GEA Lyophil

Competence in Freeze Drying and Automatic Loading & Unloading
GEA Pharma Systems – Know-How on a Global Scale

GEA Pharma Systems is part of the Process Engineering Segment of the GEA Group. It specialises in the supply of advanced technologies for the preparation and processing of Active Pharmaceutical Ingredients (APIs) for the production of oral and parenteral dosage forms.

Trusted brands
GEA Pharma Systems combines trusted technology with a continual programme of innovation aimed at maintaining price/performance leadership for its pharmaceutical manufacturing customers. The GEA scope of supply is recognised worldwide through its well established and globally known brands: Aeromatic-Fielder™ and Collette™ – batch and continuous granulation, drying, pelleting and coating; Buck® – contained materials handling; Courtoy™ – tablet compression; Lyophii™ – pharmaceutical freeze drying and automated vial handling systems; and Diessel™ – fermentation and liquid formulation.

Local supply and technical know-how
The organisation includes manufacturing and technology centres in Belgium, Denmark, Germany, Switzerland, the UK, Singapore and the USA, and additional manufacturing facilities worldwide including India and China. Based at these centres, the organisation provides a wide range of services for the pharmaceutical industry including local manufacturing and supply, test facilities for product development and process evaluation, project management and ongoing support – all backed by GEA’s unique experience and technical know-how.

Partners for productivity
GEA Pharma Systems works closely with its customers to develop new products, reduce time to market and enhance clinical effectiveness. This can include the supply of R&D-scale and standalone production equipment, through to the installation of complete integrated production lines and continuous processing technology that will maximise operational reliability and productivity while providing unrivalled flexibility and unbeatable total cost of ownership.
For more than half a century GEA Lyophil has designed and manufactured freeze dryers for the pharmaceutical and biotech industries.

During this time the company has remained dedicated to the development of freeze dryer technology and has contributed substantially both to design and process control.

GEA Lyophil was one of the first freeze drying companies to deliver Automatic Loading and Unloading Systems (ALUS™) for freeze dryers and integrate isolators and CIP Skids into a complete system with freeze dryer and ALUS™.
Freeze drying (Lyophilization) has a key role in aseptic pharmaceutical and biotech production as the main fill and finish process.

Freeze dried products retain their original properties. By adding water or other solvents they can be reconstituted easily and very quickly.

Freeze drying is widely used as a method of preservation. Each product needs individual parameters during freeze drying process. This includes the initial freezing process, which is of great importance for the structure of the final product. The selected shelf temperatures and the corresponding sublimation pressure during primary drying determine not only the drying time but also the quality of the final product. Typical quality aspects are retention of original properties, appearance of the cake, reconstitution time and shelf life.

The freezing and melting behaviour of the product is tested in the laboratory to establish the correct outcome from the start. The test results then form the parameters for further pilot testing to develop the freeze drying process, reduce time to market and ensure faithful scale up to full production.

GEA Lyophil is giving support to its customers in the development and optimisation of the lyophilization process for both the pharmaceutical and biotech industries.
GEA Lyophil’s process expertise is based on experience and innovation secured by R&D. With over 1,000 units installed worldwide and thousands of tests performed in GEA Lyophil’s own test area, the company has established a solid base of expertise related to the needs of the pharmaceutical and biotech industries.

Every GEA Lyophil freeze dryer is designed to help customers to create a product that will succeed in the market, with GEA Lyophil being a partner in reaching that goal.

GEA Lyophil’s range of supplies and services comprises: laboratory freeze dryers, the pilot range for R&D purposes and small production batches; industrial-size freeze dryers; and complete freeze dryer systems including Automatic Loading and Unloading Systems (ALUS™). In addition, the company provides the service and retrofitting of existing freeze dryers.

The design and manufacture of freeze dryers and freeze drying systems is carried out in accordance with all cGMP, CE, GAMP5 and 21 CFR Part 11 guidelines.

