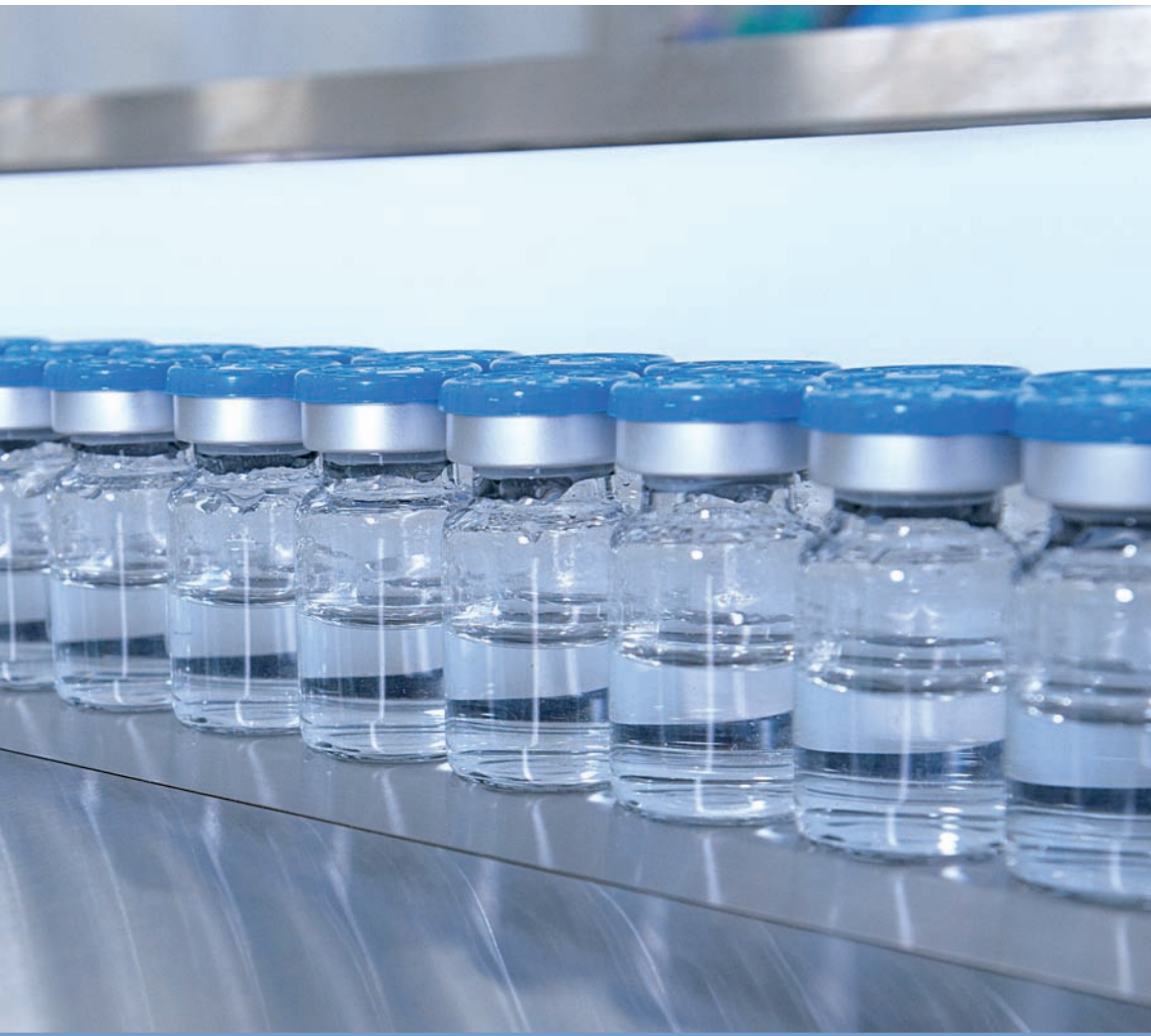


ALUS®



Lyophil™

Automatic Loading and Unloading Systems for Freeze Dryers

GEA Pharma Systems supplies advanced technologies for the processing of Active Pharmaceutical Ingredients (API) for the production of oral and parenteral dosage forms.

