

## Meeting Customer Needs With Custom Solutions

If your drug product requires custom components to meet design or compatibility needs, who can you turn to for a solution? A leading global drug manufacturer found itself in this situation several years ago and turned to West for its expertise in developing custom solutions.



### Market Need

West's customer was planning to move from a vial to a prefilled cartridge system in an effort to eliminate some of the steps needed to prepare the drug for administration. Due to drug product and patient needs, the company required that the same FluroTec® barrier film used on the vial stopper be applied to the new cartridge plungers—on both sides.

For standard prefilled syringe applications, FluroTec is most often applied only to the drug-contact side of the plunger. The plungers are oriented during machining so that the FluroTec film is applied to the proper side, and then flipped during fill finish so that the barrier film side can be inserted into the prefilled syringe. Unlike syringe plungers, cartridge plungers are designed to be the same on both sides and do not require orientation for insertion, so either end can serve as the drug-contact side. As a result, the machines that produce cartridge plungers are not designed to flip them.

For West's customer, this meant that there was no way to guarantee the FluroTec film-coated side of the cartridge plunger would always align with the drug-contact side. To solve the issue, the company needed a plunger coated on both sides with barrier film so that orientation would not be a factor. Because such a product didn't exist in the marketplace, the company partnered with West. Together they went to work to create it from the ground up.



### Discover Ideation



### Concept Development

During the course of one year, West and its partner successfully created a double-sided, FluroTec-coated cartridge plunger.

West began the process with a discovery phase that kicked off at its manufacturing and development center in Florida where the final product would be produced. West brought together its supply chain, manufacturing, quality operations and technical teams to meet with their counterparts at the client company.

Over the course of the next few months, West collaborated with the customer to draft a viable, working diagram for a prototype; perform testing; and ultimately produce the final product. This involved cross-functional conversations between the customer's technical people and West's engineers, in addition to internal problem-solving sessions at West among its packaging engineering team and the plant-level engineers who would actually manufacture the product.



## Product & Process Development

Success came down to West's expertise in FluroTec technology, West's understanding of drug product sensitivities, and West's experience in packaging and delivery systems. Based on this in-depth knowledge, West's engineers calculated how far they could extend the FluroTec film around the plunger edges. The barrier film couldn't be extended too close to the trim line, but had to be far enough to cover the entire surface area of the plunger.



## Industrialization



## Healthier Patients, Healthier World

The customer has been extremely pleased with the process, noting the good working relationship it had with West regarding understanding their unmet need, collaborating with them and developing the final solution. The customer is now moving forward with this new cartridge plunger, readying one of their manufacturing facilities for production. Their project timeline is on schedule.