The company’s expertise in freeze drying and related processes, i.e. isolator technology, sterilisation and clean-in-place (CIP), covers all kinds of pharmaceuticals and biotechnology derived products, for example: hormones, vaccines, antibiotics anti-infectives, bacteria, sera, enzymes, diagnostic agents, monoclonal antibodies (MABs) and blood products.
Each Project is different – the goal is the same:

Plants Customized for Success
Every pharmaceutical system and unit of plant from GEA Lyophil is a unique and efficient combination of proven technology and solutions for cGMP production individually configured to reflect the specific customer’s needs.

GEA Lyophil can deliver the right size and performance to meet your output demands; the right configuration for their production and process requirements; and the right barrier technology to eliminate contamination risks.

A Partnership in Every Perspective
Working with GEA Lyophil means entering a professional partnership which continues every step of the way: from first process / product testing and plant design to start up, take over of the new plant for production and professional support during years of productive operation.

GEA Lyophil’s unique service programme and retrofit concept ensures an optimised return on investment throughout the lifetime of the plant.

Total Cost of Ownership
Buying a freeze drying system means starting a relationship between customer, equipment and equipment supplier for 20 or more years. Looking at the total cost during the lifetime of a plant is essential for our clients in today’s competitive landscape.

GEA Lyophil has focused all its efforts in developing smart solutions that provide tangible benefits in terms of the efficiency and productivity of their freeze drying plant. Green, low-energy technology, state-of-the-art components and unique equipment design ensure the most economical operation of the plant. At the same time, the outstanding quality of the equipment and specific conditional maintenance programs ensure uniquely high plant performance and availability which leads to increased productivity for the user.

All our efforts serve one goal: to make our customers perform better and more cost effectively – long term.
highest efficiency and cost effectiveness
ALUS™ Automatic Loading and Unloading Systems increase efficiency and minimize contamination risks

GEA Lyophil has specialised in supplying integrated freeze drying systems for more than 20 years and can ensure high performance, reliable and trouble-free operation based on our long experience as a partner to the pharmaceutical and biotech industries. We have more than 120 validated ALUS™ installations, successfully operating for various pharmaceutical applications that demonstrate our capability.

Whether filler or capper, our extensive experience in interface design for these plants guarantees the smooth integration of a perfectly harmonized production line.

The containment requirements and product details determine whether it’s necessary to have ALUS™ with open or closed RABS (cRABS) or isolators that require the use of a Stationary Push-Pull System.
The mobile Transfer Cart System distinguishes itself owing to its high flexibility when charging several freeze dryers.

Formatting and loading can run in parallel, thus optimizing the process. Alternatively, laser-controlled, rail-less transfer carts can bring a greater degree of flexibility into the spatial arrangement of the freeze dryer. The application of the unique gapless docking technique – no gap between the freeze dryer and transfer cart – means that we can guarantee maximum product protection and ensure that the transfer of the vials occurs under a constant laminar flow. Both designs are extremely adaptable with regard to primary packing and the degree of automation. Modifications can be made, according to demand, within a range from manual to fully automatic handling. Both systems can be executed in accordance with the ATEX guidelines, are modular, and can be retrofitted to existing units.

The GEA Lyophil ALUS™ stands for safety, performance, flexibility and reliability:

- High performance by charging of up to 800 vials/min and discharging of up to 700 vials/min
- Frameless operation
- High flexibility when operating with different vial forms
- Proven operational safety, even for difficult vials (diameter-height ratio of <3) owing to our unique patented design
- Superior sterile design with excellent laminar flow properties: no moving parts above open vials so as to increase safety and avoid product contamination
- Optimum interface coordination with upstream and downstream equipment
- Zone-type construction for containment according to product flow requirements
Freeze Dryer

Lab & Pilot Freeze Dryer

Technology Leadership
GEA Lyophil supplies a comprehensive range of products and services, comprising: laboratory freeze dryers, both pilot scale for R&D and small production batches; industrial freeze dryers; and integrated freeze dryer systems.

