Coriolis Pharma

OUR SUPPORT FOR YOU

LYOPHILIZATION FORMULATION AND PROCESS DEVELOPMENT

Lyophilization, also known as freeze-drying, plays a critical role in the pharmaceutical industry by enhancing the stability and shelf life of sensitive drugs, vaccines, and biologics. This essential process helps preserve the integrity and efficacy of active ingredients, especially for products that are heat-sensitive or unstable in liquid form. As demand for reliable and long-lasting pharmaceutical formulations continues to grow, lyophilization has become a key technology in ensuring product quality, safety, and global distribution.

Lyophilization up to biosafety level 2

Lyophilization Process Development

Our advanced approaches are designed to create robust, economical freeze-drying cycles by implementing a stepwise lyophilization process development program tailored to your product's unique characteristics, formulation, and development phase.

Your Benefits

- Be fully prepared for every clinical phase and commercialization with a tailored, phase-appropriate lyophilization development package that covers all critical steps.
- Stabilize your API during freeze-drying and storage by leveraging our deep formulation development expertise.
- Save time and costs through an optimized freeze-drying cycle—without compromising on product quality.
- Ensure regulatory compliance and a smooth process transfer and scale-up by employing innovative strategies.
- Integrate a large portfolio of analytical methods backed by extensive experience in method development, qualification, and validation.

Transformation with Lyo Modelling

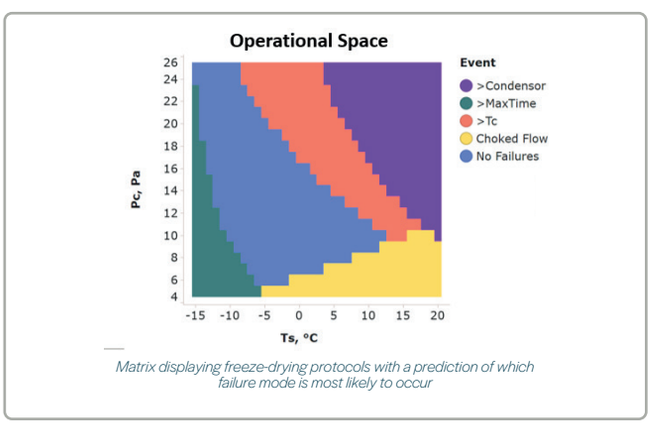
Our Lyo Modelling service is a science-based approach to optimize the primary drying phase of a pharmaceutical freeze-drying process. It addresses inefficiencies in a traditional freeze-drying optimization by integrating mechanistic modelling, risk assessment, and dynamic visualization. This enables faster development, reduced resource consumption, and robust process control for sensitive (bio)-pharmaceuticals.

Your Benefits

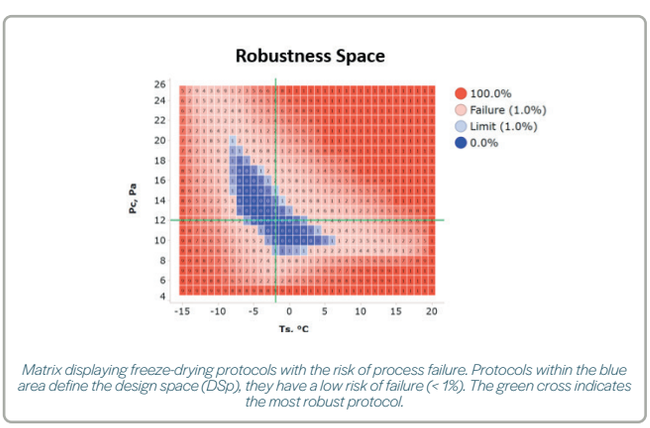
- Accelerate your development timeline and reduce material costs with efficient and resource-saving strategies.
- Minimize risk and increase reliability by preventing collapse, meltback, and equipment overload.
- Enhance product quality and consistency through optimized process design.
- Streamline regulatory submissions with processes aligned to Quality by Design (QbD) principles.

Lyo Modelling - Technical Framework

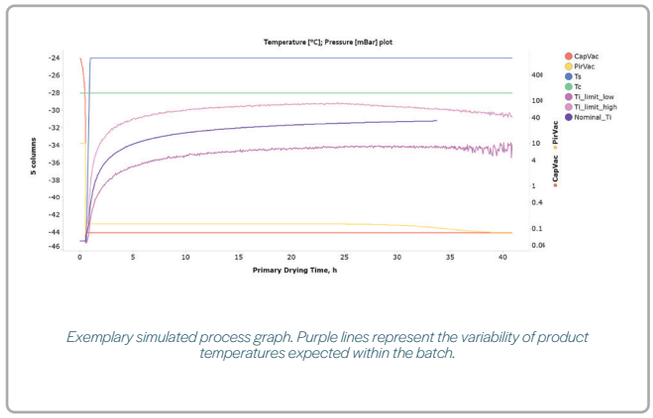
Lyo Modelling is built on a validated mechanistic framework that simulates the thermodynamics of freeze-drying using real-world inputs such as vial geometry, fill volume, and equipment-specific parameters. It yields in-process variables that are hard to measure such as sublimation rates and product temperature profiles. What sets it apart is the integration of Monte Carlo-based uncertainty analysis, which quantifies the probability of failure modes like collapse, meltback, and equipment overload under realistic variability. This probabilistic approach enables the construction of a regulatory-compliant design space (DSp) and proven acceptable ranges (PARs), allowing for flexible yet robust process control. The model has been experimentally verified at multiple scales, demonstrating its ability to support seamless tech transfer from pilot to commercial freeze-dryers.



Matrix displaying freeze-drying protocols with a prediction of which failure mode is most likely to occur



Matrix displaying freeze-drying protocols with the risk of process failure. Protocols within the blue area define the design space (DSp), they have a low risk of failure (< 1%). The green cross indicates the most robust protocol.



Exemplary simulated process graph. Purple lines represent the variability of product temperatures expected within the batch.

Why Choose Coriolis?

- Full lifecycle support with the end goal in mind from preclinical to commercial under R&D and GMP
- Development of drug products designed for global launches, specifically meeting the requirements of the FDA, EMA and Japanese regulatory standards
- Client-focused collaboration with an independent service provider, offering dedicated attention to your specific project, molecule and development phase
- Bridging the gap between discovery phase and clinical development
- Scientifically robust approach for antibody candidate selection with the best chance of becoming a drug product
- Novel innovative methods published from Coriolis' team and scientific advisors to efficiently assess your antibody's biophysical properties
- Seamless development of your antibody drug product formulation for first clinical application ensuring a risk-appropriate approach
- Guidance and support until late-stage drug development through to market authorization
- Representatives and laboratories in close proximity to you and your team in the EU and USA

Ready to optimize your freeze-drying process?

Discover our latest research, expert-led webinars, and comprehensive resources at www.coriolis-pharma.com/lyophilization-process-development/

Headquarters

Fraunhoferstraße 18 b
82152 Martinsried
Germany
Phone: +49 89 41 77 60 – 0

U.S. Commercial Organization

455 E Eisenhower Pkwy
Suite 300, #1130
Ann Arbor, MI 48108
United States
Phone: +1 (256) 400-4491

www.coriolis-pharma.com/contact