Presenters

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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.


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

- **Cell separation**
  - Microorganism Substrate Aeration
    - Fermentation
    - Self-ejecting or nozzle separator

- **Non-Live vaccine processing**
  - Harvest tank
  - Further processing
  - Waste
  - Kill tank
  - Non-Live vaccines:
    - Influenza
    - Cholera
    - Vibriosis
    - Hepatitis A or hepatitis B
    - Whooping cough (pertussis)
    - Tetanus
    - Diphtheria
    - Pneumococcal bug
    - Covid

- **Live vaccine processing**
  - Kill tank
  - Waste
  - Kill tank
  - Additives
  - Harvest tank
  - Freeze dryer
  - Live vaccines:
    - Measles
    - Mumps
    - Rubella
    - Yellow fever
    - Chickenpox
    - BCG (= Tuberculosis vaccine)
    - Typhus
    - Human rotavirus
    - Whooping cough (pertussis)

- 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

<table>
<thead>
<tr>
<th>aseptic 30</th>
<th>aseptic 170</th>
</tr>
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<tbody>
<tr>
<td>aseptic 100</td>
<td>aseptic 300</td>
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<table>
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<th>pure 30</th>
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</table>
Perfectly adaptable to your needs

Cleanability, surface texture and documentation

<table>
<thead>
<tr>
<th>Hygienic Design</th>
<th>Sanitizing</th>
<th>Qualification Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASME BPE design</td>
<td>Automatic SIP</td>
<td>Complete GMP documentation included</td>
</tr>
<tr>
<td>GEA Ribo design</td>
<td>Automatic CIP Process</td>
<td>Additional certificates for surface, materials and weldings</td>
</tr>
<tr>
<td>Hygienic design</td>
<td></td>
<td>General Certificates</td>
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GEA Pharma Separator aseptic

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<tbody>
<tr>
<td>ASME BPE design</td>
<td>Free steaming at &lt; 0.5 bar</td>
<td>Complete GMP documentation available</td>
</tr>
<tr>
<td>GEA Ribo design</td>
<td>Automatic CIP Process</td>
<td>Additional certificates for surface, materials and weldings</td>
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GEA Pharma Separator pure

Included | Adaption options
Multiple bowl variants to maximize yield
Optimum yield at solid contents of up to 30 vol%
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 bow, 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®
pharma Separator

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

GEA kytero® 500

GEA kytero® 2000

GEA kytero® is registered as a trademark in several countries worldwide.
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
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

(Please use the contact form)
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
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 > 10,000m² site

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

Multi-purpose site (MPS) serving various glocal 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 > 25,000m² site
Lyophilization (freeze drying)
Vial manufacturing

Dispensing  Solution Preparation  Filtration  Filling  Freeze Drying  Vial Closing  Inspection  Secondary Packaging

Isolator

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
LYOVAC® Freeze Dryer
Layout GT and FCM
ALUS® Portfolio
For Automatic Loading & Unloading

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

Stationary Conveyor System

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

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

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