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MAKING A LIFE-SAVING PRODUCT MORE CONVENIENT

HOW PHARMA TECH INDUSTRIES TEAMED WITH DAIICHI SANKYO PHARMACEUTICALS TO REFORMULATE ITS EXISTING CHOLESTEROL PRODUCT INTO A NEW DOSAGE FORM



The Situation:

Demand for Daiichi Sankyo Inc.'s (DSI) innovative Welchol 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, DSI decided not only to increase its production of Welchol, but also to make it available in a powder-based solution. This would make the product available to a broader age range - namely, young children and adults who may have difficulty swallowing pills.

The Challenge:

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. For Welchol, a major challenge involved maintaining the proper content uniformity of the active pharmaceutical ingredient (API) in the powdered formulation during manufacturing and packaging. Different particle sizes made the problem tantamount to pouring sand and pebbles into a jar filled with water; over time the sand migrates to the bottom more than the pebbles. Through a series of innovations, DSI developed a powder-based version of Welchol that functioned well in a controlled environment, 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 as short a time span - and over as short a distance - as possible.

The Solution:

DSI turned to Pharma Tech Industries to help improve the new formulation and, most critically, to optimize the commercial production process to make the powder economically viable to manufacture. Working collaboratively, the partnership was

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able to further enhance the new powder, yielding a more robust formulation that flowed effectively while still maintaining its content uniformity. Welchol was now more versatile and easier for a larger range of potential patients to ingest.

The Result:

After DSI partnered with Pharma Tech, the powder version of Welchol 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 DSI and Pharma Tech continue to partner for higher capacity filling and blending to handle anticipated growth.

For more information, call 706.246.3555,
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