THE WORLD OF FLUID BED

Top technology in the production of pharmaceutical solids.

The development of the fluid bed since the end of the 1950s is unique in the pharmaceuticals industry. Initially used as a simple yet extremely effective dryer, fluid bed systems quickly developed into granulators with the use of spray nozzles. The Wurster bottom spray technology enabled extremely effective coating. As a result of the rotor technology, the fluid bed system was finally predestined for manufacturing pellets. Today, no other technology in the pharmaceuticals industry covers such a wide range of methods so economically in a single system.

Parallel to the development of different methods, the fluid bed takes into account increased technical requirements: explosion protection, validation and qualification, documentation, legal requirements such as CE and ATEX, modern control systems and their connection to higher-level materials management systems, total containment, CIP etc. These are only a few of the current issues for which you as a customer demand competent answers.

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 decisive influence on the development and spread of fluid bed technology throughout the world over the past decades.

Today, Glatt employs more than 3,000 people in more than 20 companies throughout the world. 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 Glatt laboratory device or are producing a 1.5 ton batch in a production plant, with equipment from Glatt, you benefit from more than 60 years of experience in fluid bed technology.

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SERIES

THE WSG PRO SERIES

*Maximum efficiency for drying and granulating.*

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

When a nozzle is used, the dryer becomes a granulator. Fluid bed granulates are very homogeneous. The type of granulate (size, density, porosity) can be controlled over a wide range by setting different parameters.

The following applies to the WSG PRO series:

Each WSG PRO offers an optimum relationship between the air volumetric flow and the quantity of the product used. The cylindrical expansion chamber is perfectly suited for granulating and drying.
**THE GPCG PRO SERIES**

*Drying, granulating, coating, pelleting – all in a single system.*

In addition to the WSG PRO, a GPCG PRO, 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), a rotor insert (tangential spray) and a CPS insert are also available as options.

From demanding powder coating to simple drying. Whether granulation / agglomeration, particle coating or pelleting. Whether the spraying nozzle is at the top (top spray), at the bottom (bottom spray) or on the side (tangential spray): The GPCG PRO performs all important fluid bed processes.

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The following applies to the GPCG PRO series:

Maximum process flexibility: from simple drying to granulating or agglomeration to demanding powder coating. For uniformly shaped products in reproducible quality.
THE GPCG 10 SERIES

Maximum flexibility for the technical center
The GPCG 10 is conceived specifically for smaller batch sizes. It is ideal for scale-ups to the pilot scale. The GPCG 10 performs the full range of fluid bed processes, such as drying and granulating (top spray or with the new Glatt HP nozzle system), coating (bottom spray in the HS Wurster or with the new Glatt HP nozzle system) as well as pelletizing (tangential spray in the rotary insert or manufacturing micropellets with the patented CPS process).

Easy handling and easy to clean: All components, such as combo containers for drying, granulating, and coating with the Wurster, are easy to install. Everything is easy to handle and very easy to clean. Even filling and discharging - open or closed - can be handled easily. Variable through blow-cleanable material or metal filters and various bottom screens. Glatt manufactures every system according to customer requirements.
For example with SC SuperClean®, bottom discharge, or solvent EX discharge. A variety of process inserts can also be retrofitted at any time.

The following applies to the GPCG 10 series:
A flexible multi-talent that performs all fluid bed processes: Ideal for demanding scale-ups to the pilot scale.
## PROCESSING OPTIONS

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<th>Direct pelletizing</th>
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<td>GPCG PRO GPCG 10</td>
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<td>Tangential spray / Rotor</td>
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Glatt. Integrated Process Solutions.
**RANGE OF APPLICATIONS**

**Gentle 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 benefits: excellent heat exchange, ideal drying time. The product is also dried gently.

**Granulating.**

Granulating in the fluid bed is a modern method of creating granulates from powder using liquid bridges. The granulation liquid used for spraying can either be aqueous or contain organic solvents. The moist granulates are dried at the end of the process and, if necessary, cooled. Fluid bed granulates are loose and often porous, and are therefore extremely soluble.
**Drug layering and coating for pellets.**
A drug layer is typically applied to starter pellets from a liquid. A functional coating is then added to the active substance pellets. These applications require high precision to ensure that even active substance layers and dense coatings can be produced in a reproducible way. A very wide range of pellets can be produced using aqueous or organic liquids. Alternatively, active substances that are sensitive to moisture can be applied to starter pellets in powder form with the help of powder-layering technology.

**Direct pelletizing.**
During the process of direct pelletizing, active substances in powder form and auxiliary materials are directly transferred to pellets without the addition of a starter core. The centrifugal motion of the rotor or CPS disc causes moistened powder to be rounded into even pellets. Active substances can be formulated into matrix pellets using different functional auxiliary materials, with targeted release of the active ingredient.
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 and granulation processes:**
- Reduction of fine dust content
- Improvement of the flowability
- Elimination of segregation
- Homogeneous distribution of all components
- Easier to form into tablets
- Controllable bulk density
- Optimized solubility of the product

**Instantizing:**
Improved dispersibility due to:
- Increased porosity
- Even spraying of surface-active substances

**Coating processes:**
- Lipid coating
- Taste masking
- Moisture and oxidation-protection coatings
- Cosmetic coating

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.

