СИСТЕМЫ ДИСТИЛЛЯЦИИ И ФЕРМЕНТАЦИИ RAY

Технические характеристики

GEA technologies for end-to-end processing

Probiotics, nutraceuticals/functional foods, and other dietary supplements are substances that may improve basic nutrition, and/or have some benefits to health and help to treat or prevent chronic diseases. Positioned between pharmaceuticals and foods, this rapidly growing sector of R&D and manufacturing is being driven by a global consumer base that sees an important role for diet and lifestyle in maintaining and perhaps improving health and wellbeing.

Here at GEA we are harnessing decades of industry, technology and engineering knowhow to develop and offer advanced technologies, plants and components for processing highly regulated products, from bacterial starter cultures, to probiotics, bioactive proteins and enzymes, or yeast and other fungi. So, whatever your stage of R&D, scale up or commercial manufacture, our experts can work with you to configure and optimize individual technologies and plants, and end-to-end, turnkey process lines.

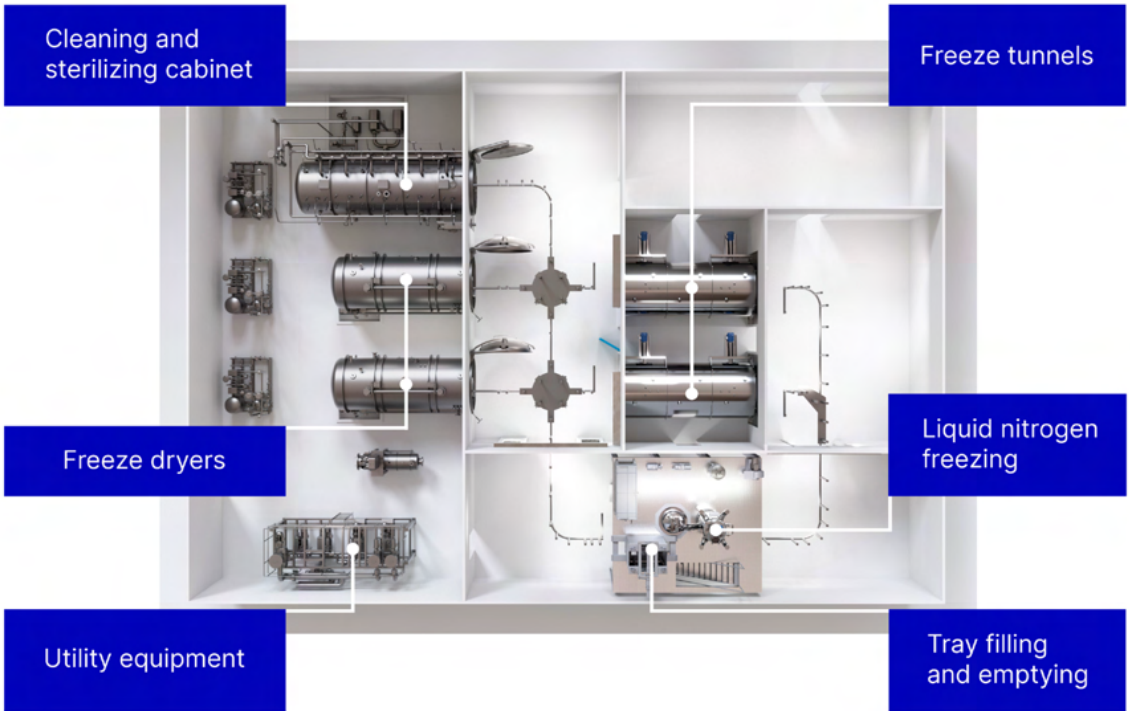
This photo shows frozen lactic bacteria pellets (left) and two strains of freeze-dried lactic acid bacteria, one with lower sugar content (middle) and one with higher sugar content (right).

