Energizing pharma

The new empowering separator lines

GEA Pharma Separators aseptic
GEA Pharma Separators pure

GEA engineering for a better world

gea.com

Two separator lines for every hygienic requirement

In pharma processing, uncompromised hygienic design, reliability and high yield are essential – but every production task and manufacturing operation is different.

The GEA Pharma Separation portfolio provides two expert lines of separator skids for every hygienic requirement to cover any product, process, viscosity, solid content and capacity.

GEA Pharma Separators aseptic

With the pharma separator line aseptic, GEA offers manufacturers a new level of performance, clean room protection, validation and cleanability.

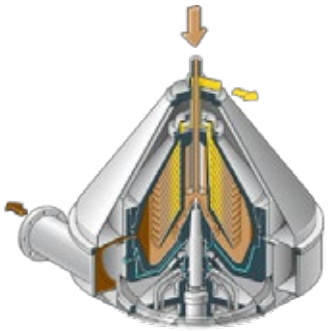
Equipped for SIP – highest hygienic demands.

GEA Pharma Separators pure

The new pharma separator pure line delivers machines that are equipped exactly to your needs with numerous combination options.

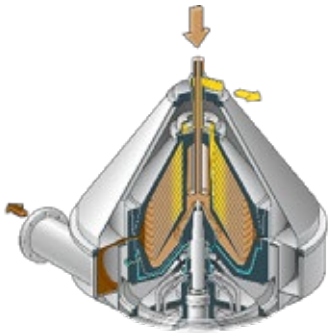
Utmost variability for your processes.

Three bowl types for solid contents up to 30 vol. %



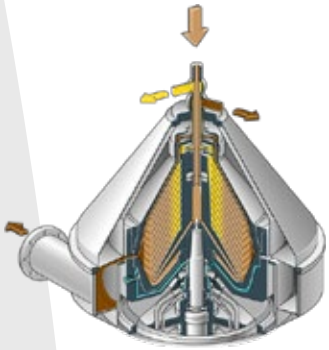
highSigma clarifier

The highSigma clarifier is a self-cleaning bowl type specialized in processing liquids with solids up to 5 vol. %.



highVol clarifier

For solids up to 10 vol. %, any GEA Pharma separator can be equipped with the highVol clarifier bowl variant.

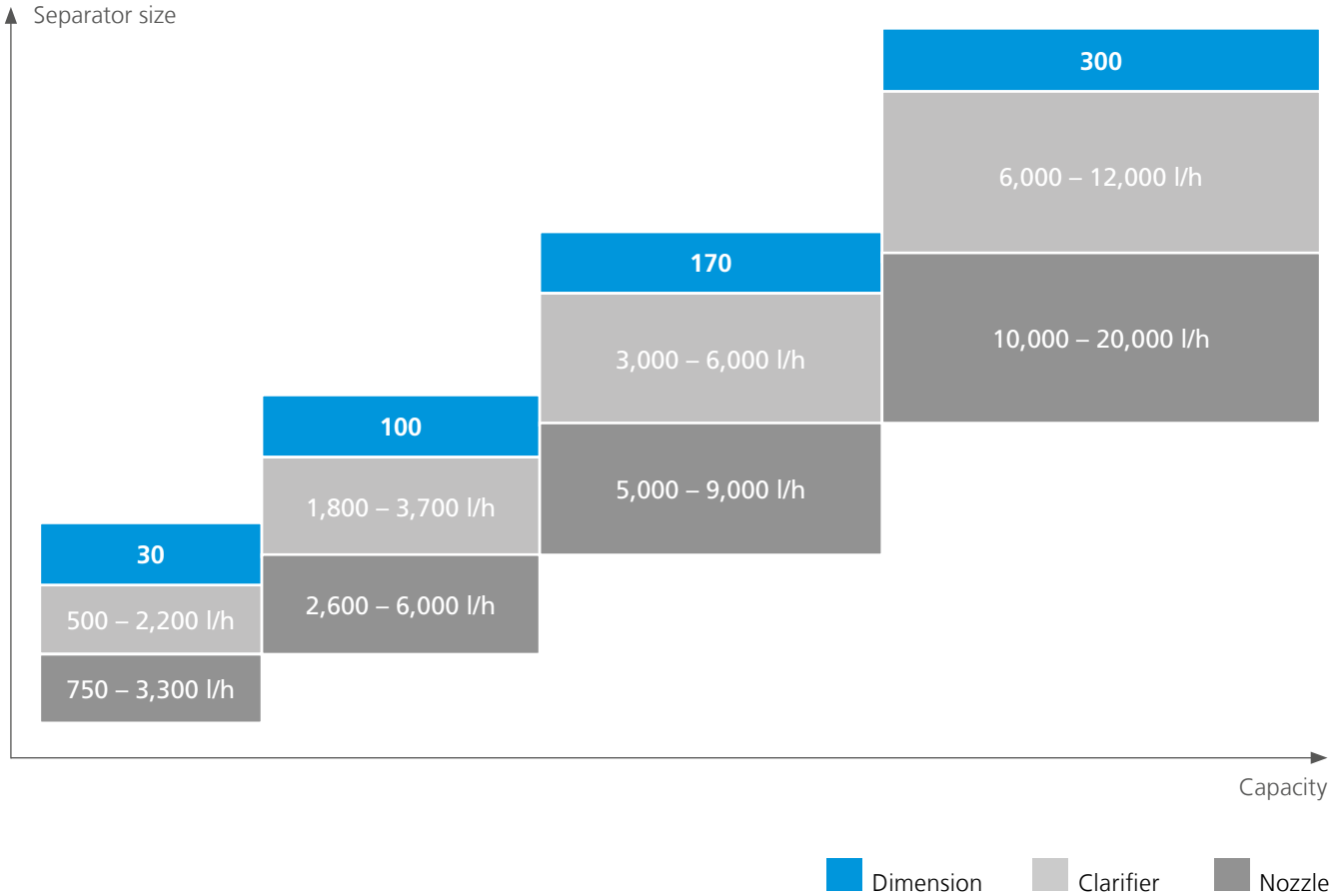


flexicon nozzle separator

The GEA flexicon nozzle bowl answers the needs of many manufacturers for a centrifuge that can handle higher solid contents – up to 30 vol. % – with better separation results (continuous decharging / desludging).

Gapless range to exactly cover any capacity

Four available model sizes for GEA aseptic and GEA pure machines with any bowl type ensure maximum efficiency of processing.



Figures based on mammalian cells.

Turning a static process line into a flexible one

NEW: GEA flexChange solution concept for producers with regularly changing products

One machine – three bowls

The GEA flexChange Concept offers up to three interchangeable separator bowls to produce any succession of products on just one skid. The exchangeable bowls ensure maximum adaptability to different capacities and processing goals, covering all feed solid contents from 5 to 30 vol %.

This multi-flexible machine transforms static process lines into multi-functional ones. Manufacturers become flexible to adapt to the next product as fast as possible, with the efficiency of a single machine delivering optimal yield for each product and capacity.

Available in the series aseptic and pure

The entire system is equipped to allow for CIP cleaning in compliance with the most stringent requirements. In addition, the exterior surface of the entire machine is very easy to clean, with no outside motor ribs.

All bowl types and sizes are available with or without the ability for steam sterilization in aseptic standard. The entire concept and its components are certified according to ASME BPE 2014.

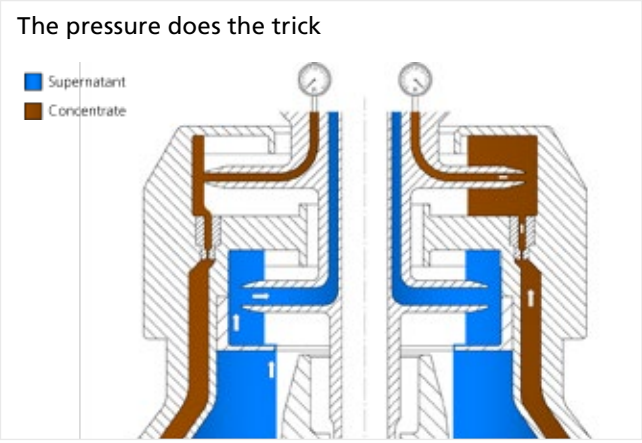
For maximum flexibility:

- Utmost flexibility to respond to changing requirements
- Product changes are substantially simplified
- Validation effort may be cut to the best possible minimum

GEA achievements bundled in aseptic and pure

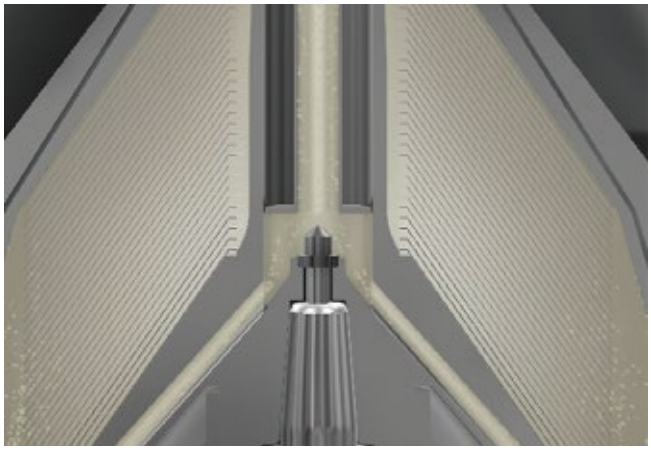
The new GEA flexicon nozzle bowl

GEA nozzle separators for pharma applications industry feature the new GEA flexicon nozzle bowl for high solids contents, ensuring perfect yield and optimum dryness of the product for further processing. Thanks to the innovative design, the nozzle settings are infinitely adjustable even during production.



ASME/GMP/Ribo test

For easiest implementation of your pharma process line, ASME BPE, GMP and Ribo type tests are fully included in GEA Pharma aseptic separators. All certificates and tests listed above are also optionally available for GEA Pharma pure skids.

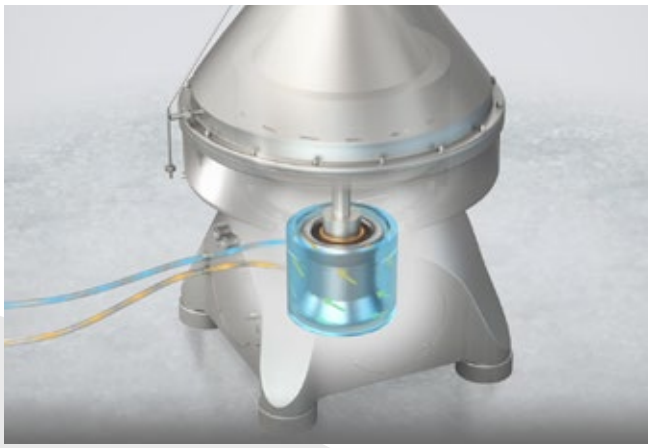


CIP/SIP capability

Separators in the aseptic line are automatically steam-sterilizable and completely sealed, designed for maximum biosafety and containment. For fully automatic CIP systems, the cleaning cycle is controlled by a programmable logic controller (also on GEA Pharma pure machines).

