

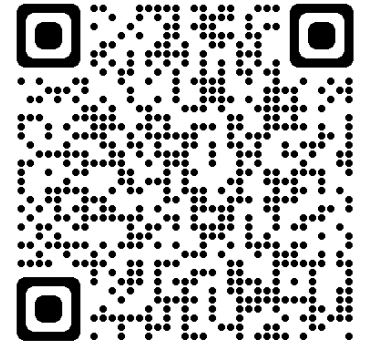
# Presenters



**Dr. Markus Kuehberger**

Senior Director Business Line Chemical & Pharma Separation

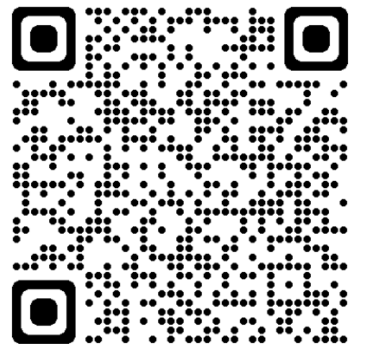
Mail: [markus.kuehberger@gea.com](mailto:markus.kuehberger@gea.com)



**Joerg Kuepper**

Sales Manager  
Lyophilization

Mail: [joerg.kuepper@gea.com](mailto:joerg.kuepper@gea.com)



# GEA IN VACCINE PROCESSING.

Dr. Markus Kühberger

Jörg Küpper



**ENERGIZING PHARMA.  
ENERGIZING YOU.**

# GEA in the pharma industry

## Core technologies

- Drying & particle processing
- Granulation
- Homogenization
- Liquid processing
- Membrane filtration
- Product handling
- Separation
- Lyophilization
- Tablet compression

## Integration expertise

- Automation
- Utilities
- Service



# GEA Separation in pharma productions



Top-efficient, GMP-compliant pharma centrifuges to meet process sterility requirements of any level – with utmost flexibility.

