upon request. Realistic scheduling plans round off the picture for your project.



'Creativity' in finding the best project solutions and the 'Precision' in its execution – these are the characteristics that make our project teams so outstanding.



Vertical or horizontal product flow, continuous or batch processes, inventory logistics, product handling, GMP, containment and automation concepts, and observations on personnel requirements – our individual concepts provide answers to your questions. Take advantage of our experience!

Basic engineering.

We develop planning solutions out of concepts. We detail the process layout in conjunction with the selection of the equipment required and formulate the challenges for the supply systems for which we are also responsible for the project planning.

All data and calculations of the participating specialist planners and their interfaces are systematically gathered and coordinated. From this we generate professional, conclusive documentation with which you will be able to obtain the authority permits you require without additional delays resulting from revisions.

Upon request, we can handle the coordination and monitoring of the planning of all building trades. This enables us to guarantee coordinated interfaces for the entire project. Compliance with regional and global regulations, GMP standards and customer specifications is a matter of course. Exact scheduling and cost determination are elementary components of our documentation.

A selection of our references:



PLANNING

The updating or compilation of risk, safety, health and environmental strategies in addition to qualification planning are also component parts of our planning portfolio.

Already in the basic engineering stage we utilize the entire spectrum of possibilities that are available to us for all building trades, e.g. with our own classes of pipes or 3D planning based on databases stored in our system, in order to be able to continue seamlessly with detail engineering.

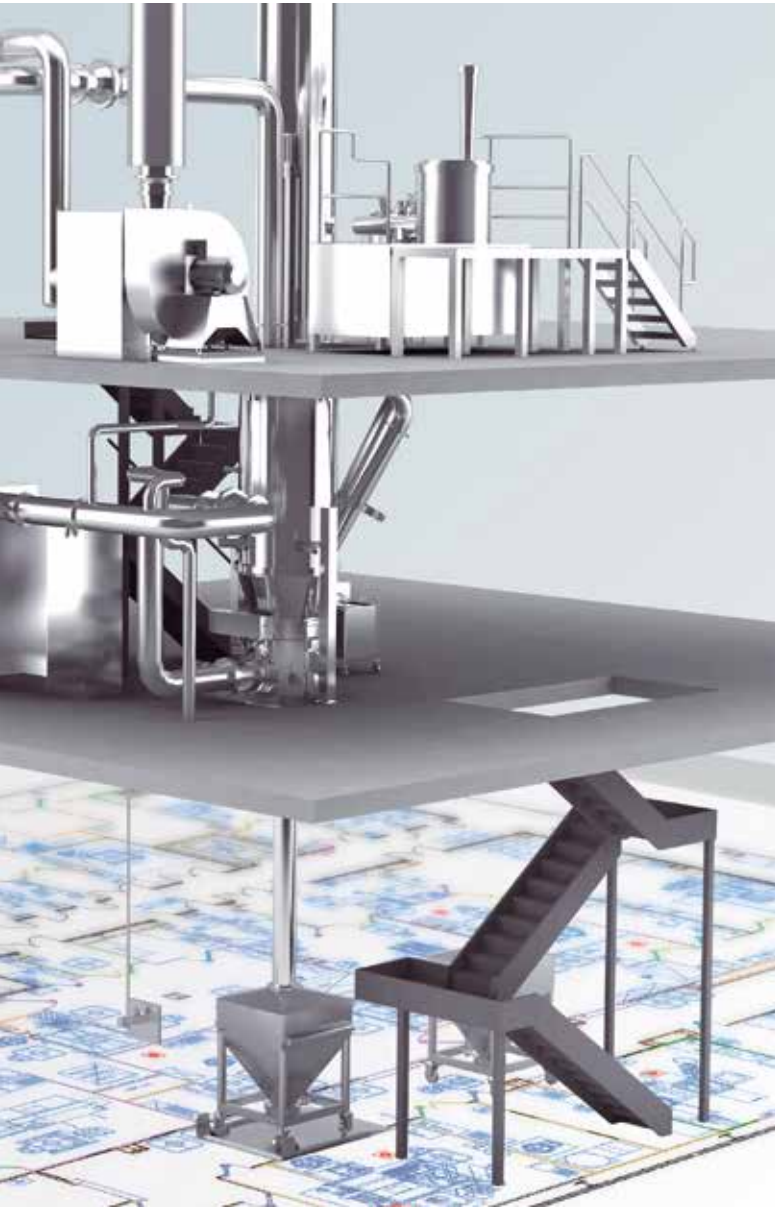
Detail engineering.