Solution provider
Plant configuration extends from specialised solutions, e.g. for highly potent products and all layout requirements, from two-storey units up to fully integrated systems with multiple freeze dryers and loading systems, optionally with integration of the chosen filling line.

• More than 60 years experience in lyophilisation process development, engineering and manufacturing
• More than 1000 freeze dryers and automated (un)loading systems in production globally
• References in compliance with cGMP, CE, GAMP and 21 CFR Part 11 guidelines
• Customer base includes major pharmaceutical companies, contract manufacturers, and generics manufacturers, demonstrating operational reliability, quality and productivity of the GEA Lyophil equipment

SMART LYO™ SL 200-D

SMART LYO™ SL 20-D

SMART LYO™ SL 80

SMART LYO™ SL 20
Product Portfolio

In-depth Process Understanding
GEA Lyophil provides standard or customised solutions based on proven technology and a thorough understanding of the individual requirements for all applications such as: bulk API, blood plasma, vaccines, hormone, antibiotics/anti-infectives, bacteria, sera, enzymes and diagnostic agent production.

All pilot and production freeze dryers are available either with steam or H2O2 gas sterilisation. Systems include Automatic Loading and Unloading Systems (ALUS™); isolators and CIP-Skids in a one-package solution with the freeze dryer.

We care about your business
Superior performance and reliability combined with best total cost of ownership help you to be most successful in your business.
Efficient freeze drying for greater productivity

Low running cost, reproducible product quality and long-term performance and productivity of the plant are key elements of GEA Lyophil’s Total Cost of Ownership programme.

LYOPLUS™ Multipurpose measurement device

LYOPLUS™ is a mass spectrometer that is fitted with advanced software enabling it to provide multiple process and equipment measurement data that indicate the quality and the performance of the process. The system is able to work alongside any existing PLC/SCADA system as a stand-alone unit or fully integrated within the control system. It can also be operated independently as a monitoring system that does not interfere with any qualified processes.

E-STAR™ Energy saving Concept

Freeze drying ranks high among the drying processes for total energy consumption. Although the process of freezing and water sublimation cannot be changed in principle, the concept describes the opportunities for significant reduction of media and electricity. It discusses the need for the correct selection of components that are highly energy-efficient and evaluates the specific energy/media saving technologies that are available. With E-STAR™ concept increased process efficiency of up to 40% is possible.

ControLyo® Nucleation on demand technology

ControLyo™ nucleation on-demand technology licensed from Praxair can deliver improved product uniformity, quality, and yield, while reducing cycle times by up to 40%. This proprietary technology controls the nucleation temperature of a solution to within 1°C of its freezing point, delivering exceptional control to a previously uncontrolled freezing process.

LYOFIT™ Control System Upgrade

While lyophilizers can remain operational for many years, lyophilizer control technology has moved on – and it is this that can render a system out of date. As a way of controlling costs, one option is to retrofit the control system alone: producing a lyophilizer that will provide many more years of reliable service, without the expense of buying new equipment.
GEA Lyophil will be your partner during every step of your project including: cycle development, analysis of your initial project requirement, selection of the best suitable layout and right size and system performance, equipment engineering and manufacture, commissioning of the plant, training and lifetime support by our service team and process experts. GEA Lyophil will be your partner during every step of your project including: cycle development, analysis of your initial project requirement, selection of the best suitable layout and right size and system performance, equipment engineering and manufacture, commissioning of the plant, training and lifetime support by our service team and process experts.

Everything from one source and based on 60 years of freeze drying expertise.

GEA Lyophil Freeze Drying Systems include the actual freeze dryer and the automatic loading and unloading system ALUS™ integrated in one package. From concept through design, assembly and FAT, it’s a seamless approach without an external interface. The benefit of this integrated concept has been tested during FAT testing of actual performance with vials. This ensures the smooth operation of the complete plant and proof of performance before the equipment is shipped to site. Our customers can be assured of a consistent security of outcome; we take responsibility.