GEA Pharma Systems strives for *Price/Performance Leadership* providing its customers with highly cost-effective, integrated systems for the pharmaceutical industry. GEA Pharma Systems is dedicated to innovation and thereby providing durable quality through its well-established brands: **Aeromatic-Fielder™** and **Collette™** - batch and continuous granulation, drying, pelletizing and coating; **Buck®** - contained materials handling; **Courtoy™** - tablet compression; and **Lyophil™** - pharmaceutical freeze drying.

GEA Pharma Systems' activities include partnering with customers to develop new products and enhance clinical effectiveness; the supply of R&D-scale and stand-alone production equipment; and the installation of complete integrated production lines.

Experienced and innovative

GEA Lyophil has specialized in the field of freeze drying for more than 50 years and over 20 years ago was the first manufacturer to introduce automatic loading and unloading systems to the market.

ALUS® (Automatic Loading and Unloading System) has been a registered trade name of GEA Lyophil since 1995 and is a recognized standard in the pharmaceutical industry. In 1989 the first ALUS® was put into operation in pharmaceutical production and in 1997 the first ALUS® contained in an isolator went into operation.



Discharge zone of a
Conveyor-Pusher
System

GEA Lyophil is the leader in freeze drying technology and automatic loading and unloading systems. We can ensure reliable and trouble-free process procedures, based on our many years of experience as partner to the pharmaceutical and biotech industries and more than 50 validated ALUS® installations for various pharmaceutical applications.

Whether filler or capper, our unique experience in interface design for these plants guarantees the smooth integration of a perfectly harmonized production line. This experience forms the basis of our considerable knowledge of your problems. We have used this knowledge to develop further ALUS® innovations, from which you can greatly profit.*

The application of our Fast Track project implementation for freeze dryers with ALUS® means that the project time is reduced considerably. The result is that your product can come to market sooner. The compact design doesn't only reduce space requirement, thereby reducing total investment, it also means a reduction in energy consumption and, therefore, production costs. The high loading and unloading speed and fully automatic size change, guarantee the highest productivity and flexibility in your production.

* EP 0 391 208 B1, EP 0 639 153 B1, WO 2004/074143 A1,
EP 1 712 859 A2, DE 10 2008 020 705.5.



Transfer cart in
production area

ALUS® by GEA Lyophil

The manual loading of a freeze dryer creates the greatest risk for both product and employees.

