SMART LYO®

High quality, affordable freeze drying:
the smart choice.

GEA Engineering for a better world.

GEA.com

DELIVERING THE RIGHT SOLUTIONS.

As a long-term partner to the pharmaceutical and biotech industries, our equipment stands for high performance, quality and reliable, trouble-free operation.

GEA supplies a comprehensive variety of standard and custom-built freeze dryers for the commercial-scale production of high-quality pharmaceutical products.

Our range of supplies and services includes pilot-scale freeze dryers for R&D purposes and small production batches, industrial-scale freeze dryers and completely integrated systems, including Automatic Loading and Unloading Systems (ALUS®) and CIP skids. In addition, we service and retrofit existing freeze dryers.

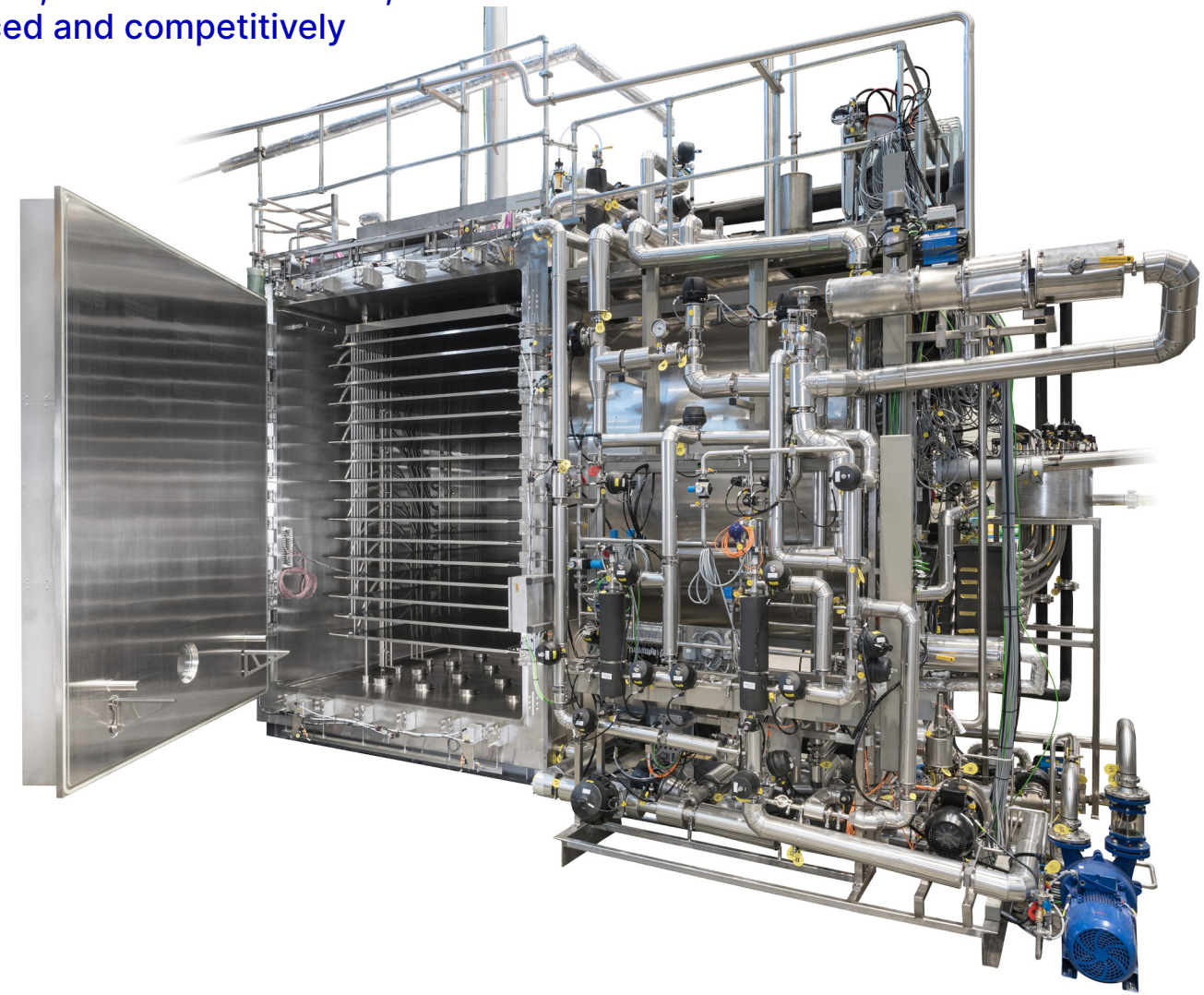
The design and manufacture of freeze dryers and freeze-drying systems is done to comply with all relevant guidelines, such as GMP, GAMP5 and 21 CFR Part 11, as well as other worldwide regulatory requirements, such as CE, UL, ASME and PED.