**Secure. Safe. Efficient.**



Global  
competence



Blood Plasma  
Separators



Biopharma  
Separators

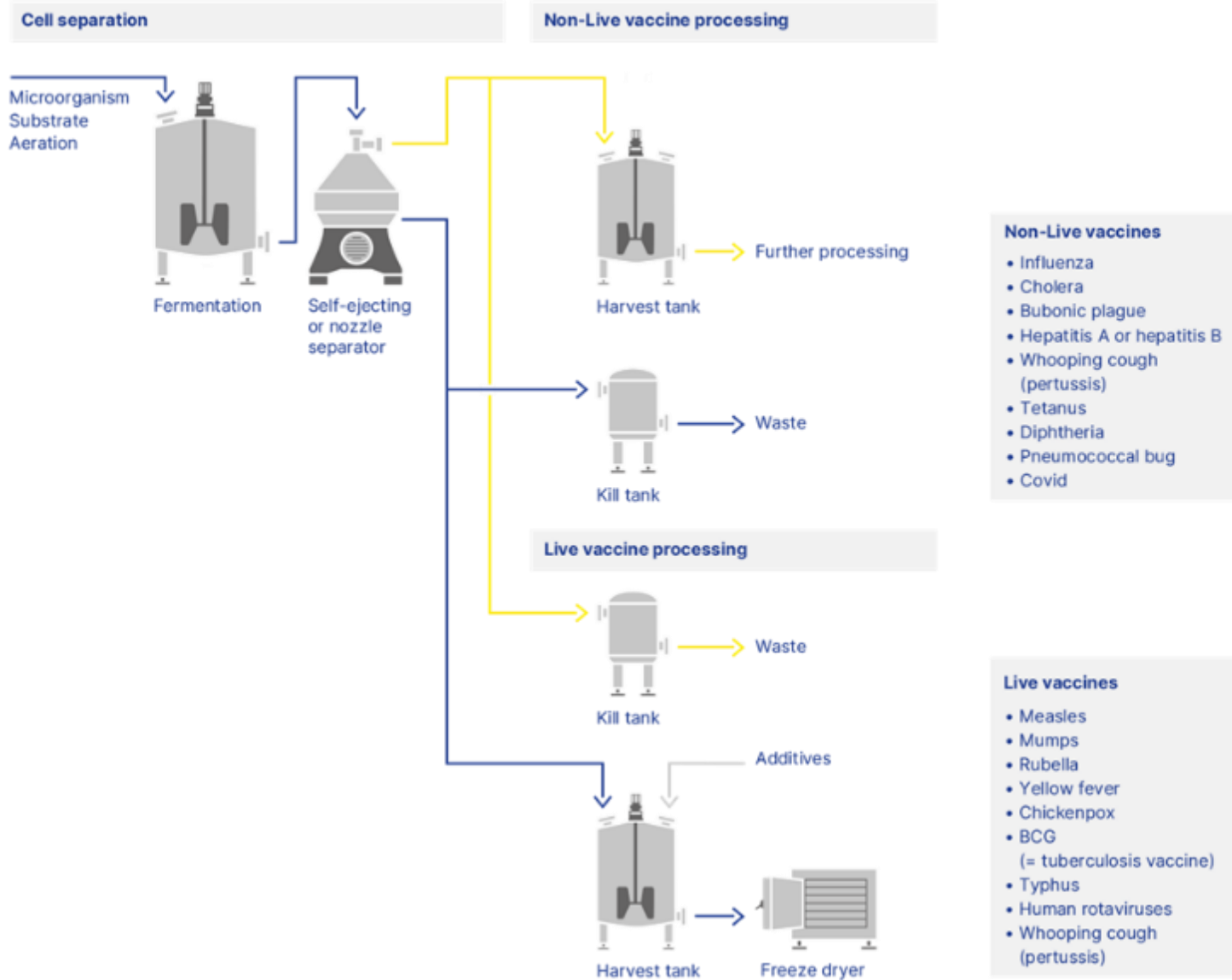


Single Use  
Separators

## Applications

Vaccines | Cell harvesting | mAbs | Human blood plasma fractionation | Hormones |  
Insulin | Microbial food cultures | Enzymes | Pharma extraction | and many more