GEA IDD Integrated Direct Drive

GEA's water-cooled, emission-free Integrated Direct Drive is suitable for the most demanding cleanroom requirements. Fewer components on the drive system also mean fewer wearing parts and easier machine maintenance.



Mammalian cells/monoclonal antibodies (MBA)

Shear-sensitive separation of monoclonal antibodies (MBA) with optimal purity and yield

Monoclonal antibodies (mAb), used to treat specific serious diseases such as cancer, are produced on the basis of highly shear-sensitive mammalian cells. These cells must not break during separation and impure the product.

GEA aseptic separator skids offer a solution for efficient mAb separation that minimizes cell shearing. Sophisticated mechanical concepts and a precisely adjustable ejection system ensure optimal product purity and high yield for mAb manufacturers.

Softest acceleration in the feed system

A unique hydrohermetic feed system guides the cells gently into the bowl. It secures soft cell acceleration at the lowest possible shear force. This pioneering solution, only available from GEA, has been tested at Bielefeld University on sensitive CHO cell cultures and published by the researchers in cooperation with GEA.

No airlock in the bowl

Thanks to the integrated self-venting function, the hydrohermetic inlet from GEA also prevents airlock in the centrifuge bowl. This is an important advantage in ensuring continuous, error-free and safe operation under increasingly competitive process conditions in mAb production.

Sensitive speed control

The speed of GEA separators can be adjusted to protect particularly sensitive cell products and so always achieve optimal separation results at maximum purity of the product.

Maximum purity

The combination of hydrohermetic inlet and bowl overflow has also proven to achieve best CIP results. To avoid product contamination from seal abrasion only one double mechanical seal is used. It is made of high-quality silicon carbide and is not in contact with the product.

COVERING ALL PRODUCTION STAGES

Apart from GEA aseptic separator skids for full-scale production, GEA also offers the GEA kytero® single-use separator skid for small production and scalable product development (see p. 34)

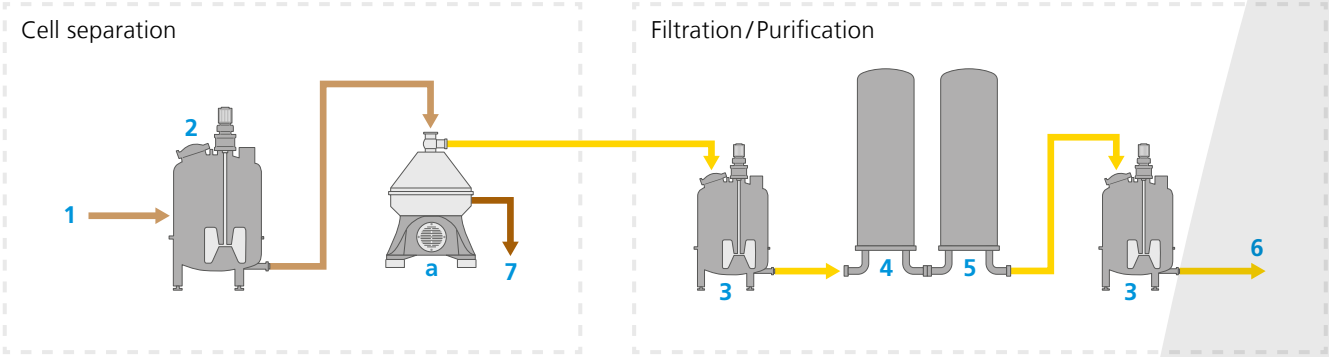
Economical plug & play skids

For fastest and easiest implementation into pharmaceutical plants, GEA can pre-assemble, test and pre-qualify any centrifuge as a complete process unit on a low-footprint skid, a solution preferred for many time-limited or space-sensitive projects.

To further save space and increase efficiency, additional systems, e.g. for depth filtration, can be mounted on the same skid or controlled from its panel.

With many mAb producers worldwide switching to continuous processing and increasing output, state-of-the-art GEA separators are the right solution for mAb harvesting with maximum success.

MONOCLONAL ANTIBODIES



Cell separation

- **1** Cell culture / substrate / aeration
- **2** Fermentation

Supernatant
Solids

Filtration / Purification

- **3** Harvest tank
- **4** Depth filtration
- **5** Microfiltration
- **6** Further processing

- **a** Self-ejecting or nozzle centrifuge

- **7** Waste

Insulin

Covering numerous steps with one modular machine type

In the efficient production of insulin, GEA Pharma separator skids make a difference with their unique versatility.

One basic type of machine can handle numerous steps in the entire process, with highly suited special solutions available for the remaining steps. This ensures consistently high product quality under fast-changing conditions – a valuable asset for producers in a dynamic market with increasing worldwide demand for life-saving insulin.

One centrifuge type for numerous process steps

To obtain insulin proteins from fermented yeast or E.coli bacteria the product is treated in a series of different process steps, e.g. cell harvesting, cell washing, polishing and removal of unwanted proteins (see process diagrams). GEAflexicon nozzle bowl separators can be applied to numerous process steps. Since the properties and densities of the solids are different in each step, extensive adjustment options are in place to ensure the handling of proteins with the highest sensitivity at each point.

Suitable for yeast and E.coli processes

Each GEA separator for insulin can be converted, at the user's discretion, to adapt it to different process steps or to ongoing changes in process development. GEA machines are designed for yeast-based as well as E.coli bacteria-based insulin processes.

GEA hycon®: A unique solution for crystal recovery

In the final crystallization stage, optimal dryness and aseptic handling of the product is of particularly high priority. GEA offers a unique solution for this task: GEA hycon®, a closed three-room centrifuge system specially designed for cleanroom applications to achieve maximum solids concentrations under aseptic cleanroom conditions.

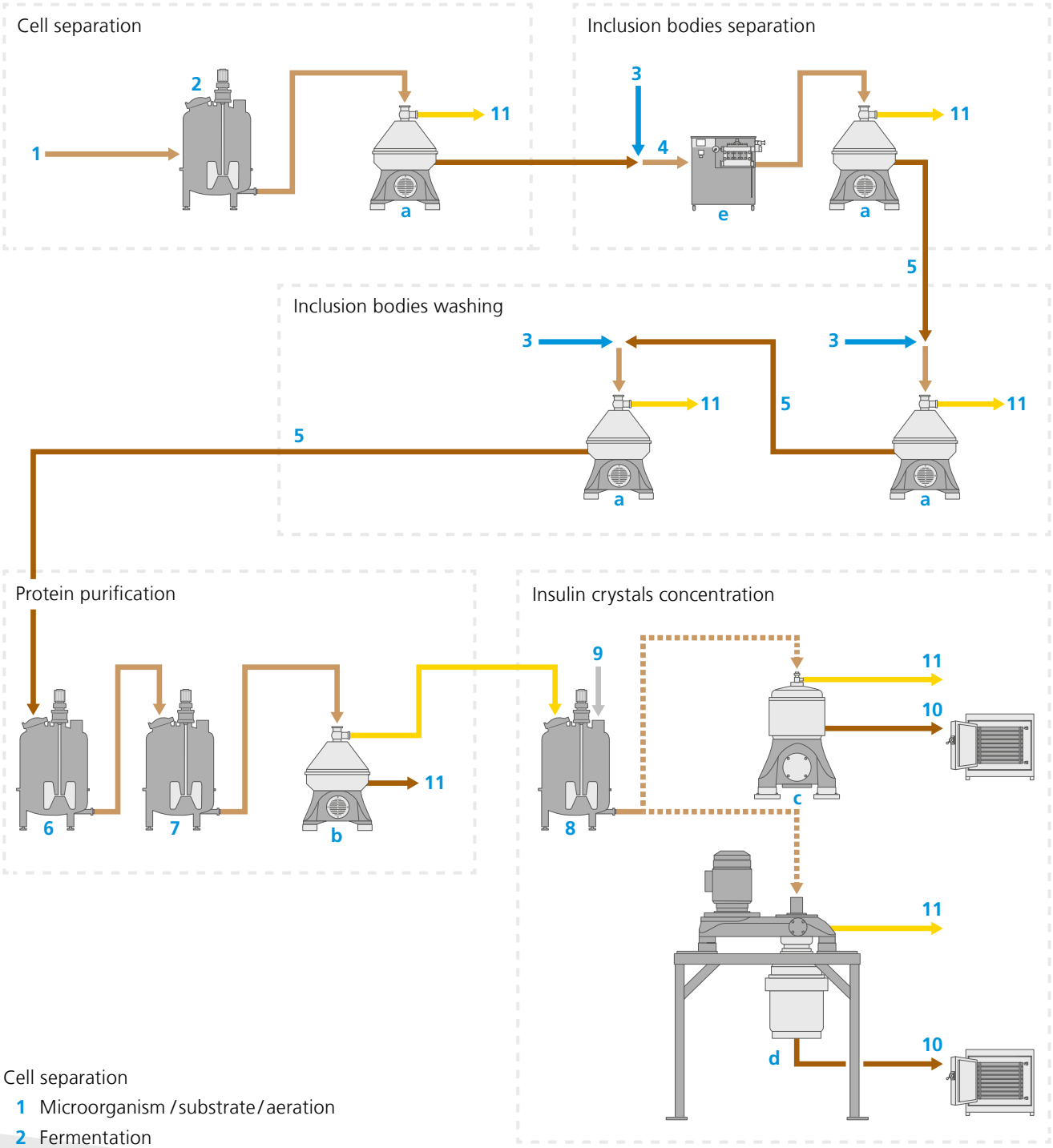
Automatic self-emptying of the GEA hycon® system eliminates the need for conventional, labor-intensive manual recovery of the solid end product.

Improved small-footprint option

As an alternative, manufacturers can also rely on GEA for a small-footprint, low-investment option for the crystallization process, which provides for manual recovery of the dry protein.

For this task, small chamber centrifuges GEA PKB 28 or PKI 45 are available. These models have been specially optimized for uncomplicated manual opening of the machines and simple recovery of solids, making the process as fast and fail-safe as possible.