The company's expertise in pharmaceutical freeze drying and related processes — isolator technology, sterilization and clean-in-place (CIP) — covers all kinds of pharmaceuticals and biotechnology derived products, such as hormones, vaccines, antibiotics anti-infectives, bacteria, sera, enzymes, diagnostic agents, monoclonal antibodies (mAbs), antibody-drug conjugates (ADCs) and blood products.

And, with more than 280 validated ALUS™ installations, worldwide, we have an unparalleled history of innovation for various pharmaceutical applications that demonstrates our capability.

HIGH QUALITY, AFFORDABLE FREEZE DRYERS.

GEA, a trusted supplier of lyophilization solutions, offers SMART LYO®, a range of high-quality, technologically advanced and competitively priced pharmaceutical freeze dryers.



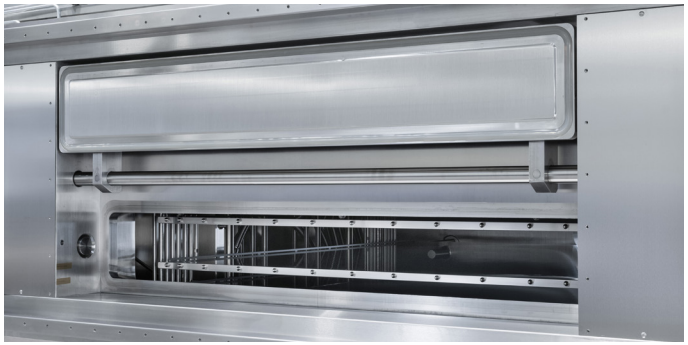
Standardized and Customized

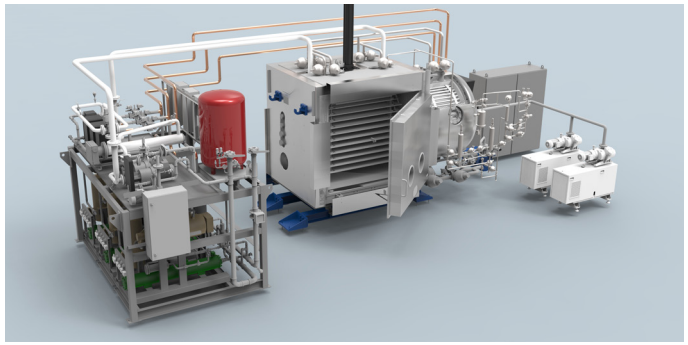
Based on proven, standardized modules, SMART LYO® pharmaceutical freeze dryers are designed and built to meet the specific size and technology requirements of each customer. As a result, SMART LYO® products are not only cost-effective, they also facilitate planning, validation and documentation, and significantly reduce delivery times. There's no need to compromise with SMART LYO®: every customer gets the plant they need, customized to suit their existing facility and production requirements, exactly when they need it.

Made in China, Designed in Germany

German engineering and project management, combined with GEA-controlled supply chains, make the SMART LYO® freeze dryer a top-quality product (the Quality Management System has been ISO 9001-certified since 1997). GEA's committed team of engineers and specialists all work to ensure that the freeze dryers are of a consistently high standard. It is this dedication and attention to detail that results in reliable, trouble-free pharmaceutical production and entire lifecycle economy.

SMART FEATURES.





Affordable
Standardized modules are more cost-efficient and reliable than bespoke systems, resulting in lower purchase and maintenance costs for the customer. Using prefabricated units also reduces delivery and validation times, providing a clear commercial advantage by significantly reducing time-to-market.

