

# Pharma glass sees heads turning with **CORNING's** new standard

Recent glass innovations offer solutions to the drawbacks of conventional glass used in pharmaceutical packaging. Here, with improved chemical durability and reduced friction, CORNING's Valor Glass minimizes breakage, delamination and glass particulates. It also addresses FDA concerns while enhancing manufacturing efficiency – which benefits both patients and manufacturers.

**E**veryday objects like glass jars, bottles or even household windows are typically made of an easy-to-melt glass composition which is fairly inexpensive to manufacture. The result here can be a glass of poor chemical durability – an 'everyday' glass that won't suffice for pharmaceutical use. Here, impurities from the primary packaging can cause such problems for pharmaceutical products as contamination, degradation of the APIs or even pH shifts. Instead glass for pharmaceutical use must have excellent chemical durability to keep the drug product stable for as long as possible – a durability that can be ably achieved by either increasing the aluminum oxide in the glass or by keeping the silica content of the glass high.





Corning® Valor® Glass



Corning® Velocity® Vials



Corning® Viridian™ Vials

## TROUBLESHOOTING THE HAZARDS OF DOWNTIME

Pharmaceutical filling lines process hundreds of vials per minute, creating glass-to-glass frictional contact that leads to scratches and breakage. That can also lead to small glass particles and cause downtime. The underlying cause of these challenges lies with conventional borosilicate glass vials. These have a high coefficient of friction surface, which increases their predisposition to jam. Consequently, operators may have to intervene - increasing the potential for contamination.

Not uncommonly, pharma manufacturers remain unaware that such problems can be either reduced or avoided. Background glass particles, for example, are considered the 'norm' - being created as vials rub against one another on the filling line. When one pharma company switched from borosilicate glass to Corning's Valor® Glass during a line trial it assumed its particle monitoring equipment was broken after the particle counts in the filling environment dropped to such low levels. What they hadn't realized is that it was possible to reduce particle counts to such low

levels by simply changing the glass!

Many glass suppliers highlight the processes used to make the glass - including how, for instance, they reduce the potential for defects. In many cases the solutions address a singular problem - one solution tackles delamination, another reduces extractables and leachables and a third might focus upon machinability. In contrast, Corning's Valor Glass was developed as a holistic glass solution to simultaneously minimize as many problems as possible.

According to Corning's R&D team the creation of Valor Glass followed a Quality by Design approach. Here the team identified the root causes of problems like delamination and breakage and used materials science to optimize the glass composition. For example, the root cause of delamination was traced to the evaporation and condensation of boron from borosilicate glass during the tube-to-vial converting process. The resulting boron-free composition of Valor Glass specifically eliminates delamination and gives the glass low extractable concentrations. The low friction external surface keeps it inherently strong and damage resistant, moves smoothly through manufacturing lines and can reduce peak particle counts by up to 96 percent.

### QUALITY ADVOCATES

The FDA has continued to raise concerns

with the quality of conventional glass packaging through both advisory and other communications. Moreover, FDA has supported -through its Emerging Technology Program- advancement of new glass packaging technologies, like Valor Glass, with the potential to improve drug product quality. Traditionally, glass manufacturers have been seen as 'just suppliers' to pharma manufacturers, with prices based on the cost of materials and manufacturing process. But there have been some negative consequences related to glass quality issues, such as drug recalls resulting from delamination or from glass particles in the drug container. Poor filling line efficiency due to jamming vials or breakages can also add to manufacturing costs. These issues can be reduced with the right glass containers. As a drop-in solution, Valor Glass will improve manufacturing by reducing the problems that could lead to delays, drug shortages or potential recalls - a win for both patients and manufacturers alike. ■

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