INSULIN BASED ON E.COLI



Cell separation
- 1 Microorganism / substrate / aeration
- 2 Fermentation

Inclusion bodies separation
- 3 Water / buffer (washing liquid)
- 4 Biomass

Inclusion bodies washing
- 5 Inclusion bodies

Protein purification
- 6 Protein folding
- 7 Precipitation of foreign proteins

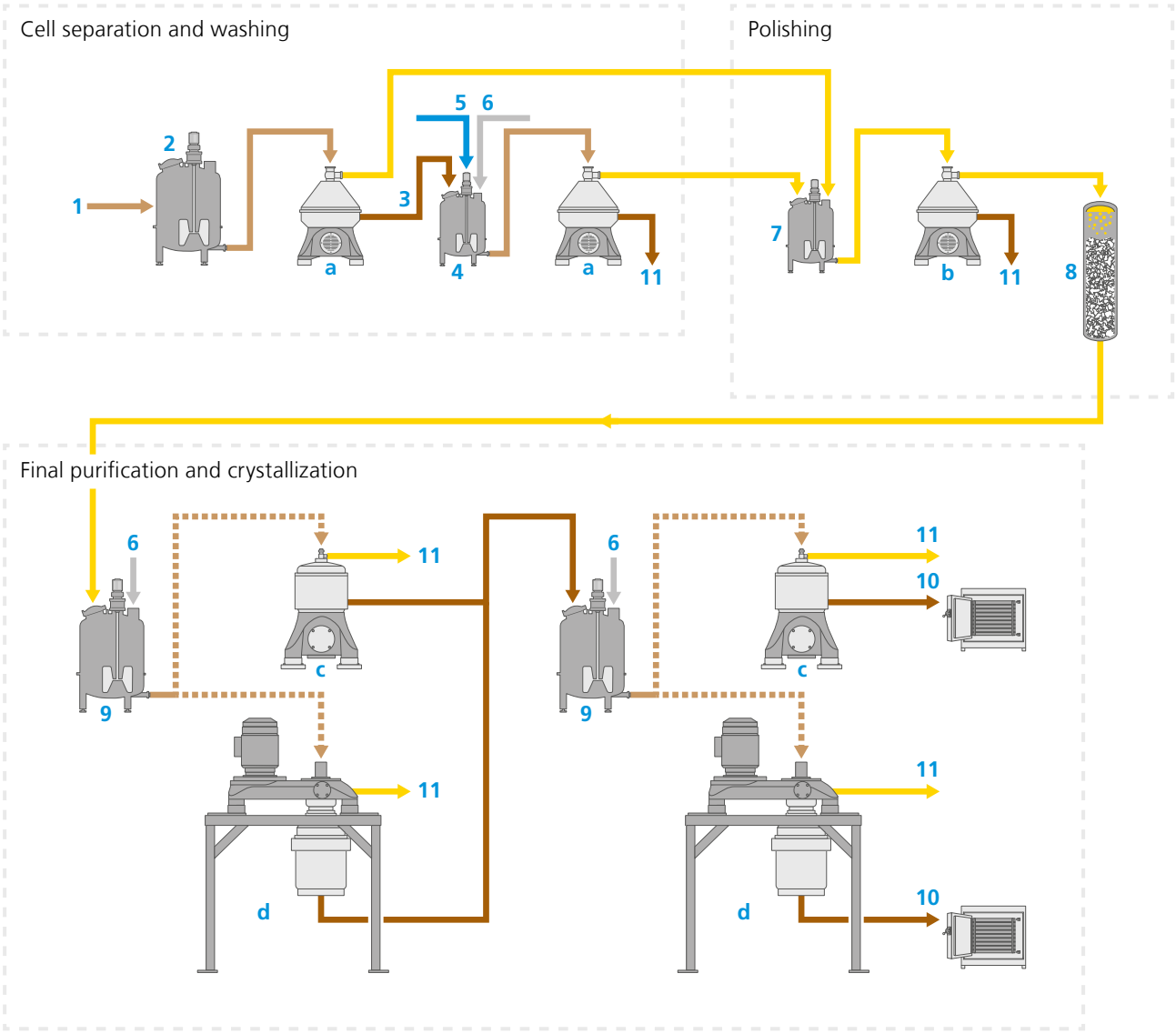
Insulin crystals concentration
- 8 Crystallization tank
- 9 Additives
- 10 Insulin crystals to freeze dryer

- a Self-ejecting or nozzle centrifuge
- b Self-ejecting centrifuge
- c Chamber bowl centrifuge
- d GEA hycon® (three-room concept with closed solids handling)
- e Homogenizer

- 11 Waste

→ Supernatant
→ Solids

INSULIN BASED ON YEAST



Cell separation and washing

- **1** Microorganism/substrate/aeration
- **2** Fermentation
- **3** Biomass
- **4** Washing tank
- **5** Water/buffer (washing liquid)
- **6** Additives

Polishing

- **7** Harvest tank
- **8** Chromatography column

Final purification and crystallization

- **9** Crystallization tank
- **10** Insulin crystals to freeze dryer

- **a** Self-ejecting or nozzle centrifuge
- **b** Self-ejecting centrifuge
- **c** Chamber bowl centrifuge
- **d** GEA hycon® (three-room concept with closed solids handling)

- **11** Waste

→ Supernatant
→ Solids

GEA HYCON® – THE CLEANROOM SOLUTION

The unique aseptic three-room solution for the crystallization stage: The GEA hycon® clarifier system for automated, high-efficiency recovery of insulin crystals in the cleanroom.

Human and veterinary vaccines

Securing biosafety and containment with steam-sterilized systems

Vaccines – both live and non-live – are critical to eliminating or reducing the risk of viral infections. Because vaccines can prevent, but potentially also trigger disease, bio-safety is of highest priority at every stage of processing. Any breach in containment and any other risk of contamination must be avoided.

Whether live or non-live vaccines, for human use or for veterinary applications, manufacturers can trust the superior separation solutions from GEA to keep hazardous substances contained, maintaining the purity of the product and the safety of the production process without compromise.

Optimized for steam-sterilization and biocontainment

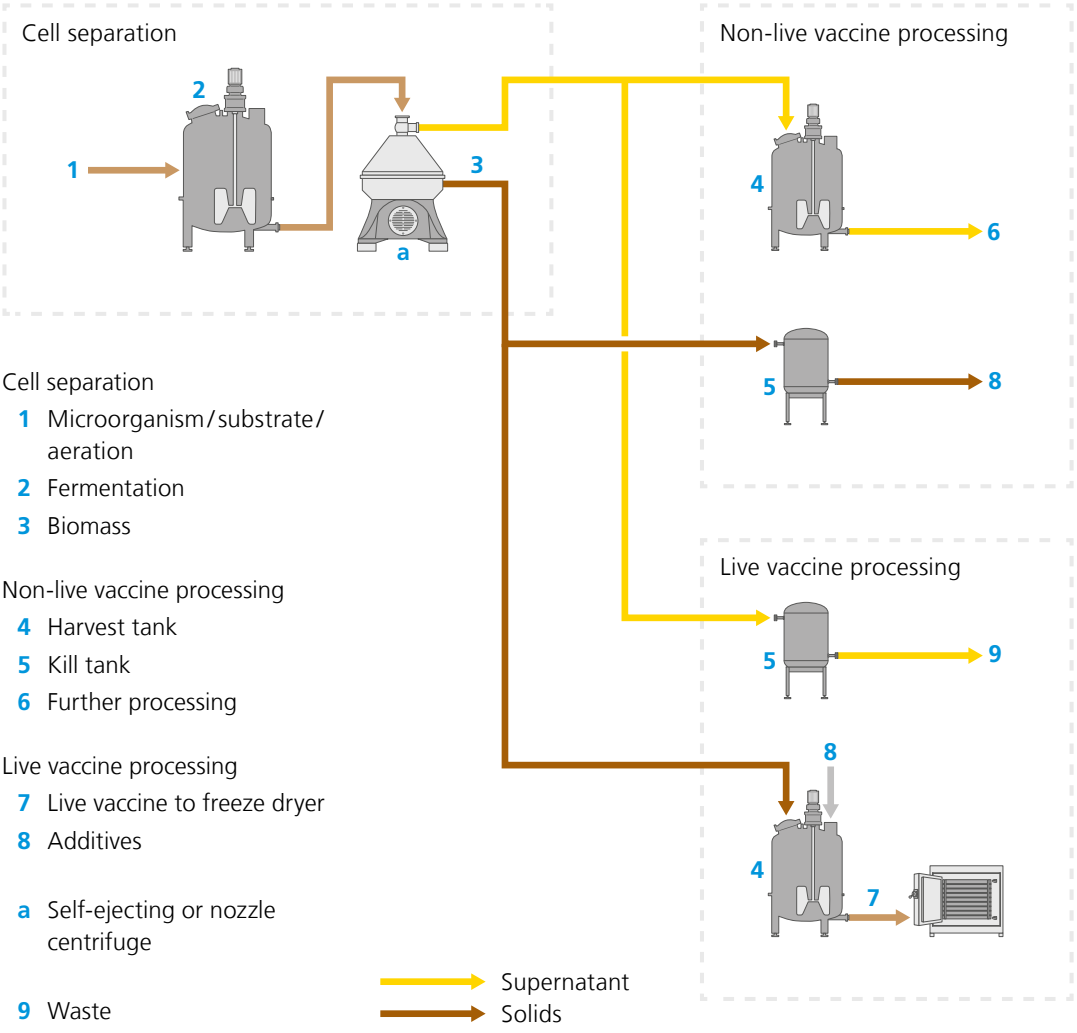
GEA centrifuges for vaccines are all available in suitable designs for steam-sterilization – the ideal solution to prevent cross-contamination of consecutive batches and to protect the operator when opening the centrifuge.

To ensure biocontainment during machine operation, the centrifuge housing is entirely sealed, including feed and discharge systems, impeding any contact between the product and the atmosphere.

Careful product handling

Extensive scientific research in cooperation with Bielefeld University has led to the development of particularly gentle hydrohermetic feed and discharge systems on current GEA Pharma separators, ensuring particularly careful handling of the product during the centrifugation process.

