

No cleanroom required

With a closed drying, milling and filling system, manufacturers can now fill APIs into continuous liners with full GMP compliance

A major international manufacturer of highly potent substances needed to develop a new method for filling Active Pharmaceutical Ingredients (APIs) whilst avoiding the constraints of a cleanroom.

A study on the elimination of cleanrooms in the filling area, mainly focusing on the improvement of containment, productivity, GMP, quality and product protection was commissioned. The objective was to come up with a pilot project to be applied by the entire group. Following close internal examination a detailed concept based on the manufacturer's specifications was developed and subsequently submitted to the Drug Administration.

Cleanroom downsides

The maintenance costs for cleanrooms are substantial, not least because of the maintenance and operational procedures needed to keep the cleanroom up to the required standards. Specialised cleanroom garments are essential, with the operator passing through specific locks to put on and take off extensive protection equipment before entering or leaving the cleanroom. The risk to operators' health must also be taken into consideration, as nitrogen used in cleanrooms can cause Anorexia and similar physical problems. In the US alone several people have died because they have inhaled too much nitrogen. Despite ventilation, the gas accumulates in so-called "nitrogen pockets" which can lead to the asphyxiation of the operator.

GMP compliant filling

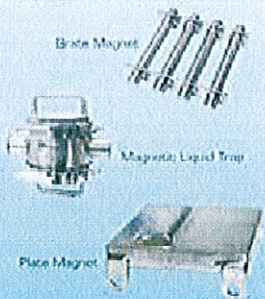
The purpose of the project was to allow a contained (<1 µg/m³) and GMP compliant filling of APIs without the need of a cleanroom in the filling area. The challenge was to achieve contained and accurate dosing and filling of customised drums from a dryer with a downstream conical sieve mill. The system had to be designed so that both contamination of the powder from the surrounding atmosphere as well as exposure of the



operator was prevented at all times. A comprehensive risk analysis rigorously developed by the customer accompanied the specifications. Following the concept's presentation to the French Drug Administration, it was sanctioned by AFSSAPS (Agence Française de Sécurité Sanitaire des Produits de Santé). This marked the beginning of the project.

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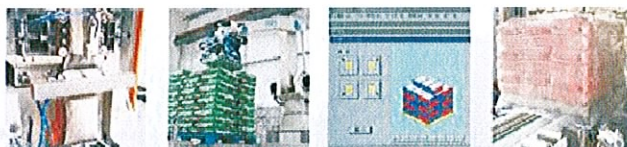
Safe and accurate filling of continuous liners

The system installed today consists of the existing filter dryer, a conical sieve mill as well as the filling station. The core of the supplied system is a Powder Transfer System (PTS) Feeder unit, which is part of the filling station, equipped with a continuous liner system, conceived for 50 kg drums, integrated into a special GMP glove box on load cells. The transfer and dosing unit PTS Feeder sucks the product from the dryer in a closed manner however the powder is not discharged through the standard outlet on the filter dryer but by automated lateral ball valve suction. The PTS Feeder is suited for the emptying and the filling of equipment, the filling and dosing of bags, drums or big bags in one single step.

The unit can be used as an emptying station for several

different installations with low height or low head space and allows the online suction of the powder from the mill between the filter dryer and the filling unit without intermediate steps. In a significant contrast to the cleanroom, the PTS Feeder eliminates the need for many stages, whilst achieving a high containment level and protecting both product and operator. The system is based on the operating principle of the PTS technology: product suction by means of vacuum. The emptying is carried out without pressure, which ensures the accurate filling of the drums. After a preset coarse dosing the system switches automatically to the fine dosing. The product is charged into drums of 50 kg with a precision of 50 g. The continuous liner is installed in the Drum Containment System (DCS).

Depending on the process requirement, a positive or negative pressure level can be used. Thus, different pressure levels are maintained inside the continuous liner, inside and underneath the glove box according to GMP guidelines. The drums are tightly closed with the system. For the closed connection and disconnection of the drums an external liner is used. The operator can reach the inner liner through the glove ports of the DCS glove box and pulls the continuous liner into the drum. Before the filling, the liner is leak checked and changed if necessary. The PTS Feeder automatically fills the drum and the final weight is controlled by a weighing unit. The continuous liner is easily changed without losing containment. A Micro



