



Purity is key

Pharmaceutical and biotech
production with GEA centrifuges



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ONE GEA – ALL COMPETENCIES

From upstream treatment to the finished product, from initial tests to global production – GEA solutions for you cover the entire range of pharmaceutical and biotech operations.

Purity is key

GEA's decisive approach to purity keeps energizing the pharma and biotech industry. Join us and transform your ideas into pure product, pure processes and pure efficiency in line with your needs.

Pure product

Ensure optimal processing to make the best pharmaceuticals or biotech products you can. Leading manufacturers and developers achieve this with GEA.

Pure process

Safeguard your operation against hazard and contamination. GEA protects your future with hygiene technology at the forefront of progress.

Pure efficiency

Turn our industry and engineering know-how into high yield, full reliability and maximum cost-efficiency for your plants and processes.



Pure product

Finest, reproducible separation of process media

A key solution for cell harvesting, product clarification, plasma fractionation and numerous other processes, centrifuge technology is driving successful product development and production in pharma and downstream biotech operations.

GEA centrifuges and pre-assembled process station skids ensure outstanding purity of separation for finest pharmaceuticals, including antibodies, vaccines, blood plasma components and other sensitive products.

Exact, reproducible separation

GEA customers benefit from meticulous engineering and manufacturing of every machine. Thanks to advanced technical concepts and effective customization options, the separation of solids and liquids from liquid process phases is carried out with utmost precision, reducible and exactly to process specifications.

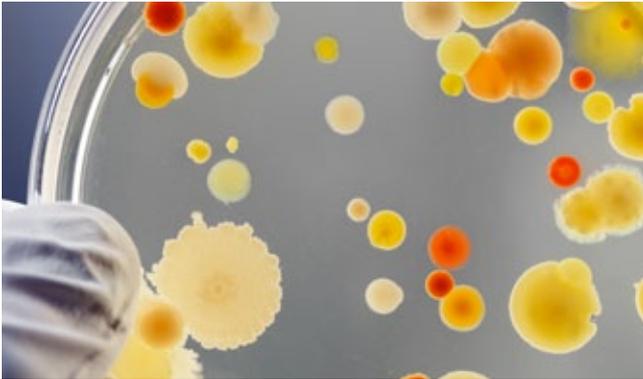
Gentle product processing

Sophisticated feed and discharge systems, only available from GEA, handle the sensitive product with maximum care during the separation process. Essential product properties, such as cell integrity and cell vitality, are kept intact to ensure superior quality of the final product.



Pure process

Steam-sterilization to ensure biocontainment



Safe, accurate manufacturing processes are essential requirements in pharma and biotech operations where any process failure can endanger the well-being of employees and consumers and jeopardize the reputation of the brand.

Separation technology by GEA includes state-of-the-art options to protect your process – from steam-sterilizable machines to aseptic two-room solutions.

Steam-sterilizable equipment

In many processes, e.g. the production of vaccines and sera, a strictly aseptic process is required. GEA ensures this level of safety with an industry-leading range of centrifuge models that can be equipped for steam sterilization.

Combined with protective hydro-hermetic feed systems on GEA machines, steam sterilization prevents cross contamination of products processed in the same machine. Toxic matter or live germs can not escape into the environment.

Perfect cleanability

All internal and external surfaces on GEA centrifuges for the pharma and biotech industry are designed and built for safe and efficient cleaning.

- Full CIP capability
- All materials with product contact in high-alloy stainless steel, 316L or better
- Product contacted surface quality of 0.8 miron. Surface quality of 0.5 miron available under request.
- Laser-welded disk spacers up to certain machine size



Pure efficiency

High yield and reliability at lowest TCO

From sophisticated mechanical design to automated control functions: GEA centrifuge expertise leaves nothing to chance in securing maximum performance for you, saving time, effort and energy.

High yield

Our centrifuges can be fully automated and optimized to secure the highest yield and full process control in every application.

Reliable operation

All mechanical parts and control functions on GEA machines have been designed for continued, dependable service. GEA centrifuges are also highly energy-efficient for sustainable, environment-friendly operation.

Superior principle

Compared to wear-prone filtration systems for product separation, extraction and clarification, GEA centrifuges are by design more effective and reliable, requiring no consumables such as filter materials for operation.





