

# SUCCESS FACTOR- CONTAINMENT

**Safe contract manufacturing with zero contamination** — Contract manufacturers are working with challenging customers and require highly sophisticated equipment. Corden-Pharma is now going the extra mile. With the construction of a new, fully-contained development lab for high potency compounds, covering all manufacturing process steps for the development and production of tablets, the company is able to achieve unequaled OEL (Operator Exposure Limit) levels of less than  $1 \mu\text{g}/\text{m}^3$ . This is the first step towards zero contamination.



View at the new  
Development Center  
in Plankstadt

## AXEL FRIESE\*

The demand for the formulation of highly potent compounds, especially for cancer treatment, remains high, not only for parenterals but also for oral solid dosage. There is a high need for the manufacture of highly potent oral solid dosage forms. Some estimate that oral oncology drugs have doubled in the past ten years. Corden Pharma is a full-service Contract Development & Man-

ufacturing Organization for APIs (Active Pharmaceutical Ingredients), Drug Products & Packaging in the global pharma and biotechnology industry. At the Corden Pharma Plankstadt facility near Frankfurt, Germany, their services are geared towards the formulation, development and manufacturing of oral oncology drugs under the company's Highly Potent & Oncology technology platform. In

2016, Corden Pharma made the decision to construct a brand new development lab for highly potent compounds in Corden Pharma Plankstadt. By making this investment, Corden Pharma wasn't only

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looking to expand capacity, but more importantly to extend their capabilities and increase flexibility during early development, requiring only small quantities of API. This in turn allows for work without full GMP requirements and change over procedures, as well as provides full safety protection and data availability during small-scale investigations.

Corden Pharma needed a technical solution which offered safe highly potent contract manufacturing with appropriate engineering controls to ensure effective protection across all OEL levels, while also providing their customers with highly flexible and efficient production methods.

Corden Pharma Plankstadt has used Glatt equipment in the production and development of highly potent substances for 20 years. In 2016 they decided to work with Glatt once again, appreciating their professional, customer-orientated approach to business and the technical excellence of their equipment and engineering. In addition, they chose Glatt equipment because it represented the best technological fit, while also adding significant flexibility to Corden Pharma's development capabilities.

### Challenging Markets

Evolving markets and more stringent regulatory requirements demand flexible solutions. This means that, during the development phase, questions are raised as to whether a containment system can keep up with demands. Glatt's equipment completes Corden Pharma's offering by adding small-scale processing capabilities (i.e. 10g to 1Kg) for the initial technical batches, allowing the pharmacists to work on early development projects with limited available toxicological information, and subsequently following the process through its development lifecycle and scale-up to support all activities related to development and commercial manufacturing in one facility, all while using the same or similar type of equipment technology, full data availability and process.

Three Questions to Jason Bertola, Director, Global Highly Potent & Oncology Platform CordenPharma

## MORE SPEED TO REACT



### What were the key reasons for making this investment?

**BERTOLA:** Corden Pharma's services at our Corden Pharma Plankstadt facility focus on the production of highly potent oral solid dosage compounds under our Highly Potent & Oncology Technology Platform. This investment not only expands our capacity but, more importantly, expands our capability and speed to react to customer inquiries. The investment further completes our full-service offering by following processes through their development lifecycle and scale-up to final commercial product.

### What finally led to the decision to go with Glatt?

Glatt's Lab Containment Technology cuts right to the chase by providing solutions to all three of the main important questions:

- How can the cleaning of the process equipment be made more efficient? By separating the technical module from the processing unit when only the processing units require cleaning.
- How can the design be made more compact? The need for a small footprint which still allows the later installation of additional equipment was achieved by integrating smart removable process tables and a technical module which forms an integral part of the containment station's

design. How can the different containment levels be mastered? The necessary flexibility was achieved by making the configuration of Glatt's containment station infrastructure as easy as possible.

### Different Containment Levels

With Glatt's Lab Containment Technology, Corden Pharma Plankstadt is now able to perform all necessary steps in the tableting process in five containment stations. The flexibility of these solutions makes it possible to carry out different lab processes consecutively by transferring the interme-

**BERTOLA:** Glatt's solution represents the best technology fit and engineering controls for our business, with the additional benefit of adding significant flexibility to our development capabilities.

### What are the technical advantages of Glatt's solution?

**BERTOLA:** Glatt's solution allows for initial formulation studies to take place quickly, in an environment with strict engineering controls and limited use of Active Pharmaceutical Ingredients (APIs). The restricted access barrier system (RABS) protects the operator, the product and the environment. It also allows several process steps to be performed concurrently.



