



Developing a Cryogenic Automated Pharmaceutical Kiosk

How Benchmark Collaborated with an Innovative Biotechnology Customer to Create a Secure, Connected, Automated Pharmaceutical Storage and Retrieval System

About the Customer

Benchmark's customer is a biotechnology company with a primary focus on advancing cutting-edge regenerative therapies to address substantial gaps in medical care. Their exclusive allogeneic (off-the-shelf) stem cell treatment is in development for various applications, encompassing neurological, inflammatory, immune, and cardiovascular disorders (as well as specific critical care conditions). Multiple clinical trials are currently investigating the company's stem cell therapy with the most advanced trial concentrating on the treatment of individuals affected by ischemic stroke.

The Challenge

The customer developed an innovative stem cell solution in which cells could be sourced from a single donor, producing numerous therapeutic doses. The therapeutic potential of this technology is underscored by critical storage challenges, which, if not addressed, could jeopardize the availability of these treatments for patients. These doses are preserved in cryogenically frozen vials, maintained at an average storage temperature of minus 160 degrees Celsius for stability. Although still in clinical trials, considerations for commercial-scale distribution are underway should regulatory approval

be granted. The aim was to create a secure, self-contained cryogenic pharmaceutical dispensing kiosk suitable for installation in hospital pharmacies, ensuring accessibility for clinicians. However, various design hurdles needed to be overcome, including:

- The stand-alone and remote nature of the solution
- Extreme temperature requirements
- Limited space
- Pharmaceutical product-tracking compliance

The unit needed to be user-friendly and safe for hospital staff. Automation is essential for vial handling and thawing, enabling rapid and secure dispensing of thawed doses within minutes for urgent, life-saving treatments. Meeting the cryogenic temperature specifications necessitates specialized components for vial handling, demanding careful material selection to consistently withstand extreme temperatures.

Beyond the physical challenges, the customer required security measures to prevent tampering and ensure distribution strictly to authorized personnel. Secure connectivity is vital for monitoring storage conditions, as the high-value inventory could become unusable without prompt servicing in the event of equipment failure. Achieving these requirements called for a multidisciplinary team with expertise in mechanical and software design, medical device design, and Food and Drug Administration (FDA) compliance for both design and manufacturing.

Initially, the company collaborated with a design house for high-level concepts but later shifted focus to include manufacturing and scalability. During an onsite visit to our facility, they encountered other specialized kiosks we were developing at the time. Both teams quickly recognized that our cloud-based unit, with features like custom robotics, sensing cameras, closed-door sensing, limit switches, and more, aligned closely with the company's needs. Our team's expertise in end-user operations, integrations, and design for serviceability combined with over 40 years of experience in medical device design and manufacturing, made us the ideal partner to design the company's unique cryogenic storage solution.

The Solution

The Benchmark team had the experience and depth of knowledge needed to develop the entire kiosk, including architecture, infrastructure, and design expertise:

1. System Integration

Integrating designs and components into a single unit is rarely straightforward, especially when multiple stakeholders and specialties are involved. As the freezer kiosk project evolved, design element modifications were continuous and ongoing to bring together separately designed components. For instance, the customer acquired the design for the central cooling system from a firm that specializes in cryogenic systems and applications, but the gripper was developed by the original design house as part of the initial concept. By drawing on our expertise in system integration and collaboration, we were able to guide the successful integration of these sub-systems by revising designs while keeping the project on track and moving forward.

Cybersecurity risk assessments also needed to be performed early in project development to ensure that proper mitigation measures were incorporated into the hardware and software design. Benchmark performed a cybersecurity threat assessment to ensure that the freezer kiosk would not be vulnerable to tampering which could potentially expose data or allow malicious actors to destroy the product. Benchmark leveraged a trusted third-party partner to provide the threat assessment and make recommendations for protecting the unit, data, and contents.

2. Vial Handling Robotic Design

Benchmark needed to create a fully customized vial retrieval mechatronic design capable of operating in a cryogenic environment required by the vial storage system. The materials for building the system were limited by the need to avoid issues resulting from condensation and repeated or long-term exposure to extreme temperatures. A considerable portion of the already small interior of the kiosk cabinet is dedicated to the cooling unit, leaving limited space for the mechanical and robotic vial-handling features

needed to support design requirements. Vial-handling features, therefore, needed to be precise with highly refined movements to ensure proper handling of the delicate vials and their contents. To achieve the range of motion needed for transporting the vials to the various recording, thawing, and dispensing stations inside the cabinet, Benchmark engineers chose to develop an x/y/dual z robot. Using separate z functions provided the flexibility needed to optimize vial handling for both the cryogenic and the general task areas.

3. Connectivity

To give hospitals guaranteed connectivity and maximum flexibility, Benchmark equipped the unit with three methods of connectivity — wired Ethernet, Wi-Fi, and cellular. Since some hospitals have restrictions on the use of their networks and cellular service can be intermittent at times (or even altogether unavailable), these redundant solutions provide flexibility at the installation location. Once connected, the freezer kiosk's cloud platform is capable of synchronizing with (and providing an interface for) the customer to access the devices in the field to confirm that kiosks are operating properly.

