

Beads of wisdom

It doesn't save the world, but the Kugler system is responsible for ensuring that even diagnostic agents at risk of explosion can be filled and sealed safely. That required a number of precautions. The project has other innovations too.

A wide range of diagnostic tests are manufactured on the system: the eight cavities per multi-cartridge are each dosed with minimal quantities of different types of liquid. These are alcohol-based products (and therefore at risk of explosion), buffer solutions and magnetic beads. The latter contain extremely small metal spheres whose surfaces are coated with antigens. Some of the suspensions are volatile enough to generate explosive environs.

Dosing takes place in the micro range – and this, the explosion protection and other requirements of the customer were realized using a Kugler Flexofill machine with various customized design solutions. The other requirements included a particularly compact design, high product utilization and simple yet reliable operation. There were business factors to consider too: little time taken up with operation and support, and low foil consumption.

One of the advantages of the Flexofill concept under precisely these conditions is its design as a compact all-rounder that performs all the necessary functions. It begins with vibration sorting for the cartridges, which also automatically ensures that they are conveyed in the correct position.

The design of the filling unit conforms entirely to the specific product characteristics. The filling unit is divided into two zones: a pair of microdosing pumps are provided for the liquids and suspensions at risk of explosion. For products and suspensions not at risk of explosion, there are also eight peristaltic pumps on the trolley, which means that only the tubes and filling needles are located directly on the machine. The actual filling technology, however, is installed separately outside the machine. This means the area does not need to have explosion protection, yet is safe.

The peristaltic pumps on the Kugler Flexofill machine are a new development. They can dose down to a lower limit of $50\mu\text{l}$ – an impressive figure. The microdosing pumps allow precise filling down to $15\mu\text{l}$. The contract with the customer stipulates a filling accuracy srel of 1.5% at a volume of $100\mu\text{l}$ water.

The dosing range at present is between 40 and $2000\mu\text{l}$.

The filling area was divided at the filling needle holder. This establishes a separate “zone” for each type of liquid – alcohol-based, buffer solution and magnetic beads. Suspensions are pumped round at both stations, while recirculation valves ensure a uniform consistency – which means that dosing can continue without any loss of product even after an unexpected machine stoppage. An air bubble sensor in explosion proof design also determi-

nes whether products that tend to foam have been filled as required.

This is followed by an unwinding and cutting device for the sealing foil, a pick-and-place unit that places the foil blanks on the cartridges, a hot-sealing station for the large contact surface and a control station that verifies the presence of the foil. The filled

and sealed cartridges leave the machine on a conveyor belt. The compact, easy-clean ma-



chine is operated under laminar flow and is suitable for operation under clean room class ISO 8.

Explosion protection

The explosion protection of the system, which is also licensed for alcohol, has been ensured by several details. Air exhausts on the filling stations of the microdosing pumps and also on the agitators or product tank remove the vapors that are produced. Below the filling station is a collecting tank with safety sensor. To minimise static charges, all size parts were made from aluminum. ATEX certification was issued by the TÜV. All products not at risk of explosion are stirred and also recirculated on a vessel trolley outside the machine.

Business benefits

The system is monitored and analyzed by a SCADA system. The business benefits are underlined by a number of facts. Previously, three workers would be tied up operating and supporting the machine for the manufacture of these diagnostic cartridges. Now, though, only one operative is required. Another detail is the use of the foil. Of 500 meters of foil, only about 20cm is wasted. While previously 10 % of the foil would be lost,

now the figure is less than 0.1 %. And, not least, a huge amount of product is saved. It used to be the case that 10% overfilling was required in order to avoid the risk of underfilling, but now this has been cut to 3 %. Thanks to the high reproducibility of the processes, that's a permanent saving of 7 % of product!

The output of the Flexofill machine for this application comes to 1,800 filled cartridges per hour, whatever the product or size. The servo-controlled product conveyor can also be accelerated to cope with products that tend to foam, with no risk of splashover. All relevant and product-specific parameters are defined and stored in the machine control, from where they are retrieved during operation. This allows the extremely flexible system to be reconfigured for processing another diagnostic product within just 30 minutes.

The system was bought by a customer in England in May 2011. Optima Group Pharma has since acquired two follow-up projects, which are now already in the implementation phase. And there's another innovation on the way: the peristaltic pumps are now also offered and installed in an explosion-proof form. ●