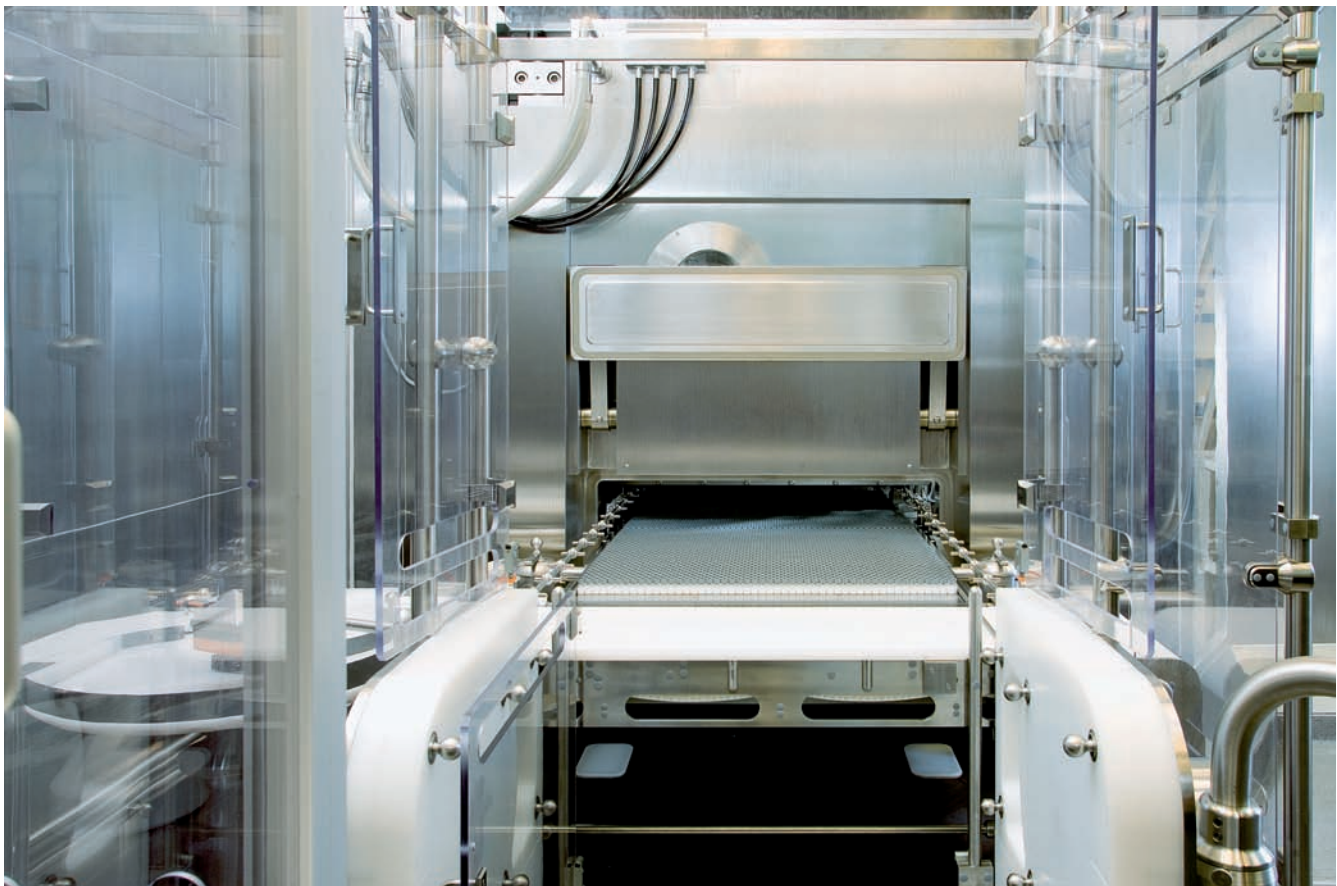
GEA Lyophil carries out, with your production team, risk analyses, which examine and evaluate the process system-wide from filling to capping. These analyses generate tailor-made solutions for your individual needs and requirements based on our experience and design standards.

ALUS® offers you solutions from half-open systems up to combinations with isolators or RABS (Restricted Access Barrier System). The combination of ALUS® with isolators or RABS provides the ideal solution for the demand for hermetically sealed systems producing toxic products in the pharmaceutical and biotechnological industries.

The input from GEA Lyophil's many years experience of integrating RABS and isolator systems will bring many benefits to your project.

One of the most outstanding characteristics of the ALUS® design is the elimination of drive systems and moving parts above open vials. This guarantees absolutely safe and contamination-free operation.

We design and construct in accordance with the specifications and recommendations of ISPE, GMP, GAMP, EN/ISO 13408, EN/ISO 14644, FDA Aseptic Guide as well as EMEA.



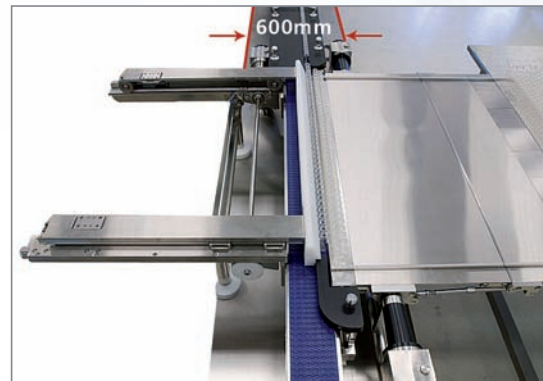
View of the open pizza door of a freeze dryer with conveyor pusher system in the RABS

Loading and Unloading System

The well laid out construction, rounded components and compact, hygienic design makes cleaning and maintenance of the ALUS® easy.

All the drives, which require routine service, as well as electrical parts, are situated beneath the base plate. This sealed separation excludes the risk of any kind of contamination and makes it possible to service the machine without breaching the sterile production area.

