



**RheaVita**

# Expanding Product Development Opportunities with Single Vial Unit (SVU)

Continuous and Controlled Freeze-Drying

**RheaVita's Single Vial Unit (SVU) is based on continuous freeze-drying technology and is specifically designed for R&D purposes to facilitate (bio)pharmaceutical product development.**



## **About RheaVita's continuous freeze-drying technology**

Perfectly suited for very fast product and process development, with minimal material consumption.

SVU data as baseline for production scale-out, from individual vial up to GMP production level.

Rapidly evaluate the impact of various process and formulation parameters on the Critical Quality Attributes (CQA) with minimal material consumption.

Many different parameters can be evaluated and screened in a matter of days, thanks to a short cycle time.

Custom software supporting fast process development and production scale-out:

- Wide flexibility in experimental design space
- In-line measurements and closed-loop process controls to preserve equivalent process conditions for scaling-out purposes



## How it works

- Controlled spin freezing with cold jet
- Controlled primary and secondary drying via infrared heater
- Identical process conditions for each vial
- Individual vial monitoring for quality release
- Equivalent process when scaling out from pre-clinical to commercial production (GMP)

## SVU enables opportunities

- Fast intrinsic continuous freeze-drying concept
- Faster time to market
- Opportunities for different types of products including:
  - › Products with low Tg' or low Tc
  - › Potentially faster reconstitution, e.g. for highly concentrated protein formulations
  - › Formulations requiring proper and well-controlled cooling and freezing rates
- Compounds compatible with RheaVita technology
  - › Amino acids
  - › Proteins and antibodies
  - › Viruses
  - › Oligonucleotides
  - › Nanosuspensions
  - › mRNA-LNPs
  - › Bacterial suspensions
  - › Small molecule APIs

<b>Dimensions (LxHxD)</b>	209cm x 172cm x 159cm
<b>Controllable rate of crystallization</b>	Through specification of constant delta-T between coolant and product
<b>Cooling rate</b>	1-50 K/min
<b>Processable critical product temperatures</b>	Down to 231 K
<b>Minimum pressure</b>	5 Pa
<b>Standard vial size (cylindrical)</b>	2R to 30R (ISO8362-1:2018)*
<b>Real-time monitoring</b>	Vial temperature & pressure
<b>Pyrometer accuracy</b>	1 K
<b>Access level control</b>	1. Viewing 2. Operator 3. Supervisor 4. Service
<b>Recipe/settings</b>	XML-based
<b>Batch record</b>	XML-based

\*contact us for customized container dimensions, including DCCs

