INTRODUCING ALUS®

GEA Engineering for a better world.

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INTRODUCING ALUS®

GEA was the first manufacturers to develop ALUS® (Automatic Loading and Unloading Systems) technology using permanently installed systems (conveyor-pusher systems) and flexible transfer cart systems.

Increasingly stringent health and safety requirements for aseptic manufacturing and contamination prevention have driven the development of ALUS®, to which GEA has made a major contribution. Automating the production process and reducing the size of isolators has made it possible to decrease human intervention in sterile areas and minimize contamination risks.

We can deliver the right size and performance to meet your output demands, the right configuration for your production and process requirements, and the right barrier technology to eliminate contamination risks.

Efficient, safe and reliable performance
ALUS® is designed to give the user the maximum layout flexibility. This can include loading and unloading from one side, loading and unloading from two sides (pass through design), loading with a push-pull system under isolator or RABS systems, and unloading using a transfer cart with RABS systems. ALUS® can also accommodate a wide variety of filler and capper options, and ATEX-compatible options are also available.

Stationary Push-Pull System: Implementing the most appropriate ALUS® will depend on the containment requirements and productrelated details. If it is necessary to have ALUS® in conjunction with closed RABS (cRABS) or isolators, then a fixed conveyor-pusher system should be deployed. Not only ideal for use with cRABS, it can also be placed within an isolator.

ALUS® Transfer Cart System: The latest ALUS®
Transfer Cart system takes the whole process further by offering a flexible layout, a more compact design and an advanced W-LAN panel-based control system. It also facilitates docking under laminar flow, or in an open RABS, and provides the ability to expand the system by adding additional freeze dryers when production demands increase. The mobile transfer cart is particularly useful when charging several freeze dryers. Formatting and loading can run in parallel, thus optimizing the process.

Up to ten freeze dryers can be loaded and unloaded by a single ALUS® transfer cart system (depending on the application) so as a system grows the additional production can easily be accommodated. This is a much more flexible system than fixed push-pull equipment and much more cost-effective.

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

ALUS® AUTOMATIC LOADING AND UNLOADING SYSTEMS.

Both the Transfer Cart and stationary systems are extremely adaptable with regard to primary packing and the degree of automation (from manual to fully automatic handling). They can also be retrofitted to existing units.

A high throughput rate of 500 vials/min. (loading) and a maximum speed of 800 vials/min. (unloading) can be achieved, with both the transfer cart system as well as the stationary push-pull system.

The Transfer Cart system has been designed with flexibility in mind and can be adapted to fit a wide range of floorplans and layouts, even if the freeze dryer is not in line with the filler or capper. Retrofit compatible, the cart can also be connected to an existing freeze dryer or installed in new lines. Multiple filling and capper lines can be accommodated as well.

Extremely efficient with short cycle times, the transfer cart delivers high-end performance without needing a power rail or battery. To ensure product protection throughout the entire loading and unloading process, an induction-powered laminar airflow guarantees constant and particle-free operation.

Able to move in six directions (right, left, up, down, forward and backward) and use a variety of track systems, GEA's transfer carts meet the stringent requirements of the pharmaceutical industry in terms of safety, hygiene and sterile design.

Tool-free size changes can be done quickly and easily, simply by exchanging prefabricated parts. A fully automatic size change for 2–50 ml vials is also possible. As such, the overall turnaround time is greatly reduced, which also benefits the customer in terms of total cost of ownership.

The latest ALUS® equipment is up to 45% more compact than its predecessors. This compact design significantly reduces the footprint to keep building costs to a minimum and allow much easier integration in retrofit applications.

The benefits of ALUS®

- 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 to increase safety and avoid product contamination
- Optimum interface co-ordination with upstream and downstream equipment
- Zone-type construction for containment according to product flow requirements.

ALUS® Buffer conveyor.

ALUS® AUTOMATIC LOADING AND UNLOADING SYSTEMS.

Containment, Automation and Handling Options.

Production Line with ALUS®
Cross moveable Transfer Cart.

Stationary Push-Pull System

Automation	Manual	Semi-automatic	Fully automatic
Handling	Frames	Frames	Trays
	Trays	Trays	Vials
		Vials	Carpules
Open RABS	•	•	•
Closed RABS		•	•
Isolator			•

• Standard

Transfer Cart System

Automation	Manual	Semi-automatic	Fully automatic
Handling	Frames	Frames	Trays
	Trays	Trays	Vials
		Vials	Carpules
Open RABS	•	•	•

• Standard

ALUS® OPTIONS.

To further enhance the productivity of GEA's Automatic Loading and Unloading Systems (ALUS®), a range of cost-effective modular options is available to customize your freeze drying system.

Each module and system component meets strict safety and regulatory requirements, and has been designed to guarantee optimal product quality and high throughput rates.

GEA LYOSENSE®
The lyophilization of pharmaceutical products such as vaccines enhances their stability and shelf-life. However, these properties can only be maintained when the resulting cake has a residual water level of 0.2–5.0%.

For this reason, regulatory guidance indicates that this parameter must be controlled and determined. Until now, however, techniques to measure such properties have been both destructive and time-consuming, and thereby uneconomical.

Real-Time Characterization of Lyophilized Products
LYOSENSE® from GEA, based on multipoint NIR measurements, provides the comprehensive and non-destructive evaluation of freeze dried product cakes in real-time. This easy-to-install and use online measuring device is a fast and non-invasive solution to moisture control, enabling the effortless detection of

- residual moisture
- cake homogeneity
- API concentration.