The depth of less than 600mm makes all areas easily accessible. All areas of the isolator can therefore be reached via the glove handshake principle. Non-productive times, such as during cleaning, can be considerably reduced. In addition, the relatively small space requirement reduces the acquisition costs of isolators and RABS as well as reducing operating costs.



Cleaning of bridge plate



Base plate with elevated transfer belt



Rotary table



Adaptable

ALUS® by GEA Lyophil



GEA Lyophil has the exact ALUS® for every requirement.

The containment requirements and product details will determine whether it's necessary to have ALUS® with closed RABS (cRABS) or isolators. In such case a fixed Conveyor-Pusher System has to be deployed. It is predestined not only for use with a cRABS but also in the isolator.

The mobile transfer cart distinguishes itself by 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

docking technique – no gap between the freeze dryer and transfer cart – means that we can guarantee maximum product protection and ensure that transfer of the vials occurs under a constant laminar flow.

Both systems are extremely adaptable with regard to primary packing and the degree of automatization. Modifications can be made, according to demand, within a spectrum 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.

	ALUS®					
	Open RABS	Closed RABS	Isolator	Open RABS		
	Stationary			Transfer cart		
	Manual	Semi-automatic	Fully-automatic	Manual	Semi-automatic	Fully-automatic
Shell / Frame	✓	✓	✓	✓	✓	✓
Vials / without frame		✓	✓		✓	✓
						

Conveyor-Pusher –System with RABS

Transfer cart in production area

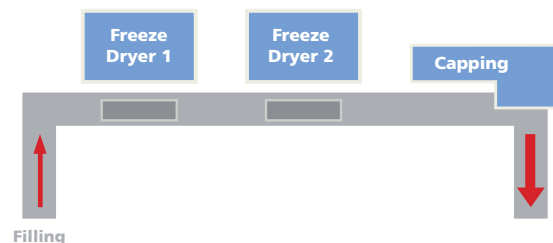
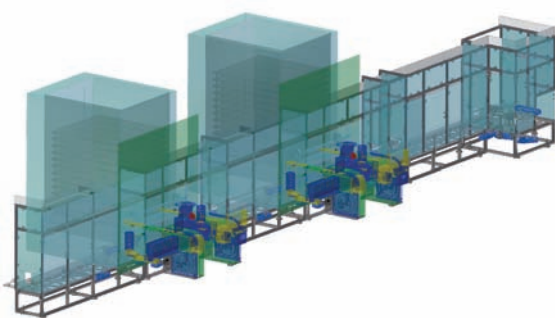
Loading and Unloading System

The GEA Lyophil ALUS® is flexible with regard to all conceivable layouts, as both the stationary Conveyor Pusher System and the mobile transfer cart can be adapted to fit the location's requirements exactly. We will discuss your requirements with you and advise how the optimum solution for your individual needs can be achieved with regard to the arrangement of freeze dryers with ALUS®, as well as the interaction between the filler and capper.

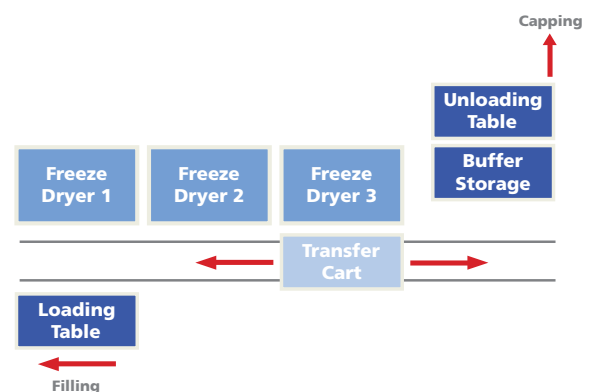
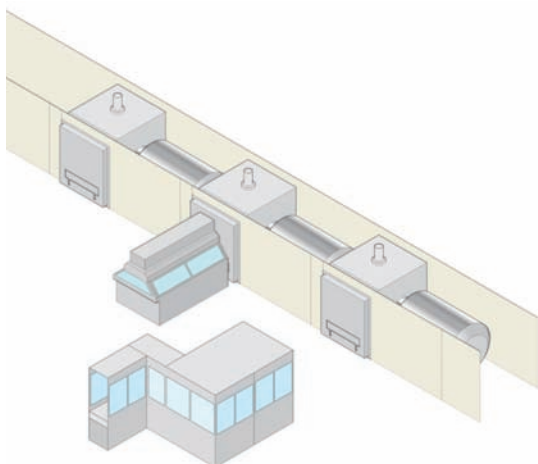
We involve at this point the manufacturers of the filling and capping machines, so as to guarantee that everything runs smoothly from planning to commissioning. Our long-standing co-operation with well-known manufacturers of pharmaceutical equipment has made us an expert in integration. Our team plans the optimum solution for every conceivable configuration and takes into account the required product flow. Here both the one-sided loading and unloading of a freeze dryer as well as

