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# 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 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.**