NEW: Unique flexibility

Introducing the new GEA pharma centrifuge series with the GEA flexChange Concept

The new GEA flexChange Concept for pharma centrifuges is here. GEA introduces the world's first three-in one centrifuge concept for pharma and biotech applications, offering superior flexibility to meet changing demands and conditions.

The GEA flexChange Concept comprises three exchangeable centrifuge bowls for numerous different separation processes. Only one machine is required. This is an ideal solution for industrial processing services and other operations that frequently change products. Your perfect choice.

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

One machine – up to three bowls

The GEA flexChange Concept offers up to three interchangeable centrifuge bowls to complement the Integrated Direct Drive and sophisticated bowl housing. All bowl variants are available in different bowl sizes.

Integrated directdrive

The water-cooled, gearless drive requires the smallest possible machine footprint, saving space as well as costs for expensive cleanroom refurbishing. The drive greatly reduces power consumption, noise, machine wear and maintenance effort.

Full ASME BPE 2014 compliance

The entire concept and its components are certified according to ASME BPE 2014.



CIP-able

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.

Optional SIP steam-sterilizable versions

All bowl types and sizes are available with or without the ability for steam sterilization in aseptic standard.



CHANGING CONDITIONS?
JUST SIMPLY ADAPT.

New, multi-purpose GEA flexicon nozzle centrifuge bowl

Infinitely adjustable nozzle for high solid loads

Ready for more than 150 different products: The new, versatile nozzle centrifuge bowl in the GEA flexChange Concept offers superior adaption options for innumerable applications and products without technical change.

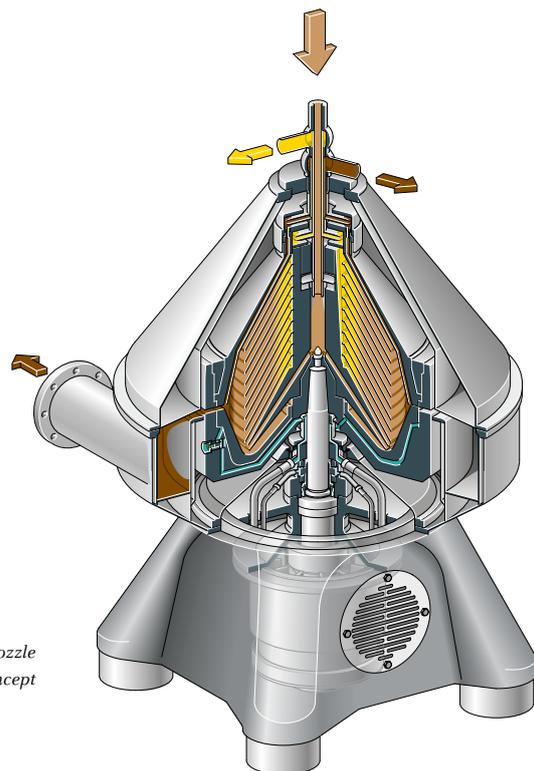
The gentle product guiding and nozzle functions protect shear-sensitive products, for maximum product quality. The bowl can process high loads of (flowable) solids (up to 15 vol %).

The operating parameters for the nozzles can be fine-tuned from the HMI control unit by means of back pressure variation, without having to open the machine. This is possible not only between batches but also during processing – a world-first from GEA to deliver highest yield and precision of separation.

By carefully balancing the separation process, reproducible solid concentrations in the output can be achieved even with changing concentrations in the feed.

Applications e.g.:

