PRODUCT SHOWCASE: perfeXion™

SCHOTT
glass made of ideas

perfeXion™ is a new quality approach from Schottt, which controls every inch of pharma glass tubing and with its launch the company pushes towards a zero-defect philosophy in pharmaceutical glass tubing production.

> "We are taking a major step towards a holistic view of quality in pharma glass production."

In quality control, details matter. When it comes to pharmaceutical primary packaging such as vials, cartridges or syringes (Figure 1), fluctuations in tubing dimensions such as the inner diameter or wall thickness can have a significant impact on the container performance – for instance, the filling or dosing accuracy for high potential drugs. Up until now, manufacturers of glass tubing have usually been monitoring quality parameters on a random sample base. However, Schott has developed a new production quality process. perfeXion™ controls and monitors every inch of the glass tubing that is later converted into a primary packaging container used by pharma companies to store and administer perhaps lifesaving drugs. With this, Schott aims to contribute to patients' safety from the very beginning of the value chain.

Figure 1: Fluctuations in tubing dimensions significantly impacts performance of syringes and other primary drug containers.

Schott officially introduced the perfeXion™ process to the industry with a presentation from Folker Steden, PhD, at CPhI Worldwide in Barcelona, Spain, on 4th October, 2016.

FROM BELIEVING TO KNOWING

"We are taking a major step towards a holistic view of quality in pharma glass production," says Patrick Markschläger, Executive Vice-President at Schott Tubing. "We could see from our existing control mechanisms, which were already extremely tight, that the quality of our glass tubes meets the highest requirements. Now with perfeXion™, we can verify that every inch of the glass tube is accurate."

This is a significant achievement, as Markschläger explains: "Pharma glass is mostly drawn in tubes when it comes from the melt. Schott as well as other quality-oriented converters use these tubes later on to produce vials, syringes, ampoules and cartridges. The challenge lies in monitoring and measuring the curved tubing surface with 100% accuracy, in a high-speed production process." This is achieved by using a combination of line scan and area cameras, laser and IR inspection systems that literally investigate the entire glass tube on-line. The measurement data is then collected and evaluated by a holistic inter-connected IT solution.

"This system recognises even the smallest defective spots in the "endless" glass tube that comes from the melt. It is then able to attribute these spots to a certain position at a single tube once the cooled down glass string is being cut," Markschläger continued. "This sophisticated system enables us to customise the quality level to the specific needs of the industry."

By storing the collected quality information in a database, measurements can be traced back even years later if needed.

Markschläger confirms that Schott has already started implementing perfeXion™ at its main site in Mitterteich, Germany. A company-wide roll-out at its other facilities in Europe, Asia and South America is underway.

With this development, Schott is not only passing another milestone of its future oriented quality roadmap. More importantly, the company's pharma glass known under the brand name SCHOTT FIOLAX® will enable even more sophisticated primary packaging solutions for advanced medical treatment than it already does today.

Each year, the international Schott Group manufactures around 140,000 tons of glass tubing and more than 10 billion pharmaceutical containers such as vials, syringes, ampoules and cartridges.

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