Reliable
Building on GEA's reputation as the reliable supplier of equipment designed to minimize product loss, SMART LYO® freeze dryers are no exception. Extensively tested and engineered with proven process technology and the expertise of the GEA team, each unit offers trouble-free operation, smooth production and minimum downtime. And, should a problem occur, the Global Service Network is ever ready to spring into action and dispatch spare parts or a service engineer to your door.

Technology
SMART LYO® freeze dryers can be supplied with filling systems, isolators and inspection services to provide a fully integrated production facility, sourced from a single supplier. Each component meets the highest possible technical requirements and the strict standards of the global licensing authorities, as well as complying with all current good manufacturing practices (cGMPs).

SMART LYO freeze dryers are available with shelf sizes of 0.57–40.00 m^2 with a condenser capacity of up to 800 kg. The shelves are manufactured at the GEA site in Germany, and the entire shelf stack is tested onsite before shipping it to our Suzhou facility for integration.

Features
- the entire plant is constructed on a single-floor frame for fast, simple commissioning; the system includes a compact chamber/condenser unit, all system modules (hydraulics, venting system, vacuum) and options such as clean-in-place/sterilize-in-place (CIP/SIP)
- the shelves are manufactured at GEA's facility in Germany; the entire shelf stack is then tested onsite before being shipped to our Suzhou site for integration
- the refrigeration unit can be installed remotely from the plant frame, on a different floor if necessary, enabling the installation to be adapted to fit the customer's infrastructure
- the electrical cabinet can be positioned in the freeze dryer plant or centrally in a control room
- frame mounting allows SMART LYO® freeze dryers to be installed in the existing building architecture (the machinery room and the sterile area); installation and assembly is, therefore, very simple, only requiring the plant to be connected to the unit frame and the switch cabinet
- the GEA Global Service Network provides rapid worldwide access to original spare parts and a comprehensive repair service that minimizes downtime and keeps costs under control.

Also available are
- Comprehensive documentation that is compliant with pharmaceutical regulations.
- LYOSPARK® for controlled nucleation during the freeze phase.
- LYOPLUS® to meet the new Annex I requirements and increase and ensure the safety of the final product.

In addition, a temperature-controlled "pizza door" can be used to speed up the post-SIP cooling phase. This also enables the isolator to run a decontamination cycle significantly earlier than usual.

TALK TO US. WE'RE HERE TO ANSWER YOUR QUESTIONS.

From its earliest applications in the stabilization of blood plasma in the 1940s, freeze drying has become a standard practice 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 several 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 a wealth of experience in the engineering and manufacturing of freeze dryers, GEA 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's thorough understanding of the freeze-drying process enables them to supply a comprehensive range of products and services, comprising laboratory equipment, 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 customized options, GEA's modular equipment extends from R&D to standalone production plants and high-capacity systems for bulk product applications.

Plant configuration capacities extend from specialized solutions for highly potent products to two-story units and fully integrated systems with multiple freeze dryers and loading systems (with or without the integration of your chosen filling system supplier). The design and manufacture of each module and system component is done to comply with all cGMP, CE, GAMP and 21 CFR Part 11 guidelines, meeting the strictest requirements and regulatory standards around the world.

Products include

- LYOSPARK®Production: SMART LYO® SL 100–SL 800 systems are constructed for fast, simple commissioning and include the compact chamber/condenser unit, all system modules (hydraulics, venting system, vacuum) and available options such as CIP, SIP and ALUS®.

Technical Data – Model SL 100 - SL 800.

Types and Sizes

Models	Units	SL 100	**SL 200**	**SL 300**	**SL 400**	**SL 600**	**SL 800**
Shelves							
Shelf area	m²	6.7	10.0	14.9	20.4	30.2	41.2
Number of vials (Ø 16mm)	Quantity	29496	44244	65690	90530	133913	182865
Number of vials (Ø 22mm)	Quantity	15498	23247	34340	47360	70356	96585
Number of vials (Ø 30mm)	Quantity	8142	12213	18400	25520	37700	51750
Number of shelves	Quantity	6 + 1	9 + 1	10 + 1	11 + 1	13 + 1	15 + 1
Shelf size	mm	914 × 1219	914 × 1219	1219 × 1219	1219 × 1524	1524 × 1524	1524 × 1803
Clearance	mm	125	125	125	125	125	125
Shelf temperature	°C	-55 ... +70	-55 ... +70	-55 ... +70	-55 ... +70	-55 ... +70	-55 ... +70
Condenser							
Condenser capacity	kg/24h	100	200	300	400	600	800
Condenser temperature	°C	-75	-75	-75	-75	-75	-75