# Centrifuges in human vaccine processes



GEA pharma Separator line aseptic  
GEA pharma Separator line pure

GEA kytero® single-use pharma Separator

# ASEPTIC & PURE

The perfect fit to your vaccine process





# GEA aseptic & pure: Two lines of individual GEA pharma process skids

GEA Pharma Separator **aseptic**



aseptic 30

aseptic 170

aseptic 100

aseptic 300

GEA Pharma Separator **pure**



pure 30

pure 170

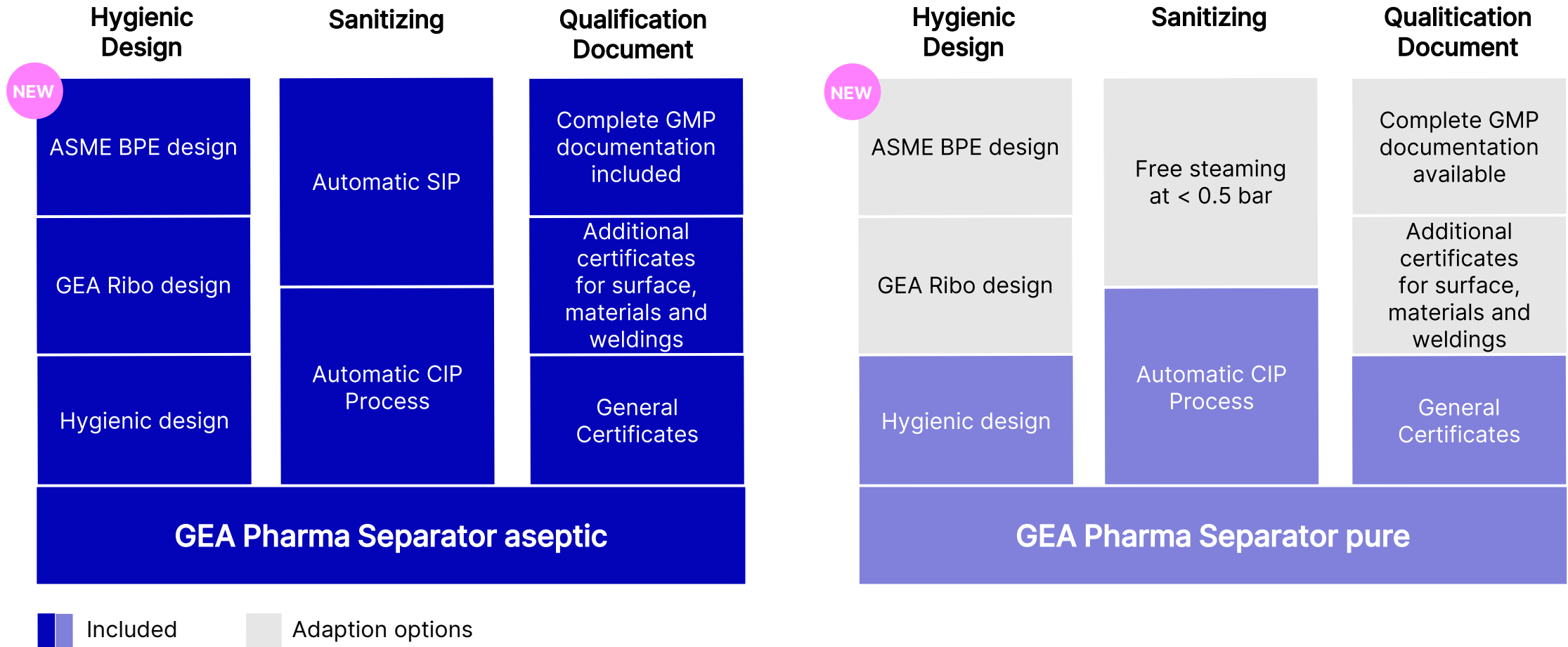
pure 100

pure 300



# Perfectly adaptable to your needs

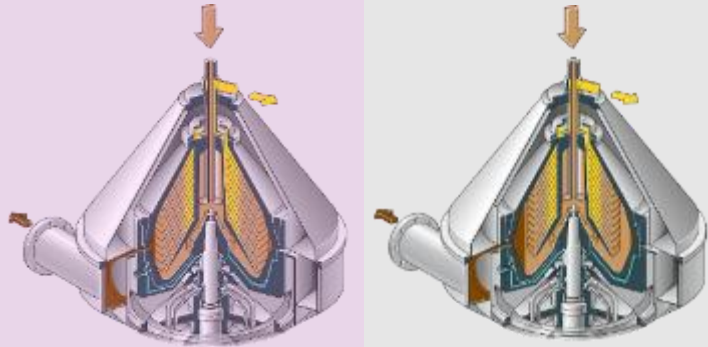
Cleanability, surface texture and documentation



# Multiple bowl variants to maximize yield

Optimum yield at solid contents of up to 30 vol%

Clarifier model  
(aseptic C | pure C)



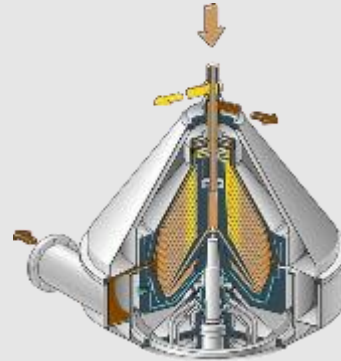
## HighSigma clarifier bowl

- Self-cleaning
- For solids up to **5 vol%**

## HighVol clarifier bowl

- Self-cleaning
- For solids up to **10 vol%**

Nozzle separator model  
(aseptic N | pure N)