HUMAN AND VETERINARY VACCINES



Cell separation

1 Microorganism/substrate/aeration

2 Fermentation

3 Biomass

Non-live vaccine processing

4 Harvest tank

5 Kill tank

6 Further processing

Live vaccine processing

7 Live vaccine to freeze dryer

8 Additives

a Self-ejecting or nozzle centrifuge

9 Waste

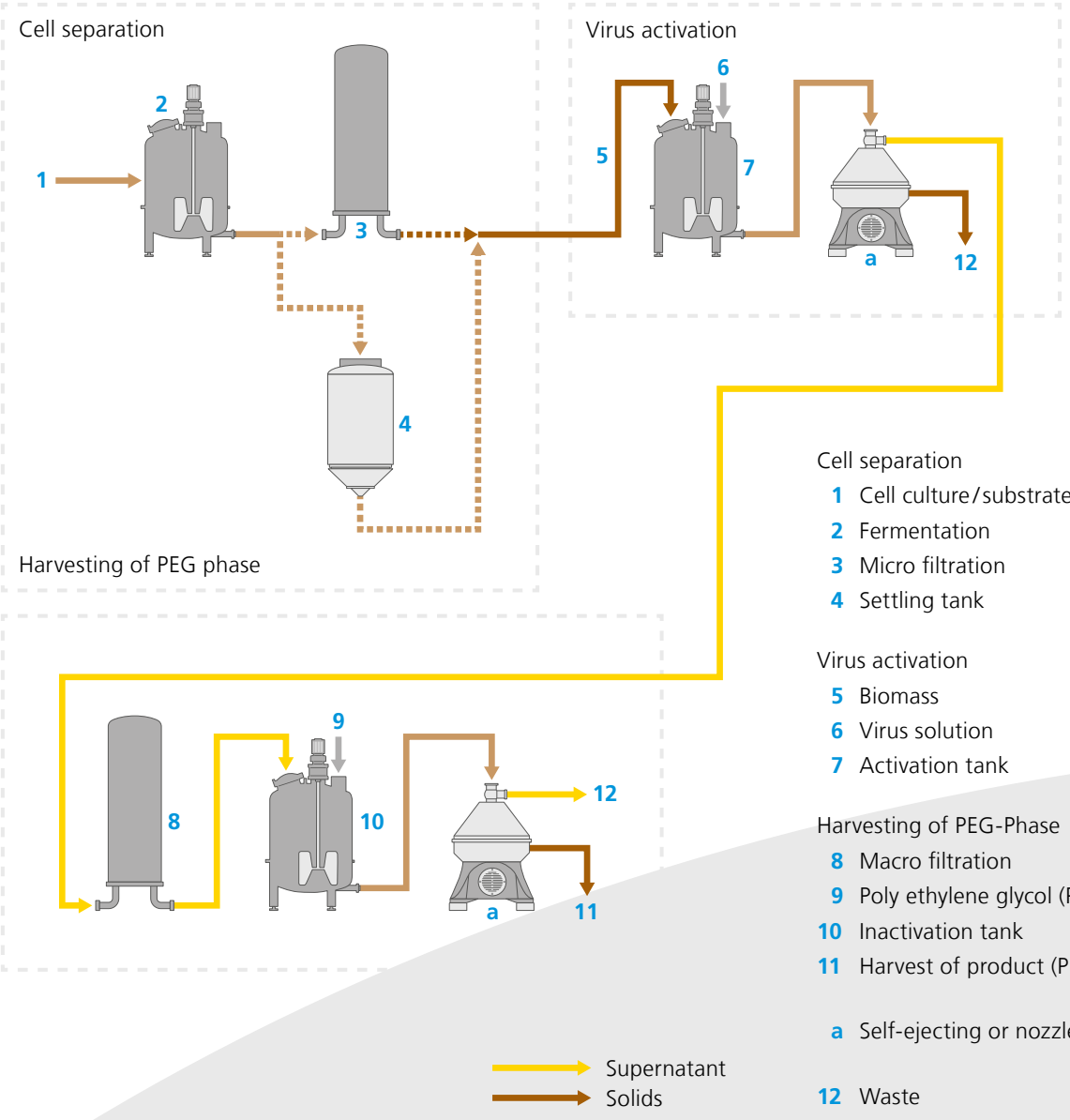
Veterinary vaccines: Protection from active viruses

Particularly dangerous conditions mark the production of some animal vaccines (e.g. specific live foot-and-mouth disease vaccines) involving a virus activation stage (see diagram). Activated viruses can be highly pathogenic, either immediately or at any point in the future, which makes maximum protection against the risk of contamination or direct infection indispensable.

To ensure maximum safety, the safety concept from GEA with biocontained machine skids in steam sterilizable design for vaccine treatment has also been tested and published together with a research team at London University.

Whatever the vaccine process, choosing the most economical machine size makes a huge difference to the efficiency of the pharmaceutical operation. The GEA Pharma separator portfolio offers sizes to fit any setup and process. The ideal size can be assessed by upscaling from test runs at GEA test centers or at the customer's site.

VETERNARY VACCINES (EXAMPLE WITH ACTIVATED VIRUS – FOOD AND MOUTH DISEASE)



Cell separation
- 1 Cell culture/substrate/aeration
- 2 Fermentation
- 3 Micro filtration
- 4 Settling tank

Virus activation
- 5 Biomass
- 6 Virus solution
- 7 Activation tank

Harvesting of PEG-Phase
- 8 Macro filtration
- 9 Poly ethylene glycol (PEG)
- 10 Inactivation tank
- 11 Harvest of product (PEG-phase)

- a Self-ejecting or nozzle centrifuge

- 12 Waste

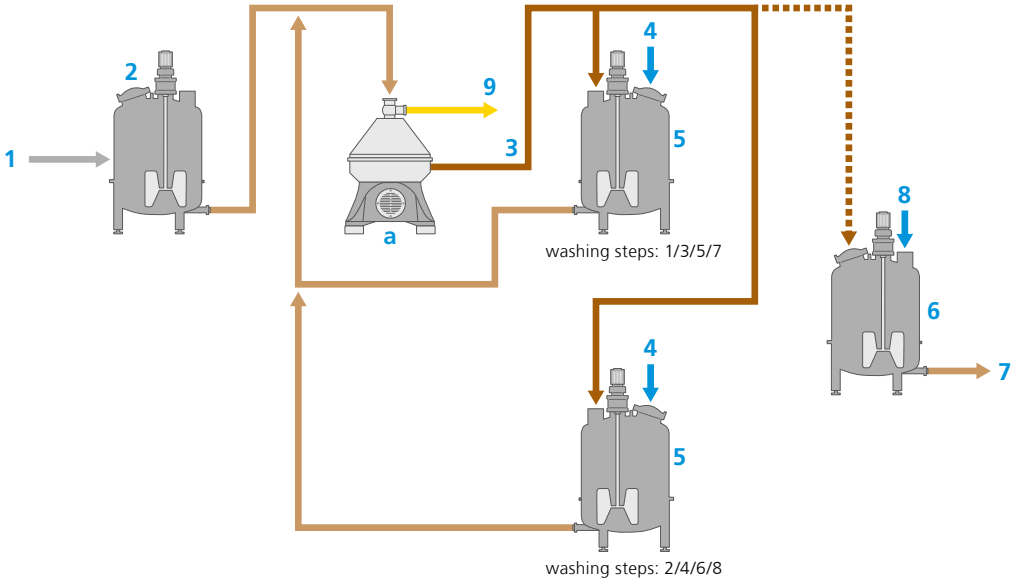
Streamlined production of adjuvants

Vaccine production includes the preparation of excipients, such as aluminum hydroxide, which themselves have no pharmaceutical effect, but boost the effect of the pharmaceutical agent. In a typical reaction, chemicals such as ammonia and aluminum salts produce a high water content aluminum gel.

Fewer wash cycles

With GEA separators, the remaining chemicals are completely removed in several wash cycles. The high-precision ejection system on the centrifuges controls output sizes and quantities with reproducible results, minimizes the number of cycles and saves time and money for the manufacturer.

ADJUVANTS (RECOVERY OF ALUMINUM HYDROXIDE)



1 WFI and additives
2 Precipitation tank
3 Aluminum hydroxide
4 Water/buffer (washing liquid)
5 Washing tank
6 Harvest tank
7 Further processing
8 WFI (Water for Injection)
a Self-ejecting or nozzle centrifuge
9 Waste

Supernatant
Solids

Starter cultures and probiotic products

Enhancing yield and vitality of living cells

Starter cultures are responsible for predictable and reproducible production processes in many industries. Probiotic products are popular with consumers for their beneficial health characteristics. All these microbial food cultures can only be successfully harvested if the vitality of the cells is protected and preserved. GEA nozzle centrifuge models achieve this with advanced systems that ensure smooth cell handling and high yields.

Gentle cell treatment for highest vitality

In order to produce microbial food cultures, the cultivated micro-organisms must be separated from the fermentation solution. A gentle hydrohermetic feed system on GEA separators ensures that the product is processed with a minimum of stress, keeping the living cells safely intact. The nozzles inside the centrifuge bowl are placed near the bowl axis, further reducing pressure on the cells. The product is thus in an ideal condition for downstream processing, e.g. freeze-drying (for some types of product) and packaging.

Innumerous cultures without technical change

Sterilizable separators from GEA are becoming increasingly important for recovering microbial products. In fact, a single GEA machine can be re-adjusted at the user's discretion to handle all typical starter cultures and probiotic products in the dairy, food, veterinary food and pharma industries.

Multi-purpose operation is easy to manage and can accommodate a wide range of feed concentrations (0.1 – 10 vol%). Different product recipes can be stored in the product panel. All settings and modifications are also done on the control panel, no changes are required on the machine.

Safe prevention of contamination

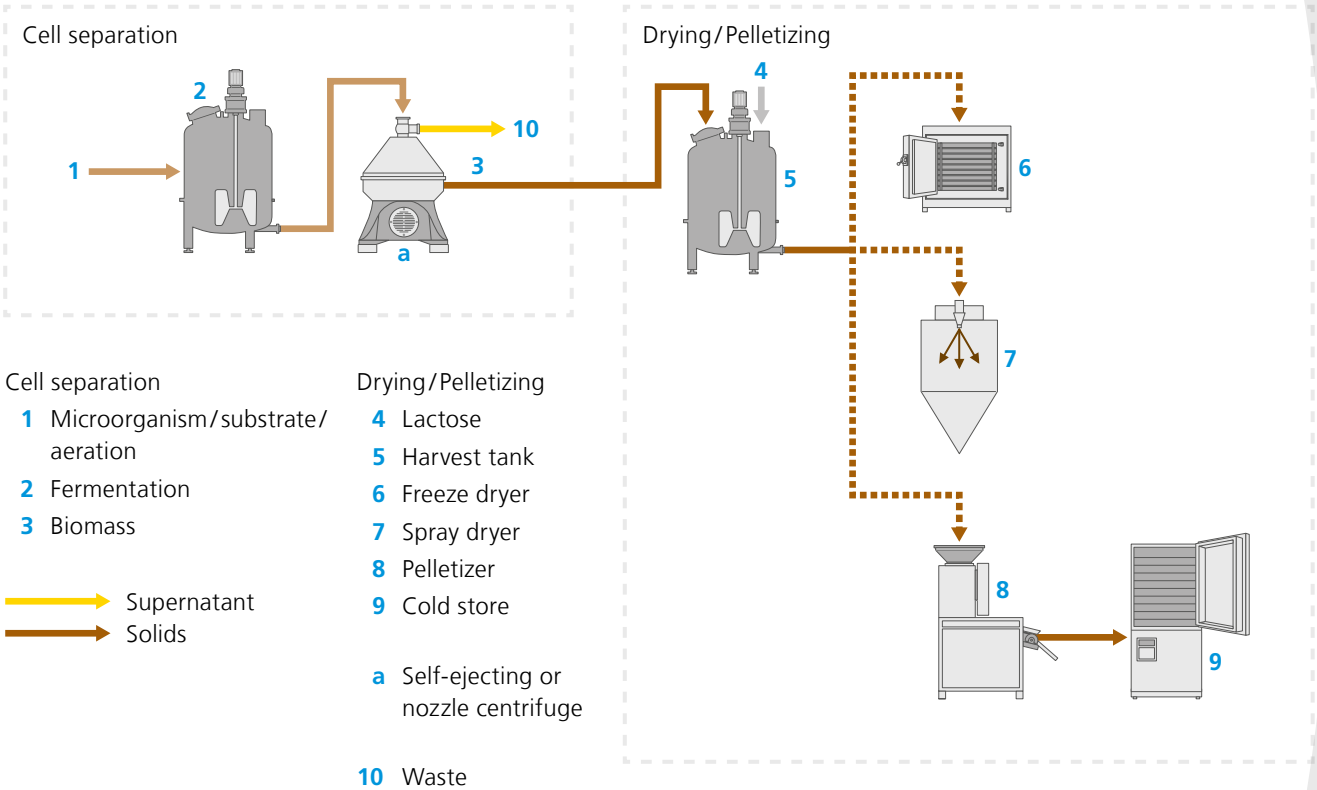
In addition to the CIP routines, nozzle separators from GEA are designed to be sterilized with saturated steam. This safely prevents cross-contamination and ensures the purity of changing product types and batches. The pressure-tight product processing zone of the centrifuge and its drive unit are separated by a double mechanical seal.

