Fluid bed systems



THE WORLD OF THE FLUID BED

The top technology for the production of pharmaceutical solids.

The development of the fluid bed since the late 1950's is unique in the pharmaceutical industry. Initially used as a simple yet highly effective dryer, with the addition of spray nozzles, fluid bed systems quickly developed into granulators. The introduction of Wurster bottom spray technology enabled extremely effective coating. As a result of the rotor technology, the fluid bed system was eventually capable of pellet manufacturing. Today, no other technology in the pharmaceuticals industry covers such a wide range of process application methods as economically in a single system.

At the same time as these various process applications were being developed, Glatt also addressed the increased technical requirements for explosion protection, validation and qualification, documentation, regulatory requirements such as CE and ATEX, modern control systems and their integration with higher-level materials management systems, total containment, CIP etc. These are only a few of the current issues for which customers are demanding solutions.

The Glatt company and the fluid bed.

The Glatt Corporation and fluid bed technology have become synonymous. Our heart beats for the fluid bed. For this reason, Glatt has had a significant influence on the development and spread of fluid bed technology throughout the world over the past five decades.

Today, Glatt employs more than 1500 people in more than 20 companies globally. Glatt systems are used in the pharmaceutical, chemical, food and animal feed industry as well as in the ceramics and cosmetics industry throughout the world for drying, granulating, coating or pelletizing. Regardless of whether you are developing a product with a single laboratory unit or are producing a 1.5 ton production batch, with Glatt equipment, you benefit from 50 years of experience in fluid bed technology.

The first fluid bed granulator





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Contents





We set the standard

SERIES

The WST / G series:

Maximum efficiency for drying and granulating.

The fluid bed ensures an amazingly fast, gentle and uniform drying. Fluid bed dryers are therefore often used in combination with high shear granulators (wet mixers).

With the addition of a spray nozzle, the dryer becomes a granulator. Fluid bed granulations are known for their superior homogeneity. The granule properties (size, density, porosity) can be controlled over a wide range by setting different processing parameters.

The following applies to the PRO

The GPCG series:

Drying, granulating, coating and pelletizing - all in a single system.

In addition to the WSG, a GPCG, with the twin-chamber filter system, offers the possibility of an uninterrupted process. Apart from the drying or granulating insert, a Glatt HS Wurster insert (bottom spray) and a rotor insert (tangential spray) are also available as options.

From demanding powder coating to simple drying whether granulation / agglomeration, particle coating or pelletizing - whether the spraying nozzle is at the top (top spray), at the bottom (bottom spray) or at the side (tangential spray): with a GPCG, anything is possible!



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DESIGNS

The PRO design.

The PRO design for the GPCG and WST / G series provides the very highest level of explosion containment. 12 bar pressure-shock resistance is state-of-the-art throughout the world. This leading design makes it possible to process practically all known pharmaceutical products - without pressure relief! The Glatt design utilizes special materials that provide the same overall weight and handling characteristics as those of traditional 2 bar pressure-relief systems. A unique advantage!

Unique 12 bar pressure-shock resistance without pressure relief.

- Ideal for total containment.
- Superior cleaning: CIP / SC SuperClean® (fully automatic CIP cleaning).
- Patented metal cartridge filter or proven bag-shake type filter.

The PLUS design.

For the GPCG and WST / G series, this is the classic approach from Glatt providing proven technology and Glatt quality: 2 bar pressure-shock resistance with pressure relief, CE and ATEX-compliant, the economic alternative, and naturally as flexible in design and function as you expect from Glatt.

- Proven 2 bar pressure-shock resistance with pressure relief.
- Excellent cleanability: WIP.
- Bag-shake type filter with a large selection of filter materials for every process.

The following applies to the **PRO** and **PLUS** designs:

Both designs are excellently suited for integration in a granulation line. Glatt offers a truly unique benefit with the PRO design: all the components of a granulation line (vertical granulator, sieves, pneumatic conveyance and fluid bed) are available in a 12 bar pressure-shock resistant design. This eliminates any discussion of additional explosion protection measures for the individual components. Simply the safest approach available today!



WST / G PLUS 2 bar pressure-shock relief

GPCG PLUS 2 bar pressure-shock relief



RANGE OF APPLICATIONS

Wet product



Dry product

Drying.

