



# Fast delivery and high quality service deliver pharma success

Hameln pharma, part of the Hameln Group, has focused on the development, production and distribution of pharmaceuticals for over 50 years. Specializing in the contract manufacturing of parenteral medicines predominately used in hospitals and intensive care, hameln pharma has worked with Bosch Packaging Technology for many years. Currently, the oldest Bosch ampoule line still in use was purchased in 1985.

## Fast delivery

In 2006, hameln pharma decided to build a new sterile facility to increase the production capacity in Hameln, Germany. Additional filling lines were to be installed so hameln pharma needed a reliable supplier of vial and ampoule filling lines with short delivery times. Other critical process parameters included compact design, energy efficiency and short training times. After making comparisons, hameln pharma decided on Bosch.

In November 2006, hameln pharma ordered a vial filling line equipped with a universal washing machine, drying and sterilizing tunnel, filling and closing machine and capping machine. Bosch delivered the line within 12 months. Another ampoule filling line was ordered from Bosch in April 2007 which was equipped with a universal washing machine, drying and sterilizing tunnel, filling and sealing machine and color coding machine. Bosch delivered this second line in December 2007, an even shorter delivery time than for the previous order.

## Increased productivity

The most important features of the vial and ampoule lines are the U-Shape with a wall installation, and the inclusion of Restricted Area Barrier Systems (**RABS**) and Cleaning-In-Place and Sterilizing-In-Place (**CIP/SIP**). To achieve maximum production efficiency, the vial and ampoule lines are set up in a U-shape with a wall installation. This greatly reduces the space required in the highest cleanroom class. The cleanroom class zone grade A can be kept smaller when using wall installed machinery. Furthermore, maintenance measures inside the filling and closing



Vial filling and closing machine *FLC 3060* with *RABS* at hameln pharma





machines can be partially carried out from cleanroom zone grade D, which reduces the contamination risk in zone grade B during maintenance, or in case of repairs.

Another benefit of the U-shape with the wall installation is that there is less movement needed for the operators in the cleanroom, especially between different cleanroom zones, which increases productivity and efficiency. The monitoring of the actual filling process in cleanroom class A can be performed by an operator that remains in the neighboring class B cleanroom.

“We had extensive meetings with Bosch at machine manufacturing sites in Crailsheim, Germany, and at Hameln to discuss our needs during the project planning, and we are very satisfied with Bosch’s fast delivery of vial and ampoule filling lines with our required U-shape

and wall installation. This helps us to increase productivity and efficiency while meeting the cleanroom standards.” says Dr. Simone Dahlmanns, Operations Director of hameln pharma.

**RABS** further reduces the risk of contamination in the cleanroom zone grade A, since most of the production process can be carried out with the doors closed. Additionally, the filling machines are equipped with CIP/SIP equipment which further reduces the risk of contamination.

With the Bosch lines, hameln pharma will expand its production capacity to handle a broader variety of container formats, batch sizes, potencies, formulations and product types. The efficient and flexible sterile facility has won the 2009 Facility of the Year Award for Operational Excellence.

“We have always trusted the reliability of the machines and the service provided by Bosch. The quick response time from Bosch in answering questions, replying to our urgent requests and supplying solutions for special needs was critical to the success of this project. The lines from Bosch have created a positive experience for us, based on the reliability of the machines. Furthermore, the modular build of the machines allows for lower storage levels of spare parts in Hameln and, in urgent cases, Bosch can deliver critical parts within 24 hours,” says Dr. Dahlmanns.

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- 1 Opening of stopper bags under laminar flow
- 2/3 Closing station of the ampoule filling and closing machine **ALF 4080**
- 4 Container infeed at the washing machine **RRU 3084**