Reproducible and scalable results

The separation results with these separators are highly reproducible and scalable, thanks to automated operation and an ingenious metering piston system. Ejection volumes and concentrations can be set externally, continuously 10 – 100% and with highest accuracy.

All functions are optimally matched in GEA nozzle separators to facilitate production control and product development.

STARTER CULTURES



Cell separation

- **1** Microorganism/substrate/aeration
- **2** Fermentation
- **3** Biomass

Supernatant
Solids

Drying/Pelletizing

- **4** Lactose
- **5** Harvest tank
- **6** Freeze dryer
- **7** Spray dryer
- **8** Pelletizer
- **9** Cold store

- **a** Self-ejecting or nozzle centrifuge

- **10** Waste

Recovery of extracellular and intracellular enzymes

Wear-protected recovery and fewer process stops

Enzymes are complex organic protein compounds located in every living cell. They accelerate organic processes such as the breakdown of starch, protein, fat or sugar as catalysts, i.e. without being expended themselves. Low-abrasion GEA nozzle separators provide a simple solution to ensure, at low costs, that both intracellular and extracellular enzymes are separated undamaged and in high concentrations.

Low abrasion and fewer process stops

To produce enzymes for industrial use, the liquid phase of the fermentation broth is separated by centrifuging with an added flocculent. This process does not require costly sterile handling of the product. However, abrasive particles from the fermented raw materials are often present in the broth and can affect the separation system. This is why specialized GEA nozzle separators are a superior choice compared to standard disk stack models: The external nozzle can be inspected and maintained externally with little effort, saving unnecessary downtime and effort.

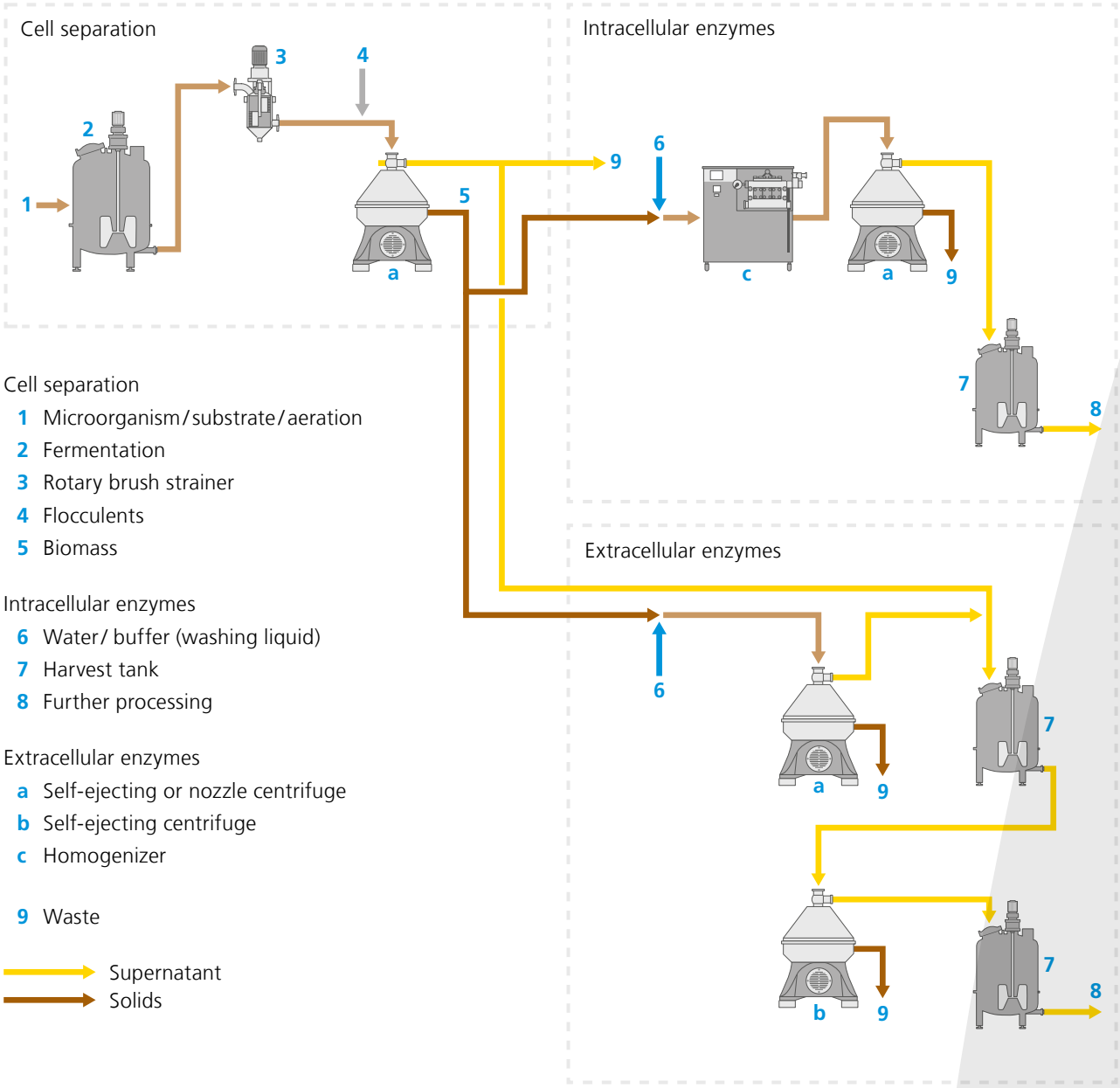
In the case of especially abrasive particles that cannot be pre-screened with sieves before separation, special reinforcements are fitted to wear-sensitive components on GEA separators.

Recovery of extracellular and intracellular enzymes

After the initial separation of cells from the fermentation broth, different process variants are used for extracellular and intracellular enzymes. In both cases, succeeding stages of washing and polishing with centrifuges further increase the yield and the purity of the enzymes.

The centrifuge solution offered by GEA is perfectly equipped to handle all these process steps. It is possible to use the same machine for different steps with little adjustment effort.

ENZYMES



Cell separation

- **1** Microorganism/substrate/aeration
- **2** Fermentation
- **3** Rotary brush strainer
- **4** Flocculents
- **5** Biomass

Intracellular enzymes

- **6** Water/ buffer (washing liquid)
- **7** Harvest tank
- **8** Further processing

Extracellular enzymes

- **a** Self-ejecting or nozzle centrifuge
- **b** Self-ejecting centrifuge
- **c** Homogenizer

- **9** Waste

Supernatant
Solids

Human blood plasma fractination

Using GEA BKI chamber separators and the GEA hycon® three-room concept for safe, temperature-controlled fractionation.

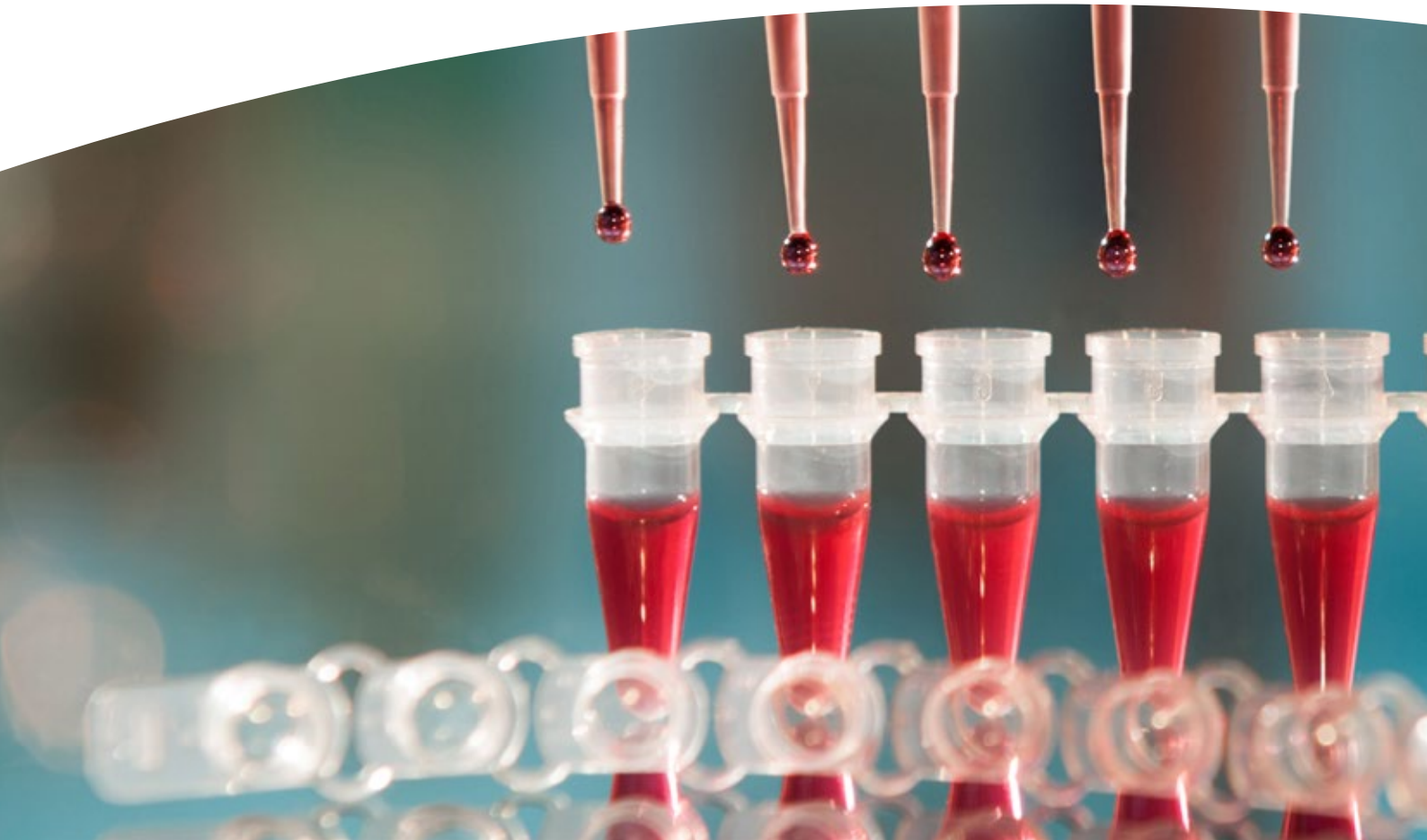
The clear plasma phase of human blood contains about five percent valuable pharmaceutical substances with important medical applications, e.g. for controlling bleeding or for treating infections or malnutrition. However, a very narrow temperature range makes it particularly difficult to separate the individual substances from the remaining phase. Using sophisticated technologies, GEA centrifuges safely keep temperature tolerances, at the same time ensuring highest product quality as well as highest plant efficiency.

