

SUPPORTING AN INNOVATIVE DOSING SOLUTION THROUGH MANUFACTURING EXPERTISE

A midsize pharmaceutical company partnered with Adare Pharma Solutions to support a secure dosing solution that helps prevent misuse and improve patient compliance by dispensing a precise dosage at scheduled times.

The customer's innovative dosing solution utilizes a precision-engineered cartridge that is pre-loaded with drug pellets. This cartridge features two chambers, one containing instant release pellets and the other extended/delayed release pellets, delivering both an immediate therapeutic effect and sustained efficacy throughout the dosing period.

The system is designed to dispense medication only when it's time for the next dose and only in the exact amount prescribed. This helps prevent misuse, such as overconsumption, sharing, or selling of the medication.

Adare was engaged to manufacture the drug pellets using our proprietary Diffucaps[®] multiparticulate technology and to manage the final device assembly, which includes filling the cartridge, integrating it into the device, performing data flashing, and completing packaging and serialization.

Adare was selected for this project due our expertise in advanced drug formulation, manufacturing, and assembly operations. The customer recognized our ability to coordinate intricate concurrent processes as well as our commitment to thorough early-stage planning prior to manufacturing.

Product Development, Manufacturing & Assembly

Regulatory Compliance

In the earliest phases of our partnership the dosing solution was still evolving, and Adare worked closely with the customer through multiple iterations during the qualification process.

As development progressed, we drew on our prior experience with the project's earlier cartridge designs to enhance the device's dispensability to better support regulatory compliance.

Our insights helped shape a final product that aligns with both regulatory expectations and real-world patient use.

Knowledge Transfer & Pellet Manufacturing

The customer's original pellet formulation, developed by a third party, was successfully transferred and optimized for production at our Vandalia facility in Ohio. The drug pellets, in both immediate and extended release profiles, are being produced using our proprietary Diffucaps[®] platform, a multiparticulate system with release-controlling polymers.

Assembly

Pellets are then shipped to Adare's Orthodox St. facility in Philadelphia site for assembly into the customer's device, leveraging our experience in segregation studies to ensure that the pellets maintaining product integrity during transfer. This seamless coordination across sites highlights the strength of our global network, allowing us to utilize the facility best suited for each phase of the project.

Adare manages the final assembly of the dosing solution, a process that includes inserting the drug pellets into the cartridge, placing the cartridge into the device, packaged into foil pouches, and cartoned.

Data Integration

The product is data-labeled and flashed to enable seamless integration with a companion app. Drawing on our expertise in data transfer and digital systems, we've worked closely with the client to ensure that each product label will be correctly linked to the patient's app, supporting accurate tracking and personalized dosing.

Manufacturing Automation

Initial batches and testing have been completed through manual assembly. Adare is in the process of integrating fully automated assembly equipment developed by the customer into our Orthodox Street facility.

Engineering, Facility Modification & Equipment Integration**Collaborative Equipment Transfer and Planning**

In parallel with product development and manual assembly, Adare has undertaken an extensive engineering effort to support the transfer, installation, and validation of the customer's automated assembly equipment. Working in close collaboration with the third-party equipment supplier, Adare's technical and operations teams have gained a deep understanding of system requirements and process parameters. To ensure alignment, we have hosted the customer on site, enabling joint walkthroughs and planning sessions that support accurate execution of each critical step.

Facility Modifications for Enhanced Capabilities & Compliance

Modifications to the dedicated manufacturing suite have been made to accommodate the new equipment and comply with both engineering and regulatory standards. This included infrastructure upgrades such as electrical and utility adjustments, the addition of compressed air lines, and the installation of enhanced environmental controls to ensure product stability and security of supply. As the customer's product is a controlled substance, the suite has been updated to meet DEA requirements, including security measures such as camera installation and restricted access.

Supply Chain Integration

A key component of the planning phase involved designing the room layout to effectively manage both material inputs and outputs. On the input side, we have developed processes that will help the manufacturing suite efficiently receive and stage critical materials, including pellets and pre-constructed device components, while addressing inbound supply chain requirements. On the output side, the automated system has been engineered to align with our existing packaging capabilities, including flow wrapping, pouching, and cartoning.

Verification, Risk Management, and Quality Controls

For the installation Adare has developed a comprehensive validation plan, which includes User Requirement Specifications (URS), Factory and Site Acceptance Testing (FAT/SAT), and full execution of IQ/OQ/PQ protocols to confirm installation, functionality, and performance of the equipment.

We have also designed intensive design verification protocols that will confirm the system performs to specification and supports the intended use case once installation is complete. As part of our risk mitigation strategy, a Failure Modes and Effects Analysis (FMEA) will be completed to identify potential points of failure and embed appropriate controls. For example, a vision system will be implemented to inspect product labels and reject any with discrepancies, helping ensure product integrity and regulatory compliance.

Looking Ahead

The fully automated assembly equipment is scheduled for installation in the fourth quarter of 2025. Qualification activities, as well as the production of clinical trial material and submission batches, are planned for early 2026. Regulatory submission is expected to take place by the fourth quarter of 2026, with commercial launch targeted for the end of 2027 or earlier.

Learn more about how Adare's manufacturing expertise and integrated end-to-end CDMO services can make your next project a success: visit AdarePharmaSolutions.com or email busdev@adareps.com



About Adare Pharma Solutions

Adare Pharma Solutions is a global technology-driven CDMO providing end-to-end integrated services, from product development through commercial manufacturing and packaging, with small molecule expertise focusing on oral dosage forms. Adare's specialized technology platforms provide taste masking, customized release, solubility enhancement, and patient-centric dosing solutions. With a proven history in drug delivery, Adare's facilities in the US and Europe have developed and manufactured more than 65 products sold by customers worldwide.