- Starter cultures, probiotics
- High cell density fermentation



Machine with GEA flexicon nozzle bowl in the GEA flexChange Concept

Two self-cleaning centrifuge bowl options

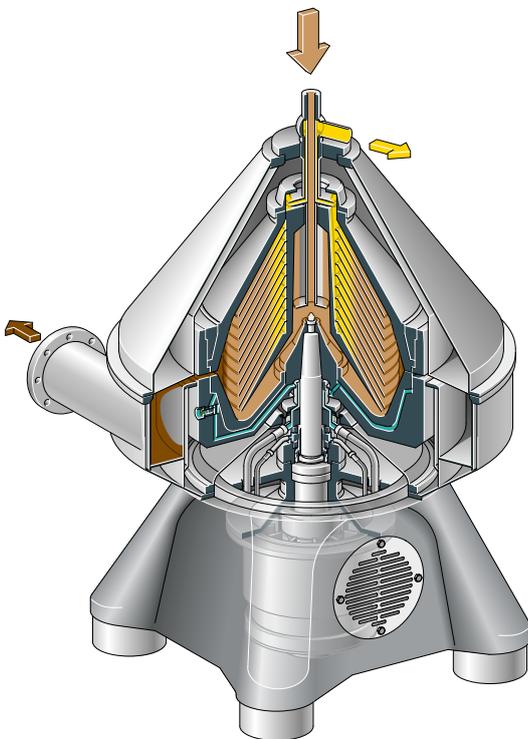
Highest yields with low solid loads

This bowl option in the GEA flexChange Concept offers highest yield and best separation results for products with low solids load (up to 5 vol %, depending on flowrate).

The bowl features a small solids holding space and a large clarification area optimized to the particle size for more efficient clarification even of the smallest particles. It can produce purest supernatant due to its enlarged separation surface.

Applications e.g.:

- Human and animal vaccines
- Hormones
- Pharmaceutical proteins



Machine with self cleaning bowl for low solid loads in the GEA flexChange Concept

Minimized losses with medium solid loads

This third bowl option offers highest yield and best separation results for products with medium solids load (up to 10 vol %).

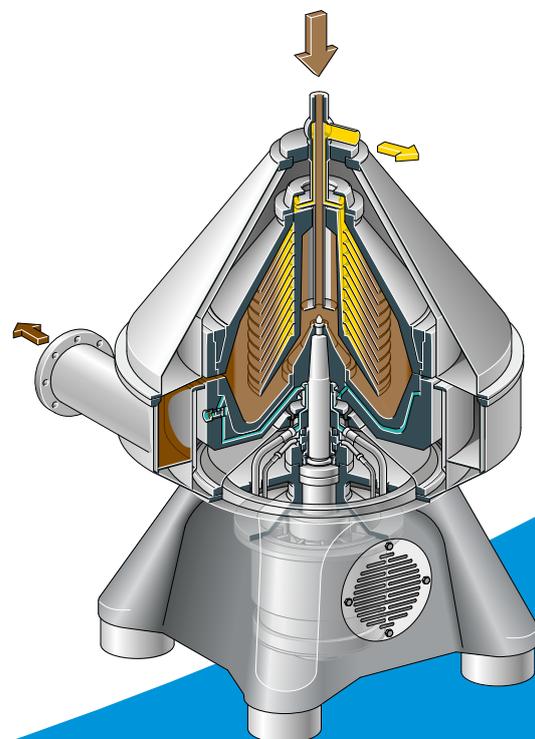
The bowl features a large solids holding space and a small clarification area optimized to the particle size for a reduced number of ejections.

Special benefits are:

- Minimized product loss
- More stable processes
- Smooth product

Applications e.g.:

- Insulin
- Probiotics
- High cell density fermentation



Machine with self cleaning bowl for medium solid loads in the GEA flexChange Concept

NEW: Unique compliance

Pioneering ASME BPE 2014 compliance

As an industry-first, GEA ensures ASME BPE 2014 compliance for all components in the new GEA flexChange Concept.

American Society of Mechanical Engineers (ASME) certification

All three bowls in the GEA flexChange Concept have been thoroughly safety-tested.

Upon request, ASME BPE conformance certificates are available from GEA to support. This greatly facilitates the approval process for the entire pharmaceutical system and ensures uncompromised operation. The state-of-the-art hygienic design concept assures highest CIP and SIP results.

Steam sterilization

All three GEA flexChange centrifuge bowls are equipped for state-of-the-art CIP cleaning, and are available in versions equipped for safe SIP sterilization with steam.



GMP-qualified, FAT-tested machines

For manufacturers of pharmaceutical products, GMP-compliant plant qualification is a prerequisite for obtaining and maintaining the ability to design and manufacture according to contract or purchase order specifications.