You decide how detailed you would like to have your calls for tender. We compile the documentation precisely suited for all component parts of your project: URS for process-relevant equipment and supply systems, P&ID, setup plans, detail drawings, function descriptions and specifications, service specifications, lists of materials and equipment, isometrics all the way to a complete, 3D model of your factory.

In addition to database-supported planning tools, we use templates we have developed ourselves and build up software for this purpose. This ensures that we can ensure effective coordination of the participating building trades, error-free collision management and defined interfaces.



The multitude of interfaces between the building trades and equipment are the actual challenges of the detail planning. This task is taken on by our engineers with the most experience.



Execution engineering.

Would you like to evaluate yourself whether the implementation of all the specifications contained in your request for tender has been technically correct regarding the parts of the contractors?

No? Assign the work to us under the auspices of execution engineering as the logical continuation of the preceding planning phases. We check the technical correctness of the offers. The plant and construction planning of all the building trades are transferred into our 3D model and checked for collisions. We answer technical queries from the contractors and supervise the entire project implementation phase from an engineering standpoint, also at the construction site upon request. Your advantage with an optimized planning process with clearly delineated responsibility is the avoidance of additional costs and delays in implementation.

General planning.

As your general planner, we are responsible for all phases of the project planning. This comes with decisive advantages for you from the very beginning: clear assignment of responsibility to a single planner, minimization of interfaces and avoidance of additional coordination tasks between the planning phases for you as the customer. Our management system guarantees that you are informed at all times about the current planning process and are able to influence this process. Naturally we also work together with selected planners for individual building trades whom you know and trust!

A selection of our references:



IMPLEMENTATION

Procurement.

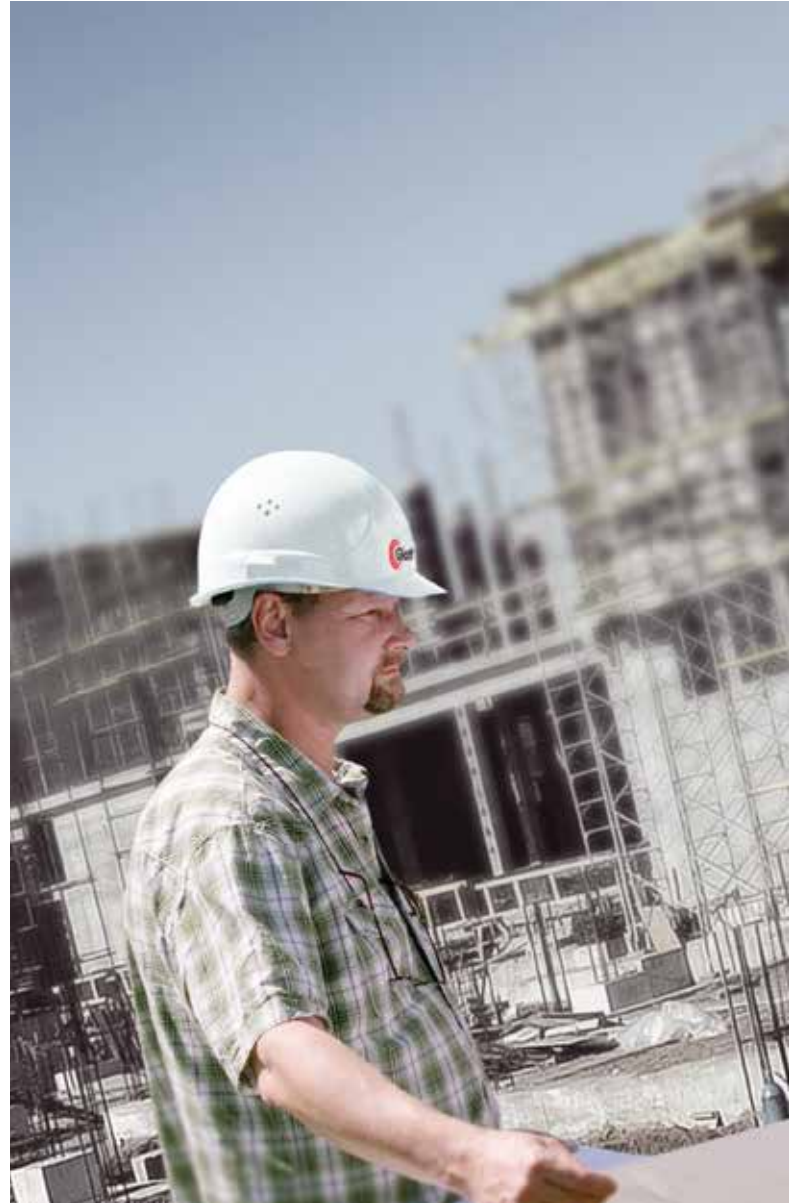
Leave the purchasing of equipment to us in the context of the implementation of your project!