## flexiCon nozzle bowl

- Continuous discharge and self-desludging
- For solids up to **30 vol%**

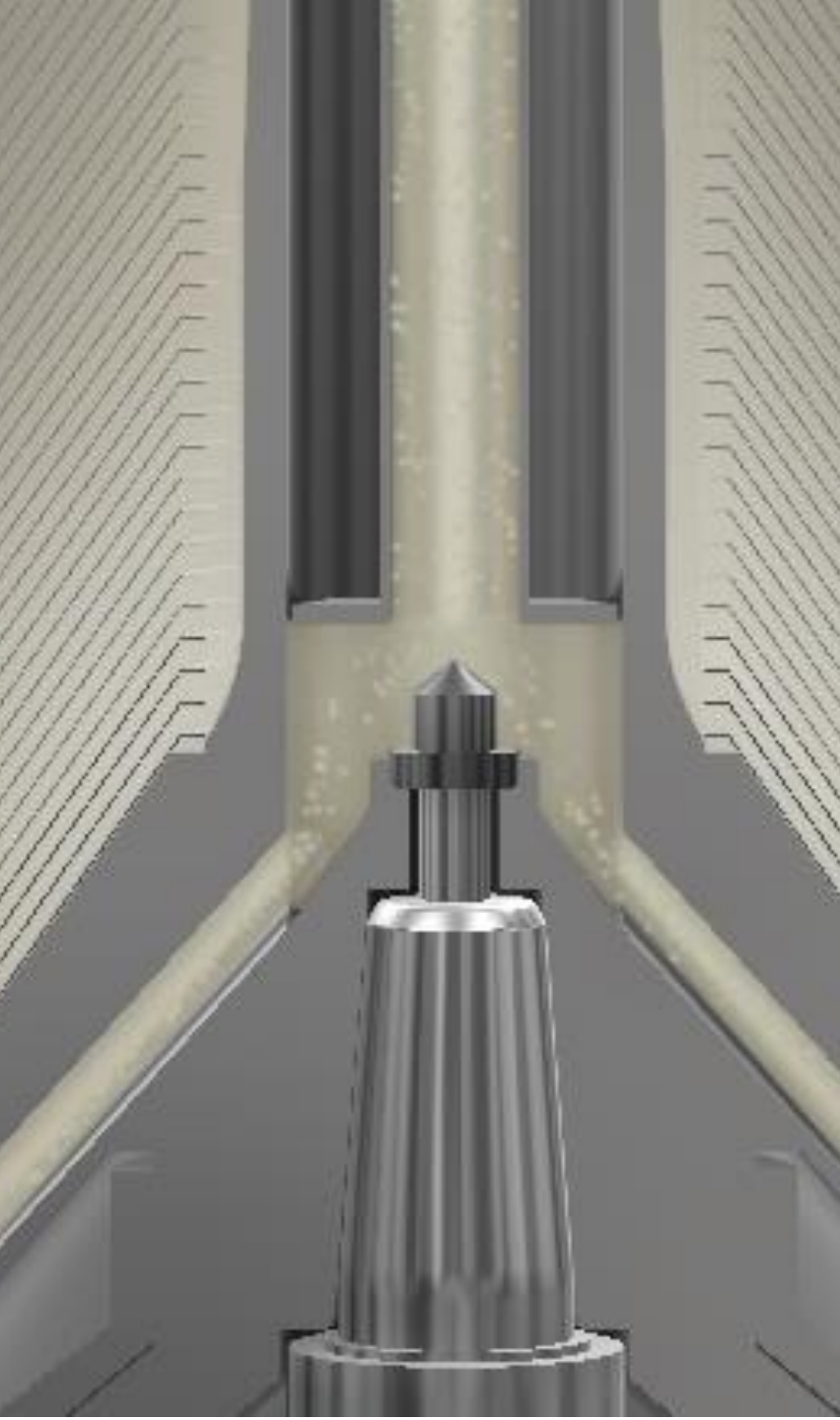
flexChange model  
(aseptic X | pure X)



## 3-in-1 solution

- Highest flexibility and yield for variable solid content / products
- HighSigma clarifier bowl
- HighVol clarifier bowl
- flexiCon nozzle bowl





# Gentle product handling

All GEA Pharma Separators aseptic and pure

- **Patented hydro-hermetic product feed inlet**

Shear sensitive products, i.e. cells, are fed gently into the filled bowl and smoothly accelerated at the axis of rotation.

- **The GEA solution**

The patented hydro-hermetic inlet feeds the sensitive product under the liquid level in the pre-filled bowl, omitting turbulences in the product.

- **No turbulences, no splashes, no shear forces**

# Benefits for your process



## Perfectly clean

Patented laser-welded disk spacers

- No dead spaces in the disk stack
- Providing the basis for a highly effective CIP and SIP cleaning
- Optionally available in pure



## Easy integration into your production line

ASME BPE Design

- ASME BPE conformance certificate
- Full GMP documentation available depending on your requirements
- Optionally available in pure



## No emission into cleanroom

Integrated directDrive

- Suitable for high clean room class level
- Less wear parts, easy service
- Space saving
- Reducing expensive cleanroom cost



# Optimized skid design

All GEA Pharma Separators aseptic and pure

- Plug & play functionality
- Easy integration into your process line.
- Checked, tested and internally wired at our factory site in Germany.
- All tests carried out on the test bay are documented.



