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Case Study

Preparing An Innovative Nasal Delivery System for NDA Submission



Pharma Tech Industries' Start-to-Finish Services Included Capsule Filling, Medical Device Assembly, Pouching, Packaging and Palletizing

Background

Pharma Tech Industries was selected to handle filling, assembly and packaging services for a sumatriptan-based migraine relief medication administered through an innovative new method: a breath-powered nasal delivery system. The formulation of the drug is powder-based, and PTI was chosen for this initiative – which included developmental steps, supporting FDA submission for approval and continued into commercial – due to the company's experience handling a broad range of powders, its technical expertise, and its ability to vertically integrate the entire production process.

The delivery system employs a novel means of administering drugs deep into the nasal cavity, enabling the treatment of both local and systemic diseases. The new technology offers a much-needed alternative to existing, slower-acting nasal inhalers, as well as to tablets and injections. The product, when taken via its patented nosepiece, helps to shorten the timeframe for relief from migraines when compared to more traditional inhalants and other available delivery systems.

Pharma Tech Industries' Solution

Pharma Tech Industries played a critical turn-key role, in developing an end-to-end packaging process and file NDA batches. Utilizing a Planeta Capsule Filler from leading equipment manufacturer MG2, PTI developed the powder into capsules with a precise fill weight at speeds up to 12,000 per hour. From there, the capsules were loaded into special unit-dose cartridges. PTI then packaged each cartridge independently – along with the primary nosepiece and an instruction insert for the end-user – into individual cartons, where they were mechanically packed into cases and palletized for shipping. This end-to-end approach allowed the customer to focus its efforts on marketing and selling the product and developing other new drug innovations.

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.