

NovaPure® Components

Case Study

Short term work for long term gain: A proactive approach to reducing particulate risk

The Challenge

A biotechnology company that manufactures injectable large molecules was seeking to evaluate elastomeric components that would help them to attain the highest quality standards for their manufacturing lines. The company took a proactive approach to meeting and exceeding regulatory guidelines concerning the cleanliness of their life-changing medicines and were keen to learn how a supplier's tight packaging specifications could help them with their approach.

Pharmaceutical regulations are always driving improvements, including elevating the importance and scrutiny of particulate risk on finished drug products. For example, USP<1> states that finished injectable drug products must be “essentially free from visible particulates.” Regulators and drug manufacturers have been working together to continuously improve the quality of drug products by focusing on particulate reduction to ultimately minimize patient risk.

The Considerations

This company recognized the critical impact that parenteral components and packaging have on particulate levels. Components made with dimensional and inspection controls were important to ensure high-quality levels, demonstration of zero defects and consistent machinability on their filling lines. Additionally, they needed a sterile, ready-to-use component that they could count on for all their drug products. By improving product quality of the packaging component, they hoped for a reduction in end of line rejects, which would positively impact the amount of critical medicine they could get to their patients.

The Solution

By selecting NovaPure® stoppers, the company felt they were bringing a better sense of control and a higher degree of reliability to their quality processes. The 100% vision inspection and industry leading visible and subvisible particle specifications assured them of a high-quality product, reducing the potential risk of particulate sometimes found with elastomeric stoppers. The selection of NovaPure components helped the company mitigate the risk of the stopper being a potential contributing source of particulate, enabling them to focus on process variability and defects. When asked if they were to offer advice to other companies about their manufacturing and fill-finish experience with West components, the company recommended NovaPure stoppers. This high-quality component allowed them to decrease the costs and risk associated with failures, enabling them to focus on the core of their business, delivering medicines safely to their patients.