GEA RAY® Concept freeze drying technology

The ability to reproducibly manufacture stable formulations of high value, but often heat sensitive and easily degraded microorganisms and biomolecules is critical to final product quality and activity, shelf life, and safety. As a manufacturer you are challenged with securing high cell viability, and product bioactivity. Of course, it's critical to minimize the risk of contamination and to meet regulatory requirements for safety and hygiene. And ultimately you want to maximize yield and quality and achieve high process reproducibility, efficiency and sustainability.

The patented GEA RAY® Concept freeze drying process represents what we believe is an ideal solution for the industrial-scale manufacture of high-value, sensitive probiotics, starter cultures, yeast and fungi, along with proteins and other bioactive products. The unique design of our solution integrates all of the process steps in a single, closed loop plant for industrial-scale production. The system enables fast semi-automatic and semi-continuous (continuous operation of product in batches) transportation of product in the freeze drying line, under hygienic conditions. We've demonstrated that using this system the drying time can typically be reduced by a factor of two, when compared with a typical pharmaceutical freeze drying process.

And as far as we are aware, GEA is unique in offering a commercial solution that combines in a single line all the steps for large-scale freeze drying of microorganisms. The entire RAY® Concept production line may also operate in a clean room environment.



GEA RAY® Concept process overview

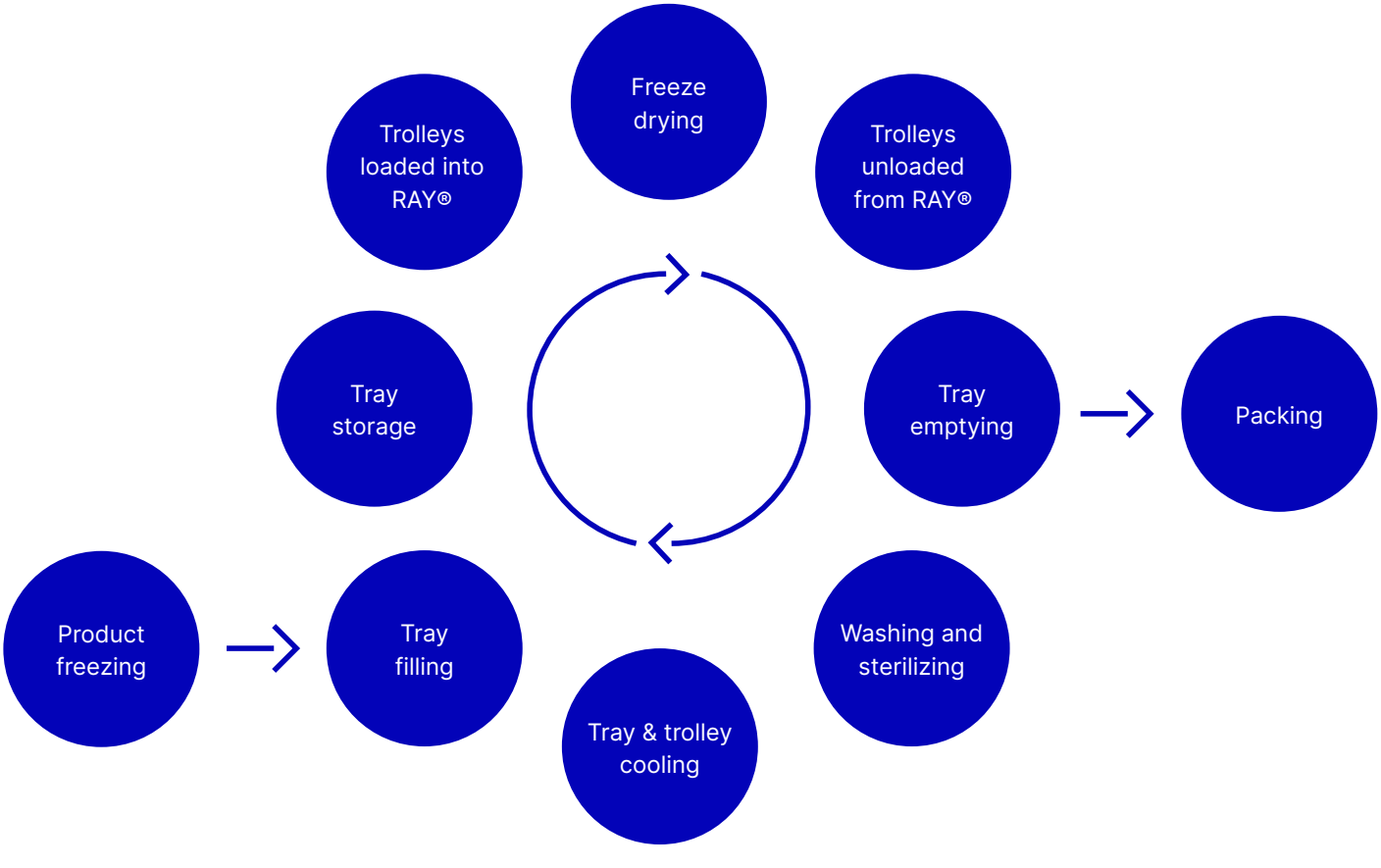
The RAY® Concept combines freeze drying in a RAY® batch freeze dryer with upstream and downstream steps, including liquid nitrogen freezing (LNF) of the product prior to freeze drying, storage of product in a freezing tunnel, and thorough, automated CIP/SIP in a cleaning and sterilizing cabinet (CSC). The whole system has been designed with an overhead rail system that conveys the trays, loaded into trolleys, between each stage quickly and with minimal manual intervention, to reduce the risk of product defrosting between stages.