Our Service Team offers 24/7 HOTLINE support.

Intelligence built into the system, with our conditional maintenance programme, ensures the operational availability of the plant and the highest productivity.

Working with GEA Lyophil means entering into a partnership with dedicated experts who all have one goal: to support you to be the best in your business.
LYOVAC™ FCM 400-D Freeze Dryers
From its earliest applications in the stabilization of blood plasma in the 1940s, freeze drying has become a standard process in the life science industries. Since that time, the freeze dryer — or lyophilizer — has evolved from a simple device for low temperature vacuum drying to an extremely sophisticated and integrated system that combines a number of processes to ensure that a product is consistently delivered to exacting technical and biological specifications, while complying with a number of economic, safety and environmental issues.

With 60 years of experience in the engineering and manufacturing of freeze dryers, GEA Lyophil has delivered more than 1000 installations and conducted thousands of freeze drying tests for the pharmaceutical and biotechnology industries, underlining the company’s technological leadership and unparalleled expertise.

GEA Lyophil’s thorough understanding of the freeze drying process enables them to supply a comprehensive range of products and services, comprising pilot plant for research and small-scale production batches, industrial size production freeze dryers as well as complete freeze dryer systems consisting of one or multiple modules plus ALUS™ (Automatic Loading and Unloading System), integrated isolators and CIP-skids. Offering a variety of both cost-effective standard and highly customised options, GEA Lyophil’s modular equipment extends from R&D to standalone production plants and high-capacity systems for bulk product applications.

Plant configuration capacities extend from specialised solutions for highly potent products to two-storey units and fully integrated systems with multiple freeze dryers and loading systems (with or without the integration of your chosen filling system supplier). Product-based containment requirements will determine the need to use ALUS™ with closed RABS (cRABS) or isolators, whereby a stationary push-pull system can be deployed. Otherwise, a mobile transfer cart offers flexibility and the ability to format and load in parallel when charging several freeze dryers. Both systems are extremely adaptable in terms of primary packing and degree of automation (from manual to fully automatic), are modular, ATEX-compliant and can be retrofitted.

The design and manufacture of each module and system component is done in accordance with all cGMP, CE, GAMP and 21 CFR Part 11 guidelines, meeting the strictest requirements and regulatory standards around the world.

**Products include**

- **Pilot**: the SMART LYO™ SL 10-80 range (shelf size 0.4-8 m²) is ideal for product development and optimization, scale-up and small-scale production.

- **Production**: the industrial LYOVAC™ is the ultimate pharmaceutical lyophilizer from GEA Lyophil, allowing users to specify individual manufacturing requirements. The LYOVAC™ is available with 8-55 m² of shelf space and a condenser capacity of more than 1000 kg to ensure high drying rates.

- **Production**: SMART LYO™ SL 100-SL 800 systems are constructed on a single-floor plant frame for fast, simple commissioning and include the compact chamber/condenser unit, all system modules (hydraulics, venting system, vacuum) and available options such as CIP and SIP, interfacing to ALUS™.

From pre-engineering studies to plant specification and site acceptance tests (SATS), and from qualification to validation support, GEA Lyophil’s experts are always available to ensure that the equipment is delivered, installed and operating efficiently and reliably in the shortest possible timeframe. Professional operator training, preventive maintenance and an excellent spare parts, application support and after-sales service guarantee the trouble free and profitable operation of GEA Lyophil freeze dryers.

In addition, the company’s retrofit expertise enables customers to extend the life of their freeze dryers and to cope with changing requirements and regulations. Lyophil™ freeze dryers help to reduce the cost of freeze drying while maintaining quality and performance, making validation and documentation easier and reducing delivery times.
We live our values.
Excellence • Passion • Integrity • Responsibility • GEA-versity

GEA Group is a global engineering company with multi-billion euro sales and operations in more than 50 countries. Founded in 1881, the company is one of the largest providers of innovative equipment and process technology. GEA Group is listed in the STOXX® Europe 600 index.