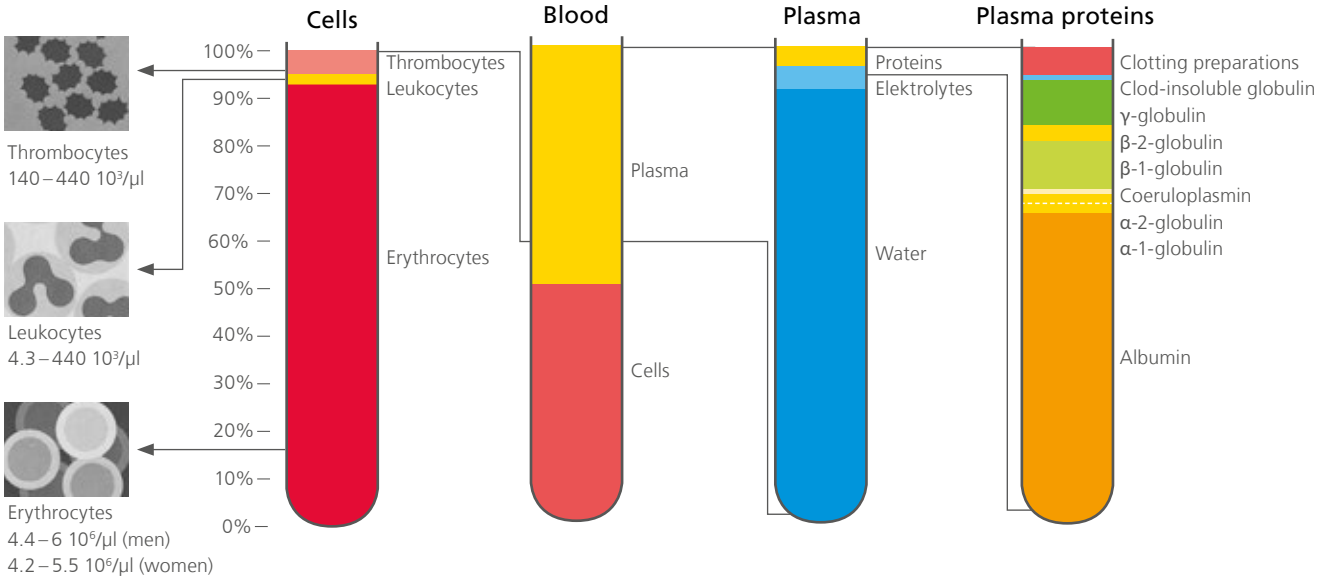
Maximum-safety cooling system

The permitted temperature range for processing blood plasma and plasma components is merely +2 °C to –7 °C and must be maintained under all circumstances so as not to render the sensitive product unusable. To ensure maximum safety, a direct cooling system is integrated into GEA chamber centrifuges for blood plasma fractionation. Using ethanol/water at up to –20 °C temperature as a refrigerant, the system cools the machine bowl during operation so that the processed solids are always kept exactly at the pre-selected temperature and iso-electrical value, at no greater tolerance than +/– 1 °C.

One machine type for all fractionation cycles

GEA chamber separators for blood plasma fractionation can be applied to all the different steps of the Cohn fractionation



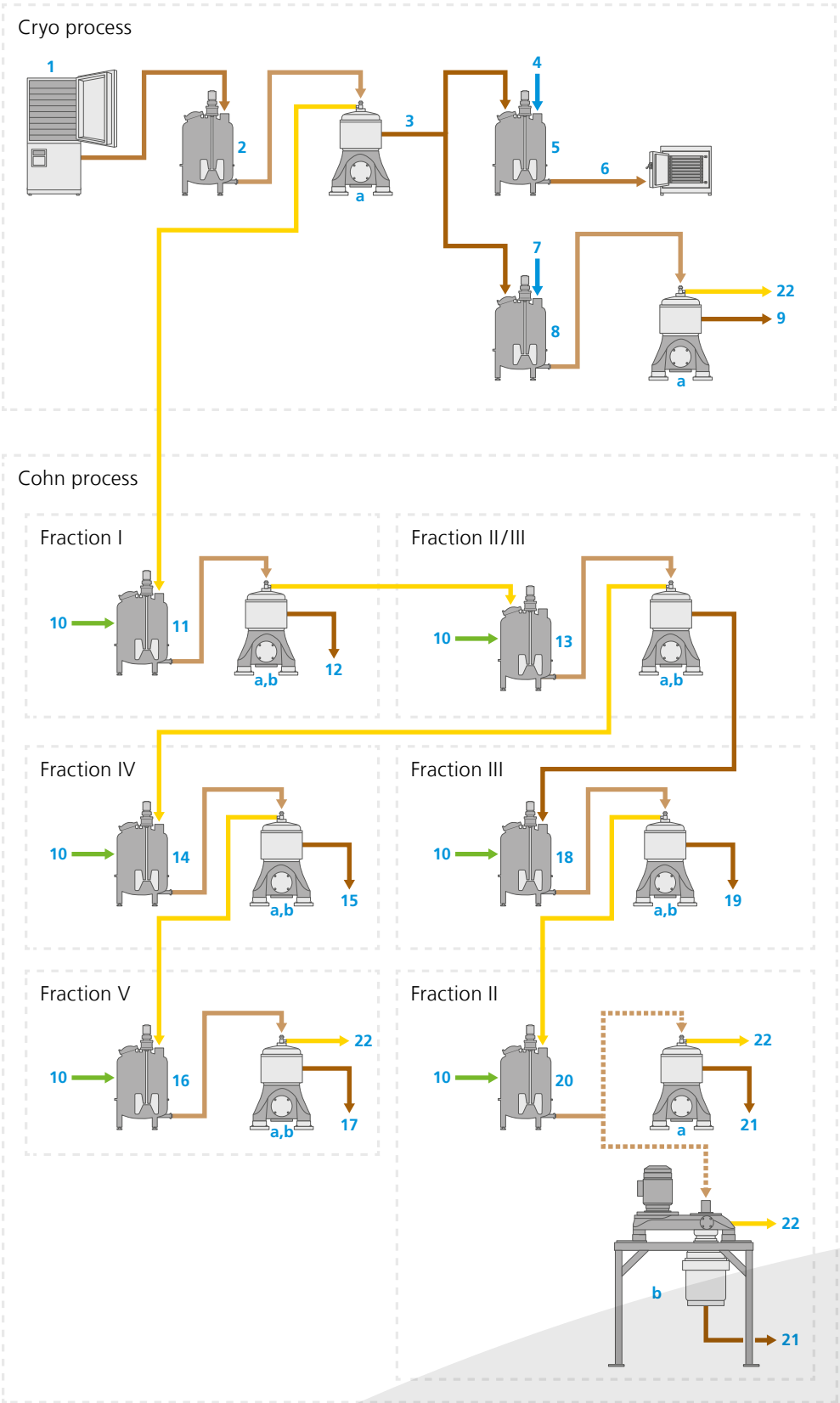


process, presenting a particularly economical solution to facilitate efficient plant management as well as future changes in processes or capacities.

In preliminary steps, substances such as cryoprecipitate and the prothrombin complex (PPSB) can be separated from the fresh plasma. In further steps, the remaining plasma undergoes several chemical cycles at changing settings for temperature, alcohol concentration and pH in order to deliver individual fractions such as fibrinogen, gamma globulin, alpha and beta globulin and albumin.

Thanks to extensive options for adjusting speed, separated particle sizes and discharge volumes, the same type of GEA separator can cover all these steps at optimum performance.

HUMAN BLOOD PLASMA FRACTIONATION



Cryo process

1 Cold store
2 Thawing tank (temp. appr. 0 °C)
3 Cryoprecipitate
4 Washing liquid
5 Washing tank (temp.appr. 0 °C)
6 Cryoprecipitate to freeze dryer
7 Buffer
8 Re-suspension tank (temp. appr. 0 °C)
9 Factor VIII concentrate

Cohn process

10 Alcohol, pH, temperature
11 Protein precipitation (Alcohol content = 8 %, temp. = –3 °C, pH = 7.3)
12 Fraction I (Fibrinogen)
13 Protein precipitation (Alcohol content = 25 %, temp. = –5 °C, pH = 6.8)
14 Protein precipitation (Alcohol content = 40 %, temp. = –5 °C, pH = 5.9)
15 Fraction IV (- and - Globulin to waste)
16 Protein precipitation (Alcohol content = 40 %, temp. = –5 °C, pH = 4.8)
17 Fraction V (Albumin)
18 Protein precipitation (Alcohol content = 8 %, temp. = –5 °C, pH = 5.1)
19 Fraction III (- Globulin to waste)
20 Protein precipitation (Alcohol content = 25 %, temp. = –6.5 °C, pH = 7.3)
21 Fraction II (- Globulin)

a Chamber bowl centrifuge
b hycon® (three-room concept with closed solids handling)

22 Waste

Supernatant
Solids

Maximum dryness of separated solids

Manufacturers need the fractionated solids to be as dry as possible, but without stress on the product. Based on decades of experience, GEA centrifuge technology ensures unsurpassable and reproducible quality of the product in terms of dryness, product integrity and preservation of product properties. Careful handling of the product is ensured by the hermetic inlet, which has been confirmed by CFD calculations.