Depending on the requirements, different bottom versions are available. Proven and used a hundred times over: the 100 pm metal sieve fabric. For damp and sticky products, easy to clean: the single-layer Conidur bottom. Also excellent for cleaning and the first choice for CIP / SC SuperClean® systems: the wedge-wire bottom.

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<tr>
<th>Series</th>
<th>WSG PRO</th>
<th>GPCG PRO</th>
<th>GPCG 10</th>
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<tr>
<td>Granulation insert</td>
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BOTTOM SPRAY IN WURSTER INSERT

The Wurster bottom spray method is for coating pellets and particles with the highest quality: 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.

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

Process and product. Experience and know-how.
Products have individual characteristics, and processes are geared to specific requirements. Every installation also has its own constructional conditions. Hundreds of installations in operation worldwide provide you with the necessary assurance: 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.

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<th>Series</th>
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<td>Wurster insert</td>
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Glatt. Integrated Process Solutions.
HP PROCESS INSERT

The Glatt HP® high-performance spray system allows for very effective granulating and coating processes. The HP spray nozzle is installed in the fluid bed system container in combination with a flow bed that directs the air flow. The nozzle sprays liquid into the fluidized product bed from underneath the bed, distributing the sprayed liquid over the material. The controlled movement of both air and product enables homogeneous granulates to form. These granulates can have a higher bulk density than granulates produced when spraying from the top.

The HP nozzle developed by Glatt specifically for this process is very hard-wearing and easy to use. The nozzle’s design means that it can be removed while the process is still running. It has a minimum number of sealing rings and individual components.

New machines are easily fitted for later installation of a Glatt HP® high performance spray system.

Agglomeration and granulation processes:
» Reduction of fine dust content
» Improvement of the flowability
» Elimination of segregation
» Homogeneous distribution of all components
» Easier to form into tablets
» Controllable bulk density
» Optimized solubility of the product

Coating processes:
» Lipid coating
» Taste masking
» Moisture and oxidation-protection coatings
» Enteric coating
» Cosmetic coating

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<th>Series</th>
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<td>HP insert</td>
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TANGENTIAL SPRAY IN THE ROTARY INSERT AND CPS TECHNOLOGY IN THE CPS INSERT

The fluid bed rotor process allows a whole series of methods with specific advantages. Special emphasis should be placed on the manufacture of pellets by direct pelletization and different types of powder layering. With powder layering, the amount on starter cores is multiplied in a short amount of time!

As a further development of the rotor technology, the CPS procedure with its improved geometry provides optimal solutions for pellet production.

**Granulation processes:**
- Improved dissolving behavior
- Better compactibility
- Higher density
- Spherical morphology

**Direct pelletizing:**
- High bulk density without starter cores
- 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
- High bulk density

**Coating:**
- Film coating
- Enteric coating
- Delayed release
- Hot melt coating

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<td>CPS insert</td>
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The tangentially positioned nozzle is fitted directly in the product bed. The adjustable air gap of the rotor makes it possible to always select the right air flow.

The CPS technology stands for very exact and uniform pelletizing. Ideal for the production of micropellets with higher content of active ingredients.

Glatt. Integrated Process Solutions.
MATERIAL FLOW

Horizontal or vertical - the perfect system for every requirement.

The kind of equipment required for a system is generally determined by the product flow. The material flow concept depends on the constructional conditions, 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 their range of products that cover almost every application.

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.

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 is the quickest and most effective method for discharging a fluid bed system.

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.

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<td>Horizontal product flow</td>
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<td>Vertical product flow</td>
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Charge port | Turnable wedge wire bottom for vertical discharge | Conidur bottom for side discharge | Side discharge
SPRAY SYSTEMS

Granulation, coating and pelleting – 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 data of this Glatt development also guarantee easy handling and very good cleanability. The Glatt single-arm nozzle works according to the binary principle and can therefore be ideally adjusted 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 μm).

For direct pelleting and coating in the rotor or HP system, the nozzle sprays laterally directly into the product bed. In the case of powder layering, a special 3-component nozzle is used that precisely meters the powder together with the spraying liquid and ensures a perfect layering.

Spraying liquid pumps.
The right thing 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 spraying amount by a peristaltic pumping head that is assigned to it. The individual pumping heads are driven centrally.

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<td>Granulation (top spray)</td>
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<tr>
<td>Coating (bottom spray)</td>
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<tr>
<td>Granulation / coating (HP system)</td>
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<tr>
<td>Pelletizing (tangential spray or CPS)</td>
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FILTER SYSTEMS

For all cases. Filter versions.
Whether utilizing the single-chamber or the twin-chamber principle, a back-shake or pulse blow-back filter, filter bags or cartridges, fabric or metal filters: Each system has its specific advantages and is recommended and supplied by Glatt according to the individual product and the process.