Based on the calls for tender, we send inquiries to suppliers, compare offers using build up software, negotiate and conclude procurement contracts. Take advantage of successfully tested supplier relationships and profit from our experiences. This minimizes your technical and entrepreneurial risk and guarantees an optimized cost-benefit ratio in accordance with your project criteria.

We know the benchmarks for the respective equipment or package units. We purchase from your preferred vendors or manufacturers in accordance with our supplier evaluation and selection. Our purchasing agents have experience with expediting reports or with the compilation of complex supplier documents, e.g. for servicing letters of credit. The procurement of export licenses and certificates in the export business rounds off the array of services we provide.

Delivery.

We deliver worldwide. Whether it be consolidated transports for reducing costs with large-scale projects, one or two intermediate storage arrangements – together with your logistics partners we will find the optimum logistics concept for your project.



The imposing level of quality and amount of work involved as outlined in the project planning at the actual construction site, is often underestimated. We do not do that, and we know how to do it right.



Our logistics management takes responsibility for drawing up the delivery documents, checks that packaging and labeling are in accordance with the respective contracts, ensures timely shipment in accordance with the construction sequence and guarantees that the material arrives complete and undamaged at the correct destination

Building and construction supervision.

The monitoring of building and construction is a significant component for the success of a project. Builders often underestimate the time that has to be invested and the professional requirements for the coordination of the work of different building trades and suppliers and for the monitoring and technical supervision of their interfaces, which leads to avoidable downtimes.

We generate the necessary construction sequence and installation schedules, assume responsibility for construction site logistics and manage the construction site in compliance with all the regulations involved, in particular with respect to occupational safety and general safety regulations.

We supply the construction and installation management and coordinate all activities in close cooperation with the customer and the subcontractors all the way to complete finalization.

A selection of our references:



IMPLEMENTATION

Commissioning (SAT) and training courses.

After installation, our engineers put the new production line into operation for the first time. We actively include your personnel in this process. Your operators become familiar with the new plant and identify themselves more quickly with their new workplace. Suitable education and training measures in accordance with the plan we have compiled, including GMP education, round off the services we offer to this end.

You can also use our Technology Training Center TTC for Glatt's in-house educational courses for this purpose.

After sales service.

Maximum plant availability is an important prerequisite for achieving your personal key production figures.

Already during the planning process and no later than during delivery of your systems, your requirements for service, maintenance and spare parts supplies will be clearly defined and documented.

Even after commissioning, we make sure that your plant is professionally cared for and maintained. No matter whether Glatt or third-party products are installed, we offer suitable service and spare parts agreements, even beyond the warranty period.



Our responsibility does not end at the edge of the desk. Project heads and engineers are on-site and also at the time of commissioning.



Upon request, all after-sales services for all plants can be obtained from a single source. There are many options. Longterm service and spare parts agreements with defined conditions can be executed for this purpose. Since we know the plant better than anyone else from the start of production, you are guaranteed a high degree of availability in conjunction with our range of services.

A selection of our references:



VALIDATION & QUALIFICATION

Having an integrated concept right from the start of your project is an important requirement for GMP compliance and efficient validation and qualification period.

Comprehensive GMP compliance.

We offer you comprehensive GMP compliance regardless whether your equipment is laboratory or production scale, for media supplies or maintaining clean room conditions, the qualification of the rooms or the validation of computer systems. We work according to your selection on the basis of your templates, our own qualification documents or the model documents of third parties.

Integrated concept.

The qualification procedure must be logical, comprehensible and documented. Inspection-proof qualification and validation does not begin as late as the compilation of a qualification plan, but rather a long time before that.

Begin therefore with the definition of a well-thought-out qualification strategy, the validation master plan, and the identification of risks with risk analyses.

On the one hand, this makes it possible to keep costs within limits. On the other hand, you are thus showing the inspector the logical approach to the qualification and suitability of your equipment for production purposes.



Qualification and validation are necessary and useful – and require much effort. We cannot relieve you of this work altogether, but we can make it much easier.



With this approach you will be fulfilling international standards in every phase of the qualification and validation. It is for that reason that we are at your side with comprehensive competence in the pharmaceutical industry.

