

# PRO·CESS

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## WORLDWIDE

# HIGH-CONTAINMENT IN THE HIGH MOUNTAINS

**Chilean pharmaceutical manufacturer uses HPAI production plant** — Where do you look to find someone with the initiative to precisely install a sophisticated high-tech system in the country which the locals say is “at the end of the earth”? An initiative such as this is anchored in the heads of visionaries who are undeterred by borders and barriers.



The HPAI production plant includes four stations, which combine flexibility and high-containment.

### MAURO ZOCCHI\*

It was back in 1992 that I first set foot on this fertile ground situated between the Andes and the Pacific Ocean. At that time, the topic on people’s lips was mostly the consequences of dictatorship. Nowadays, Chile is politically and economically stable. This fact, among others, has helped to ensure a friendly working relationship there between a local pharmaceutical manufacturer and Frewitt.

This situation wasn’t to be your typical “business as usual” case. This company, which is focusing on an expansion strategy and joined forces with a pharmaceutical corporation, needed a partner for complete solutions. Planning,

engineering, design and installation were all to be provided by the same firm, which had to be an expert in the field of milling technology—an ideal prerequisite for Frewitt. The Chilean pharmaceutical manufacturer had decided to make sensitive and challenging products and had therefore opted to create a brand-new process. Because it would have to be possible to process products containing HPAIs (highly potent active ingredients) on the planned system, the process would have to be closed.

The system would have to be fully mobile, as well as adaptable to the buildings or rooms. The Chilean company also required flexibil-

ity in the process, along with compliance with a high OEB level. It also wanted a solution which enabled connecting, transporting and cleaning of containers, drums, conveyors and glove boxes in the easiest way possible. Flexibility was a must for the batches and containers too: It had to be possible to connect containers with capacities of 300, 600 and 1,000l to the exact same storage system. Once the system was complete, it was to be accepted in the Frewitt factory

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(FAT) and then on the customer's premises (SAT).

### Contamination-free working

Probably the most important difference compared to a conventional procedural system is the closed process in those places where product is transferred from one process module to another. In the system described, product transfer from the container, to the vacuum conveyor, to the mill, to the vacuum conveyor and so on is considered "problematic" in this sense, as is the manual product supply into the closed process in particular. Frewitt was therefore keen to integrate its Profi-Flex system, which it developed itself, into the system. Profi-Flex is a flexible containment system which can be used for the dust-free addition of product to the process without contaminating the operator space. Unobstructed access to the machine's tools and components was to make working under high-containment conditions easier. The material coming into contact with the product also had to be easy to dispose of and clean. The active and passive valves which the customer wanted assembled at the container outlet and the drum inlet would also serve to ensure cleaner product transfer. Last but not least, product discharge into the operator space was to be effectively prevented due to the pressure equalisation in the drum and the product residue being cleaned from the filter using Profi-Clean.

### Good planning is key

To prevent follow-up deliveries to the country on the other side of the Andes, the system had to be meticulously planned, right down to the smallest details. The following was listed in the introduction to the proposal: first IBC emptying station; second station comprising TW-C20 milling head with Profi-Flex (without drive); third station comprising HW-6 with drive, Profi-

Flex and conveyor assembled on mobile lifting column; fourth station comprising conveyor on lifting column for filling drums. Much like in the last section, the most important elements which helped to meet the high demands are listed below.

First station: This is made up of a frame, which can hold IBCs with capacities of 300, 600 and 1,000l. There is an active valve with a DN200 design at the IBC's outlet. Below, there is a passive valve with a WIP connection, which can be used to rinse all the places and to wet the parts in contact with the product to effectively prevent prod-

>> The HPAI production plant combines process flexibility and the compliance with high OEB level.

uct particles from escaping from the system. A fluidisation system with antistatic filter is assembled in the hopper downstream of the passive valve, and there is a dust-free conveyor connection at the outlet. Unlike the three other stations, the first station is not mobile, so it is not positioned on castors, but rather on steel feet which can easily be adjusted to the required height.

Second station comprising TW-C20 milling head on our Fredrive platform with Profi-Flex and conveyor, the whole assembled on our mobile lifting column (Fre-Lift). Optimum product homogenisation is performed by the Turbo Witt or, more precisely, the TW-C20, which is made up of a milling head with cylindrical sieve and is connected to the Fredrive drive system.

Third station comprising HW-6 milling head on a second Fredrive platform with Profi-Flex and conveyor assembled on our mobile lifting column (Fre-Lift). The Profi-Valve-150 dosing system with pneumatic drive for continuous product delivery; the feed hopper with fill sensor to prevent the hopper from overflowing; the milling head of the HW-6 hammer mill secured with Tri-Clamps; an outlet hopper with a fluidisation system equipped with an antistatic filter according to the FDA standard; the Fredrive drive system with a freely controllable speed of 1,000 to

6,000 rpm; and the associated PLC with drive control, formula management and alarm diagnostics which is assembled in the control cabinet.

Fourth station: Finally, product filling takes place on the fourth station. The DN200 active valve, a passive valve with WIP connection, a conical outlet hopper and the autonomous Profi-Clean 90 de-dusting system, which cleans the product residue from the interface of the antistatic de-dusting filter, are assembled on the lifting column arm.

The operation of the entire system is controlled by level probes. Each individual process module can be manually adjusted to the correct height on the lifting column and easily connected. Product is transferred with an individually controllable pneumatic conveyor. The entire system is modular and can easily be adjusted to the spatial circumstances and the customer's process requirements.

Products containing HPAIs are now being processed in Chile, to the customer's full satisfaction, on what is probably the most flexible containment system that Frewitt has installed to date. Many factors contributed to this result: the customer's economic situation and Frewitt's experience in implementing complete solutions.

### PROCESS-Tip

At Achema 2018 you will find Frewitt in Hall 3.1, Stand D27.



As requested, production worker are able to connect the glove boxe easily – for example to a hammer mill HW-6.