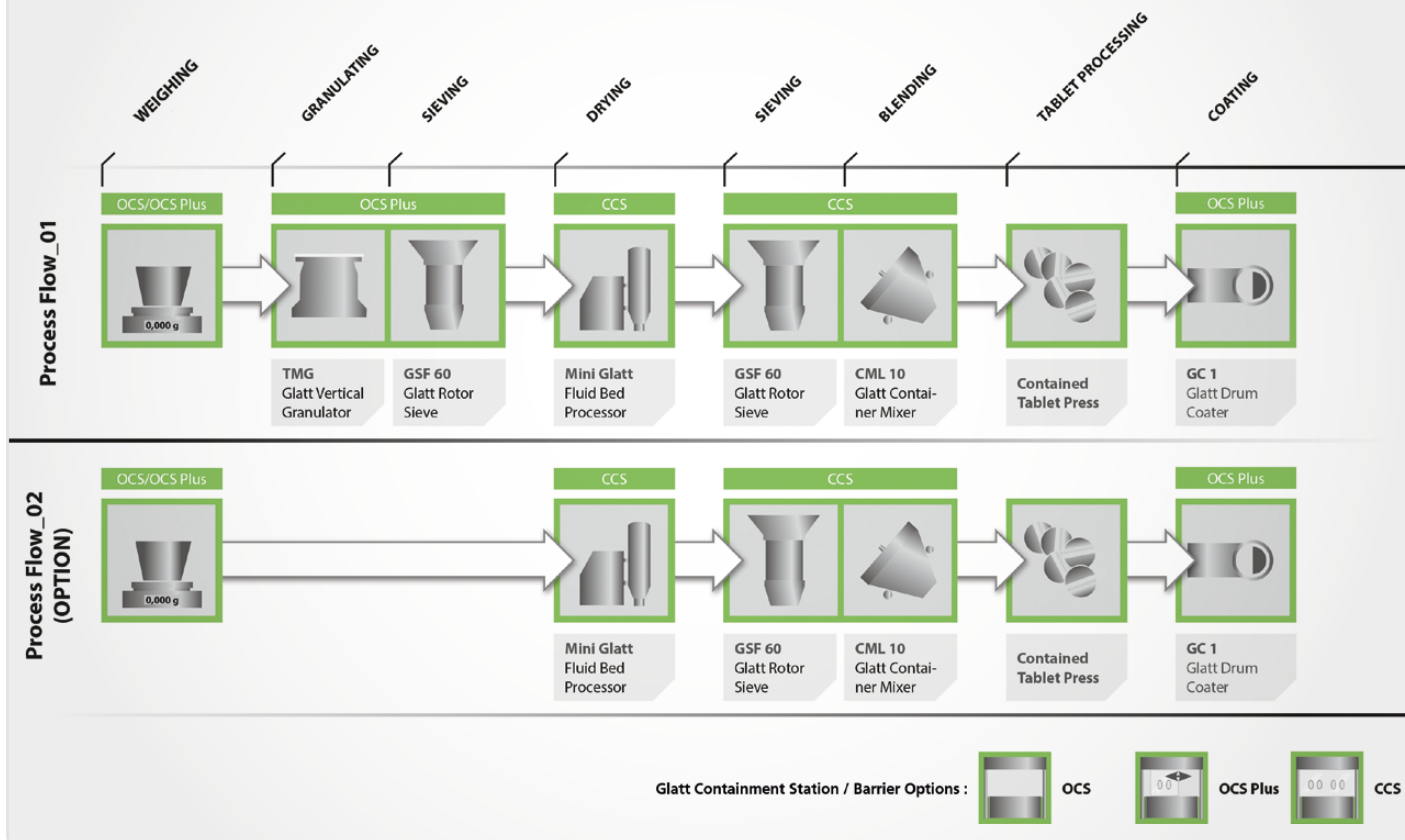
Glatt Containment Station (Barrier) can be executed in three configurations, shown above, (left to right): OCS Open Containment up to OEL 4; OCS with a sliding pane is fitted with glove ports to enable ergonomic working up to OEL 4/5; CCS Closed Containment System similar to Isolators and RABS, up to OEL 5.

Source: Corden Pharma International

Source: Glatt

Process Flow

# LAB CONTAINMENT TECHNOLOGY



Source: Glatt

diate material from one barrier to the next under full containment, resulting in customized and highly efficient operations. The ergonomic design has simplified operations such as the docking and undocking of the process tables. The RTP port allows the safe and contamination-free filling and discharging of the raw materials and components at all times. The design of the process equipment makes handling easy, even with the use of gloves in isolator mode.

The lab containment technology is available with three different OEL working range levels, enabling maximum flexibility for each requirement:

- The first option allows working with an open pane down to the OEL “>10 µg/m<sup>3</sup>”. This OCS (Open Containment System) is based on clean air technology which prevents contamination and allows safe operation.
- The second option, known as OCS Plus, is an open containment system which includes a sliding glass pane.

- The third option, a CCS (Closed Containment System) is equipped with a closed front window and allows operations at OEL levels below 1 µg/m<sup>3</sup>. During the entire production process, the highly potent product is surrounded by a defined airflow which reliably keeps particles away from the personnel and contained in the barrier system, avoiding contamination of the surrounding area and maintaining product integrity.

Each of the containment stations mentioned are equipped with an inflatable seal which automatically secures the process table in place in the containment station’s clean room area. The containment stations can be connected through the RTP port. The product and components can be transferred in and out of the individual barriers by an RTP container.

Whatever containment requirements one may have, Glatt offers solutions where various lab-scale processes can be operated in parallel, such as weighing, granulat-

ing, drying, blending, coating, and even a full wet granulation line, each in different Containment Stations/Barriers separated from each other while still fully contained.

Glatt’s containment expert Michael Maintok states: “At Glatt, we focus on keeping lab processes safe at all times. We formed an excellent partnership and, by pooling our know-how to achieve the very best results, we developed an innovative technology which was implemented in cooperation with the barrier manufacturer Weiss Pharmatechnik.”

## Strong Partnership

Corden Pharma’s expertise in the production of highly potent APIs and Drug Products is derived from decades of experience, the systematic application of new technologies and scientific learning, a risk-based approach as part of their Quality by Design (QbD)-driven development strategy, and their Glatt Lab Containment Technology.

### PROCESS-Tip

Pharmtech & Ingredients will be held from November 21–24, 2017 in Moscow/Russia. CIS is presenting equipment, raw materials and technologies for manufacturing pharmaceutical products, nutritional supplements, blood products and cosmetics. Meet the experts at Stand B101, Pavilion 2 Hall 8.