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Case Study

Pharma Tech Industries and the Development of a Heat-Stable Auto-Injector



How Pharma Tech Industries' broad capabilities helped an innovative company get a game-changing product to market quickly, economically, and safely

Project Background: Biotech Innovation in Heat-Stable Epinephrine Auto-Injectors

A biotech company focused on medical devices for severe allergies engaged Pharma Tech Industries to develop an innovative auto-injector designed to administer heat-stable epinephrine. This device aims to treat anaphylaxis resulting from acute allergy attacks and features a unique delivery system that enhances temperature resilience and extends the shelf life of the medication.

Challenges In Developing and Manufacturing: Finding the right Pharma CDMO expertise for a sophisticated solution

- 1. Complexity of a Custom Auto-Injector Design:** The auto-injector's design includes a special system for mixing powders and liquids, a departure from traditional liquid formulations. This complexity presented a challenge in finding a suitable pharmaceutical contract manufacturer with the required expertise.
- 2. Cost and Commitment Issues:** Many sterile-fill-finish providers were deterred by the unique, unorthodox nature of the product and proposed costly solutions or lacked the willingness to commit to an effective timeline.

- 3. Urgency in Scaling Up:** The biotech company required rapid scale-up from lab-scale development to commercial-scale production, which added urgency to the project.

Pharma Tech Industries' Solution

1. Detailed Proposal and Expertise in Product Development & Manufacturing

- **Proposal:** Pharma Tech Industries responded to the RFP with a comprehensive proposal, demonstrating their ability to handle the project's complexities. This proposal was supported by input from experts in the field, showcasing Pharma Tech Industries' depth of knowledge and capability.
- **Expertise:** Pharma Tech Industries assembled a dedicated team with extensive experience in the area of auto-injectors and powder-based formulations. This team was crucial in addressing the technical challenges and ensuring smooth project execution.

2. Facility Adaptation and Equipment

- **Facility Setup:** Pharma Tech Industries utilized its 300,000 square feet cGMP pharma facility in Georgia to set up a new custom Pharma Suite. The installation of bespoke equipment including isolator chambers was completed in less than four months, demonstrating



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Pharma Tech Industries' ability to rapidly adapt its infrastructure to meet the specific requirements of the medical device packaging project.

- **Commercial-Scale Equipment:** Pharma Tech Industries swiftly scaled up from lab-scale to commercial-scale production by integrating advanced pharma manufacturing equipment specifically designed for the auto-injector project.

3. Comprehensive Pharma Manufacturing Process

Pharma Tech Industries' manufacturing process for the auto-injector includes:

- **Strategic Sourcing:** Preparation and handling of the active pharmaceutical ingredient (API), process consumables, and device components.
- **Forming and Filling:** Formation and filling of the drug product into its primary container closure system.
- **Processing:** Sealing of the primary drug container for further processing, including downstream sterilization and final device assembly.
- **Medical Device Packaging:** Completion of both primary and secondary packaging processes.

4. Commitment to Product Development Timelines

- **Speed:** Pharma Tech Industries' ability to work quickly and efficiently was a key factor in their selection. The contract pharmaceutical company was committed to aligning with the biotech company's tight timelines and ensuring that the project progressed without delays.

Successful Outcomes Developing the Heat-Stable Auto-Injector

- **Technical Batches:** Technical batches of the auto-injector were successfully produced in April 2023.
- **Registration Batches:** Production of registration batches is scheduled for 2025, in line with the project's timeline.

Pharma Tech Industries' Role in Bringing Heat-Stable Auto-Injectors to Market

Pharma Tech Industries was chosen as the contract manufacturing partner due to their comprehensive and detailed approach, rapid adaptation to project needs, and ability to scale-up production effectively. Their dedication to meeting the project's technical and timeline requirements made them the ideal partner for the biotech company's innovative auto-injector project. This case highlights Pharma Tech Industries' strengths in handling complex and unique manufacturing challenges while delivering high-quality results within tight deadlines.

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.