# EFFICIENT CELL SEPARATION IN A SNAP.

GEA kytero® single-use pharma separator line  
for development and production







GEA kytero® 500

## GEA kytero® pharma Separator

All our competence  
in an easy-to-operate  
**single-use system.**



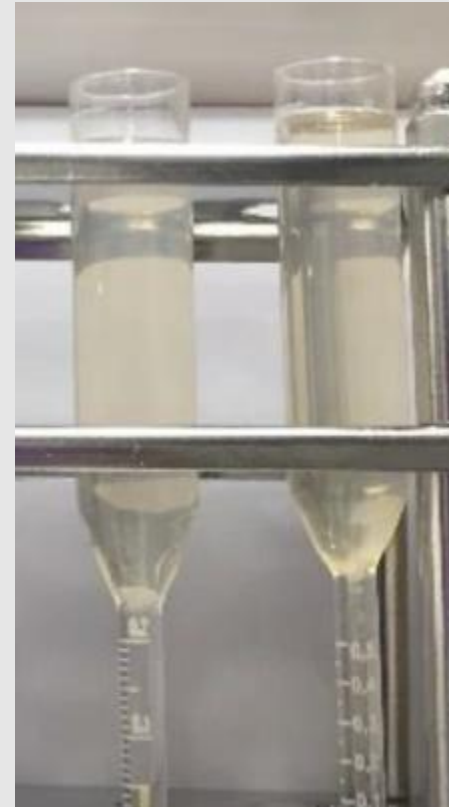
GEA kytero® 2000

# Proven high-yield disk stack technology

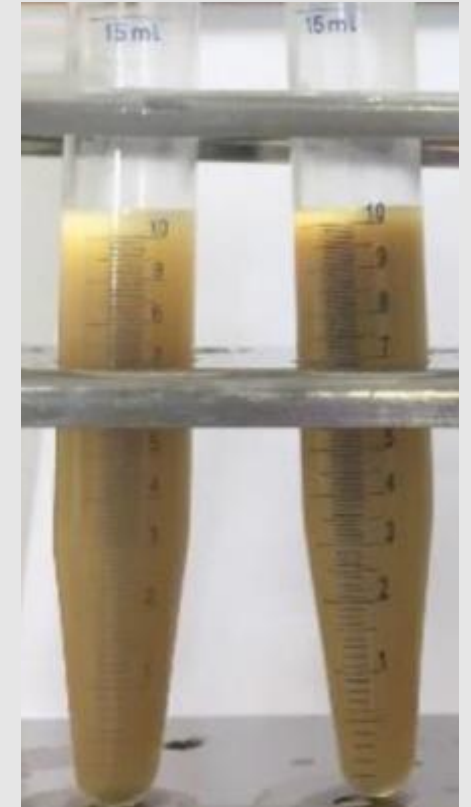
Gentle continuous processing

## Excellent clarification - solids removal > 99%

- Excellent clarification with more than 99 % solids removal rate
- High flow rates
- Gentle continuous processing



centrate (product)