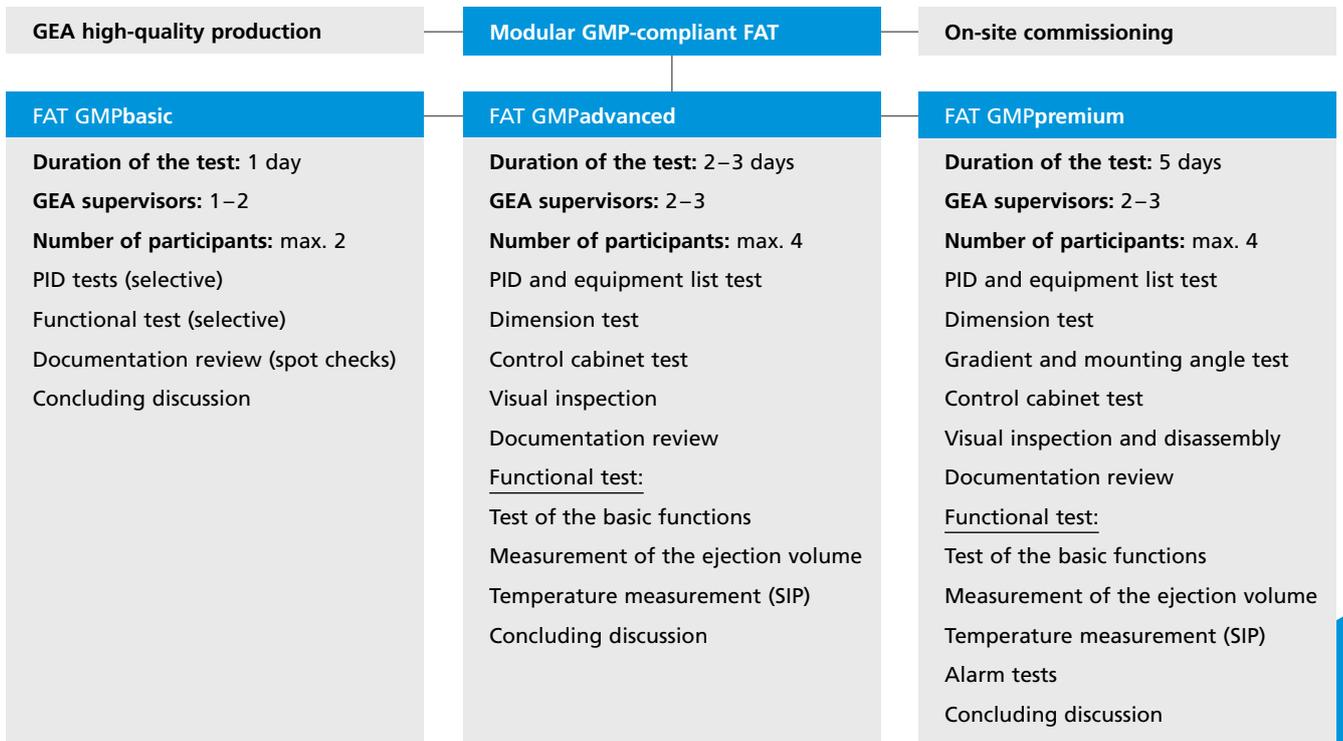
Good Manufacturing Practice (GMP) qualification

GMP-compliant Factory Acceptance Tests (FAT), an important GEA service, take place after the preliminary GMP test in Oelde, Germany. The test includes full documentation and is verified in the form of an installation test (IQ) and a functional test (OQ).

All GEA centrifuges are assessed according to the quality requirements determined prior to installation and for GMP compliance.

Modular Factory Acceptance Test (FAT) packages

The pharmaceutical test bay at GEA offers flexible FAT concepts that facilitate approval by regulatory authorities and ensure the faster on-site commissioning of the centrifuge package unit. Depending on the scale and depth of the individual test, three FAT concepts are available.



Global test center network

Innovate, partner and prosper with GEA

Driving your future

By combining advanced in-house technology with a thorough understanding of the processing industries, we help our customers to maximize their development results, gain more know-how and discover additional opportunities for their applications.

Driving solutions

From new product and feasibility trials to scale-up studies, training programs and process support, we believe that our services greatly benefit anyone involved in industrial R&D, equipment selection, process optimization and product development.

Driving technologies

Overcoming technical barriers throughout the entire process chain, there's no limit to where the GEA global network of test centers can take your research.

The GEA global network of test facilities offers teams of experts who work closely with their customers to optimize procedures and evaluate their products, enabling them to achieve their process and production goals.

GEA test center Separation

At the GEA test center, customers can test both new and established products in a wide range of separation operations or perform comparative process studies with our skilled operators. Other test programs in GEA test centers around the world can be involved to test entire manufacturing lines.

