



A guide to cryopreservation equipment and freezing programs

Finding the right solution for your company and employees

About this guide

This guide is designed to be an informative resource to help employers who are new to cryopreservation equipment have informed discussions about what type of controlled-rate freezers and accessories are the best fit for their needs.

An introduction to cryopreservation

Cryopreservation is a deeply researched process that involves freezing biological materials, such as cells, tissues, or organs, at extremely low temperatures to preserve them for long-term storage. It is well understood that by cooling the samples to very low temperatures, usually below -130°C (-202°F) or even lower, cryopreservation slows down or halts biological activity, effectively preserving the samples in a state of suspended animation.

Several advancements and innovations have contributed to developing the field of cryopreservation, including breakthroughs using more effective cryoprotective agents such as glycerol or dimethyl sulfoxide (DMSO). More recently, there have been improved designs of specialized equipment that help achieve proper freezing of samples at a slower controlled rate. Altogether, these efforts helped lay the foundation for the development of successful cryopreservation techniques across various academic and industrial disciplines.



The cryopreservation process remains vital to several important research workflows that support scientific discovery. Freezing biological samples allows them to be stored for extended periods without significant degradation. This is particularly crucial for valuable or rare samples, such as stem cells, tissue samples, or endangered species' genetic material. In this manner, researchers can store samples for future experiments and analysis.

Similarly, biobanks around the world utilize cryopreservation techniques to maintain large collections of biological samples, enabling scientists to access diverse resources for various studies. One common example includes assisted reproductive technologies such as *in vitro* fertilization (IVF). Sperm, eggs, and embryos can be frozen and stored, allowing individuals to preserve fertility options, overcome fertility challenges, or facilitate reproductive planning. Another example is organ transplantation: by freezing organs, it may be possible to extend the time window for organ transportation, reducing the limitations imposed by organ availability and improving the success rates of transplants.

Lastly, the increasing value of cryopreservation during drug development is driving better product delivery. Cryopreservation has become critical to therapeutic cell pipelines and testing. Preserving engineered cell lines or primary cell cultures in a frozen state allows for long-term availability of standardized samples, enabling researchers to conduct experiments and test the efficacy and safety of drugs.

Overall, cryopreservation has revolutionized the field of sample processing and storage. Through ongoing research and technological advancements, scientists continue to refine cryopreservation techniques, improving the viability and recovery rates of frozen samples.

Key considerations when purchasing a controlled-rate freezer

To help frame our discussion, we've organized the range of topics into three key areas that are important to think through:



1. Performance specifications
2. Regulatory compliance
3. Product and application support

This framework focuses on key considerations for choosing a controlled-rate freezer and evaluating several potential uses to meet your needs in an academic or industrial biopharmaceutical environment.

1. Performance specifications

- **Temperature range:** Verify that the freezer's temperature range aligns with your specific research requirements. The freezer should be capable of reaching and maintaining ultra-low temperatures, typically at -90°C or below -150°C , which is considered below the glass transition temperature. It is best to freeze samples to an endpoint temperature closest to the long-term cold storage unit.
- **Cooling rate:** Consider the programmable cooling rate of the freezer, which refers to the speed at which the temperature drops. Look for models that offer fast and consistent cooling to ensure the integrity of your samples. A unit with a dedicated low-pressure LN_2 supply will offer the most efficient method (in terms of energy and time savings) to achieve the optimal cooling rate for mammalian cells.
- **Scalability:** Assess the freezer's sample capacity, including the number and size of vials or containers it can accommodate. As sample volumes increase and cryobags are implemented, this will change the chamber layout, potentially requiring larger units. It is important to maintain a robust and reproducible program across all units.
- **Temperature uniformity:** Opt for freezers with excellent temperature uniformity throughout the storage space. This minimizes temperature variations within the freezer, reducing the risk of sample damage. The use of racks with proper vial or canister spacing is vital to allow the cold air flow to reach every sample. Ensure the sample probe is positioned in an accessible location that is representative of the thermal load.
- **Alarm and monitoring system:** A reliable alarm and monitoring system is crucial for maintaining sample integrity. Look for controlled-rate freezers that offer advanced features such as temperature alarms, power failure alerts, and remote monitoring capabilities. The sooner your operators are aware of a potential deviation in the cooling process, the faster a decision can be made to evaluate the freezing curve and the stability of the samples.

2. Regulatory compliance

Ensure that the controlled-rate freezer complies with relevant regulations and industry standards. Consider the following aspects:

- **Good Laboratory Practices (GLP):** If you are conducting academic research, ensure the freezer complies with GLP guidelines to maintain data integrity and sample quality. Any new pieces of equipment should be intuitive to facilitate training of staff.
- **Good Manufacturing Practices (GMP):** If your research involves pharmaceutical applications, verify that the freezer adheres to GMP guidelines to ensure product safety and quality. This includes proper access to proprietary information or other detailed reports. The reproducibility of an experiment with high cell recovery and viability is a key differentiator in cell manufacturing.
- **FDA regulations:** If your research is part of drug development or clinical trials, check if the freezer meets the applicable regulations outlined by the U.S. Food and Drug Administration (FDA). When a medical device is necessary for your workflow, it is important to utilize an appropriate model with documentation indicating its fitness for storing biological materials being returned to a human body.
- **CE marking:** If you are based in Europe or plan to export the freezer to European markets, ensure it has the CE marking to indicate conformity with European Union regulations.
- **21 CFR Part 11 compliance:** For pharmaceutical settings, consider freezers that offer compliance with 21 CFR Part 11 regulations, which establish guidelines for electronic records and signatures. This feature may exist in the form of complete run and event files that are password-protected and readily available in the event of an audit.

3. Product and application support

Choosing the right supplier is essential to ensure a successful purchase. Evaluate the following factors:

- **Supplier reputation and experience:** Select a supplier with a solid reputation and extensive experience in providing controlled-rate freezers. Research their customer reviews, testimonials, and track record.
- **Subject matter expertise:** Having a conversation with a specialist will help determine what sizes and configurations best suit your research requirements. A stronger vendor will also have the necessary accessories and resources available to customize a request. As controlled-rate freezer applications grow, specialists will have insight to common techniques and subtle improvements that can lead to greater success.



- **After-sales support:** Ensure the supplier offers comprehensive after-sales support, including installation, calibration, training, and ongoing technical assistance. Prompt support can minimize downtime and ensure smooth operations. This support may exist as a qualification or temperature mapping to help get your equipment up and running faster.
- **Warranty and service contracts:** Inquire about the warranty options and service contracts available. Understand the coverage, duration, and terms of the service agreements provided by the supplier. With regular maintenance, a controlled-rate freezer with minimal mechanical parts can last a decade or longer.
- **User training and documentation:** Check if the supplier provides adequate user training resources, user manuals, and documentation to assist with equipment setup, operation, and maintenance. Often this information is shared electronically alongside videos and training around product unboxing or start-up, as well as maintenance schedules to enable a better user experience and confidence to operate.

Request quotes from multiple suppliers and thoroughly compare the specifications, compliance features, and customer support offerings before making a decision.

If you're interested in learning more about Thermo Scientific™ controlled-rate freezers or requesting a demo, please get in touch with one of our [sales representatives](#).

Learn more at thermofisher.com/cryosystems

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