4. Thawing

To avoid damage to the delicate cells, a custom thawing station was developed for the unit to warm vials at a controlled rate. Thawing takes approximately 20 minutes using a custom flex cable designed by the Benchmark development team to drive heat to the exact location it is needed. Warming is not done at a constant rate as one might expect, but instead is done at a variable rate that has been optimized for speed, consistency, and safety to protect the vial contents. The custom thawing station uses electronically controlled power that can be adjusted by the second to achieve this level of optimization.

5. Tracking and Tracing

Benchmark equipped the kiosk with an information chamber to record pertinent tracking and quality control information and to identify any potential issues such as leaking or heat damage. The information chamber also contains a radio frequency identification (RFID) reader, a temperature sensor, a camera, and a scale.

Prior to thawing, vial information is recorded, and the vials are moved by the robot to the thawing station. Vial information is recorded again after thawing to determine whether leaking or heat damage has occurred.

6. User Interface and Industrial Design

The front door design, which has several subcomponents, went through numerous iterations to meet specifications. Some of the key elements of the door include a large touch screen with a graphical user interface and a signal fiber that offers color-coded communication to indicate the conditions of the kiosk and product to the user, a combined power supply for the external monitor and computer, and a custom dispensing mechanism equipped with a worm gear driven, four-bar linkage system developed by the Benchmark team.

Benchmark also exceeded our customer's industrial design requirements, having added hidden door hinges which was challenging due to the size and weight of the door and subcomponents. The fully loaded door (which stands six feet tall and two-and-a-half feet wide, weighing over 100 pounds) can cause sagging. The development of the custom hidden hinges, therefore, required Benchmark's industrial design team to perform finite element analysis (FEA) to optimize the design and meet the customer's design requirements.

7. Speed to Market, Scalability, and Cost

A key part of product realization is scalability. That is why Benchmark's approach to product design takes cost, manufacturability, and supply chain challenges into account during the design process. One key example of this commitment focused on prototype design. While the client had initially wanted the entire unit to be 3D printed from plastic, this method would have significantly increased the cost of the prototype unit and would have introduced potential accuracy issues due to the bonding of the many panels required to form the entire enclosure. By leveraging our vendor relationships, the Benchmark team was able to offer a solution by creating a one-piece plastic-and-foam door and forming the rest of the enclosure using a custom sheet metal design.

8. Collaboration

Benchmark takes a highly collaborative and iterative approach to design projects and offers customers full access to its diverse teams and knowledge base. This project was no different. As this customer focused on developing their treatment, they opted to have Benchmark perform all the design engineering work for the pharmaceutical kiosk. But that didn't mean the Benchmark team worked separately from the customer. Benchmark's design team met often with the customer's team to discuss design progress, exchange feedback, and identify next steps.

9. Two Fully Functional, Cloud-connected Alpha Prototypes in One Year

The Benchmark team designed, built, and tested two fully functional, cloud-connected alpha prototypes of the freezer kiosk in approximately one year. The first prototype passed verification testing on every final endpoint the customer requested for the entire program. The freezer kiosk can store, retrieve, thaw, and present the vials to the end user autonomously.

The Results

Average Storage Temperature of Minus 160 Degrees Celsius

The kiosk maintains an average storage temperature of minus 160 degrees Celsius. The unit can provide real-time informatics on product inventory, storage, system access, and usage. It tracks inventory from end to end and supports first-in first-out (FIFO) inventory management requirements.

A Savings of \$200,000 Per Prototype Unit

By moving from the concept of a 3D printed unit made solely from plastic and turning to Benchmark's advanced design, we not only saved the customer

considerable time but upwards of \$200,000 per prototype unit. As an added benefit, the investment in tooling now means that subsequent units will be easy to replicate and can be made at significantly reduced costs.

Fully Functional Kiosk Pulls, Records, and Warms Vials in 20 Minutes

The industrial design of the freezer kiosk is sleek and unobtrusive, easily blending into the hospital environment. The multiple locking interfaces, including a fingerprint scanner, a 2D barcode scanner for badges, a near-field communication (NFC) reader for RFID tags, and on-screen password entry, ensure the kiosk contents are always protected.

Secure, safe, and easy to use, the freezer kiosk simplifies product preparation to a single step after order entry. Hospital staff can request the therapeutic either at the unit or over the cloud. In a little over 20 minutes, the unit pulls, records, gently warms the vials, and waits to dispense them until the user is physically present at the machine, logged in, and authorized by the security systems within the unit. This automated system allows hospital staff to focus on what they do best — saving patients' lives.

About Benchmark

Benchmark provides comprehensive solutions across the entire product lifecycle, leading through its innovative technology and engineering design services, leveraging its optimized global supply chain, and delivering world-class manufacturing services. The industries we serve include commercial aerospace, defense, advanced computing, next-generation communications, complex industrials, medical technologies, and semiconductor capital equipment.

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