On-site trials and test centers

Centrifuges are available for process trials at the operator's site to assess the feasibility and profitability of individual process steps and combined operations.

For small test centers in the pharma and biotech industry the GEA *pathfinder* is available as a special test centrifuge solution. It is designed for high-precision product development applications and secure scale-up to industrial production.

Prosper with GEA

Book your ticket to success at gea.com/contact



GEA pathfinder

GEA Global Test Center



Monoclonal antibodies (mAb)

Shear-sensitive separation of mammalian cells
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 centrifuges 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 centrifuges 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.



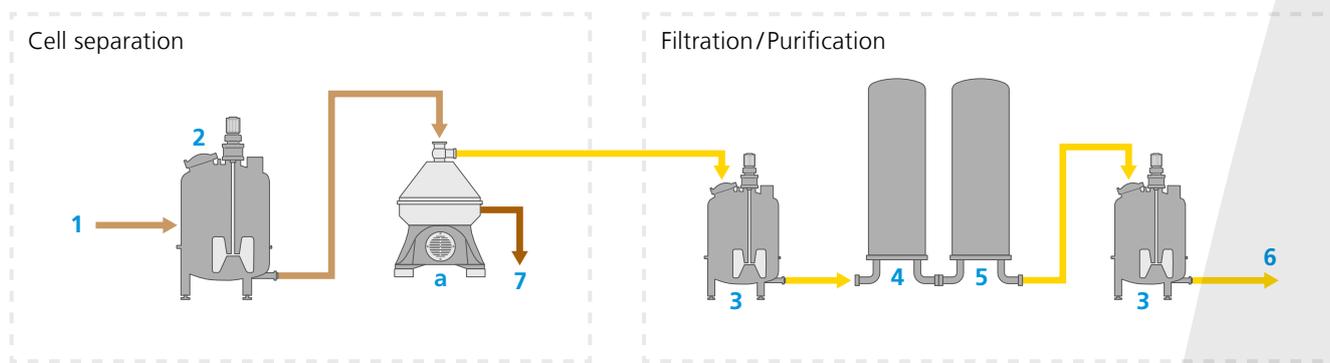
Economical plug & play skids

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 centrifuges 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

GEA CSE 170 CENTRIFUGE SKID

Ensuring purity and high yield: The GEA solution for mAb harvesting. Sensitive to the cells thanks to the unique hydrohermetic feed concept. Pre-assembled as a complete process unit on an easy-to-install skid including all feed and control components.

Insulin

Covering numerous steps with one modular machine type

In the efficient production of insulin, GEA centrifuges 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). GEA nozzle centrifuges are designed from a sophisticated modular concept so the same machine can be furnished and 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 centrifuge 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 two-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.

