

Application Note

CryoVault® is the Industry's Most Secure E2E Process & Logistics Solution for Freeze & Thaw

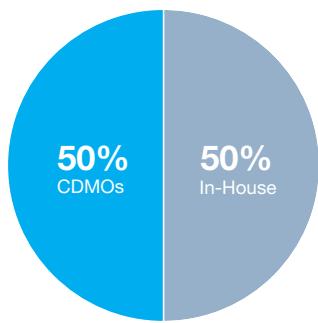
Introduction

CryoVault® is an end-to-end process and logistics solution for freeze and thaw, designed to deliver security, flexibility, and scalability across modalities and manufacturing environments. Engineered to ensure an optimized, consistent freeze profile, CryoVault® protects product quality, integrates with material handling systems, and scales seamlessly from process development to large-scale commercial production. From benchtop process development labs to global CDMOs and in-house manufacturers, CryoVault® delivers a platform solution that meets the needs of today's dynamic biopharma landscape.

CryoVault® Containers

CryoVault® offers seamless scaling from process development through clinical to full scale commercial production. The containers are offered in the following maximum fill volumes (per container sizes): 30 mL (40 mL), 100 mL (120 mL), 1 L (1.25 L), 5 L (6 L), 16 L (20 mL) and 75 L (100 L).





User Landscape: A Balanced Portfolio

CryoVault® has achieved a balanced footprint across both Contract Development and Manufacturing Organizations (CDMOs) and in-house manufacturers with a fifty-fifty split in usage.

For CDMOs

The CryoVault® platform offers unmatched flexibility and reliability in multiproduct environments. With six container sizes made with a single-use, rigid design, CryoVault® enables fast changeover, maximizes yield, and readily adapts to current manufacturing environments—making it ideal for contract-driven operations.

In practice, this means a CDMO supporting multiple clients can switch between the 16 L and 75 L maximum fill volume CryoVault® formats without modifying the freeze-thaw setup or overhauling equipment. Once installed, the CryoVault® infrastructure remains consistent—allowing for rapid adaptation to different batch sizes and process requirements with minimal operational disruption.

The robust, high-density polyethylene design eliminates the risk of failure during freeze, thaw, or handling. The minimal hold-up volume ensures nearly complete product recovery. These features directly translate to reduced product loss and maximum yield—especially critical for high-value or limited-availability drug substances.

For In-House Manufacturers

In-house teams benefit from the CryoVault® platform's ability to maintain process continuity from development through commercial scale. The uniform freeze path length across all container sizes ensures consistent freezing behavior across scale-up, simplifying validation and process transfer.

For example, one manufacturer used the 30 mL maximum fill volume stability container during early-phase studies, 1 L maximum fill volume for pilot plant and clinical manufacturing, the 16 L maximum fill volume for commercial production, is now evaluating the 75 L maximum fill volume as forecasts show increased demand. The system integrates easily into existing upstream and downstream operations, so the transition requires no major process re-engineering. This continuity reduced their validation burden, as they could leverage existing data across scale-up. Additionally, the robust, all-in-one container reduces handling risk, enabling safer global transport of bulk drug substance to downstream drug product sites.

In both settings, the CryoVault® platform's robust design and logistics integration reduces product loss, ensures cold chain security, and supports delivery of critical therapies to patients worldwide.

CryoVault® Scalability



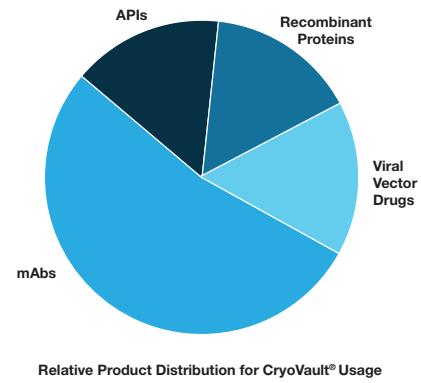
FPL (Freeze Path Length)



2 x FPL (Freeze Path Length)

Therapeutic & Modality Breakdown

CryoVault® is a platform-agnostic solution currently supporting the manufacture of biologics, small molecules, and advanced therapies. Its implementation spans programs in immunology, oncology, neurology, metabolic disorders, and infectious diseases. Whether it supports the manufacture of monoclonal antibodies, viral vectors, recombinant proteins or active pharmaceutical ingredients (APIs), CryoVault® provides a consistent freeze-thaw solution that protects product quality across diverse modalities.