Fluid bed drying is an especially effective way of drying solids. During fluidization, liquid is withdrawn from the entire surface of every single particle. The advantages: excellent heat exchange, ideal drying time. The product is also dried gently.

Granulation / agglomeration.

Agglomeration in the fluid bed is a modern method of creating granulates from powder using liquid bridges. The sprayed liquid can be either water or an organic solvent, a powder dissolved in solution or another binder. The moist granulates are dried and, if necessary, cooled. As a result of the relatively low mechanical forces in the fluid bed, the agglomerates / granulates are loose, have a low bulk density and are outstandingly soluble in water.

Powder coating / particle coating.

Modern film coating selectively influences the product characteristics through the application of protective films. A very uniform application of the coating material is important during coating. The coating must provide an absolute seal – without mechanical damage or tears. Film coating is a technically demanding process that can be used over a very wide spectrum.

Pelletizing.

During pelletizing, powder is mixed and moistened. At the same time, a solvent or binding agent can be added. The centrifugal motion produces agglomerates, which are spheronized into uniform, dense pellets. Selective product characteristics can be realized through direct pelletizing or layering.





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Energy supply



Top spray in granulation insert

In addition to the very effective drying process, granulation and coating processes with the top spray method offer many advantages in the fluid bed.

Agglomeration or granulation processes:

- Reduction in the amount of fines
- Improvement in the flowability
- Elimination of segregation
- Homogenous distribution
 of all components
- Improved compressibility for tabletting
- Controllable bulk density
- Optimized solubility

Instantizing:

Improved dispersibility due to

- Increased porosity
- Uniform application of surface-active substances

Coating processes:

- Lipid coating
- Taste masking
- Moisture and
 oxidation-protection coatings
- Enteric coatings
- Visual appearance



Granulation nozzle





Conidur bottom



Wedge-wire bottom





Nozzle height adjustment

Depending on the requirements, different bottom screens are available. Proven and used a hundred times over: the 100 micron Dutch weave (PZ) as a standard. For wet and sticky products, easy to clean: the single-layer Conidur bottom. Also excellent for cleaning and the first choice for CIP / SC Super-Clean® systems: the wedge-wire bottom.

Important factors for granulation and coating processes are a uniform volumetric flow in the product container as well as a nozzle that can be adjusted for very different requirements, thus working in a reliable and reproducible manner.



Tangential spray in the rotor insert

Rotor nozzle

This rotor insert allows an entire series of processing methods with specific advantages. Special emphasis should be placed on the manufacture of pellets by direct pelletization and different types of powder layering. Powder layering, for example, can increase the initial weight of the original batch up to 10 times!

The following methods can be displayed:

Granulation processes:

- Improved dissolution behavior
- Better compressibility
- Higher density
- Spherical morphology

Spheronization:

- Higher density
- Production of pellets
- Higher content of active ingredients possible
- Smooth surfaces

Layering:

- From solutions and / or suspensions
- Powder layering
- Higher content of active ingredients
 possible
- Narrow particle size distribution
- Higher density

Coating:

- Film coating
- Enteric coating
- Delayed release
- Hot-melt coating







Tangential spray in the rotor insert

The tangentially positioned nozzle is optimally located directly in the product bed. The adjustable air gap of the rotor makes it possible to always select the correct air flow.





Bottom spray in Wurster insert

The Wurster bottom spray method makes it possible to attain high-quality results in coating pellets and particles: The combination of the nozzle positioned directly in the product bed and the controlled product motion made possible by the inner partitions results in an extremely quick and thus economical process. It allows:

Coating:

- Aqueous or organic
- Polymer solutions or dispersions
- Controlled release
- Enteric coating
- Coating of very fine particles
- Active-ingredient layering

High-speed HS Wurster. Patented performance.

This high-speed method, which is available exclusively from Glatt, guarantees higher spraying rates than any comparable system. This comes with perfect product quality and very high economic performance. In addition, the HS Wurster makes it possible to coat particles less than 50 μ m.



Wurster nozzles 46"





Wurster inner partitions 32"



Wurster removable nozzles 32'



Manual partition height adjustment





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Bottom spray in Wurster insert

High-performance package. We coat almost everything.