the pass-through principle, where loading is carried out on one side and unloading on the other, are possible. It's also possible to load individual or multiple freeze dryers.

Put your trust in our competence and our many years of experience to guarantee the optimum solution for your production process along with the best possible flexibility.



Example layout for 2 freeze dryers with stationary Push-Pull System



Example layout for 3 freeze dryers with Transfer Cart System

ALUS® by GEA Lyophil

Automatic loading and unloading has another advantage – the process times can be drastically reduced. The application of a transfer cart in combination with several freeze dryers brings about the most effective reduction, as formatting and charging can be run in parallel.

A high throughput rate of 500 vials/min by loading and 700 vials/min by unloading can be achieved, not only with the Conveyor Pusher System but also with the transfer cart. The speed depends upon whether loading is single-row or multiple-row. A maximum loading speed of 800 vials/min is possible by multiple-row loading.

Size changes can be carried out quickly and easily by exchanging pre-fabricated format parts. We guarantee that it is possible to change the size parts manually within a few minutes without having to use tools. A fully-automatic size change for vials with sizes from 2ml to 50ml is also possible. We can, therefore, offer maximum performance with high flexibility.

We carry out complete system tests on the freeze dryer and ALUS® as well as isolator during the Factory Acceptance Test in our factory. The testing of the interfaces guarantees faster installation times as well as shorter test times at your premises.



View of a Conveyor-Pusher System with RABS after freeze drying. The photos show the discharging sequence before the downstream capping machine.



Button



Tool-less changeovers

High Performance

Loading and Unloading System

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

- High performance by charging of up to 500/800 vials/min and discharging of up to 700 vials/min
- Frameless operation
- High flexibility when operating with different vial forms
- High operational safety, even for difficult vials with a diameter – height ratio of <3
- High quality sterile design with excellent laminar flow properties
- Optimum interface coordination and integration of the ALUS® with the freeze dryer or a complete production line with upstream and downstream processes
- Trouble-free transfer of the vials from ALUS® to the freeze dryer with patented design
- No moving parts above open vials so as to increase safety and avoid product contamination
- Zone-type construction for containment possible according to product flow requirements
- Easy-to-use integrated software
- System solutions from a single supplier means fewer interfaces and trouble-free project handling.



Control panel



Conveyor-Pusher System in the isolator during charging



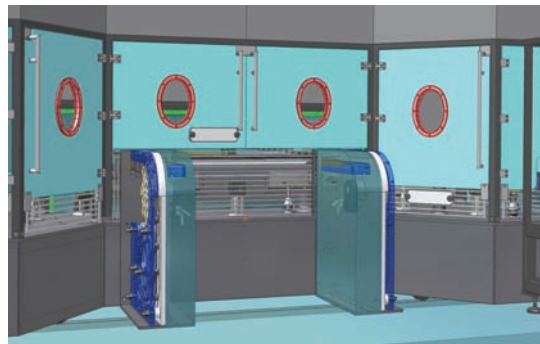
Conveyor-Pusher System with RABS

In good hands from start to finish

GEA Lyophil will accompany you every step of the way during your project – from the very first requirement analysis, through the design layouts, engineering, manufacture, commissioning of the plant right up to Life Time Support from our service department. Everything from one supplier.