Key Drivers for Adopting CryoVault® as the Freeze-Thaw Solution of Choice

Based on customer feedback, the benefits of CryoVault® are realized across your operations. Ranked customer priorities include:

Security

Minimize the risk of product loss and avoid costly deviations. CryoVault® minimizes the risk of biocontainer failure, ensuring consistent batch success and reducing the burden on manufacturing, QA, EHS, and MSAT teams.

Platform Scalability

Once the CryoVault® infrastructure is installed, it supports scale and product expansion. The system accommodates various therapeutics, batch sizes, and freeze profiles—offering a future-proof investment across DS and DP networks.

High Volume Capacity

CryoVault® enables large batch freezing, with unitized pallet loads holding up to 300 L of bulk drug substance. The system also supports smaller volumes for process development and clinical production.

The robust, high-density polyethylene design eliminates the risk of breakage during freeze, thaw, or handling while minimal hold-up volume ensures nearly complete product recovery. These features directly translate to reduced product loss and maximum yield—especially critical for high-value or limited-availability drug substances.

Reliable Supply

CryoVault® containers are backed by a dependable, agile supply chain that scales with your needs.

Product Integrity

Engineered to maintain consistent freeze profiles and minimize cryoconcentration, CryoVault® protects sensitive biologics from the impact of ice bridging (i.e. denaturing or aggregation) preserving both quality and yield.

Logistics & Transport Readiness

Built for global use, CryoVault® includes end-to-end material handling and validated shipping options. From the manufacturing floor to cold chain transit, CryoVault® ensures your product arrives safely and intact.

Customer Testimonials

“We've used CryoVault® since early development, and being able to scale without changing our freeze conditions saved us major validation work. It's become a key part of our platform approach.” — **Process Development Scientist**

“The robustness of the CryoVault® system significantly reduced deviation events related to freezing. That's a huge quality and compliance improvement for us.” — **Quality Assurance Lead, Commercial Site**

“It's rare to find a container system that addresses freezing and global transport equally well. CryoVault® closed a critical gap in our cold chain process.” — **Cold Chain Logistics Coordinator**



Real-World Impact

The CryoVault® platform has been adopted across a wide spectrum of manufacturing settings and therapeutic areas, spanning both clinical and commercial programs. Its reliability and scalable design make it a trusted choice in high-stakes biopharma workflows—from infectious disease prevention to chronic condition management.

For instance, leading manufacturers rely on CryoVault® in the production of a viral vaccine targeting vector-borne disease for deployment in tropical regions. In the autoimmune space, CryoVault® supports a monoclonal antibody therapy for a systemic inflammatory condition, where product yield and security directly affect batch success rates. A next-generation gene-delivered biologic for neurodegenerative disease uses the CryoVault® system to streamline bulk drug substance handling prior to downstream fill.

Across these varied applications, CryoVault® delivers consistent value: operational confidence, product security, and readiness for global distribution.

Conclusion

CryoVault® has been deployed globally to drive the manufacturing and delivery of life-saving treatments—where safeguarding every dose is essential to ensuring patients receive the medicine they rely on. Its scalable design ensures a flexible fit—no matter your product, process, or plant—and delivers consistent performance from early development to global distribution. By supporting operations throughout the full drug manufacturing lifecycle, CryoVault® empowers biopharma teams to protect product quality, streamline logistics, and reduce operational risk at every stage.

How Can CryoVault® Help You?

Our team of freeze and thaw experts is ready to consult with you on tailoring a CryoVault® solution to meet the unique needs of your process and pipeline. For additional information about the CryoVault® Freeze and Thaw Platform, Please visit www.meissner.com/cryovault.