Our range of services:

- » Qualification and validation strategies
- » Master documents such as validation and qualification master plans, quality assurance and project plans
- » Risk analyses on the basis of established procedures, e.g. FMEA, FTA, HACCP
- » Qualification plans (DQ/IQ/OQ/PQ)
- » Qualification tests
- » Qualification reports (DQ/IQ/OQ/PQ)
- » Consultation for the implementation of the process and cleaning validation
- » Preparation, performance and documentation of factory approvals (FAT and SAT) on behalf of the customer
- » Compliance training in GMP regulations for your employees
- » Auditing of companies (supplier audits, supplier qualifications) on behalf of the customer
- » Document maintenance, management and updating in accordance with customer specifications
- » Customer-specific advanced training measures for qualification, process and cleaning validation

A selection of our references:



PROJECT MANAGEMENT

Project management and project control for achieving the defined project goals are elementary component parts of our certified internal quality management system.

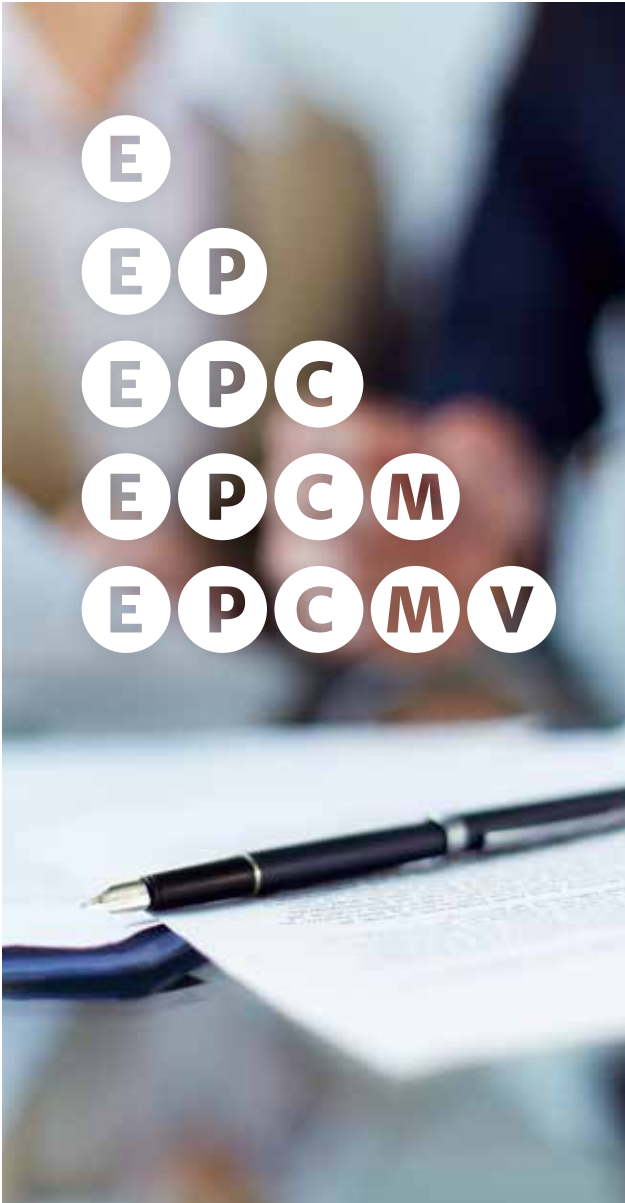
For all projects.

Project execution instructions, project structure plan, defined work packages, resources, scheduling and communication plans, tools for reporting, change management and project controlling for securing and controlling all processes are only a few elements of this efficient system. This guarantees a structured working approach, short decision paths, rapid response times and open communication.



*Professional project management is a success factor in all phases of a project.
And in addition to this, our maxim also applies:
Adherence to schedules and budgets while upholding the highest quality requirements.*

FLEXIBLE SERVICE PACKAGES



Whether it be individual service or total package – you decide how much responsibility you are putting in our hands. We can be your reliable partner in all stages of the project and in many areas of specialization.

Consultants and specialist planners.

Take advantage of our expertise for special tasks, e.g.:

- » GMP audit
- » Technical due diligence
- » Process design and optimization
- » Storage and logistics
- » Supply systems
- » Clean room design
- » Qualification

General planner or general contractor.

We assume total responsibility for all building trades, from initial draft to final implementation, including:

- » Construction and architecture
- » Procurement and delivery
- » Installation and commissioning
- » Training
- » After-sales service

A selection of our references:



Unfortunately we are not allowed to mention all our clients we are working for.



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