

RheaVita

Fast, Flexible Freeze-Drying Process for GMP Production

Continuous and Controlled Freeze-Drying



Innovative manufacturing technologies are necessary to make current and future drug products available for each patient, worldwide. As a pharmaceutical manufacturer, your processes can be conducted at a higher quality standard while being more efficient and cheaper.

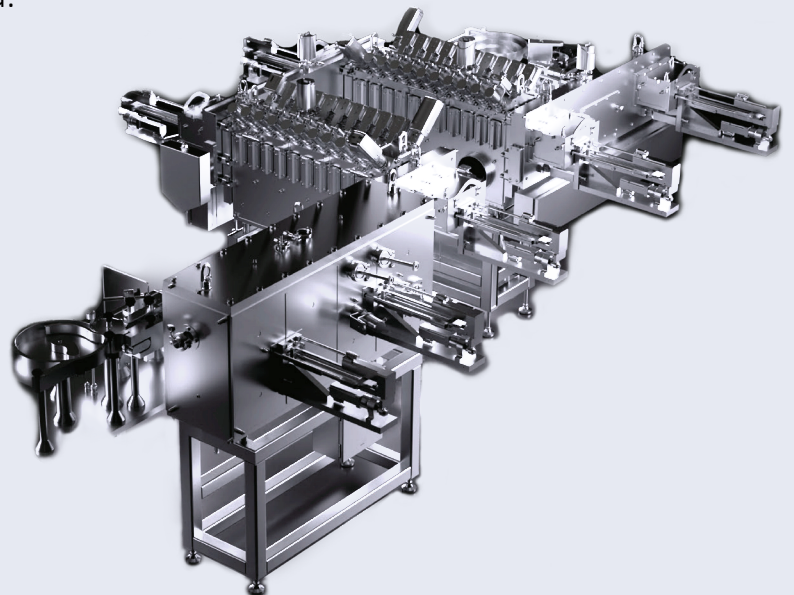
Conventional batchwise manufacturing processes are being replaced with more continuous and controlled processes that can boost efficiency.

The RheaVita technology brings advanced process control to (bio)pharmaceutical freeze-drying.

The GMP-Flex line uses the same freeze-drying recipe developed on the SVU R&D equipment. Pure scaling out principles.

Thanks to the flexibility of our continuous GMP-Flex line, any number of vials can be processed; no minimum batch size is required.

The GMP-Flex with its integrated process control systems enables freeze-drying of your compound under its most optimal conditions.



Time and financial savings:

- **Faster freeze-drying process:** hours instead of days
- **Major time and cost savings** thanks to scaling-out, not scaling-up
- **Manufacturing:** no large batch consumption for upscaling revalidation
- **Regulatory:** GMP drug candidate material in preclinical studies is comparable to FIH (first-in-human) material thanks to scaling-out
- Beneficial in lean manufacturing strategies
- **Closed processing equipment** requiring less clean room complexity, reducing CAPEX and OPEX
- Eliminate risk of whole-batch rejection
- Short change-over times

Improved quality:

- Fast and consistent handling of vials in a continuous flow
- Flexible freezing rates for optimal ice crystal formation
- Process control at the single vial level
- Smaller Proven Acceptable Range thanks to individual PAT
- No batch-to-batch variability

Improved flexibility:

- Suitable for a wide range of compounds
- Flexible production volumes
- Compatible with upstream and downstream continuous manufacturing steps



GMP-Flex ensures product quality in every single vial while increasing the production efficiency and reducing operation costs.

RheaVita has turned pharmaceutical freeze-drying from a multi-day process into a fast, flexible, and agile process while guaranteeing quality at the individual product level. This is critical to delivering new therapeutics all over the world and making medicines more readily available.

The **GMP Continuous Freeze-Drying Production Line (GMP-Flex)** enables aseptic processing and matches existing upstream and downstream continuous manufacturing processes.

GMP-Flex offers these benefits:

- Aseptic processing
- Uniform high quality from pre-clinical to commercial production
- Equivalent process signature for all products
- 100% integrated PAT
- Flexible production volumes
- Scaling out instead of scaling up
- Modular approach

