



Alcan Uses SPC System for Vial QA

Alcan Global Pharmaceutical Packaging—Glass Tubing Americas (Millville, NJ) works closely with pharma and bio-pharma customers to ensure that vials and ampules meet customer requirements. As customers require better quality from their suppliers, Alcan has responded by investing in the latest technology and quality system tools at manufacturing sites. The investment includes shop floor Statistical Process Control (SPC) solutions.

“The branded pharma marketplace is requiring their suppliers to meet more stringent product quality requirements. Alcan has begun to partner with strategic customers to define and better understand these needs and specifications,” says Robert Hayes, director of quality, Alcan Global Pharmaceutical Packaging—Glass Tubing Americas.

Hayes says the market is moving from a standard acceptable quality limit (AQL) methodology for product acceptance to a quality assurance plan that ensures 100% percent compliance to customer specifications through the use of automatic inspection systems.

“Historically, pharma, bio-pharma, and medical device companies had less stringent product requirements for purchased components,” he says. “Once the drug or device is packaged, the customers apply tighter AQLs to the final product inspection to manage risk appropriately.”

“Our customers are requiring suppliers to help in the reduction of finished product nonconformities, and to help increase their machine efficiencies with better quality and more consistent products,” Hayes adds.

The glass division has expanded its use of automatic vision systems to meet the new quality levels. Inspection capabilities have been moved upstream in the container production process. Vision inspection has been added at the tube drawing plant, where tubes are produced prior to the vial converting stage. “It is less expensive to throw away any non-conformities upstream when they are discovered prior to being used in the vial converting process,” Hayes says.

Alcan implemented a shop floor SPC solution from InfinityQS. “We invested hundreds of thousands of dollars to implement the latest technology for vision systems and shop floor SPC to meet customers’ new product requirements. The investment completes the vertical integration of technology required to control the entire manufacturing process.

“The new system provides real-time results at the point of manufacture, beginning with the tube drawing operation and continuing through the vial converting and packaging processes,” Hayes says. “The manufacturing data is analyzed in real time with the appropriate statistical methods to provide a picture of what we are making in production of a batch or production lot.”

Alcan can use the technology to generate electronic batch records that will include the customer requirements, product drawings, operator logs, and critical manufacturing data that can be shared on line with internal and external customers.



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