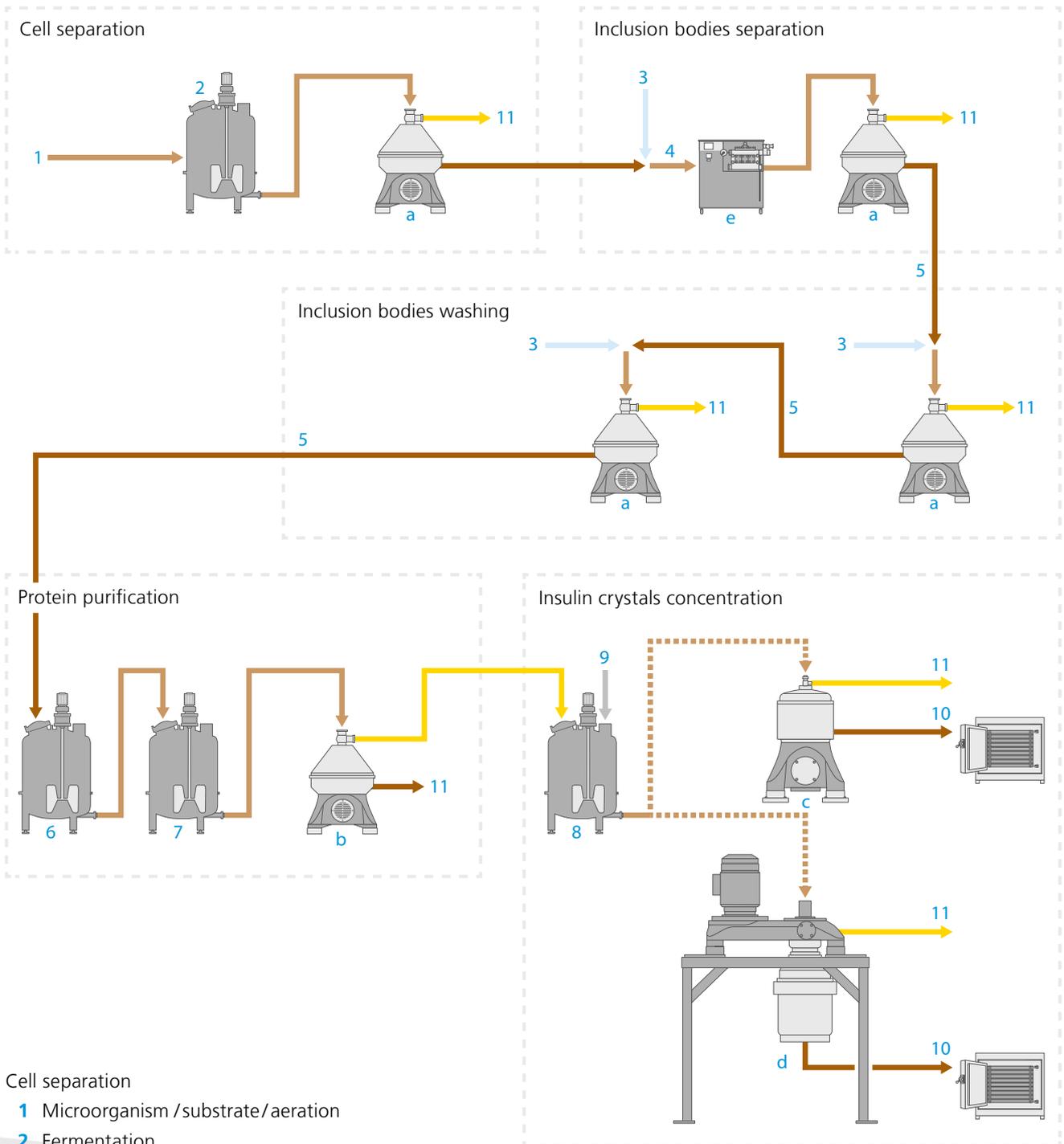
For this task, small chamber centrifuges GEA PKB 28 or PKI 45 are available. These models have been specially optimized for uncomplicated manual opening of the machines and simple recovery of solids, making the process as fast and fail-safe as possible.



GEA CFI 100 NOZZLE CENTRIFUGE

A GEA centrifuge with the new multi-purpose GEA flexicon nozzle bowl – the bowl is exchangeable within the GEA flexChange Concept.

