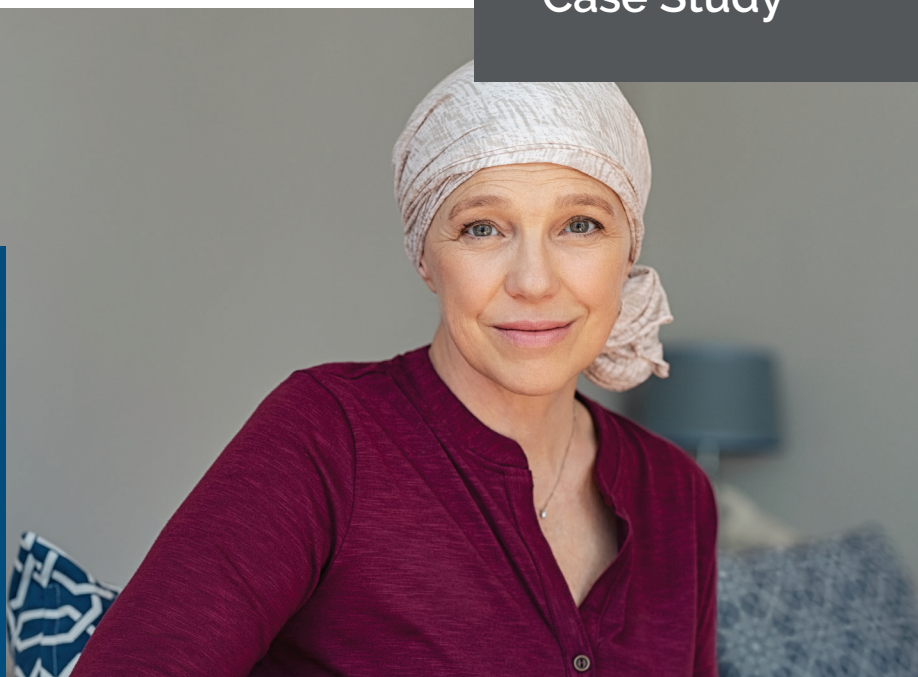




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Case Study

Pharma CDMO Case Study: Pharma Tech Industries and the Delivery of a Cancer-Fighting Rx Product



How Pharma Tech Industries' flexible packaging expertise facilitated a swift delivery of a cancer-fighting drug for phase one clinical trials

Background: Developing a Powder-Based Cancer Therapy for Clinical Trials

A biopharmaceutical company, specializing in therapeutics aimed at reducing cancer risk and other diseases, sought Pharma Tech Industries to help develop and produce a new powder-based version of their promising drug. Initially developed as a tablet, the molecule showed potential as a treatment for high-risk neuroblastoma and was on Fast-Track with FDA. The company wanted to leverage the Fast-Track status by advancing a Phase One Clinical Trial in the powdered form, intended for oral dosing as a reconstituted liquid.

Challenges Packaging for Clinical Trials

1. Creating Precise and Compliant Packaging for Multiple

Dosages: The company required precise packaging solutions for DFMO in three distinct powder dosages: 0.5g, 1.0g, and 5g. The challenge was to ensure safe, effective, and compliant packaging to support the clinical trials.

2. Rapid Product Development Turnaround: Given the urgency to advance the product into clinical trials, Pharma Tech Industries needed to deliver a solution quickly while adhering to strict handling and safety protocols for the active pharmaceutical ingredients (APIs).

3. Custom Pharma Packaging Needs: The packaging had to be tailored to the needs of clinical trials, including individualized dosage information and compliance with FDA regulations.

Pharma Tech Industries' Packaging Solution

1. Listening and Customization

- **Needs Assessment:** Pharma Tech Industries' leadership team engaged closely with the company to understand their specific needs. They used their extensive industry experience to devise a solution that met the project's unique requirements.
- **Packaging Proposal:** Pharma Tech Industries proposed a comprehensive packaging solution to the customer that included foil sachets with printed dosage information, ensuring each dosage (0.5g, 1.0g, and 5g) was clearly identified.

2. Implementation of the Packaging Solution

- **Handling and Safety:** Pharma Tech Industries established rigorous handling requirements and safety protocols to manage the APIs. This included enhanced safety measures and specialized staff training to maintain product integrity.



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- **Pharmaceutical Packaging Design and Development:**

Pharma Tech Industries' cross functional team conducted a detailed analysis of the size and structural requirements for the sachets. The development team created distinctive visual designs and color layouts for each dosage to avoid confusion and enhance trial accuracy.

- **Folding Cartons and Labels:** Pharma Tech Industries prototyped folding cartons for the sachets and applied FDA-compliant clinical labels. This step ensured that the product was not only safe but also compliant with regulatory standards.

- **Distribution:** The finished cartons were packed and prepared for distribution to various clinical test sites, including universities and children's hospitals across the nation.

3. Rapid Execution

- **Fast Turnaround:** Pharma Tech Industries' ability to execute the project efficiently enabled the customer to move the DFMO powder-based formulations quickly to clinical test sites, significantly reducing the time to market.

Outcome: Successful DFMO Phase One Clinical Trials Achieved with Pharma Tech Industries' Expertise

Pharma Tech Industries' expertise in flexible packaging and robust manufacturing capabilities allowed the company to meet their clinical trial needs effectively. The comprehensive solution provided by Pharma Tech Industries ensured that the DFMO powder was safely and accurately packaged for Phase One Clinical Trials. This rapid and efficient execution played a crucial role in advancing a potentially life-saving cancer treatment to those in need.

Conclusion: Pharma Tech Industries' Commitment to Advancing Cancer Therapies

Pharma Tech Industries demonstrated its ability to deliver customized, compliant, and timely packaging solutions for a critical cancer-fighting drug. By leveraging their flexible packaging expertise and adherence to safety protocols, Pharma Tech Industries helped expedite the clinical trial process for DFMO, illustrating their commitment to advancing innovative therapies and supporting the urgent needs of its customer.

Pharma Tech Industries, a family of companies with locations in Georgia and Missouri, is a trusted solutions provider for powder-based products and custom packaging services. The companies provide development to high-volume commercial-scale production capabilities and offer a wide variety of delivery systems and formats, including sachets, stick packs, bottles, pouches, effervescent, tablets, capsules, drug-devices, and medical swabs.