

Frequently Asked Questions

What is ControlLyo®?

ControlLyo® is a state-of-the-art controlled nucleation technology that enhances lyophilization processes. It is part of the advanced Line of Sight™ lyophilization technologies and PAT (Process Analytical Technology) tools, designed to complement existing freeze-drying workflows.

How does ControlLyo® improve freeze-drying?

ControlLyo® ensures uniform and consistent freezing of all vials, leading to superior product quality and unparalleled uniformity. It addresses key challenges in lyophilization, such as heterogeneous ice nucleation, by allowing for controlled nucleation at your desired time and temperature.



What are the key benefits of using ControlLyo®?

- **Control:** Freezing is typically an uncontrolled process is now a controlled and repeatable process.
- **Faster drying:** Reduces primary drying time by approximately 3% for every 1°C increase in nucleation temperature.
- **Reduced Product Rejection:** Enhances homogenous cake morphology with no visible collapse or shrinkage, due to increased cake pore size and reduced dry layer resistance.
- **Ease of Replication:** Enables reproducible results across different freeze dryers, facilitating more efficient scale-up. Can be added to almost any pressure rated lyophilizer..
- **Freezing stress:** Minimizes protein aggregations, improving the stability of protein formulations and reduce vial breakage due to formulation ingredients.

How does ControlLyo® contribute to regulatory compliance?

ControlLyo® conforms to the regulatory framework required for Quality by Design (QbD) by controlling process inputs, ensuring that the lyophilization process meets the necessary quality standards.

Do I need to change my formulation to use ControlLyo®?

No, ControlLyo® does not require a formulation change or the introduction of foreign materials. This makes it easier to integrate into existing workflows.

What are the applications that can use ControlLyo®?

ControlLyo® is applicable in various fields, including but not limited to:

- Vaccines
- Drug Development
- Antibody Drug Conjugates
- Wound Care and Tissue
- Engineering
- Diagnostic Kits
- Bulk Lyophilization