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Case Study



Making a Life-Saving Product More Convenient

How Pharma Tech Industries teamed with a global pharmaceutical company to reformulate its existing cholesterol product into a new dosage form

Background

Demand for this company's innovative product – designed to help treat high cholesterol – grew steadily after its launch. However, the drug was only available in rather large tablet dose form and, to work effectively, required the consumption of six tablets daily. As a result, the company decided not only to increase its production of the product, but also to make it available in a reconstituted powder-based solution that would be easier for the consumer to administer. This would make the product available to a broader age range - namely, young children and adults who may have difficulty swallowing large tablets.

Challenges

Reformulating a drug from a tablet into a dissolvable, single-dose powder that could be poured into an eight-ounce glass of water is not a simple process. A major challenge involved maintaining the proper content uniformity of the active pharmaceutical ingredient (API) in the powdered formulation during manufacturing and packaging. The disparity of the particle size of the API and the raw materials in the formulation caused a susceptibility to segregation. Through a series of formulation and process enhancements with PTI, the company developed a

More than
1,100 BATCHES
produced commercially

powder-based version of the product, yet the new formulation was hygroscopic, meaning it had a tendency to absorb moisture when exposed to air. This required the product to be manufactured and packaged in a controlled, low-humidity environment.

Pharma Tech Industries' Solution

The company turned to Pharma Tech Industries to help improve the new formulation and, most critically, to optimize the commercial manufacturing process in a low-humidity production suite to make the powder economically viable. Working collaboratively, the partnership was able to further enhance the new reconstituted powder-based product, yielding a more robust formulation that flowed effectively while still maintaining its content uniformity. The product was now more versatile and easier to consume for a larger range of potential patients.



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Outcome

After the company partnered with Pharma Tech Industries, the powder version of the product was shipped to pharmacies nationwide. The response was immediate and positive; in fact, the preferred usage rate for the powder formation was many times higher than predicted. Both the company and Pharma Tech Industries continue to partner for higher capacity filling and manufacturing to handle anticipated growth.

Pharma Tech Industries is a trusted solutions provider for powder-based products and custom services, offering development to high-volume commercial scale production services across a wide variety of delivery formats and systems.