Some products are especially challenging. This can be due to the size, shape or mechanical stability of the final product. In order to coat these special products perfectly as well, Glatt has developed the optional HP (high-performance) package.

A number of individual measures make it possible to treat all particles in an extremely gentle and uniform manner during the process. As an added benefit, the effectiveness of the process is increased further at the same time.

Process and product. Experience and know-how.

Products have individual characteristics, and processes are geared to specific requirements. Every installation also has its own facility requirements. Hundreds of installations in operation worldwide provide the proof of success. Whether a vertical or horizontal product flow, automatic or manual charging, bottom discharge or center discharge with a pneumatic PCS system, nozzles that can be removed during the process etc: Glatt supplies the optimum solution for your requirements.



HP design nozzles



Partition Gentleflow



GPCG 120 with Wurster insert 32'





Filter bonnets



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Material flow

Horizontal or vertical the ideal system for every requirement.

The type of equipment required for a system is generally determined by the product flow. The material flow concept depends on the facility requirements, such as the available floor space and the room height. Product characteristics such as flow properties and the particle size distribution play an equally important role, of course. The toxicological data also has to be taken into consideration. Glatt has many different designs in its range of products that cover almost every application.

Vertical product flow fast and effective.

Vertical product flow with automatic charging from above and turning bottom discharge below. This concept allows a completely closed product flow (total containment). In addition, the turning bottom discharge system is the fastest and most effective way of discharging a fluid bed machine.

Horizontal product flow full flexibility.

With horizontal product flow, charging can be done either manually, with a lifting device, or by means of pneumatic conveyance. Discharge is then done either manually, by means of a lifting device, side discharge or pneumatic conveying. Naturally, both systems can also be combined with each other. Depending on the product and the requirements, various types of product container bottoms are available.

Components.

In addition, there is an entire range of additional equipment available: containers, charging and discharging silos, product containers with agitators and / or choppers - to mention just a few.



Charge port flush with the wall



Wedge-wire turning bottom for vertical discharge





Vertical product flow



Side discharge





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Spray systems

Granulation, coating and pelletizing – with the unique Glatt nozzles

The nozzle is of central importance to granulation and coating processes. The Glatt single-arm nozzle has been the exclusive choice here for many years. The superior design and optimum spray pattern performance of this Glatt development also guarantees easy handling and very good cleanability. The Glatt single-arm nozzle utilizes a binary operating principle and can therefore be adjusted ideally for each granulation process.

The patented Glatt HS method is used for coating processes in the Wurster (bottom spray). The nozzle, which was specially developed for this application, guarantees very high spray rates and makes it possible to coat even microfine particles (>50 μ m).

For direct pelletizing and coating in the rotor, the nozzle sprays tangentially and directly into the product bed. In the case of powder layering, a special 3-component nozzle is used. It precisely meters the powder together with the spraying liquid and ensures a perfect layering.

Spraying liquid pumps. A perfect fit for every case.

There is a reason why peristaltic pumps are so popular worldwide. Easy to assemble, they reliably feed the spray medium to the nozzle and can be visually monitored. It is no problem to change the spray liquid – simply change the hose. When several nozzles are used, each individual nozzle can be supplied with exactly the same spray volume and pressure by a peristaltic pumping head that is assigned to it. The individual pumping heads are driven centrally.





3-head single-arm granulation nozzle



Bottom nozzle 32" in a Wurster insert





6-head single-arm granulation nozzle





For special media or requirements, gear, piston or membrane pumps and other systems can also be easily supplied.



Eccentric screw pump

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Filter systems

For all applications. Filter versions.

Whether utilizing the single-chamber or the twinchamber principle, a bag-shake or pulse blowback filter, bags or cartridges, fabric or metal materials of construction: each filter system has its specific advantages and is recommended and supplied by Glatt in accordance with the individual product and the process.

Ingeniously simple. Shaking filters made of fabric.

If they didn't exist, we'd have to invent them! A shaking mechanism combined with filters made of fabric offers by far the widest range of applications. The bags combine a maximum filtration area with simple and effective dedusting using a pneumatic shaking cylinder to cause the filter fabric to fold and unfold, thereby dislodging dust and fines. The choice of different filter fabrics (naturally FDA-compliant) makes even difficult processes possible - e.g. drying very wet products - without trouble. These filters are also very easy to change: just remove, clean and reinstall. For this reason, Glatt uses fabric filter bags as a standard feature.

