

CryoVault®

Frequently Asked Questions (FAQs)

What are the platform options available?

The CV300 platform allows for batch freeze and thaw of up to 300 L of BDS using containers with maximum fill volumes of 75 L, 16 L, and 5 L for enhanced operational flexibility. Similarly, the CV96 platform allows for batch freeze and thaw of up to 96 L of BDS using both the 16 L and the 5 L maximum fill volume containers. Each of the CV300 and CV96 platforms feature their own freeze-thaw units and material handling equipment.

Can CryoVault® containers be recycled or how they are disposed?

Most single-use systems contain multiple polymers, which makes recycling nearly impossible. CryoVault® containers are made from a single plastic material, HDPE, which is a very recyclable material accepted by most waste streams. Of course, there must be a decontamination step first, but companies can work with their municipalities to explore recycling options.

How has the market has been receiving the new technology?

CryoVault® has been adopted by over 20 locations globally. Our clients realize that this is a unique solution for an obviously critical process step, and rightly so, as there is a high level of vetting by potential users.

How can I ensure that mixing performance will meet the needs of my process?

Comparative homogeneity and shear data has been collected to ensure equal or better mixing performance with representative process fluid. Please refer to the Rotary Impeller Mixing Brochure for a selection of this data. Additional data may be available upon request, and Meissner's cross-functional mixing team is available for support with additional on-site and/or in-house mixing performance studies tailored to address any gaps between available data and your unique process requirements.

What differentiates CryoVault® from vessels like carboys, which historically have been another common container for freeze-thaw of BDS?

The key differentiator is the science behind the container design. There was intentional design around how bulk drug substance freezes and thaws. It was important to create consistent freeze path lengths, which is easier to control in a rectangular design than in a circular shape like a carboy.

Controlling the last point of freeze has a direct correlation to product integrity by preventing cryoconcentrations, and container integrity by preventing pressure buildup due to ice bridging. Consistent freeze path lengths permit scalability as more BDS can be put into larger containers while freeze-thaw performance remains the same. This provides a faster freeze-thaw cycle, which is critical from an operations perspective.

What is currently available for the freeze and thaw of critical biopharmaceuticals?

Cryovessels have been the predominant technology. However, with recent adoption of single-use systems, new technologies such as biocontainer assemblies (bag assemblies) with outer support containers are available for freeze-thaw applications.

How does CryoVault® compare with competitive freeze-thaw products?

CryoVault® is an end-to-end (E2E) platform solution that addresses the common challenges associated with bulk drug substance freeze-thaw operations. CryoVault® containers feature a rigid wall with customizable top works that, together, create a complete single-use assembly. The storage containers are modular in size and are available in maximum fill volumes of 75 L, 16 L, 5 L, and 1 L to provide operational flexibility.

CryoVault® is a single-use system for controlled freeze and thaw with all the benefits of single-use and all the features and robustness that you would get with a more traditional rigid cryovessel.

What are the advantages and disadvantages of each of the options?

The advantage of a cryovessel system is that you can process large batches. The disadvantage, or area for improvement, is that the cleaning, sterilization, and validation of these systems require extensive infrastructure and labor to maintain.

Single-use film-based products have all the advantages of single-use but there can be integrity issues during freeze and thaw. Thin films are fragile and susceptible to tears during material handling processes. In addition, scalability is a big challenge as the largest volume options include 16 L maximum fill volume per system. Large scale BDS volumes require proper material handling throughout the freeze-thaw cycle.

What led to the development of the CryoVault®?

There was an industry need for a freeze-thaw solution that was single-use, robust (offered greater security than existing systems), and was scalable to large volume, particularly with the proliferation of decentralized Drug Substance (DS) and Drug Products (DP) processing sites.

What is CryoVault®?

CryoVault® is a next generation, single-use freeze/thaw platform, primarily directed at critical high value process fluid such as bulk drug substance. It provides a real change in terms of scalability and robustness compared to current solutions.

For more information on our freeze & thaw platforms for bioprocessing, visit www.meissner.com/products/cryovault-freeze-thaw-platform or call +1.805.388.9911.