Loading the trays with frozen product can be completed in under 15 minutes for each trolley, which is an advantage for an environment above freezing point. Loading the entire batch of product into the freezer takes less than 5 minutes. Rapid tray filling and trolley loading into the freeze dryer leaves time for the room to be cleaned between batches.

Importantly, trolleys can be manually conveyed along the rail system between stations with minimal effort, and there is no manual lifting of trays. This semi-automated handling complies with international standards for and

recommendations on manual worker safety.

Trolleys carrying the trays are progressed through each station, in sequence. There is full traceability at each stage of the cycle, and also after each batch. Automated equipment cleaning, washing and (if required) sterilization is designed to help ensure that there is no cross contamination between batches or after product changeover. As well as reducing the need for manual intervention, and so operator time, automated CIP can reduce system down time, and may also save on chemicals, energy and water usage.



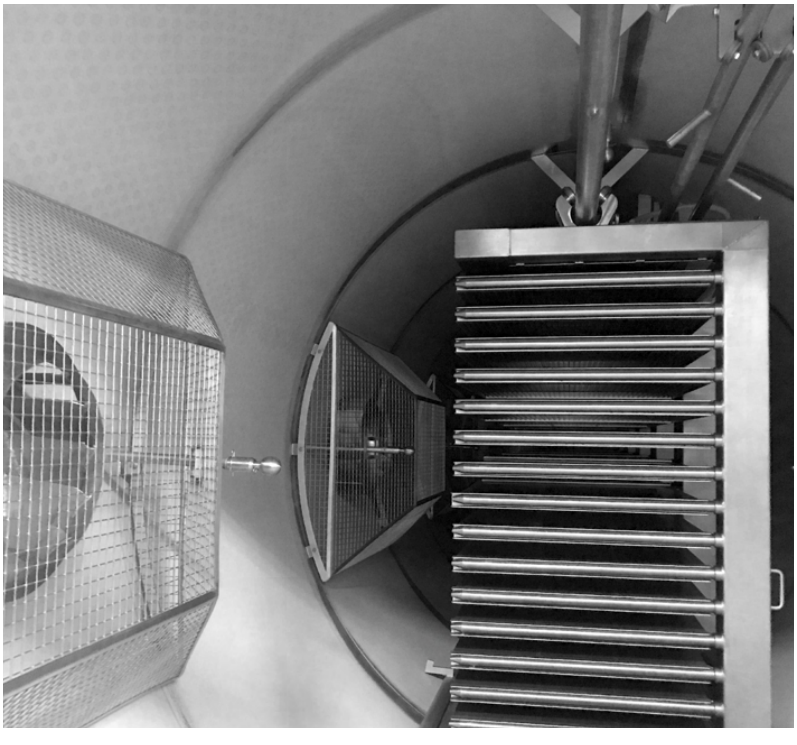
GEA RAY® Concept process step by step

The stages in the RAY® Concept process:

- Product freezing (liquid nitrogen freezing; LNF)
- Tray filling (filling station)
- Product storage (freezer tunnel)
- Freeze drying (RAY® freeze dryer)
- Freeze dryer cleaning (CIP/SIP)
- Tray emptying (emptying station)
- Tray and trolley cleaning (cleaning and sterilizing cabinet; CSC)
- Tray cooling and storage (freezer tunnel)

Importantly, the key process stages of product prefreezing using liquid nitrogen, tray cooling and storage in the freezer tunnel, and the freeze drying itself, are separately controlled, and can be started and stopped at any time, independently.

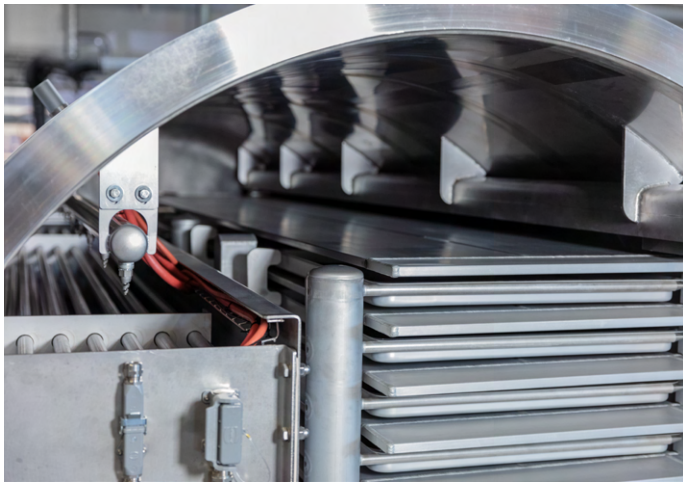
Multiple batches coming out of the bioreactor/fermenter upstream can be stored in the freezer tunnel until the freeze dryer is available, giving you even greater possibilities for process flexibility, helping to maximize use of your key equipment, and potentially speeding return on your technology investment.



Washable freeze tunnel for pre-cooling trays and for storing trays containing frozen pellets.

Freeze drying process parameters are set in recipes stored in and selected from the unit's control system. All data for temperatures and pressures are logged at each cycle, so there is full traceability. The system's HMI is user friendly, and keeps all key process data available.

The GEA RAY® Concept process in more detail



Washable freeze tunnel for pre-cooling trays and for storing trays containing frozen pellets.

RAY® freeze dryer

The RAY® freeze dryer represents what we think is the go-to system for freeze drying high value, sensitive cells and biomolecules. The technology has been developed to support the viability of microbial cells, and whereas other technologies may result in 40-60% cell survival, freeze drying using the RAY® Concept system can support cell survival of 80-90%.

With a high sublimation rate during freeze drying, RAY® freeze dryer technology exhibits a high sublimation capacity – up to 2.5 times that of other freeze drying processes, our studies have shown. Sublimation is driven by radiation-based heat transfer, which results in a more even and uniform heat transfer to the products and trays, when compared with direct, conductive transfer. This uniformity of radiated heat transfer and distribution ensures that a higher energy flux can be maintained for a longer period of time, resulting in faster drying.

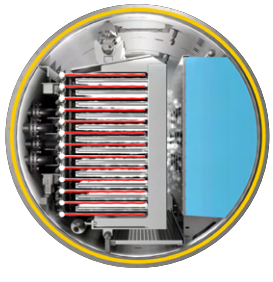
The finned tray design further aids in the uniform distribution of heat/energy within the product layer, which positively impacts on drying speed. The freeze drying trays are the only parts in the freezer and freeze dryer that come into contact with the product.

