

## Monitoring of the loading and unloading process during freeze drying

In recent years, an increasing number of freeze dryers used within the pharmaceutical industry have been equipped with automatic loading and unloading systems. This leads to a significant increase in productivity and better product protection from contamination. In addition, the number of highly active products – in the form of hormones, antibiotics and oncologics, which require some form of operator containment – has also increased. Since the exposure of the operator to these substances could have fatal consequences, the use of automatic loading and unloading systems is hard to avoid.

Although the sophistication of automatic loading and unloading systems continues to increase, irregularities during production can still lead to difficulties, for example:

- Vials without stoppers
- Incorrectly placed stoppers
- Vials with an incorrect filling volume
- Incorrectly sealed vials

Owing to the high throughputs and sometimes low operator control, such defects are often only detected at inspection, which often occurs offline or following quarantine. Although this procedure is, in the view of drug safety, acceptable, it does have several disadvantages for efficient and safe production. Firstly systematic variations, e.g. reproducible filling volumes, cannot always be monitored and corrected during a running process and can lead as a worst-case to batch loss. In the case of highly active products, a missing stopper can for example lead to product contamination and a considerable operator safety issue when the vial leaves the containment boundary. To solve these issues, Baumer and GEA Lyophil have been working on

a solution to monitor this process, which offers not only maximum product safety, but can also be retrofitted onto existing lines with a very high level of flexibility. Until now the possibility of 100% inspection between filling and packaging did not exist. "Our requirements were very comprehensive with operator safety and process security being top of the list. This

is particularly important when processing highly active substances," said Johannes Selch, Product Manager at GEA Lyophil. But compact build, cleaning design and flexible operation also needed to be considered. When working on this solution, Baumer was able to draw on a wide product portfolio and long experience. As a result the company could offer a



*The inspection tasks (jobs) for the simultaneous closure and level control of the vials are configured in the user-friendly VeriSens® software. The jobs can be selected according to vial size.*

combination of vision sensors and special light barriers as the optimal solution. The *VeriSens*® vision sensor is very well suited for such applications. This vision sensor is the easiest solution and offers exactly the performance required for image-based quality control including the integrated *FEXLoc*® technology for position recognition. In this way incorrectly sealed vials, vials without stoppers, and vials with an incorrect filling volume can be detected and reliably rejected. Further, the *VeriSens*® can also read barcodes and other identification marks. The vision sensor can inspect up to 32 different features simultaneously. The *VeriSens*® is easy to integrate and can be configured intuitively; it provides convenient job switching according to changes in vial size or inspection features. The trigger signal for the image acquisition

came from one of the new *SmartReflect*™ light barriers. Thanks to the new *SmartReflect*™ technology, these light barriers are the first on the market that do not need a separate reflector. The benefits of this technology become particularly apparent in the hygienic design of this application: Thanks to the elimination of the superfluous reflector, the installation of the sensor into the compact design of GEA Lyophil ALUS® is highly simplified. Furthermore, there is no reflector that must be cleaned and replaced regularly, i.e. HACCPs are reduced. With the top-quality transparency detection of the *SmartReflect*™ technology all applied transparent glass and plastic vials are detected reliably. If a freeze dryer is loaded and unloaded on the same side then all inspection criteria can be tested using just one unit. For a pass

through design, with unloading at the front and loading behind, two inspection systems are required. "In this way we can provide a low-cost system that fulfills the demands of quality and product security," said Johannes Selch. The combination of a vision sensor and the *SmartReflect* technology ensures that no damaged or open vials leave the containment barrier and also that unsealed vials cannot contaminate the equipment. This means that in the future 100% inspection including traceability will be possible between the filling and packaging line. Additionally, images of all rejected vials can be saved which will greatly aid trouble-shooting.

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