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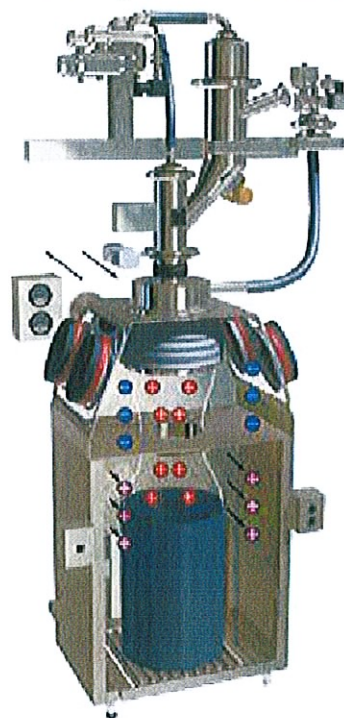
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The concept of different pressure levels:
Positive inside the liners
Negative inside the DCS glove box
Positive air flow underneath the DCS glove box

Powder Transfer System (MPTS) draws a reproducible and GMP compliant sample directly from the PTS Feeder into a customised sample bottle.

Safety barriers

Numerous safety barriers have been provided with the risk analysis to prevent product contamination and ensure absolute integrity of the system even in degraded operation mode. In the event of the failure of one barrier, there are still additional barriers which maintain the required security to prevent contamination.

The equipment is suitable for CIP and explosion protection zone 1/21. The control is exclusively pneumatic and can remain close to the system.

Depending on the application, this concept can be adapted to

suit a multitude of individual circumstances, with the different pressure levels of the system being adapted according to the priority (GMP, product or personal protection).

The handling of APIs according to GMP guidelines is always a challenge. A cleanroom to protect the product and an isolator system to protect the operator and the environment require high investment, but this concept allows a simple, compact and cost effective alternative.

Through the "open" space and the natural air circulation the use of nitrogen in the operating environment is no longer a danger whilst product contamination and exposure of the operator to dust is prevented at all times.

For more information contact Dietrich Engineering Consultants on tel: +41 21 694 20 40 or visit: www.dec-sa.com

Sew it up

Sewing remains ideal to close bags of all kinds of material: cotton, jute, burlap, polyethylene, paper, woven polypropylene... Fischbein introduces the Twin Needle Sewing Head and Systems.

Twin needle sewing head

The Twin Needle Sewing Head closes a bag by sewing 2 parallel lines on it. The stitches between the two lines are offset to further minimise/eliminate sifting of product through the sewn closure.

This "low vibration" Sewing Head is used for plain sewing, double stitch type 401, of open mouth bags.

Twin needle sewing system

This Twin Needle Sewing Head is installed on a single leg pedestal to build a sewing system to close paper and woven polypropylene (WPP) bags. This Twin Needle Sewing System must of course hold four thread cones and must have routing for all four threads to the twin needle Head: two threads for the needles, two for the loopers.

Until now, Fischbein has produced industrial systems with twin needle Heads installed on a pedestal only for manual operations, the bag being introduced by hand by the operator.

The sewing process starts when the feeler switch is activated. At the end, the pneumatic chain pusher pushes the thread chains into the knives to cut them!

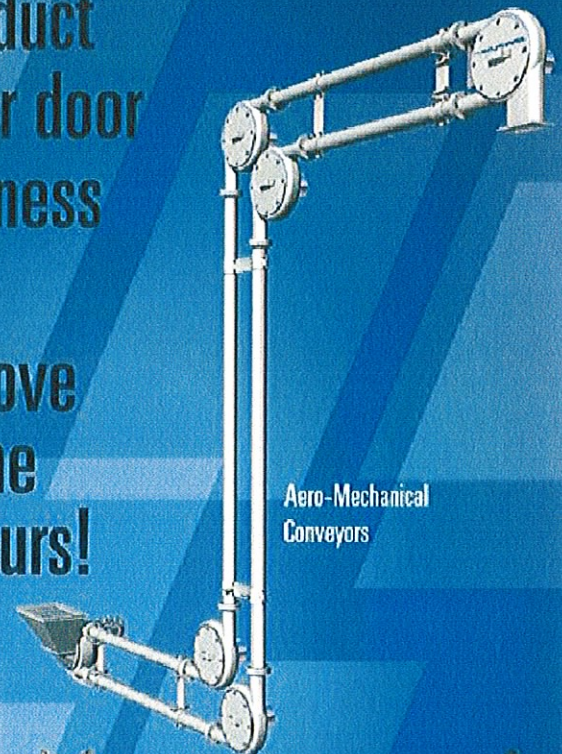
To have a smooth operation of the system, a conveyor is required.

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