Compared with traditional freeze drying technologies, GEA freeze dryers used in the RAY® Concept process could allow you to reduce the drying cycle time for, probiotic bacteria from 72 hours to 48 hours, and in some instances to just 14 hours. Similarly, the drying cycle for bacterial cultures for silage can be reduced from 75 hours to 24 hours.

Vapors from freeze drying are collected on vapor traps inside the chamber, and these are automatically de-iced during freeze drying to help maintain low vacuum and reduce energy consumption.

RAY® freeze dryers feature internal vapor condensers, and the larger RAY® freeze dryer units include a built-in continuous de-icing (CDI) system, which is unique to GEA. This CDI capability means that one condenser can be defrosted without having to stop freeze drying. One section is sealed off and the other takes over the condensation function. Direct switchover when the next de-icing cycle is needed can be carried out without loss of operating vacuum.

Illustration of freeze drying process:



Subliminated vapors travel from product to vapor trap

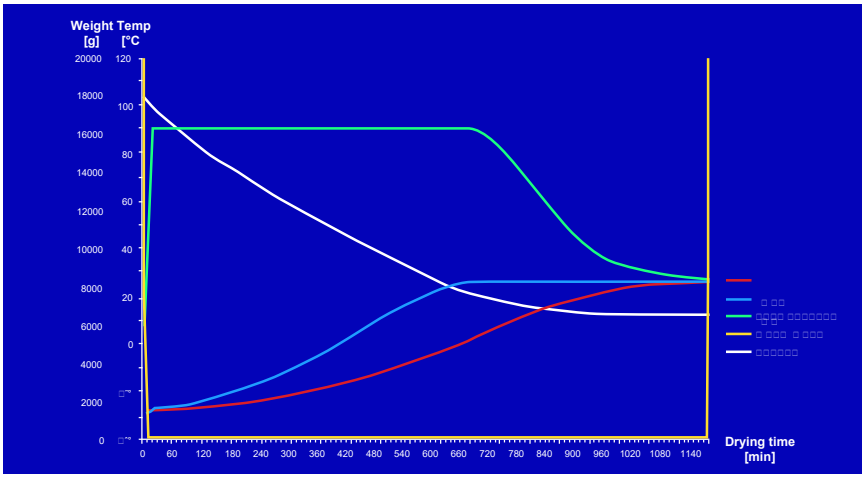
Hover over the diagram to view the sublimation process

GEA RAY® freeze drying, at a glance

Benefits of RAY® freeze drying for microbial cultures and bioactive products:

- Uniform, fast freeze drying
- Minimal product loss
- Simple, reliable operation
- Comparatively low energy consumption
- High sublimation capacity