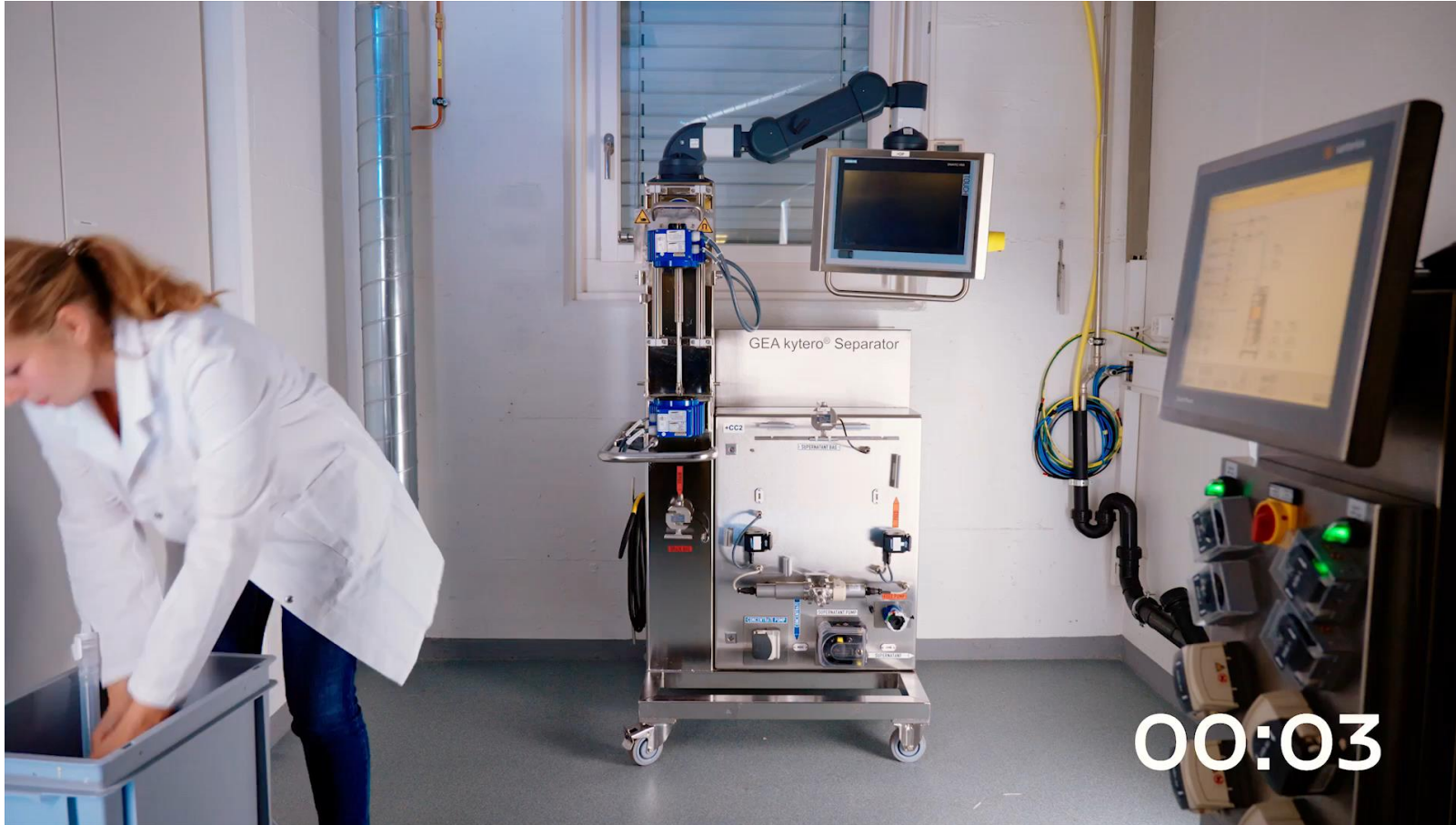
concentrate

A photograph of a GEA kytero Separator machine. The machine is primarily white with a central purple cylindrical component. It features blue motor housings at the top and bottom. A stainless steel handle is visible at the bottom left. A control panel with a screen is mounted on the right side. The text "GEA kytero® Separator" is printed on the white panel.

GEA kytero® Separator

## breezeDrive® revolution

- Zero risk of contamination
- 100% biocontainment-proof
- Minimum temperature increase
- Very low noise level
- No mechanical seals



## Easy and time-saving operation

Mobile plug & produce unit with smallest footprint

Minimum set-up and changeover time

No utilities required





# TEST IT NOW!

[gea.com/kytero](http://gea.com/kytero)

(Please use the contact form)



Exclusive  
**Test offer**  
for DCVMN  
members

# Further state-of-the-art components for liquid pharma processing

GEA Hilge Sterile Pumps



GEA pharma Valves



GEA pharma Homogenizers



Complete portfolio Separation, Valves, Pumps, Homogenizers:  
[gea.com/energizing-pharma](https://www.gea.com/energizing-pharma)



# LYOPHILIZATION



# Lyophilization / Freeze Drying - Site Brief

## GEA Lyophil GmbH, center of excellence, Hürth, Germany



GEA Lyophil GmbH is a center of excellence based in Hürth, Germany

Full turnkey project company specialized in GMP Freeze Drying applications

More than 1,000 units installed worldwide

Roughly 250 staff and > 10,000m<sup>2</sup> site

## GEA Process & Equipment Technologies (Suzhou) Co., Ltd., China



Multi-purpose site (MPS) serving various global customer industries

Through its strong localization and value-added depth, on-time, in-quality and cost-efficient state-of-the-art manufacturing.