The somewhat different filter. Filter bonnets.

Coating processes are normally sensitive to dust. In these cases, fine dust must not be returned during the process. Instead of a fine filter material, the fine filter is replaced by a wide-meshed bonnet here. This retains coated particles on the one hand and allows fine dust to be discharged from the machine on the other hand.

Simply ingenious.

The patented Glatt metal filter.

A design highlight is the SC SuperClean® filter developed and patented by Glatt. Mechanically, it is extremely durable and therefore practically wear-free - blow-back pressures up to 8 bar are no problem. The filter material on the process gas side guarantees 100% surface filtration. The overall cleaning concept allows automated, validated cleaning in the closed machine, providing the best conditions for perfect CIP and total containment.



SC SuperClean® blow-back filter



Pulse blow-back filter





Filter bonnet



*Optionally available for selected WST / G as well

Twin-chamber shaking filter

Safety concepts

Trust is good. Safety is better.

Dust mixtures as well as most solvent mixtures present an inherent risk of explosion, thus creating a potential source of danger to people and machines. Glatt has done pioneering work in explosion protection for decades. Each year, Glatt makes a significant investment in the design, development and practical testing of safety systems so that you can work with Glatt technology as safely today as in the future.

2 bar pressure-shock resistance*. PLUS technology.

Reliable 2 bar pressure-shock resistance through pressure relief of the machine tower. A Glatt quick-action stop valve is incorporated in the exhaust air duct (optionally in the inlet air ductwork), which protects components which are not pressure-shock resistant from damage in the case of an accident. Glatt quick-action stop valves are always made of stainless steel and are tested in accordance with ATEX designs.

12 bar pressure-shock resistance*. More than PRO is not possible.

The PRO concept from Glatt sets new standards for non-vented fluid bed safety with a full 12 bar pressure-shock resistance for contained systems. It does not matter whether you know the precise explosion characteristics of your products or not; all well-known pharmaceutical products are covered by the PRO design without any need to vent the pressure produced by the explosion. And if you want to produce new products with your system in the future – you will be armed for the challenge with 12 bar pressure-shock resistance.



#As a contained system

Explosion suppression. The alternative.

Explosion suppression is an economical alternative particularly for large, contained systems. A sensor detects an explosion while it is still developing. Extinguishing agents are introduced within milliseconds to limit the increase in pressure to a safe value.



Extinguishing agent tank



Glatt quick-action stop valve (QASV)





*Our systems naturally meet all relevant regulations such as VDI 2263 and 3673

Grounding and grounding monitoring. Playing it safe.

There can be no explosion without an ignition source. The greatest potential risk of ignition is the static charging of system components. Consequently all critical parts are carefully grounded. If desired, the grounding circuit can be monitored by the control system.



2 bar system with QASV pressure relief in the exhaust air duct



12 bar system without pressure relief, QASV in exhaust air ducts and air inlet ducts

Air processing

Our concern for air quality isn't just hot air.

Your product needs air - for drying, granulating, etc. In addition, the quality of the air entering the process must be reproducible. Quality here means a constant temperature, uniform purity and, if applicable, consistent humidity. The exhaust air from the fluid bed must not harm the environment, either through product particles, solvents or noise. For all these requirements, Glatt offers individual, modular solutions.

Preconditioned inlet air. For the well-being of your product.

As a standard, the air is prefiltered and heated by means of a face and bypass system (for optimum, fast control accuracy) and then fine-filtered. From this filtering stage onwards, we use only stainless steel for all parts that come into contact with process air. Freeze-protection heating, humidification, dehumidification, increased heating capacity, HEPA filters, and housing interiors made completely of stainless steel... you receive the optimum air processing unit for your individual needs.

Filtered exhaust air. For the well-being of the environment.

The exhaust air is already filtered in the machine tower. To meet special requirements for exhaust air purity or for safety reasons, we incorporate final dedusters with automatic dedusting and / or HEPA filters as police filters. The exhaust fan noise can be effectively reduced by a silencer and/or sound insulation.



Solvent recovery. Economical and ecological.

