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NEWS

## **Ready Advances in Aseptic Filling**

A new system comprising ready-to-fill pharmaceutical vials eliminates the need for vial cleaning prior to filling, allowing drug manufacturers to cost-effectively simplify filling programs while ensuring sterility.

To demonstrate this, Aseptic Technologies, a subsidiary of GlaxoSmithKline Biologicals (GSKb), is using a selfbuilt filling line at its Gembloux, Belgium, facility. The Crystal Closed Vial Filling Line (CVFL) is designed to fill cyclic olefin copolymer (COC) vials supplied with thermoplastic elastomer stoppers in place. ISPE (the International Society for Pharmaceutical Engineering) has recognized Aseptic with a 2009 Facility of the Year Award in Equipment Innovation.

Aseptic will be operating the CVFL as a GMP-compliant contract packaging line at its facility; also offered are line development, installation, and validation services for drug companies' own facilities. The Belgium line was developed with "quality-by-design" principles in mind, the company reports.

"This line has been built in order to simulate the new aseptic-filling process concept and to support clients who wish to invest in the technology with the filling of stability lots and first clinical trial batches," explains Jacques Verhees of Aseptic.

Rexam Pharma produces the Crystal vials, which are molded and robotically closed in a Class 100/Grade A/ISO 5 cleanroom and then gamma irradiated. The vials are then shipped sterile and ready-to-fill to the aseptic filling plant.

The closed vials are loaded into the CVFL either via rapid-transfer ports (RTPs) using beta-bags, VHPsanitized airlocks using polyethylene bag wrapped vials, or manual loading in an area under HEPA-filtered unidirectional air flow and surrounded by soft walls, with e-beam stopper sterilization.

Once on the CVFL, the stopper is pierced with a filling needle specially designed to avoid coring. (The needle and needle holder are steam sterilized before use and brought in through an RTP in the Class 100 environment. The whole filling operation remains in a class 100 environment, so no contamination could occur, says Verhees.) After filling, the stopper is immediately resealed with a low-energy laser beam. Caps, which enter via the RTPs or VHP airlocks, are then applied in a Class 100/Grade A/ISO 5 aseptic environment.

"A comparative study at GSKb showed us that the number of particles found in the COC closed vial is significantly lower [than that found in a traditional glass/stopper system], especially for the very small particles, such as 5- and 10-µm particles," Verhees reports.

TOPAS Advanced Polymers (Florence, KY) provides the COC for the vials. "COC is less prone to breakage compared with glass, so the material facilitates automation and the efficiency of the concept, along with safety and convenience," explains Timothy Kneale, president of TOPAS COC. "It enables Aseptic to offer a system that is reported to be much more efficient than existing industry-standard vial-filling practices."

"COC also offers purity and inertness for medication stability, which we find results in less agglomeration and less reactivity with surface ions as compared with that of glass." Kneale adds COC attracts few particulates, suiting it for Aseptic Technologies's process.

"We believe that "this process is a safer and easier way of aseptic filling," Verhees concludes. "Safer for the patient because the level of aseptic filling has been raised, and easier as the vial is delivered "ready to fill." Aseptic Technologies will present the technology at ACHEMA in May 2009.

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