



USM – Machine for detraying/traying of syringes



Interior view FLS in isolator



# Precision

## all the way along the line

Merckle Biotec is banking on Bosch as a total-systems supplier for their new syringe-filling system for pharmaceutical products from the Ratiopharm Group and for new products, including biotechnologically derived active substances. The core of the system is the FLS, which sets new standards in injection-syringe processing.

A member company of the Ratiopharm Group, Merckle Biotec's business segment is the manufacture of biotechnologically derived substances and of drugs made from these.

### **The challenge: fewer interfaces**

Merckle Biotec aimed to replace an existing line to stay abreast of the increased demands for capacity and flexibility in the production of prefilled syringes. The challenge lay in keeping the cost of interface clarifications as low as possible despite the size and complexity of the project. The crucial factors for placing

Time pressure filling system  
with fully automatic  
in-process control



the order with Bosch were the convincing product portfolio covering all the processing stages and an isolator solution, which, in effect, is already adapted to the filling and sealing machine.

#### **The challenge: integration into the existing space**

The next challenge was to integrate the complex line into the existing building. Here the space-saving concept of the FLS machine proved to be of particular advantage, allowing the machine dimensions to be kept to a minimum despite the many processes involved.

#### **European premiere: ultrasonic pre-cleaning of syringes**

With the RRU washing machine, an ultrasonic cleaning process for syringes is being brought into use for the first time in Europe. The syringes travel through a water bath where they are also cleaned with ultrasonics. After washing, the syringes are siliconised to ensure optimum sliding-in properties for the stoppers.

#### **A tunnel that sterilizes itself**

Heat sterilization is the final step before the syringes are sluiced into the isolator for filling. Here too Merckle Biotec put its money on Bosch process know-how and decided to fit the tunnel with a sterilizable cooling section. As a result, reproducible standards of cleanness are guar-

anteed at the critical interface between the tunnel and the isolator. Another important step towards even greater pharmaceutical security!

#### **FLS: Slim. Precise. High-performance.**

The core of the line is the FLS filling and sealing machine, providing numerous innovations for the processing of syringes. The conveyor system reduces the mechanical load on the delicate syringes to a minimum, as all the filling and sealing processes take place without additional transfers. The slim design of the machine also allows workstations to be accommodated flexibly at the front and rear, thus combining functionality with the optimum use of space. Yet another innovation used on the FLS are the newly developed pharmaceutical handling units for a variety of handling tasks in sterile areas, featuring simple sizepart changeover and maximum precision.

#### **Integration instead of interface: isolator technology and filling machine from a single source**

With the use of a Bosch isolator, Merckle Biotec receives not only the latest in Clean Room technology but also a fully integrated system making the interaction of operators, machine and product simpler and more secure than the interface solutions of various other manufacturers.



*Bosch would like to thank Mr Klaus Berghaus, Head of Sterile Medications at Merckle Biotec GmbH, for his kind help in writing this article.*

#### **For more information please contact:**

**Klaus Ullherr**

Phone +49 7951 402 517

[klaus.ullherr@boschpackaging.com](mailto:klaus.ullherr@boschpackaging.com)