We have at our disposal the space and the specialists to install ALUS® together with the freeze dryer in our factory and to carry out a complete Factory Acceptance Test of the system with you.

Our service team offers round-the-clock support with its 24-hour hotline. Preventative maintenance, carried out by our specialists, ensures the operational availability of the plant and therefore the highest productivity possible.



Planning and engineering are carried out completely in 3D CAD System



ALUS® assembly by the GEA Lyophil team



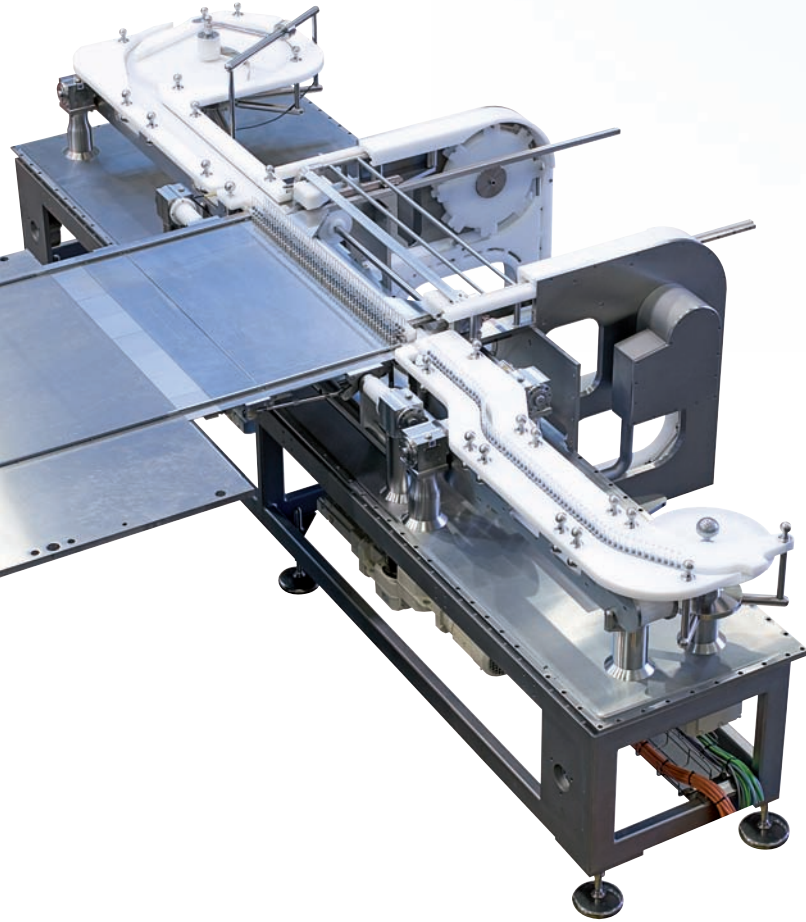
Mock-up is carried out with our customers so as to facilitate optimum ergonomics.



We will assemble the plant for the Factory Acceptance Test, when necessary with the freeze dryer, on a 1:1 basis. The complete test in the factory facilitates quick and smooth commissioning on-site.

