

NovaPure[®] Components

Case Study

Partnering to Ensure High Quality and Optimized Functional Performance Based on Quality by Design (QbD)



The Situation

As trends toward self injection continue, developing self-injection systems that are easy to use, intuitive and help keep patients adherent with their treatment programs has become a priority for pharmaceutical and packaging manufacturers. Most elastomer products are not developed with an auto-injector delivery system in mind. Issues such as silicone migration and break loose and extrusion forces vary greatly in auto-injectors. With a prefillable syringe system, the end-user can usually overcome any issues, but similar challenges in an auto-injector can result in incomplete injections, compromising patient safety.

The Challenge

When a long-time customer needed a partner to develop a high-quality component for a precision auto-injector based on a tight quality target product profile for a prefillable syringe system, West helped to develop a plunger component that would ensure complete compatibility with the device, and ultimately lead to market success.

The Solution

Through a unique development agreement, West and its partner used a QbD approach and consistent collaboration to ensure that a NovaPure prefillable syringe plunger met the stringent quality needs for an auto-injector platform. The result was a significantly improved plunger product for use in a pre-filled syringe within an auto-injector drug delivery application. Working together, West and its partner ultimately solved the issues associated with a syringe system, and developed a new plunger option to aid functionality, machinability and provide more consistent injection rates.