Other critical process parameters, such porosity, melt and glass particles, can also be assessed.

For 100% vial inspection, machine communication capabilities and easy integration into both lab and production environments, this miniaturized probe is simple to calibrate and enhances product development by facilitating Quality by Design.

Fully GMP and 21 CFR Part 11 compliant and supplied with IQ/OQ/PQ support, the LYOSENSE® provides the following benefits:

- whole cake assessment with multipoint measurement
- fast measurement and evaluation (5 ms)
- no required consumables
- simple and easy user interface and operation.

LYOSENSE® is compatible with other GEA innovations such as LYODATA® for continuous monitoring and full traceability, and the ALUS® automatic loading and unloading system.

LYOSENSE®

ALUS® Bellow Pusher.

ALUS® OPTIONS.

Backpusher
The ALUS® backpusher provides the following benefits: improved user access and cleanability, cost-effective containment (only the product zone needs to be LAF protected) and enhanced leak test compatibility. Furthermore, all moving parts are bellows protected and completely contained within the freeze dryer chamber, facilitating CIP/ procedures. In addition, the system is fully Annex 1 compliant, with no parts present above the vials during unloading, and suitable for flat front and isolator containment operations.

Bellow pusher
Providing a clear and defined barrier between the product and user areas, the ALUS® bellows pusher offers improved cleanability, better user access and a cost-effective containment option (only the product zone needs to be LAF protected). All moving parts are bellows protected and, like the backpusher, flat front and isolator containment is possible.

Starwheel
During freeze dryer loading, the ALUS® starwheel module serves to position, count and stop — if necessary — the vials received from the infeed conveyor to a pusher conveyor. With processing speeds of up to 500 vials/min, the starwheel is both time and cost-efficient and comes in an easy to modify format for rapid product changeovers.

Cold shelf loading
The ALUS® cold shelf loading module from GEA offers an efficient way to load vials onto precooled freeze dryer shelves. Prepared vials are transported by the intermediate pusher to the final shelf position at a rate of up 400 vials/min. No additional change parts are required, there's no extra cost involved and no added buffer time for shelf changing. In addition, the number of moving package rows is freely selectable using the existing HMI software.

Single row unloading
Fully compatible with all types of containment (oRABS, cRABS, isolator), the ALUS® single row unloading module from GEA offers an efficient way of unloading single rows of vials at speeds of up to 400 vials/min. The patented design provides easy vial sample handling (track and trace) and optional vial traceability.

Offering Shorter Cycle Times, Improved Productivity and using State-of-the-Art Monitoring Systems, ALUS® Reduces Operational Costs.

TOTAL VIAL TRACEABILITY.

In collaboration with SCHOTT and HEUFT, GEA has developed a vial traceability solution that will help the pharmaceutical industry to implement the EU's drug anticounterfeiting directive, safeguard the rights of trademark and patent holders and, ultimately, protect patients.

The clock is ticking! The European Commission's Directorate General for Health and Food Safety will soon be implementing the Falsified Medicines Directive. Pharmaceutical manufacturers now have limited time to meet the requirements of the new legislation and ensure the end-to-end verification of drug authenticity.

Whether it's a fad or the future, 100% vial traceability is becoming an increasingly important consideration in the pharmaceutical freeze drying industry. The current situation is that traceability can only be done at batch level, which provides very little information about the time, position or condition (weight, for example) of a vial. Essentially, all vials are equal and anonymous. The ideal situation is that "every vial has a name" and can be individually tracked and traced.

Continuous Monitoring and Full Traceability: LYODATA®
A new type of system for the continuous traceability of primary packaging, including complete process and product data backup, could provide the ideal solution. LYODATA® provides unique marking, clear identification and the consistent traceability of pharmaceutical primary packaging, making drug counterfeiting practically impossible. The system also offers continuous quality inspection, 100% line clearance and precise sampling.

Ensuring distinctive and unmistakable marking and the 100% traceability of pharmaceutical products in vials or containers by laser coding and code verification, the system also includes process and product monitoring data from primary packaging production, grading and freeze drying, right up to the final finished product!

Unique Marking and Clear Detection
SCHOTT technology is used to laser mark a 2D barcode onto the glass vial or bottle during production. HEUFT's innovative all-round code verification system, which is fully compatible with GEA's Automatic Loading and Unloading System (ALUS®) and suitable for oRABS, cRABS and isolator use, then checks the (GS1) coding. Loading speeds of up to 500 vials per minute are achievable, with each vial being subjected to a full examination both before and after lyophilization.

With the ultimate aim of guaranteeing a unique identification code for each sample, tracking it during the freeze drying process, having real-time access to the data and vials in process and to be able to document that data for customer use, GEA has made a commitment to 100% vial traceability. This not only prevents drug counterfeiting and protects intellectual property, it also helps to uphold the health of the patient.

"The pharmaceutical and biotech industry has long been looking for a solution," says GEA's Johannes Selch, adding: "Manufacturers needed to progress from a batch-based system to achieve precise vial control and traceability during the entire sterile production process. Now, there's no more hide and seek, any vial can be located at any time or process step. It's a simple case of 10,000 vials in and 10,000 vials out."

Whether it's a fad or the future, 100% vial traceability is becoming an increasingly important consideration in the pharmaceutical freeze-drying industry.

Further information
GEA Pharma & Healthcare
pharma@gea.com
gea.com/contact

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GEA.com

GEA Lyophil GmbH
Kalscheurener Str. 92
50354 Hürth, Germany

Tel +49 (0) 2233 6999 0
pharma@gea.com
gea.com/contact