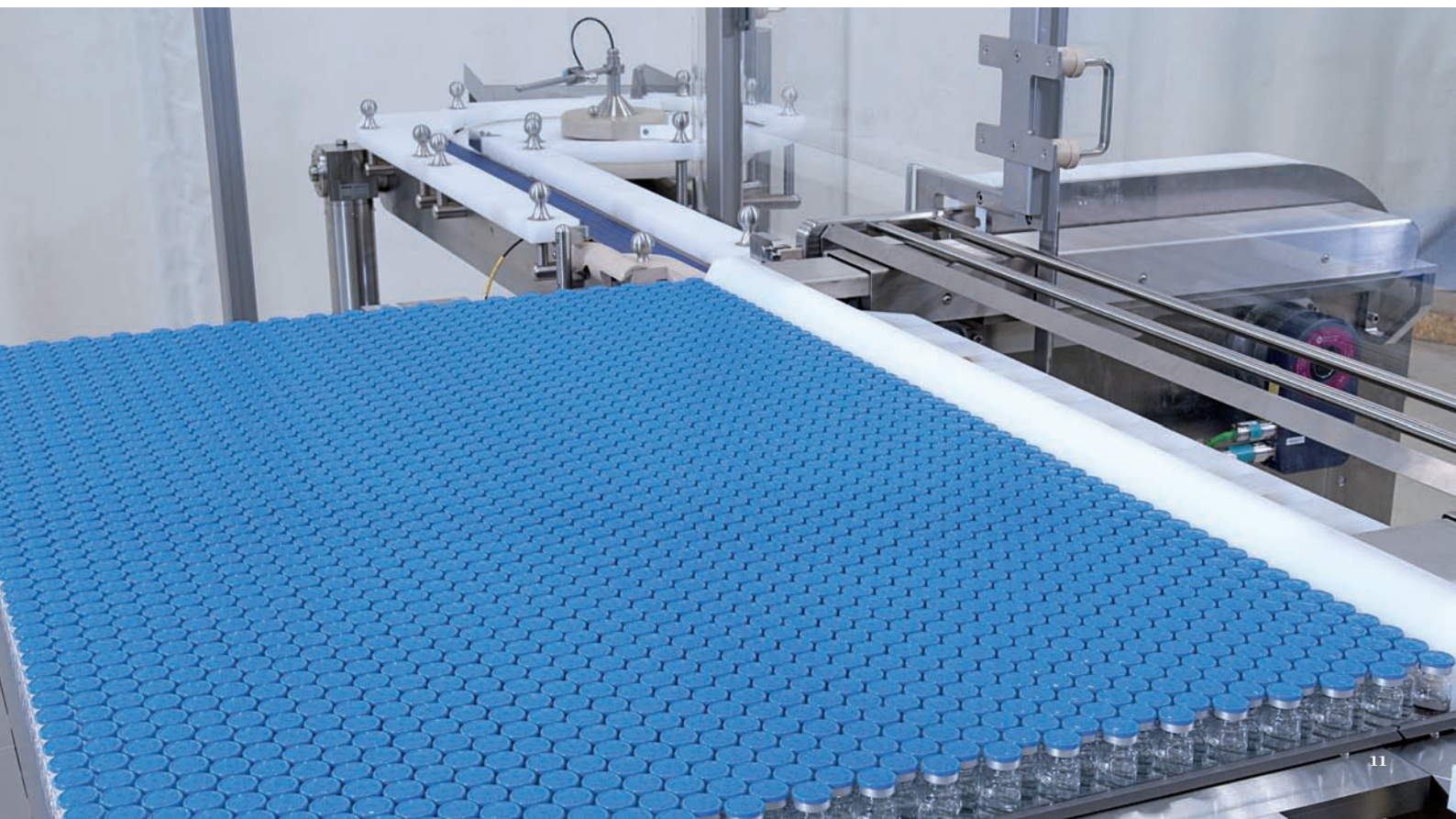


Our specialists are on site during commissioning to ensure that the plant can be put into operation reliably and quickly.



The Lyophil ALUS® -
Performance at the very highest level designed for long-term stability – an investment for the demands of tomorrow.

Conveyor-Pusher System with infeed and rotary table





Central Know-How on a Global Scale

Based on a strong commitment to research and development, pharmaceutical technology centres in Belgium, Denmark, Switzerland, the UK, Singapore, and USA provide global technical support and know-how to the pharmaceutical industry. These centres

of excellence give customers access to a range of test facilities and expert teams with technical and process know-how. Our teams work closely with our customers to optimise processes and evaluate their products, enabling them to achieve their process and production goals.



Contracting Profitable Experience

A world leader in supplying pharmaceutical equipment, GEA Pharma Systems offers manufacturers all over the world the opportunity to enter into a profitable partnership for development and contract. GPS combine advanced in-house technology with a thorough

understanding of the pharmaceutical industry to help customers maximize their development results.



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GEA Pharma Systems

GEA Lyophil GmbH

Kalscheurener Strasse 92, D-50354 Hürth, Germany

Tel: +49 2233 6999-0, Fax: +49 2233 6999-10

info@gea-lyophil.com