If it did not exist, it would have to be invented: Shaking filters made of fabric offer the widest range of applications by far. The bags combine a maximum filtration area with simple and effective dedusting using a pneumatic shaking cylinder.

The choice of different filter fabrics (naturally FDA-compliant) makes even difficult processes possible – e.g. drying very wet products – without any trouble. These filters are also very easy to change: remove, wash, refit. For this reason, Glatt uses fabric filter bags as a standard feature. Furthermore, for continuous filter cleaning, the textile blow back filter is available.

The filter with something different. 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 filter bonnet here. This holds back 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.
An absolute highlight is the SC SuperClean® filter developed and patented by Glatt. Mechanically, it is extremely sturdy and therefore practically wear-free – blow-back pressures up to 8 bar are no problem. The filter fabric on the raw gas side guarantees 100% surface filtration. The overall cleaning concept allows automated, validatable cleaning in the closed machine. The best conditions for perfect CIP and total containment.

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<td>Shaking filter, twin-cham.</td>
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<td>Blow-back filter, textile</td>
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<td>Blow-back filter, metal</td>
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SAFETY CONCEPTS

Trust is good. Safety is better.
Dust mixtures and sometimes solvent mixtures both naturally present a certain inherent risk of explosion. They are thus a potential source of danger to people and machines. Glatt has done pioneering work in explosion protection for decades. Each year, Glatt invests a large sum of money in the development and practical testing of safety systems. So that you can work with Glatt know-how as safely today as in the future.

12 bar pressure-shock resistance*. More than PRO is not possible.
The PRO concept from Glatt sets new standards for safety. 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. 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.

Grounding and grounding monitoring.
Playing it safe. There is no explosion without an ignition source. The greatest potential risk is the static charging of system parts. All critical parts are therefore carefully grounded. If desired, the function of the grounding can be monitored by the control system.

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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 must be reproducible. Quality here means a constant temperature, uniform purity and, if applicable, stable humidity. The exhaust air 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.
In the standard version, 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 which come into contact with process air. Freeze-protection heating, humidification and dehumidification, increased heating capacity, HEPA filters, housing interior made completely of stainless steel – you receive the optimum inlet 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 dusting 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 heeded. A recirculation system with condensation not only effectively avoids emissions but even allows solvents to be reused in some cases. Depending on the solvent, the process and the product, or according to regulations, washing or adsorption systems, combustion or other alternatives can be used. We will be happy to advise you.

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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 to the integration of complete process lines and the connection of corresponding logistic and auxiliary processes. The systems are consistently developed according to the GAMP directives. All systems with electronic records and electronic signatures (ER / ES) comply with the requirements of FDA CFR 21 Part 11. Explosion protection is a core competence of Glatt. For use in explosion-protection zones, Glatt offers ATEX-compliant solutions. 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 Allan Bradley PLCs as a standard. Other makes can be integrated if desired. We implement process visualizations 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 goal-oriented 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.

One system. All possibilities.
GlattView Batch provide intelligent solutions for complex requirements. With the intuitive GlattView Batch operating concept process management becomes easier and safer.

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<td>GlattView Batch</td>
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Glatt. Integrated Process Solutions.
WIP / CIP CLEANING

The ideal cleaning – or: How clean is clean?
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) means a thorough pre-cleaning which nevertheless requires manual final cleaning to attain the desired cleaning result.
For WIP, the machine must always be opened. Of course, a WIP process can also be validated. 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 negligible residue is 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 too. Filters of traditional constructions – whether filter bags or conventional cartridge filters – are not CIP-capable.

Cleaning stations for WIP / CIP.
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 are automatically controlled. A once-through system is normally used for WIP cleaning. For CIP cleaning or complicated WIP cleaning cycles, circulation cleaning is 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 ducts is only < 0.8 μm.

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<th>WSG PRO</th>
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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? 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. SC SuperClean® design.
If necessary, the systems are equipped with the unique SC SuperClean® technology.

At the same time, the SC SuperClean® version provides total containment. The product is charged into the closed machine and discharged by means of bottom discharge (alternatively 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 on existing machines as well. The machine is cleaned by a specially developed system of different nozzles. This arrangement also allows the cleaning of problematic areas up to the SC SuperClean® filters.

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

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

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<th>Series</th>
<th>WSG PRO</th>
<th>GPCG PRO</th>
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<tr>
<td>SC SuperClean®</td>
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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 requirements are made of the systems engineering. This concerns the observance of the OEL level as well as the contained cleaning of the system after a process.


Only contained systems able to withstand pressure shocks of 12 bar are used. All seals are designed and optimized for this purpose. The inclusion of upstream and downstream processing systems is required and necessitates the corresponding know-how. It is generally possible to integrate process systems from well-known machine manufacturers.

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 contamination-free valve developed for this application. The patented design prevents substances from being released in an uncontrolled way.

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ACCESSORIES

Glatt supplies (almost) everything connected to your fluid bed system. Some examples:

**Individual adaptation. Tailor-made delivery**

Whether it concerns system-specific accessories or, for example, handling equipment such as sieves, lifting devices, containers, container-mixers, isolation valves, weighing systems etc.