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

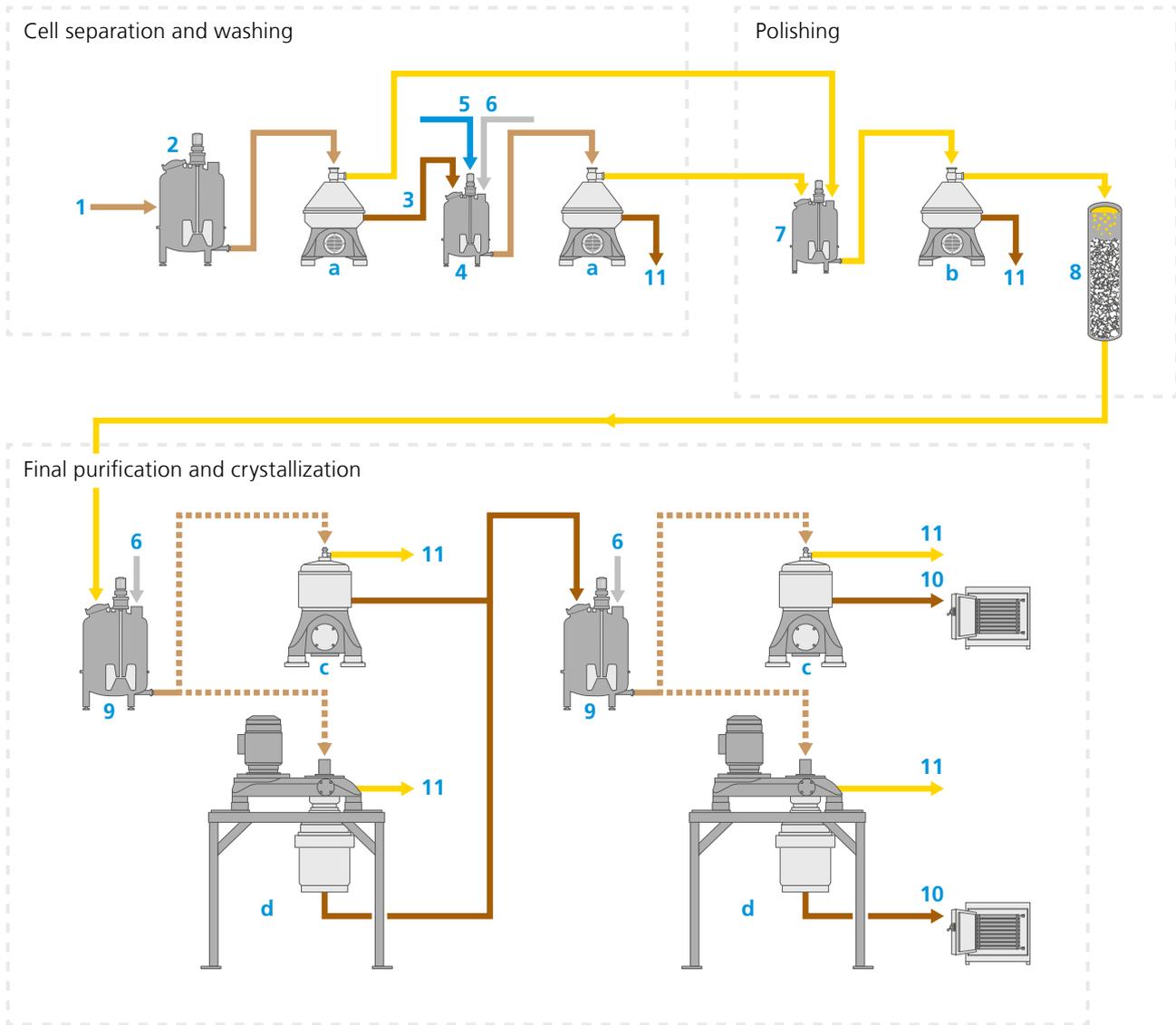
Insulin crystals concentration
8 Crystallization tank
9 Additives
10 Insulin crystals to freeze dryer

a Self-ejecting or nozzle centrifuge
b Self-ejecting centrifuge
c Chamber bowl centrifuge

d GEA **hycon** (two-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** (two room concept with closed solids handling)

- 11 Waste

- Yellow arrow → Supernatant
- Brown arrow → Solids



GEA HYCON – THE CLEANROOM SOLUTION

The unique aseptic two-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, biosafety 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 centrifuge 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