If solvents are used, current emission control regulations must be respected. A recirculation system with condensation not only effectively avoids emissions but even allows solvents to be reused in most cases. Other alternative solvent abatement systems such as adsorption, absorption or scrubbers are also available depending upon the solvent, the process, the product, and the prevailing regulations. We will be happy to advise you.





Fluid bed closed-loop system



Fluid bed closed-loop system with $\mathrm{N_2}$ inertization and solvent recovery system



Fluid bed system according to the once-through principle with inlet air and exhaust air treatment

Control systems

Many requirements. A true challenge.

Glatt offers modern, future-oriented control systems. Their modular structure allows the use of individual system controls up through the integration of complete process lines and the connection of corresponding logistical and auxiliary processes. The systems are consistently developed according to the GAMP guide. All systems with electronic records and electronic signatures (ER / ES) meet the requirements of FDA CFR 21 Part 11. Explosion protection is a core competence of Glatt. For use in explosionprotection zones, Glatt offers ATEX-compliant solutions as well as meeting NFPA and NEC requirements. At the same time, the control system must remain logical, clearly structured and as easy as possible to use for the operator.

Flexible. Take us at our word.

Glatt develops, plans and produces the software and hardware for the control systems in-house. This results in a high degree of flexibility with regard to individual customer requirements. Glatt works with Siemens and Allen Bradley PLCs as a standard, enhanced with integrated PCs depending upon the desired system functionality. Other PLC manufacturers can be integrated if desired. We implement SCADA functionality including process graphics with industrial standards such as GE Fanuc Intellution and Wonderware.

Validation and qualification. Documented quality.

As a professional and application-oriented partner, Glatt makes qualification a goaloriented process. We work in compliance with the principles of GMP. Your equipment and control systems are qualified based on the GAMP lifecycle, which produces clearly structured documentation.



Control system integration. No man is an island.

We offer solutions for integrating our systems in customer networks and systems, such as data historians, manufacturing execution systems (MES) or enterprise resource planning (ERP).

MegaView operating pane



EcoView operating panel

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Two systems. All possibilities.

ERP

GLATT

MES

Manufacturing Execution

System

GLATT SCADA

Dispensing Weighing Granulation Tabletting Coating

Glatt

Automation

& Controls

Ware

House 2

The basic control system EcoView stands for PLCsupported machine operation. MegaView is PC-supported and offers all options, e.g. for SCADA and network connection.

WIP / CIP cleaning

The ideal cleaning – or: How clean is clean?

Cleaning stations for WIP / CIP.

You provide the answer! In the pharmaceutical industry in particular, several products are usually produced in one fluid bed system. Each time a product is changed, there is a considerable need for cleaning, which is often complicated by extensive personnel protection measures. CIP (Cleaning In Place) has therefore become a key factor for the industry. Systems are often marketed under the name CIP, however, although they have little to do with genuine CIP. These systems only carry out a pre-cleaning process at best. Final cleaning must then be carried out manually.

WIP – Washing In Place.

WIP (Washing In Place) provides a thorough precleaning which nevertheless requires manual final cleaning to attain the desired cleaning result. For WIP, the machine must always be opened to provide access for final cleaning. Of course, a WIP process can always be validated but there is a manual portion in the cleaning SOP. In a WIP process, the pre-cleaned filters are always removed from the machine and the closed machine is thoroughly cleaned using special integrated washing nozzles. The residuals are negligible and can be removed manually.

CIP – Cleaning In Place.

CIP (Cleaning In Place) is a fully automatic, reproducible cleaning process with a defined cleaning result. At no time must the machine be opened. Of course, this process can be validated as well, but there is no manual intervention during the cleaning process. Filters of traditional constructions - whether filter bags or conventional cartridge filters - are not CIP-capable.



A WIP / CIP skid supplies cleaning nozzles with the required quantity of water at the required pressure. The ideal temperature and, if necessary, the metering of the correct cleaning agents is automatically controlled. A once-through system is normally used for WIP cleaning. For CIP cleaning or complex WIP cleaning cycles, recirculation systems are often the more economical solution. Naturally, all skids meet the requirements of GMP for materials, surface quality etc. For example, all welding joints are orbitally welded and the surface roughness of the piping is kept below 0.8 μm.



CIP cleaning SC SuperClean®

Fully automatic cleaning. Many questions. One answer.

