



Process Engineering  
Division

Niro Pharma Systems

AEROMATIC  
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# GEA Lyophil

## Freeze Dryers for the Pharmaceutical & Biotechnology Industries

Freeze drying - or lyophilization - has a key role to play as the main fill and finish process during the aseptic handling of liquids and formulations in solution.

GEA Lyophil is one of the market leaders in freeze drying technology for the pharma and biotech industries. With more than 50 years experience and over 500 freeze dryer installations worldwide, GEA Lyophil is a reliable and quality assured partner for aseptic production, certified to ISO 9001 and performing in full compliance with the cGMP, GAMP4 and other relevant guidelines.



GEA Lyophil offers a wide range of cGMP freeze dryers from pilot to production plant size for the pharmaceutical and biotechnology industries.



#### **Automatic Loading and Unloading Systems (ALUS®)**

GEA Lyophil has its own proprietary system for Automatic Loading and Unloading Systems ALUS®, either as a pusher conveyor or a transfer cart system to work alongside the freeze dryer.



#### **Isolator Technology and RABs**

Integration of the (ALUS®) in the lyophilization system is achieved using either RABs or Isolator technology, whichever is most appropriate in each case.

The company covers all project activities from conceptual design and engineering to assembly and commissioning including IQ/OQ and SAT. In addition GEA Lyophil offers:

#### **Qualification Services**

GEA Lyophil's services include qualification and validation support that achieves fast validation of the freeze dryer and provides detailed qualification documents and test data prior to shipment and after installation on site.

#### **Application Support**

Optimized processes increase the production efficiency. GEA Lyophil application support experts can assist customers with the development and optimization of the freeze drying process cycle.

**A typical lyophilization system from GEA Lyophil incorporates the following system components:**

- multiple freeze dryers
- Automatic Loading and Unloading Systems (ALUS®)
- integrated CIP system
- isolator or a Restricted Area Barrier system (RABs)
- 21 CFR Part 11 compliant SCADA system adhering GAMP regulations

GEA Lyophil production systems increase the efficiency by improving the loading and unloading performance. Additionally, they minimize human involvement thereby minimizing contamination risks during the production of pharmaceuticals and maximizing operator security especially when handling potent products.



#### **Production Systems**

GEA Lyophil production systems fulfill the requirements of the pharmaceutical industry for reliable, validated production. GEA Lyophil can deliver both standard and customized plant configurations and make sure that individual process requirements are met. Depending on the customers' space and installation requirements the production freeze dryer plant can be installed on one or two floors.

## **Niro Pharma Systems**



*Niro Pharma Systems unites the technologies of Aromatic, Buck, Collette, Courtoy, Fielder, Lyophil, Nica and Niro to supply advanced processing solutions for solid dosage forms to the pharmaceutical industry.*

Niro Pharma Systems  
9165 Rumsey Road  
Columbia · Maryland 21045, USA  
Tel: +1 410 997 7010 · Fax: +1 410 997 5021  
E-mail: info@niroinc.com



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A company of GEA Group

WWW.NIROINC.COM