Roughly 400 staff and > 25,000m<sup>2</sup> site

# Lyophilization (freeze drying)

## Vial manufacturing



 GEA core technology    Strategic partnership    Sourced technology



# Freeze Drying

## Why is freeze drying done?

The main reasons are:

- Good conservation
- Good solubility/reconstitution
- Good opportunity if drug is sensitive to heat

## How is freeze drying done?

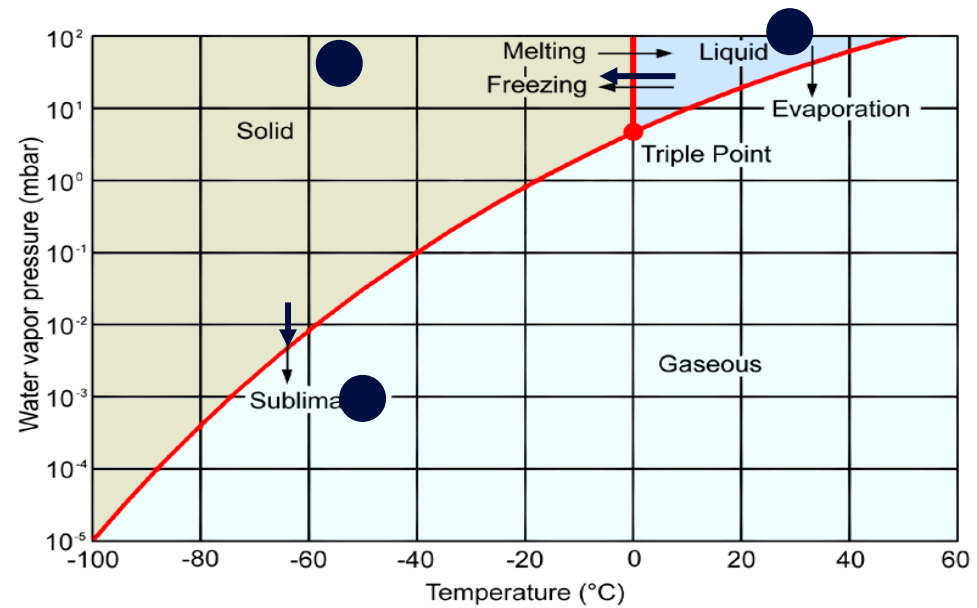
Freeze drying is removal of water from a product by freezing and a combination of sublimation and desorption.



# Freezing and melting points

**Freezing point** and melting point of the solution are the substantial parameters for process development and improvement.