The SC SuperClean® design is Glatt's convincing answer to all questions about CIP in the fluid bed. How should problem zones such as the sealing joint or sight glass be cleaned? What happens with the bottom screen during cleaning? And above all: how are filters cleaned to a defined standard? How can optimum personnel protection be achieved? Glatt has developed a perfect solution for each specific problem and has brought them together in the SC SuperClean® series.

Details. Patented know-how.

A large number of innovative Glatt solutions have been patented. The metal filters, for example, which combine optimum filtration with outstanding cleaning properties, are a Glatt development. Their shape gives them extreme mechanical stability that allows blow-back pressures of up to 8 bar. This, and the exclusive use of stainless steel, give Glatt metal filters the same long service life as all Glatt systems. The sealing system O-PLUS, which is also patented, seals gaps and openings, for example with bullseye windows, sight glasses or nozzle ports to comply with CIP standards.

Top. The SC SuperClean[®] version.

If necessary, PRO systems are equipped with the unique SC SuperClean[®] technology which provides total containment. The product is charged into the closed machine and discharged by means of bottom discharge (optionally by pneumatic conveying). Even when the product is changed, the machine always remains closed. This guarantees a reproducible cleaning result and optimum personnel protection.

The wedge-wire bottom is easy to clean and, incidentally, can be easily retrofitted onto existing machines. The machine is cleaned by a specially developed system using a variety of different cleaning nozzles. This system allows the cleaning of all the so-called "hard to clean" areas up to and including the SC SuperClean[®] filters.



SC SuperClean® metal cartridge filters



Feed port flush with the wall



Wedge-wire bottom

Of course, the upstream or downstream systems of a solid dosage production line can also be equipped with SC SuperClean® technology and integrated into a common cleaning concept.





Hydraulically extending washing nozzle

A fixed nozzle in the spraying zone would be intrusive here. Our patented cleaning nozzle, which automatically extends when exposed to water pressure, is designed to seal flush with the wall when not in use.



Total containment

Comprehensive protection. For people, products and the environment.

The processing of highly efficient substances requires complex protection measures for the operating personnel and the environment. In order to prevent the personnel from having to wear full protective gear, special demands are made of the fluid bed system's design. This concerns the observance of the OEL level as well as the contained cleaning of the system after a process.

Maximum safety. Systems engineering.

Only contained systems able to withstand pressure shocks of 12 bar are used. All seals are designed or optimized for this purpose. The integration of downstream and upstream process systems is a prerequisite and requires corresponding expertise. It is generally possible to integrate process systems from various machine manufacturers.



Charging with the SKS valve system

Contained product flow. Charging and discharging.

These substances must be charged and discharged absolutely dust-free. This is a challenge especially when containers are docked and released. For this purpose, we use a contaminationfree valve developed for this application. The patented design prevents substances from being released in an uncontrolled way.



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Accessories

Individual adaptation. We supply made to measure.

Whether it concerns system-specific accessories or, for example, handling equipment such as sieves, lifting devices, containers, container-mixers, isolation valves, weighing systems etc.: Glatt supplies (almost) everything connected to your fluid bed system. Some examples:



Through the Wall design



Lifting device LD 120 with sieve GS 180





Pneumatic conveying system PCS PRO 50

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Services

Process and product development. Clinical samples, scale-up and cGMP, complete product development & optimization with the latest technologies – the Glatt Technology Center provides this range of services, naturally under

GMP conditions. It has a modern range of systems and machines as well as an analytical laboratory that is completely up to date. And all that includes 50 years of experience in process technology.

Engineering.

We plan our systems to fit your building. Glatt is also the right partner for individual process lines and total concepts right up to full turnkey planning and execution.

Training and courses.

We train your operating and service personnel under practical conditions – even before your systems are delivered. This saves time and money in going from commissioning to commercial production. In the framework of our TTC program (Tech Transfer Center), we offer a practical range of training courses for your engineers and operators. It also provides an ideal platform for users to exchange experience.

Assembly, start-up, service.

Your satisfaction is our success. To be able to put a system into operation quickly, we offer you an all-round service, from assembly, to system start-up, and on to regular maintenance. Spare and wearing parts are available at short notice.



Glatt Binzen, Technology Center



We set the standard

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