CASE STUDY

CONTINUOUS PHARMACEUTICAL FREEZE-DRYING WITH INNOVATIVE DRY PUMP SOLUTION

edwardsvacuum.com

Revolutionary continuous freeze-drying for pharmaceuticals made possible with collaboration between Edwards and RheaVita

The age old process of freeze-drying has been monumental for the advances in the pharmaceutical industry where process cycles can last from a few days to a week or more. It can be an extremely long and energy-consuming process especially when done in large batches. The existing pharmaceutical freeze-drying process lacks fundamental control of critical processes to achieve higher throughput per vial. RheaVita has developed a revolutionary continuous freeze-drying process whereby process measurement and control is established at an individual vial level. Cooling is achieved by jetting temperature-controlled cold inert gas at the vial whereas sublimation and desorption is achieved by applying radiant heat while the vial slowly rotates for homogeneous heat transfer.

Drying in freeze-drying occurs under vacuum where water vapor is removed by vacuum pumps. Traditional freeze-drying uses cold-condensers for effective water-vapor pumping which are entirely eliminated in the new continuous process thanks to the state-of-art Edwards GXS dry screw pumps which offer an optimal solution. In particular, the modular structure of the Edwards vacuum pumps is ideal when scale-up is required.

GXS Dry Screw pump and pump/booster combination

nXRi Multistage Roots pump

LR1D liquid ring pump

Edwards vacuum pumps used in the RheaVita GMP continuous freeze-drying system.

RheaVita's SVU (single vial unit)

RheaVita

KEY FACTS

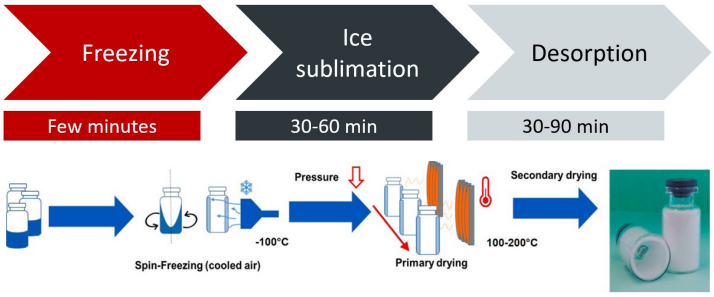
Customer	**RheaVita**
Sector	**Pharmaceutical & Biotechnology**
More info	**www.rheavita.com**

The RheaVita freeze-drying concept for a continuous process is built around modules with standard interfaces and connections. Each module contains a separate process step. There is a spin freezing module, a sublimation module, and a desorption module, connected through load locks.

Transfer from one module to another is executed through handlers. During the desorption and especially the sublimation phase high condensable vapor loads are removed from the product. In the absence of a condenser the entire vapor load needs to be handled by the vacuum pumps.

The Edwards GXS pump with its unique screw technology and world-leading high-efficiency drives enables advanced temperature control and offers long service intervals. Built with an oil-free pumping chamber and operating at internal temperatures that prevent condensing of vapor in the pumps, the GXS series can work under most challenging process conditions.

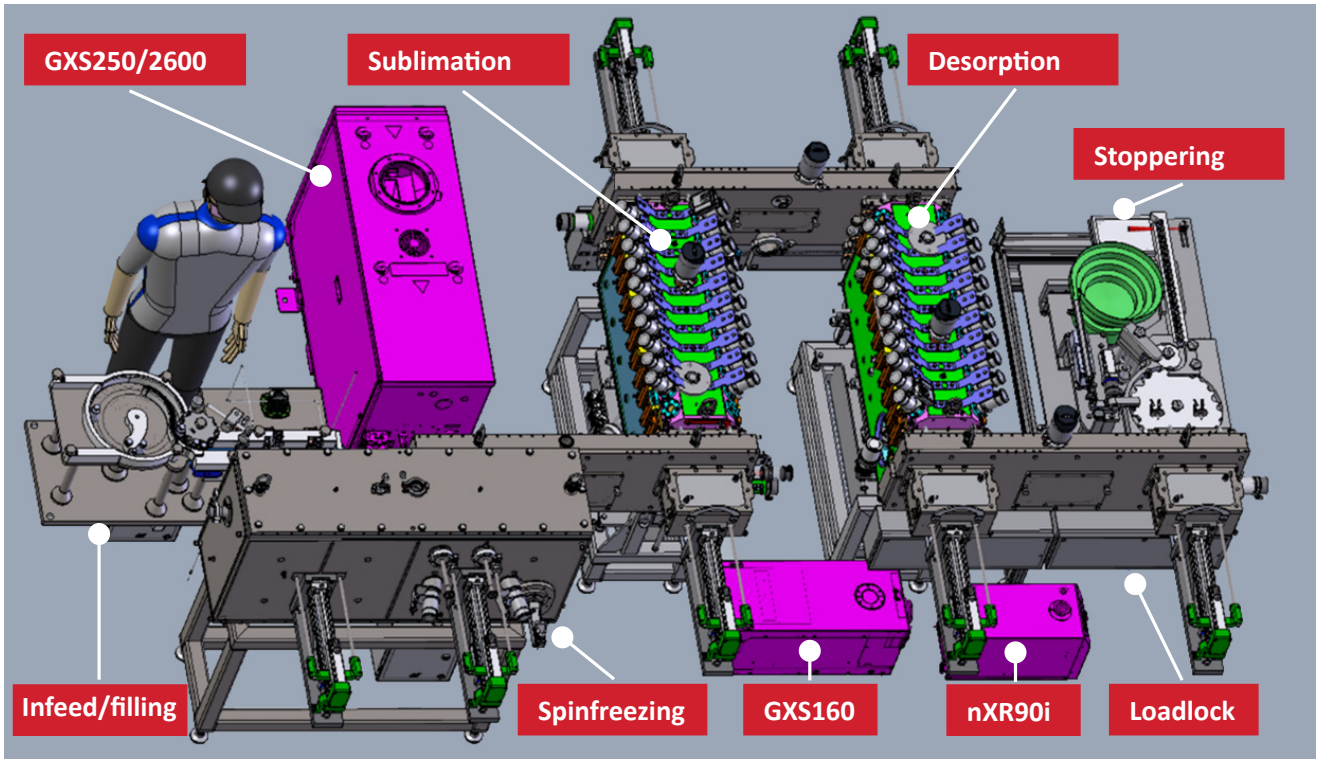
The oil-free contactless pumping mechanism provides continuous pumping performance and a stable vacuum level. Additionally, with an oil-free pump there is no risk of contamination of the highly valuable products by back-streaming of hydrocarbons.



Overview of the freeze-drying process and duration.

For GMP-readiness it is essential to achieve sterility for all direct and indirect product contact parts. This means that all modules internally need to be cleaned in place and need to undergo sterilization, in our case using clean steam at 125°C.

This process needs to be validated and the conditions monitored. Further, in a continuous system it is needed to achieve control of the process conditions for each individual vial based on information on the product status. A clear separation needs to be achieved between the aseptic environment where the vials with product reside and the auxiliary equipment such as the vacuum pumps.



Overview of the complete RheaVita freeze-drying arrangement including the applied Edwards vacuum pumps.

Edwards, along with applications support, provided a full vacuum solution for the continuous freeze-drying system. Apart from generating an oil-free environment, dry pump technology - like the Edwards GXS and nXRi dry pumps - provides an ideal working environment with minimal noise, low vibrations, and a compact footprint to easily integrate in the freeze-drying system.