Freeze drying profile - bacteria



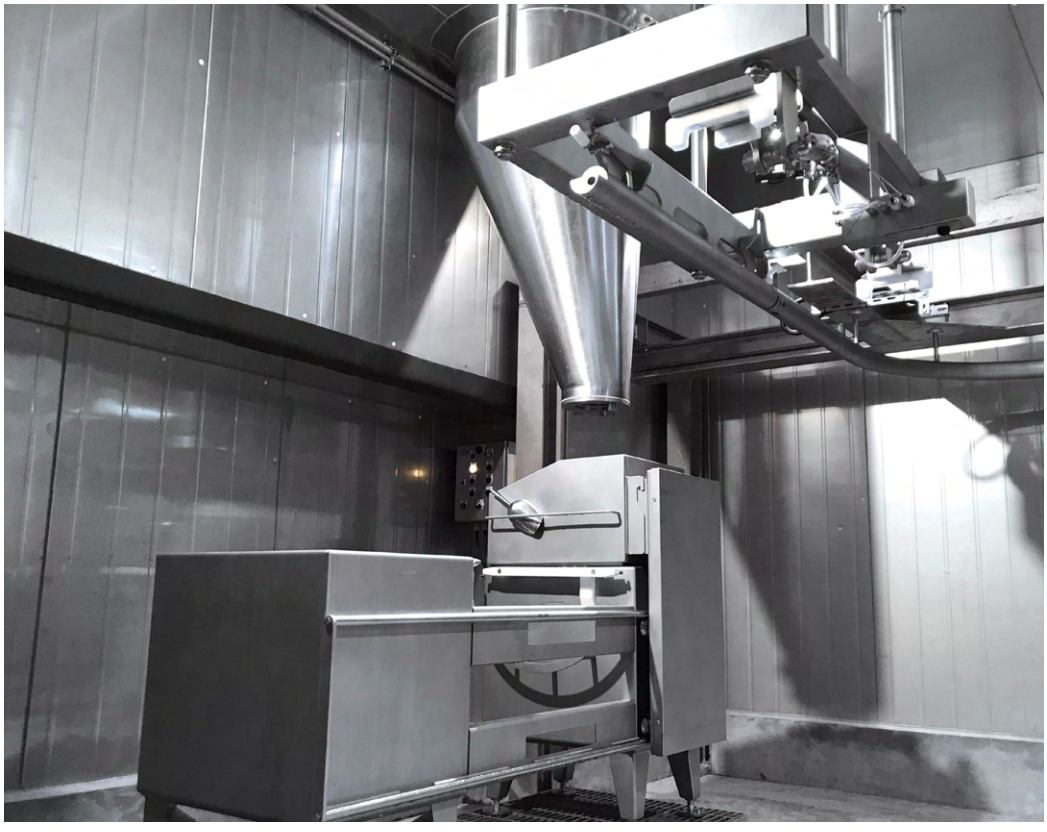
Drying times for pelletized probiotic products will typically range from 16 hours to 24 hours, but will depend on parameters specific to the product, for example, the type of bacteria. The temperature is constantly monitored and regulated according to the set recipe, to ensure the product won't reach temperatures that would impact on cell viability.

Pellets in finned trays

Plant Type	Drying Surface	Batch Size	Drying Time	Output (1% RM)*
1xRAY®30	27,4m²	470 kg/batch	18-20h	109 kg/day
1xRAY®40	36,5m²	560 kg/batch	18-20h	129 kg/day
2xRAY®30	54,8m²	940 kg/batch	18-20h	217 kg/day
1xRAY®60	56,3m²	1.016 kg/batch	18-20h	246 kg/day
1xRAY®90	79,2m²	1.429 kg/batch	18-20h	346 kg/day
1xRAY®120	112,6m²	2.030 kg/batch	18-20h	490 kg/day

*Output <3% RM (residual moisture) with 23.5% DM (dry matter), output is based on 1 batch per 24 hours

Preparation is key...



Tray filling station with buffer vessel and trolley elevator installed in a +5°C room.

Equipment preparation

The RAY® Concept process starts with great preparation ahead of freeze drying. Empty product trays are stacked upside down in trolleys running on the overhead rail system. The trolleys and empty trays emerging from the CSC unit are transferred into the freezing tunnel, where they are cooled to at least -40°C. This reduces the risk of prefrozen product melting while it is loaded into the trays.

The freezing tunnel is kept cold by circulating refrigerant in the tubular shell. The fully welded design makes it possible to clean the tunnel between batches without degrading the insulation. And if you need really quick cooling times we can equip the freezing tunnel with fans to circulate the air.

Precooled trolleys and empty trays are transferred from the freezing tunnel, one trolley at a time, along the rail system to the filling station. The first tray is pulled out of the transport trolley, rotated so that it is open side up, and filled by volume with product, which has also been prefrozen using our liquid nitrogen freezing (LNF) system.

When the tray is full it is then pushed back into the trolley, and the entire trolley is lifted up a level so that the next tray can take its place for filling. When all the trays are filled and reloaded the trolley is pushed back into the freezing tunnel and stored at -45°C.

When the freeze dryer is ready to process the next batch, the trolleys with product-laden trays are quickly moved from freezer tunnel storage into the freeze dryer, the product temperature probes are connected and the chamber air is evacuated to the freeze drying pressure, which is typically around 0.3 mbar.

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