



Delivery and loading of the empty vials to the compact line in the washing room



- 1 The filling machine is integrated into the separation wall between clean room and washing room
- 2 The *FLC* vial filling machine is equipped with an automatic non destructive checkweighing system
- 3 Clear separation of machine operation and checkweighing analysis with 2 panels

# Filling first, packaging after

Axellia is the leading producer of fermented, anti-infective, active pharmaceutical ingredients (API) and injectable finished products. Looking to expand its manufacturing capacity for injectables, the company turned to Bosch Packaging Technology for a compact injectables filling line solution with integrated end-of-line secondary packaging.

## Fully automated filling

In order to meet its customers' diversified requirements, Axellia recently began producing dosage forms of APIs in injectables. This enables the company to offer both raw APIs as well as finished products in an injectable format.

Axellia's existing filling line for injectables was exclusively devoted to powder filling, which was limited to only a few API products. To expand capacity for finished injectables and extend its portfolio to different API products, Axellia sought a liquid filling solution with sterile processing and lyophilization capabilities. Due to the unstable nature of certain API products, they must be freeze-dried into a dry powder form, after being filled into

injectable vials, to ensure a reasonable shelf life of the finished product.

Axellia ordered a complete filling line from Bosch in the summer of 2007, consisting of a washing machine, sterilization tunnel, filling and sealing machine, and an overseal capping machine. To meet the unique requirements of this project, Bosch delivered the **FLC 3080** filling and sealing machine, which offers time-pressure filling, automatic cleaning-in-place (CIP) and sterilizing-in-place (SIP) systems, and an automatic checkweighing system.

The time-pressure filling system was selected instead of the traditional pump filling station because it is easier to



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validate the CIP and SIP process. There are less mechanical parts in the time-pressure filling system compared to the pump filling system, which minimizes maintenance and offers an easier cleaning and sterilization process.

The automatic CIP/SIP system offers major benefits to Axellia. Firstly, it covers the in-line integrated sterilizing filter so there is no need to dismantle the system. The system also complies with GMP regulations, minimizing production times and eliminating the danger of product contamination.

**Automated checkweighing**

The fully automated, non-destructive checkweighing in-process control system ensures the best product quality control. The filling machine runs on an eight-hour shift at a speed of 300 vials per minute. The check weighing system controls eight random samples every three minutes and incorrect dosage amounts are automatically rejected without process interruptions. At the same time, the checkweighing system gives real-time, in-process feedback to the time-pressure filling to ensure accurate dosing. This fully automated system reduces the necessity of having quality insurance engineers on site, thus reducing labor

costs and minimizing the total cost of ownership.

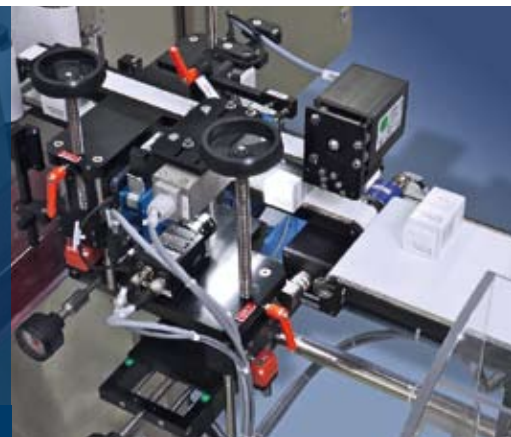
Uniquely for Axellia, the checkweighing in-process control offers a tracking system, designed by Bosch engineers in cooperation with the supplier of the freeze driers. This tracking system provides direct communication between the filling machine, the freeze driers and the capping machine, which ensures that incorrect vials are automatically rejected, even after the freeze-drying process. The whole automatic process and communication gives Axellia further quality assurance.



- 1 Axellia vial packaging line
- 2 Bosch horizontal cartoner type *CUC 2001*
- 3 Carton erection system with counter vacuum
- 4 Online carton printing and verification



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### Whole-line integration

When Bosch delivered the complete filling line in the summer of 2008, the project manager at Axellia, Mr. Knud-E Andersen, was impressed with the on-time delivery and the overall quality of the system. At the same time, he was also looking for an end-of-line secondary packaging solution to package the vials into cartons. As a result, Axellia again turned to Bosch for a solution.

For the end-of-line packaging, Axellia needed a labeling machine, a turntable, a cartoning machine, checkweigher, stretch bander and a case packer. However, Axellia didn't want to source these individual modules from different suppliers. Bosch was able to offer a customized, one-stop-shopping solution by sourcing the labeling machine, stretch bander and case packer from outside vendors and integrating them with its own cartoning machine and checkweighing unit. Thus, Bosch provided Axellia with a complete end-of-line packaging solution together with on-site installation and support.

The *CUC* cartoning machine from Bosch offers excellent accessibility. The servo technology, industrial PC control systems and the ergonomic touch screen operating panel provide secure, reliable and trouble-free production runs. The product insertion, from the back of the machine, significantly reduces maintenance time and allows easier cleaning and trouble-shooting. The encapsulation of the drive components and the slanted guards considerably reduce the time required for line clearance.

The modular *KWE 4000* checkweighing system meets pharmaceutical safety and cGMP requirements, as well as offering simple operation and easy line integration. The control cabinet at the rear of the checkweigher and the operator terminal allows excellent accessibility. Production statistics, trend curves and current weight are displayed on the standard screen, which can be configured to show further information if required. The weight display can be changed to large numbers for at-distance reading by one single touch on the screen.

From fully automatic filling lines to customized cartoning lines, Bosch has provided Axellia with highly reliable machine quality, easier validation processes and excellent customer service. The exceptional level of Bosch's service and support has also given Axellia the convenience of interacting with only one supplier and makes the whole line integration and validation process easier. As a result, Mr. Knud-E Andersen has been generous in his praise for Bosch and said: "I have had a good experience with Bosch. We believe in Bosch, that's why we buy it from Bosch."

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