Chamber centrifuges: hundreds in operation

Fractionation by the Cohn process is executed by reliable, cooled chamber centrifuges. GEA chamber separators operate in performance ranges from 60 to 1,000 l / h. They have become a proven global standard and show their value in around 600 their worth in sold machines for human blood plasma fractionation.

Aseptic GEA hycon® three-room concept

In addition to classic chamber separators, the groundbreaking GEA hycon® solution is also available for the blood plasma fractionation process. GEA hycon® is a three-room system especially designed for aseptic production environments. It is equipped to operate fully automatically, avoiding the effort and risk of manual intervention.

GEA BKI 45 CHAMBER SEPARATOR SKID

The classic solution for all blood plasma fractionation stages is available on a pre-configured skid with an additional independent GEA plasmacool cooling unit to ensure a failsafe process.

Temperature control with special GEA technologies

The compliance with a narrow temperature range of +2 to –7 °C is important for the fractionation process. In clarifying centrifuges of the series GEA BKI, this is achieved by triple cooling: a direct bowl cooling which extracts the heat created by air friction at the outer bowl, an upper frame cooling which extracts the heat of the cooling medium from the bowl and a hood cooling, which extracts the heat from the bowl top and the lock ring. The cooling solution introduced into the cooling chambers has a temperature of up to –20 °C, so that the outer surfaces of the centrifuges are completely iced during operation. With this system, a controlled product temperature can be achieved with a tolerance of +/– 0.3 °C. In this process, the temperature of the product must not rise or may rise only slightly. This has also been adressed in the development of the GEA hycon®.

GEA plasmacool – securing the individual batch

GEA plasmacool unit is an individual cooling skid to secure the requested process temperature stable at any time, thus protecting the valuable product and money.

Thermal balance under control

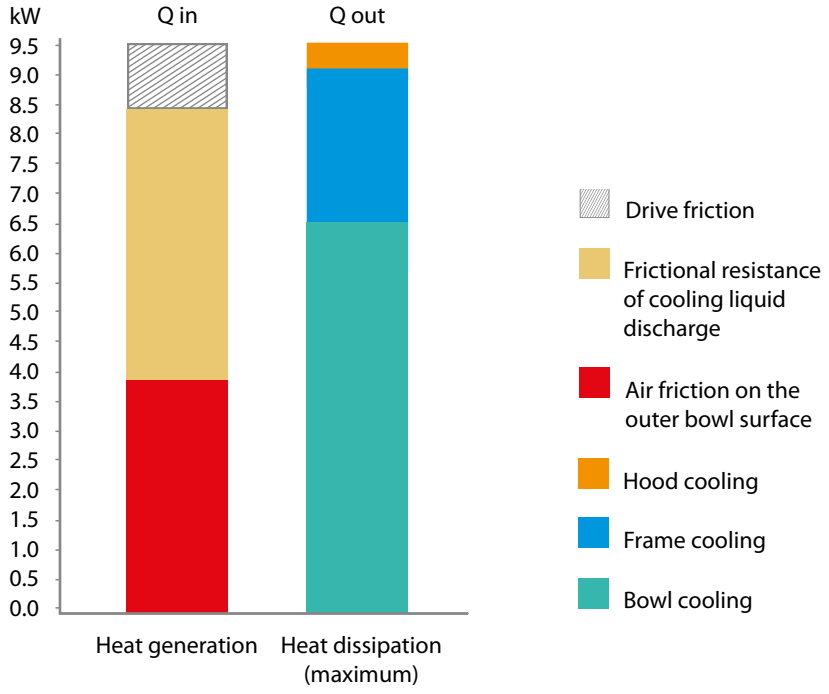
The bar diagram shows the results of measurements in a centrifuge type BKB 28 with an 11 kW (9.3 kW) motor. The GEA special cooling system keeps the thermal balance under control: it distracts exactly the amount of heat which is generated during operation by the machine and the surrounding. The heat balances were calculated under constant conditions. The left bar shows the main amounts of introduced heat. The right

UTMOST SAFETY WITH GEA PLASMACOOL

Coupled to the GEA human blood BKI, the skid cools one machine and batch individually. For more flexibility in the process, and utmost safety for the valuable product.

bar indicates the amounts of heat which can be extracted at the lowest temperature of the cooling medium (–20 °C). It can be seen that controlled product temperatures can be adjusted and that cooling can even be achieved under certain conditions with this type of centrifuge.

Similar heat balances can also be realized with the hyperconcentrator through targeted implementation of these findings in the conceptual design of the GEA hycon®.



GEA HYCON® CLARIFIER

The fully automatic, self-cleaning clarifier enables "one-touch" production for the separation of blood plasma and plasma proteins.

Nothing but the best

Pharmaceutical processing relies on the most sensitive product handling, minimum product losses during the process and reliable biocontainment capabilities.

State-of-the-art GEA **direct**drive

GEA Pharma separators are equipped with the integrated GEA **direct**drive with all its advantages: the bowl is driven directly by an integrated, frequency-controlled, three-phase motor and is infinitely adjustable. Furthermore, the drive concept has proved to be exceptionally maintenance-friendly: lubrication is not needed and the demand for spare parts is less. The GEA **direct**drive reduces the space required for the centrifuge by 35 percent.

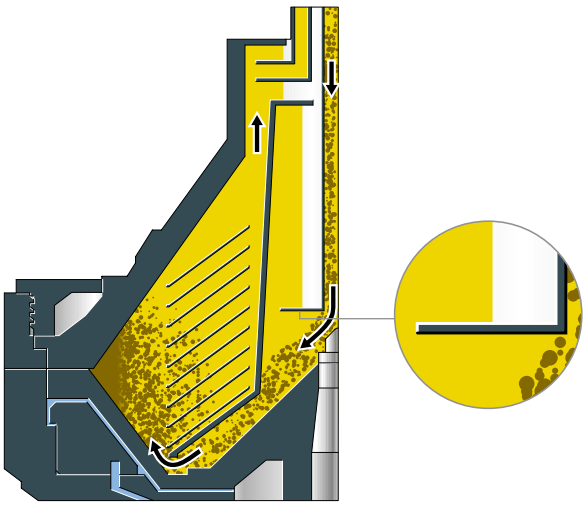
Centrifuges with integrated sound insulation

Besides efficient and economical operation, design measures for the improvement of environmental conditions are also important today. Greater attention has been drawn to a reduction of noise levels. Here, the water-cooled motor works considerably more quietly than an air-cooled equivalent. By integrating sound insulation in the centrifuge, noise levels have been substantially reduced. The operating noise (sound pressure level) of these centrifuges is less than 78 dB (A). External sound insulation measures are not necessary.

Hydrohermetic inlet for gentle product feed

The GEA hydrohermetic feed system ensures that the product is always fed into a filled bowl (product in product). This ensures a maximum smooth product handling, minimized shear forces and utmost protection of cells. The product is gently introduced into the filled bowl and smoothly accelerated to the circumferantial speed of the bowl. The patented GEA hydrohermetic inlet has been successfully tested and published on mammalian cell cultures by the University of Bielefeld.

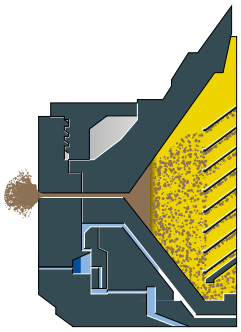
*Machine with integrated GEA **direct**drive.*

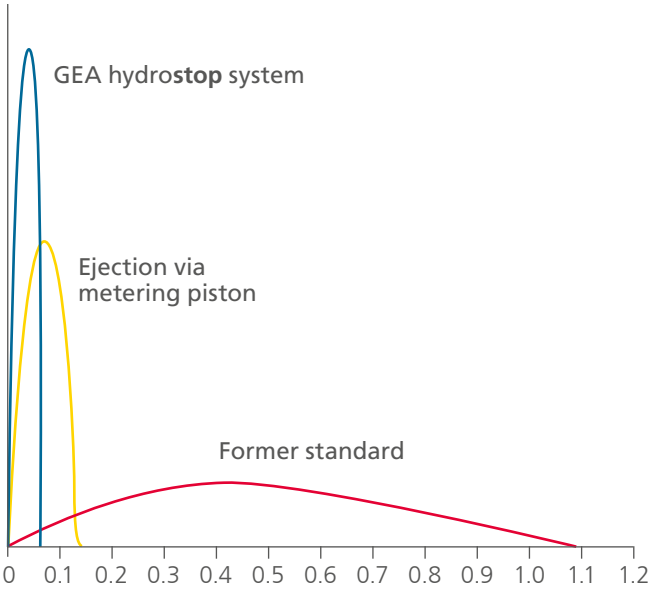


The hydrohermetic disk ensures the product flows in under the surface level, avoiding shear forces and foaming. The product is accelerated most gently and protected in the best possible way.

Fast and precise ejection with GEA hydro**stop**

The GEA hydro**stop** ejection system can be adjusted precisely and reproducibly to specific requirements regarding the concentration of solids. This patented system allows for the shortest possible ejection sequence – less than 1/10 of a second – and also for partial ejection of about every two minutes. The fast ejections of this innovative technology result in higher yields and extreme precision even with smallest volumes with an accuracy of 10 percent. Fine adjustment of the ejection volume assures adaption to the process conditions. Fast, precise and defined ejection volumes logically result in highest solids outlet concentration. They minimize product losses and ensure a substantially increased quality yield.

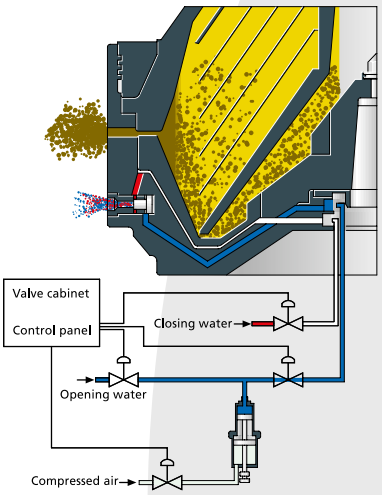




*The GEA hydro**stop** system ensures that even small volumes from 1.5 to 2 liters can be ejected reproducibly with an error margin of less than 10 percent.*

Ejection with metering piston at only 1.5 bar

High-purity water from ring systems is often employed as the operating water. Pressures of 1.5 to 2 bar usually prevail here. For this reason, GEA centrifuges with pneumatically-operated external metering pistons have a proven track record as they only require an operating water pressure of just 1.5 bar. The volume of opening water can be varied with an adjusting screw. The metering device is filled with water through the inlet valve. Compressed air is then injected through the valve into the lower chamber of the metering device. After the opening water valve has been operated, the air pressure applied to the piston of the metering device injects the adjusted volume of water into the opening chamber. The air pressure for the metering device should be 4–4.5 bar. A pressure converter installed in the metering device ensures correct ejection, overcoming the resistance of the piping, valve and injection chamber.



