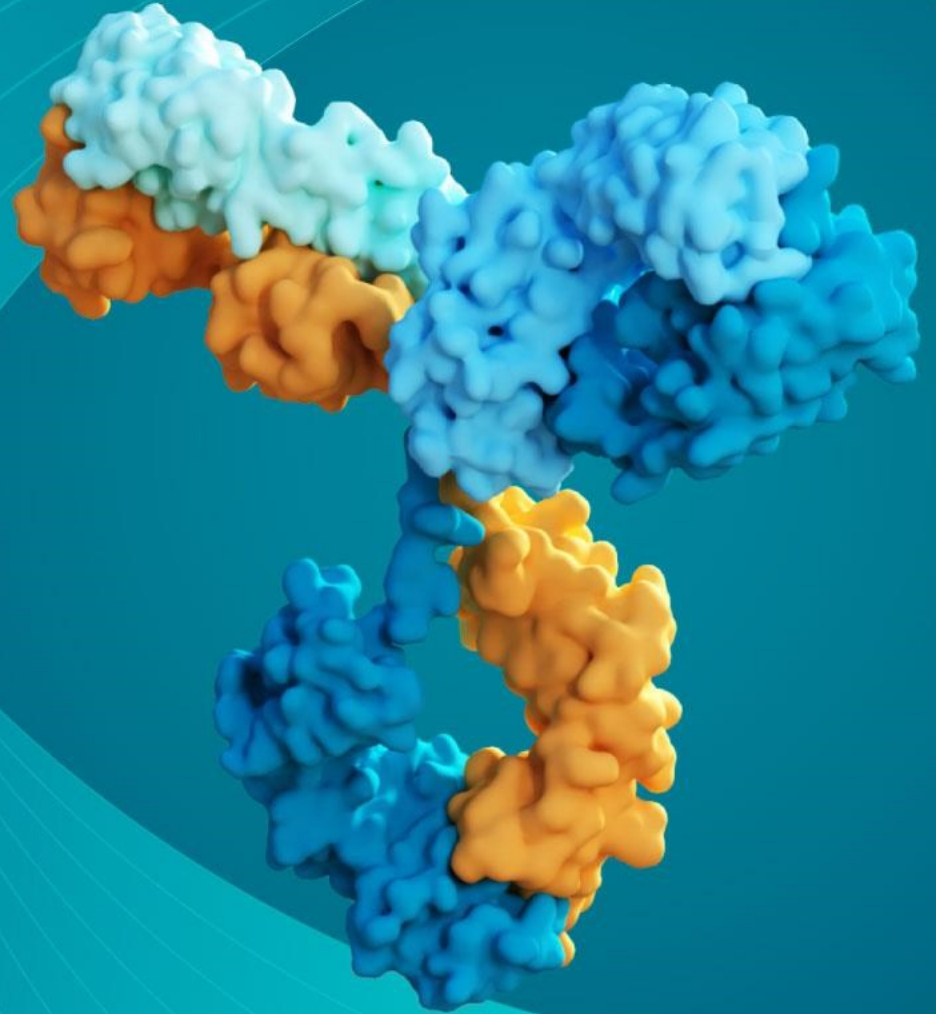


Coriolis Advanced Freeze-Drying Technologies for Drug Product Development

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Scientist



Coriolis by the Numbers

- ✓ Full life-cycle support for liquid and lyophilized drug products under R&D and GMP
- ✓ Drug development, analytical, and manufacturing services for biologics, gene and cell therapy products up to biosafety level 2



17+

years of experience



930+

drug substances supported



160+

peer-reviewed articles



145+

formulations developed



15+

commercial products supported



2,700+

projects performed successfully



800+

global clients from preclinical to commercial



200+

analytical methods in-house

Drug Development, Analytical, and Manufacturing Services



Drug Development Services

Non-GMP and GMP

Developability Assessment

Formulation Development

Stability Studies

Container Closure Selection

Forced Degradation Studies

Clinical In-Use Studies



Analytical Services

(Non-GMP) R&D Analytics

Particle Identification and Characterization

Method Development and Transfer

Fast-Track Analytics

Stability Study Analytics

GMP Analytics

PPQ/Validation

Release Testing

Compendial Method Verification

Stability Study Analytics



Manufacturing Services

Non-GMP Filling Services

Tox Study Manufacturing

Filling of Reference Material

DP Manufacturing support

(Lyo) Process Development / Scale-Up

Comparability Studies

Process Characterization

Troubleshooting

Your Way to a Successful Commercial (Drug Product

Discovery/Preclinical



Early Phase



Late Phase/Commercialization



Commercial Services



Challenges

- ✗ Some molecules are unstable in liquid state. Freeze drying is an alternative.
- ✗ Biopharmaceuticals can be highly temperature-sensitive and degrade quickly.
- ✗ Most liquid formulations require continuous cold chain storage (2–8°C or lower).
- ✗ Short shelf life complicates global distribution and storage.