Technical Information

Models	**Units**	**SL 100**	**SL 200**	**SL 300**	**SL 400**	**SL 600**	**SL 800**
Utilities							
Pure steam	barg	1.5	1.5	1.5	1.5	1.5	1.5
	°C	126	126	126	126	126	126
CIP water	barg	3-4	3-4	3-4	3-4	3-4	3-4
	°C	80	80	80	80	80	80
	m³	4	4.5	5.5	6	6.5	7
Cooling water	°C	< 25	< 25	< 25	< 25	< 25	< 25
	m³/h (peak)	10.6	16	20	30	40	40
Electrical power supply	kW	80	120	140	200	250	280

Technical Data – Model SL 100 - SL 800 – Features.

Models	SL 100-D - SL 800-D
Chamber	
Rectangular chamber	•
Material 316 L	•
Ports 3d	•
Door	
Full size service door	•
Automatic locking	•
Slot door (constant loading level)	•
Condenser	
Side	•
CIP	
CIP chamber + condenser	•
Recirculation	∘
Second cleaning media	•
SIP	
PED	•
ASME	∘
GB-150	∘
Chamber recooling after SIP	•
Hydraulic	
Lift / lower shelves + stoppering	•
Shelf package	
Rails and fully collapsible	•
Bellow	•
Second temperature sensor (redundant) at the silicone oil inlet	•
Interface for ALUS®	•
Refrigeration	
Piston compressors	•
Screw compressors / LN_2 / LYOAIR®	∘
Second silicone oil pump (redundant)	•

Models	SL 100-D - SL 800-D
Vacuum	
Dry pumps + roots pump	•
Second pump set (100% redundancy)	∘
Pressure regulation	
On/off	•
Flow controller	•
Process sensors	
Chamber: 2x MKS (redundant) and 1x Pirani	•
Condenser 1x MKS	•
Venting system incl. filter	
Sterilizable	•
Second venting media	•
Second venting filter	•
Automatic WIT test	•
Control system and documentation	
Siemens	•
SCADA - WIN CC	•
GAMP5	•
Audit trail	•
21 CFR Part 11	•
FAT / SAT	•
IQ/OQ documents and tests	•
Material certificates	•
Welding documentation	•
Technology	
ALUS®	•
LYOPLUS®	∘
LYOSPARK®	∘
Fluid condenser	•
Preparation for wireless product temperature measurement	∘
Temperature controlled slot door	•

• Included ∘ Option ≠ Not available

General Technical Data for all Models.

System requirement	Data
Chamber	
Surface finish	Ra ≤ 0.8 µm, satin polished
System leak rate (applicable to the total freeze dryer with chamber, condenser, piping etc.)	≤ 0.01 mbar*l*s-1
Shelves	
Flatness in the usable area	≤ 1 mm/m
Surface finish on top side	Ra ≤ 0.8 µm
Surface finish on bottom side	Ra = 1.6 to 2.2 µm
Shelf cooling rate from +20 to -40°C	45 minutes (no load)
Shelf heating rate	> 1.5 K per minute (no load)
Regulating temperature range during drying	- 50°C to +60°C
Temperature distribution on one shelf	± 1 K from mean (-40 to +40 °C)
Temperature distribution on the shelf stack	± 1.5 K from mean (-40 to +40 °C)
Condenser	
Inner surface finish of the condenser	Ra ≤ 0.8 µm
Surface finish of the condenser coils	Ra ≤ 0.8 µm mirror polished
Final temperature (measured at the pipe surface)	≤ -75°C
Defrosting of ice	40-60 minutes at maximum ice capacity
Vacuum	
Final vacuum of the vacuum pump set	< 0.005 mbar
Final vacuum of the freeze dryer	< 0.01 mbar (cold condenser)
Pump time from 1000 to 0.1 mbar	≤ 30 minutes (cold condenser)
Sterile piping and valves	
Surface finish	Ra ≤ 0.6 µm

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