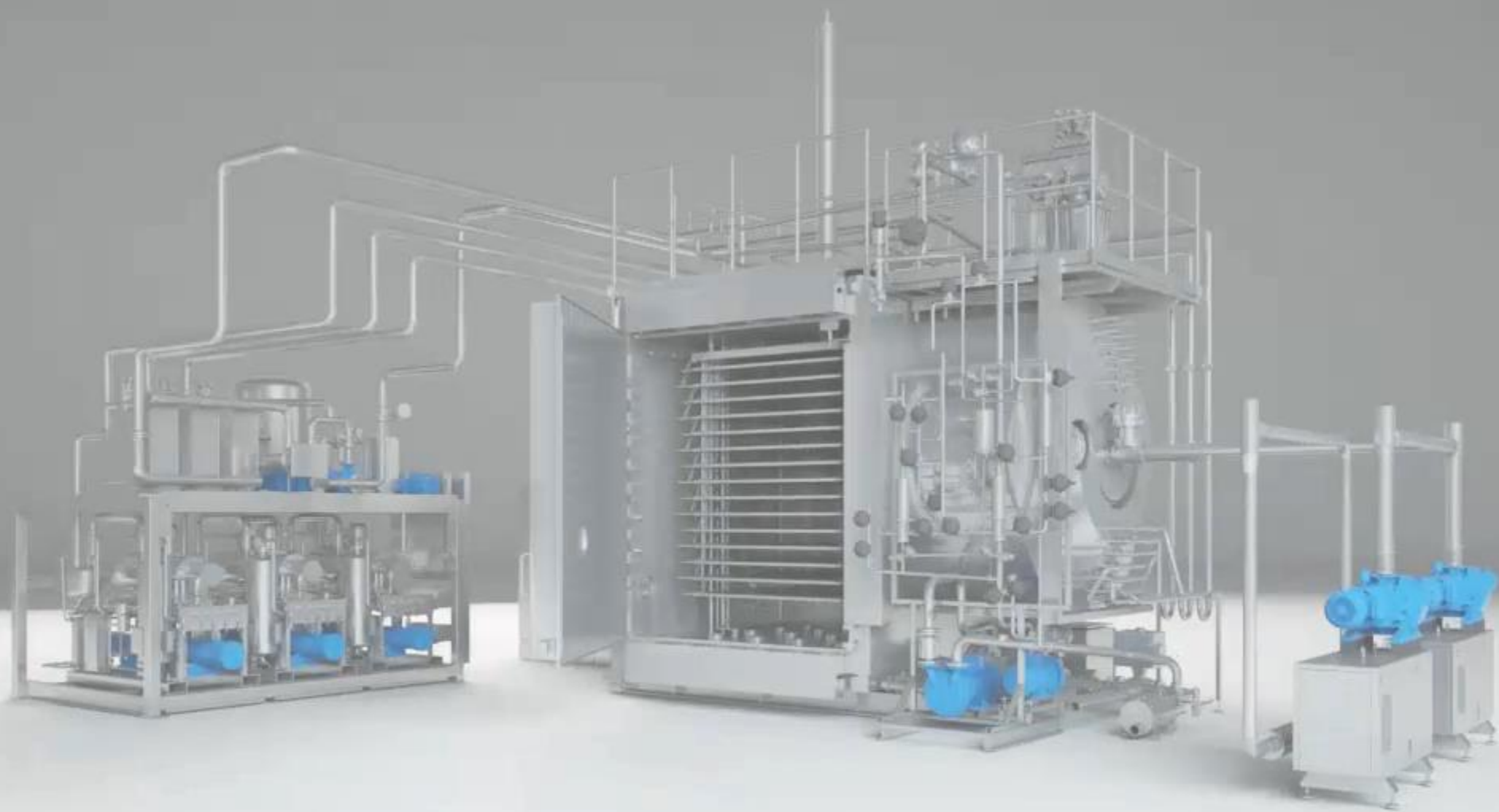
Triple point for pure water is at 6.13 mbar (273.16 k)



# Freeze Drying Process

**LYOPHILIZATION**





GEA



# LYOVAC® Freeze Dryer

## Layout GT and FCM





# ALUS® Portfolio

## For Automatic Loading & Unloading

### Stationary Conveyor System



- High level throughput (500 V/min load 800 V/min unload.)
- Small Footprint

### Transfer Cart System



- With more than 3 freeze dryers, a more flexible and cost-effective solution
- High level throughput (500 V/min load. 800 V/min unload)

# ALUS® Fixed System

**GEA** Engineering  
for a better  
world.

## ALUS® PUSH – PULL (PP)

Fixed Automatic Loading and Unloading System





# SMARTLYO® Freeze dryer

## High quality, affordable freeze drying systems

### Why?

- Reduced time to market thanks to modular design.
- Competitive pricing thanks to standardization.
- German design.
- Built to strict technical requirements within GEA controlled supply chains
- ALUS integration

### Features

- Compact build
- Flexibility in the positioning of components and skids
- Documentation package including FS/HDS/SDS and full IOQ documentation package
- Sub-processes of DF, CIP, SIP, FIT, leak testing
- FAT in person or virtual



**ENERGIZING PHARMA.  
ENERGIZING YOU.**

# We are glad to answer your questions



**Dr. Markus Kuehberger**  
Senior Director BL Chemical & Pharma  
Separation  
Mail: [markus.kuehberger@gea.com](mailto:markus.kuehberger@gea.com)



**Joerg Kuepper**  
Sales Manager  
Lyophilization  
Mail: [joerg.kuepper@gea.com](mailto:joerg.kuepper@gea.com)