Precisely metered discharge volumes at only 1.5 bar water pressure.

Steam sterilization and cleaning

In many processes the centrifuge must be easy to clean and is also a part of a sterile, completely closed system. GEA ensures the sterility of such centrifuges according to the FDA specifications (Food and Drug Administration). This has been tested successfully and certified by the "Helmholtz Zentrum für Infektionsforschung" (HZI, formerly known as GBF) in Brunswick and has proven favorable in more than 800 steam-sterilized centrifuges installed world-wide.

Steam sterilizing (SIP) – securely sterile

Sterilizing our self-cleaning disk centrifuges is conducted on a stopped centrifuge with hot steam under pressure at a temperature of over 121°C. The sterilizing period depends on the type of bacteria and the cell count. After sterilizing, the centrifuge is filled with sterile air for cooling and blanketing until the next production run. Sterilization prevents cross-contamination of different fermentation products which are processed by the same separator. It also prevents toxic bacteria or living germs from escaping to the exterior and endangering people (biocontainment). This concept has been proven and published by the UCL (University of London).

Cleaning capability (CIP) – securely clean

Chemical CIP cleans process lines without the need to dismantle or open individual machines. Apart from hot water, 2 percent sodium hydroxide solution at a temperature of up to 80°C is used as the cleaning liquid. This is circulated until all organic sediments have been dissolved. 0.5 percent nitric acid solution at a temperature of up to 80°C is used to dissolve anorganic sediments. The last stage of the CIP chain is rinsing with high-purity water.

Good design

Apart from the specified steps of cleaning, a good machine design is very important. This particularly includes a good draining capability, the prevention of dead spaces, easily cleaned, smooth surfaces and an optimum wetting of the surfaces in contact with the product by the CIP media. GEA achieves this by installing spray nozzles at different points in the separator and ensuring the wetting by an riboflavin test, the employment of separators and system components with little dead space such as laser-welded spacers and diaphragm valves, surface roughness of $R_a \leq 0.8$ µm or better and a minimum pipe inclination of < 2 percent.

Automatically safe

GEA not only supplies centrifuges, but also fully automatic CIP systems. The cleaning cycle is controlled by a programmable logic controller. The program sequence for cleaning can be adapted according to the local requirements. The volume of cleaning agents is metered by the installed pumps. A conductivity sensor adjusts and monitors the concentrations of the media in the respective cleaning circulation systems.

Patented laser-welded disk stacks available in CSC/CFC 6/15 and aseptic 30/100/170.

Three-room GEA hycon® concept

When centrifuges are installed in clean rooms, special attention must be paid that no particles are emitted to the surroundings and that the machinery can be easily cleaned. At GEA, this is achieved by direct frequency converter drives (no centrifugal friction clutches), stainless steel control cabinets and the integration of machine components such as pilot valves and pressure reducing valves in a valve cabinet. A breakthrough development by GEA has been the three-room GEA hycon® concept.

To achieve a sterile process, the drive section (drive system and motor) and the process room (bowl and solids discharge) are sealed hermetically from each other by gas-lubricated slide ring seals. The design is such that the respective components are located apart from each other.

The three-room concept is implemented by the suspended bowl and solids discharge in the clean room. This precludes contamination of the process room by the drive equipment.

GEA's hycon® fully automatic clarifier – an optimal solution for the separation of blood plasma and plasma proteins.

GEA Service – For your continued success

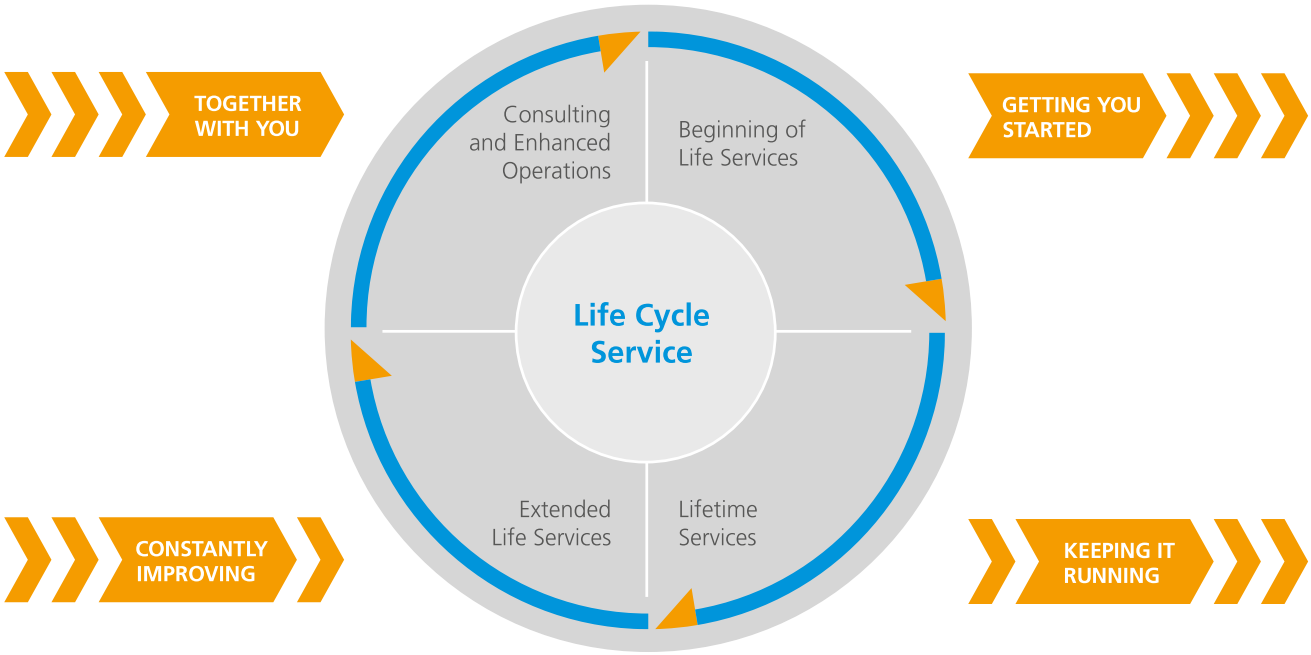
GEA Service offers dedicated teams of service experts. Our focus is to help our customers build, maintain, and improve their performance, market presence and competitive edge for the entire life cycle of their plants and equipment.

Partnering with GEA gives you the benefit of our world-renowned, customer-tailored service and recommended spares upgrade, modernization and optimization services.

With our support you can be certain that every piece of GEA equipment and technology will operate optimally from day one, and for its complete lifespan, to give you maximum return on your investment.

- Getting you started – Seamless support for instant productivity and performance
- Keeping it running – The cost-efficient way of ensuring safety and reliability
- Constantly improving – Sharing our knowledge to safeguard your investment
- Together with you – Enduring commitment to you and your business

OUR FOUR STAGES OF CONTINUED SUCCESS



GEA Pharma machine range

Machines are available in the aseptic and pure range for all pharma applications and as special solutions for specifc areas of application or production environments.

Machine type	Product throughput depending on the product and process conditions (in l/h)	Applications
Self-cleaning disk stack centrifuges		
FSC 6*	100–200	Pharmaceutical proteins, monoclonal antibodies (mAb), insulin, starter cultures and probiotic products, extracellular and intracellular enzymes
FSC 15*/PSC 15	250–500	
FSC 20*	500–1,000	
pure 30	500–1,800	
pure 100	1,800–3,700	
pure 170	3,000–6,000	
pure 300	6,000–12,000	
Self-cleaning dick stack centrifuges with nozzle		
pure 30	1,200–2,500	Pharmaceutical proteins, monoclonal antibodies (mAb), insulin, starter cultures and probiotic products, extracellular and intracellular enzymes
pure 100	3,000–6,000	
pure 170	5,000–9,000	
pure 300	10,000–20,000	
Steam-sterilized, self-cleaning disk stack centrifuges		
CSC 6	100–200	Aseptic processes, pharmaceutical proteins, monoclonal antibodies (mAb), insulin, human and veterinary vaccines, starter cultures and probiotic products
CSC 15	250–500	
CSC 20	500–1,000	
aseptic 30	500–1,800	
aseptic 100	1,800–3,700	
aseptic 170	3,000–6,000	
aseptic 300	6,000–12,000	

Machine type	Product throughput depending on the product and process conditions (in l/h)	Applications
Steam-sterilized, self-cleaning disk stack centrifuges with nozzles		
CFC 6	150–300	Aseptic processes, pharmaceutical proteins, monoclonal antibodies (mAb), insulin, human and veterinary vaccines, starter cultures and probiotic products, extracellular and intracellular enzymes
CFC 15	300–600	
aseptic 30	1,200–2,500	
aseptic 100	3,000–6,000	
aseptic 170	5,000–9,000	
aseptic 300	10,000–20,000	
Single Use disk stack centrifuges		
GEA kytero® Single Use disk stack centrifuge	10–150	Mammalian cells, bacteria
GEA kytero® Single Use disk stack centrifuge	40–600	
GEA kytero® Single Use disk stack centrifuge	600	
Chamber centrifuges		
PKB 28	300–600	Insulin, pharmaceutical proteins
PKI 45	500–1,000	
BKB 8	100–200	Human blood plasma
BKB 28	300–600	
BKI/BKB 45	500–1,000	
Hyperconcentrators–hycon®		
PSH 30	500–1,500	Aseptic processes, insulin, pharmaceutical proteins
CSH 30	500–1,500	
BSH 30	500–1,500	Aseptic processes, human blood plasma
Solid-wall bowl centrifuges		
FTC 1*	30–60	Technical centers and pilot plants, human blood plasma
Other self-cleaning disk stack centrifuges		
pathfinder GMP FSC 1*/5*/8*	15–300	Technical centers and pilot plants
Easyscale 10*	150–300	
FSD 1*	20–50	

** This design will be offered without polished surfaces and limited GMP documentation.*

engineering for
a better world

We live our values.

Excellence • Passion • Integrity • Responsibility • GEA-versity

"Engineering for a better world" is the driving and energizing principle connecting GEA's workforce. As one of the largestsystems suppliers, GEA makes an important contribution to a sustainable future with its solutions and services, particularly in the food, beverage and pharmaceutical sectors. Across the globe, GEA's plants, processes and components contribute significantly to the reduction of CO_2 emissions, plastic use as well as food waste in production.

GEA is listed on the German MDAX and the STOXX® Europe 600 Index and also included in the DAX 50 ESG and MSCI Global Sustainability indexes.

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