Case Study

Transforming an IV-Administered Drug Product into an On-Body, Home Delivery System

The Challenge

Developing new drugs forces companies through a gauntlet. On one side, there's the constant, ever-growing pressure to accelerate timelines. On the other, there's the ongoing focus on controlling development costs, improving quality, and upholding regulatory requirements.

As if these competing pressures weren't enough, therapies have become increasingly complex as patient and payor expectations continue to grow. The combined effect results in new demand for more intricate drug delivery systems. And the growing preference for home administration means more products are being developed with devices in mind. But to deliver a great patient experience, these devices must be easy-to-use and empower patients to take control of their health.

These were the roadblocks a pharmaceutical company faced as it looked to find an on-body device capable of delivering its proprietary formulation in a safe, reliable manner.

The Considerations

The company's primary goal was to assess and select a device to serve as a critical aspect of its drug delivery program. But a secondary aim proved equally as vital: selecting a partner that could ensure success from start to finish.

Recognizing the interwoven nature of these two objectives, the company explored its options and ultimately entered into a study examining the feasibility of delivering its formulation using West's SmartDose® Drug Delivery System. The study quickly took shape as a multi-faceted assessment. It focused not only on how well the device's functional aspects aligned with the company's needs, but also West's ability to provide effective support across multiple areas.

The assessment proved positive. This prompted the company to enter into an Integration Solutions Development Agreement with West, partnering with our Innovation & Technology, Regulatory, Human Factors, Packaging, Fill-Finish, Operations, and Laboratory Services teams to help guide its development work.

The Solution

From an overarching perspective, this Agreement centered around West providing technical expertise to support clinical trials and future regulatory submission. Fulfilling it required West to coordinate multiple functions and resources on the company's behalf.

For instance, developing a combination product usually means purchasing components from multiple

suppliers. The shift into other delivery formats—e.g., vial to syringe, cartridge, or wearable—can introduce rework if the original container materials aren't compatible with the new device. But because West provided an extensive range of compatible packaging, containment, and drug delivery products, the company could more effectively scale production, improving time to market and operational efficiency without additional risk. Access to West's network of manufacturing partners, meanwhile, provided greater flexibility when sourcing products, further accelerating production.

To aid in decision making throughout the early stages of the development process, the company utilized West's large-scale library of data packages—as well as the scientific expertise behind them—to make smart, confident choices that would help to improve the chances of regulatory acceptance. The company also tapped into West's analytical services to manage compatibility, safety, and human factors testing, which created a continuous flow of information between drug and device development.

This early-stage data collection and decision support prompted the company to collaborate with West on a tailored go-to-market roadmap for utilizing West's SmartDose device. Building the roadmap surfaced key considerations, such as qualifying both device and drug and passing essential performance requirements. In turn, this illuminated strategies the company could use to take advantage of lifecycle management opportunities while continuing to mitigate risk.

When it came to navigating regulatory guidelines, the company relied on West's years of experience bringing combination products to market. It also tapped into our extensive knowledge of global regulatory pathway requirements, helping to clarify essential, up-front requirements, save time, and mitigate filing and approval issues.

Then came the final—and perhaps most important—step: making sure the device could deliver an appropriate patient experience. To this end, West used human-factor testing that mimicked how patients would actually use the device to validate its performance, confirm the operating instructions are clear and direct, and evaluate and mitigate the potential for inappropriate usage.