Coriolis' problem-solving strategies

- ✓ **Enhancing Stability:** Extension of shelf life from months to years.
- ✓ **Room Temperature Storage:** Reduction of reliance on cold chains.
- ✓ **Preservation of Biological Activity:** Reduction of aggregation and chemical degradation.
- ✓ **Can be tailored** for different modalities up to biosafety level 2

State-of-the-art equipment

Flexible, state-of-the-art facilities totaling ~5,000 m² (~54,000 ft²) allow Coriolis Pharma to serve the comprehensive drug product development, analytical service, and manufacturing service needs of wide-ranging biotherapeutic modalities under R&D and GMP conditions.



Batch Freeze-dryers

- **Epsilon 1-6 CC** (M. Christ), freezing unit, liquid nitrogen.
- **Epsilon 2-12D** (M. Christ), pilot scale.
- **Epsilon 2-10D** (M. Christ), pilot scale
- **Epsilon 2-65D** (M. Christ), small production scale.

Continuous Freeze-drying

- **RheaLyo Mono (RheaVita)**, continuous freeze drying; thin film freeze drying.

Freeze-drying at Coriolis: Batch freeze-drying



Batch freeze-dryers key features

- Gene and Cell therapy freeze-drying under biosafety level S2
- Liquid nitrogen fast freezing
- Controlled nucleation
- Individual shelf closure
- Comparative pressure measurement
- Wireless temperature sensors
- Optical fiber sensors (incl. crystallization events).

Freeze-drying at Coriolis: RheaVita LyoMono

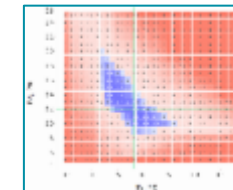
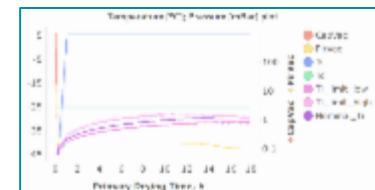
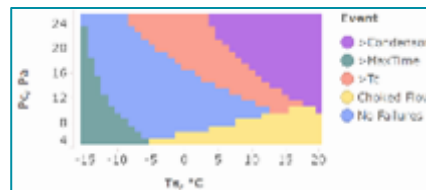
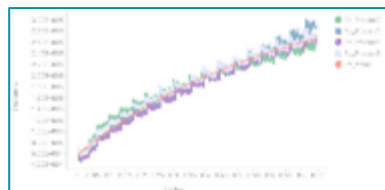
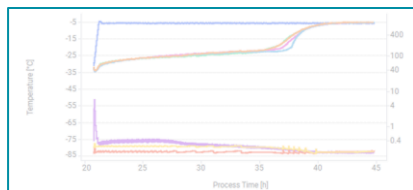


Continuous FD key features

- Spin freezing / thin film freezing
- Controlled nucleation
- Non-invasive temperature monitoring
- In-process automatic control based on feedback loops from temperature readings
- Heating for sublimation by radiation
- Fast process time: < 3 h.



Modelling as a real Alternative



Process Data

Parameter Estimation

Process Simulation

Risk Assessment

Process Verification

Conservative process data
as a start point

Get reliable parameters with
their variability

Construct a graphical
operational process space

Verify robustness of selected
protocol

Simulate the operational
space with risks and failures

Experimental verification of
protocol

Iterative process

Time Saving with a Model Based Approach

We take your formulation on a journey supported by the newest techniques and model your lyophilization cycle, supporting you in every step until your product is manufactured at your commercial CMO site.

Traditional approach

- ✓ Formulation development and lyophilization feasibility for Phase I/II
- ✓ Evaluation of Critical Product Temperatures
- ✓ Process Development
- ✓ Process Optimization
- ✓ Process Robustness Testing
- ✓ Process Scale-Up
- ✓ Process Transfer

Model based approach

- ✓ Formulation development and lyophilization feasibility for Phase I/II
- ✓ Evaluation of Critical Product Temperatures
- ✓ Lyo Modelling
- ✓ Process Optimization and Robustness Testing
- ✓ Process Transfer

The Coriolis effect



- ✓ **Coriolis Pharma:**
Your partner in drug development, analytical, and manufacturing services.
- ✓ **Freeze-Drying Expertise:**
Cutting-edge solutions, from batch to continuous freeze-drying.
- ✓ **Innovative Approaches:**
Model-based lyophilization for efficiency and scalability.
- ✓ **End-to-End Support:**
From preclinical development to commercial manufacturing.

Let's accelerate your path to market—together!



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