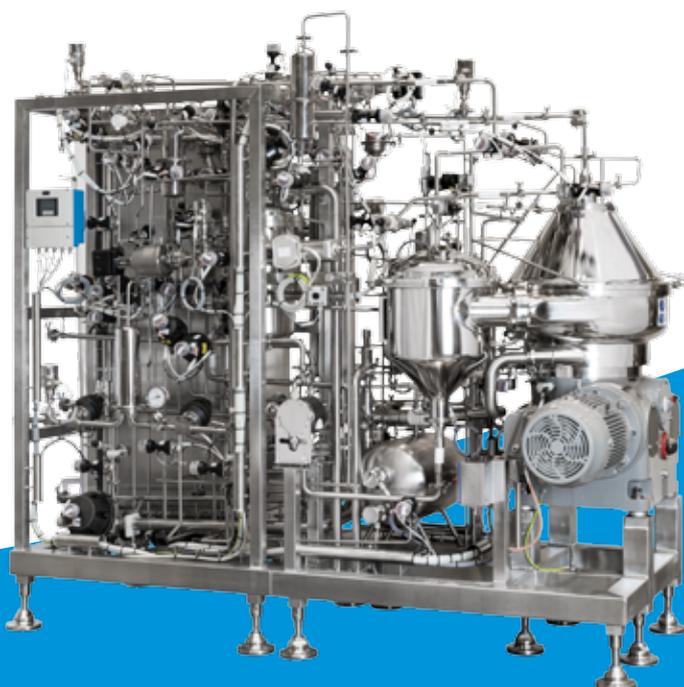
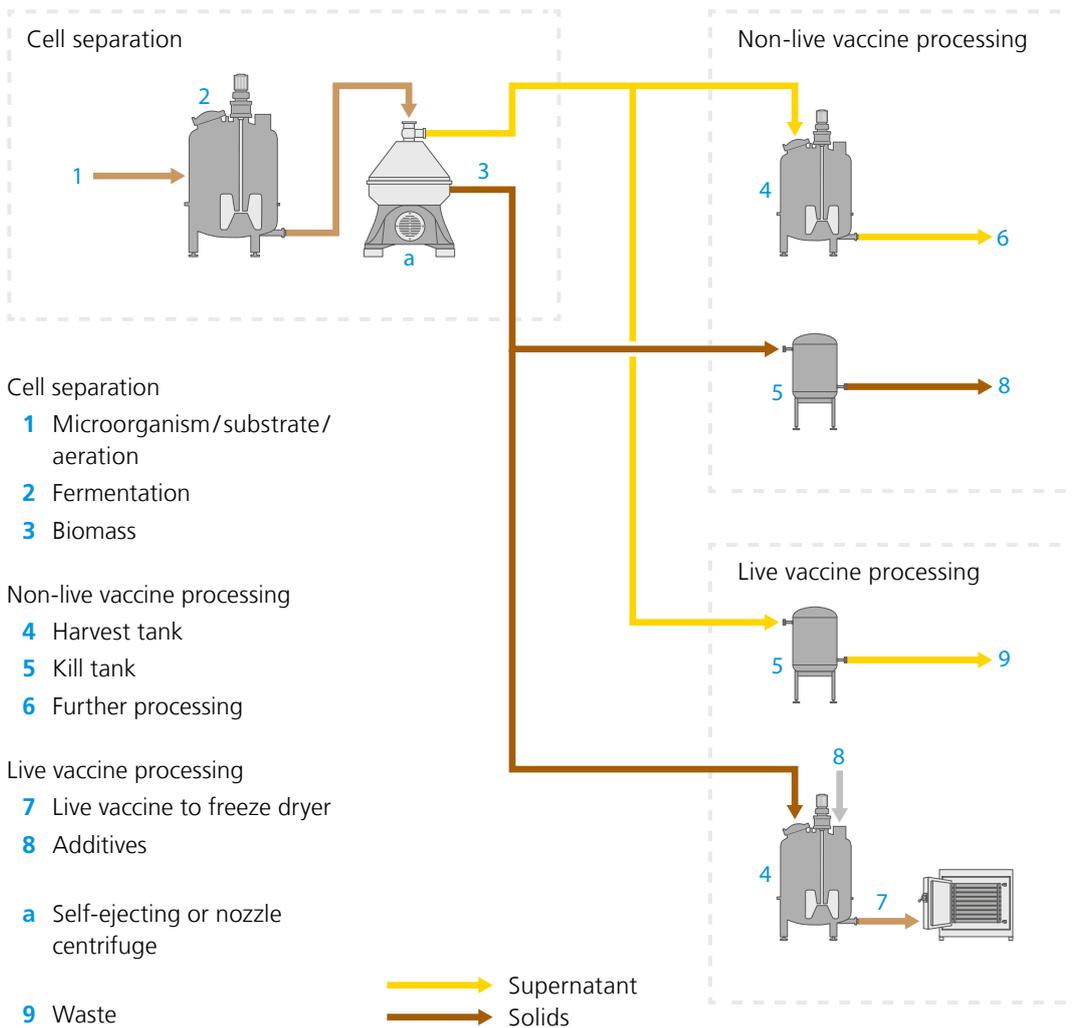
GEA centrifuges for vaccines are all available in suitable designs for steam-sterilization – the ideal solution to prevent cross-contamination of consecutive batches and to protect the operator when opening the centrifuge.

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 centrifuges, ensuring particularly careful handling of the product during the centrifugation process.

HUMAN AND VETERINARY VACCINES



GEA CSC 20 WITH FULLY AUTOMATIC SIP PACKAGE

Steam-sterilizable and completely sealed, GEA CSI/CSE/CSC centrifuges for vaccine processing are designed for maximum biosafety and containment.

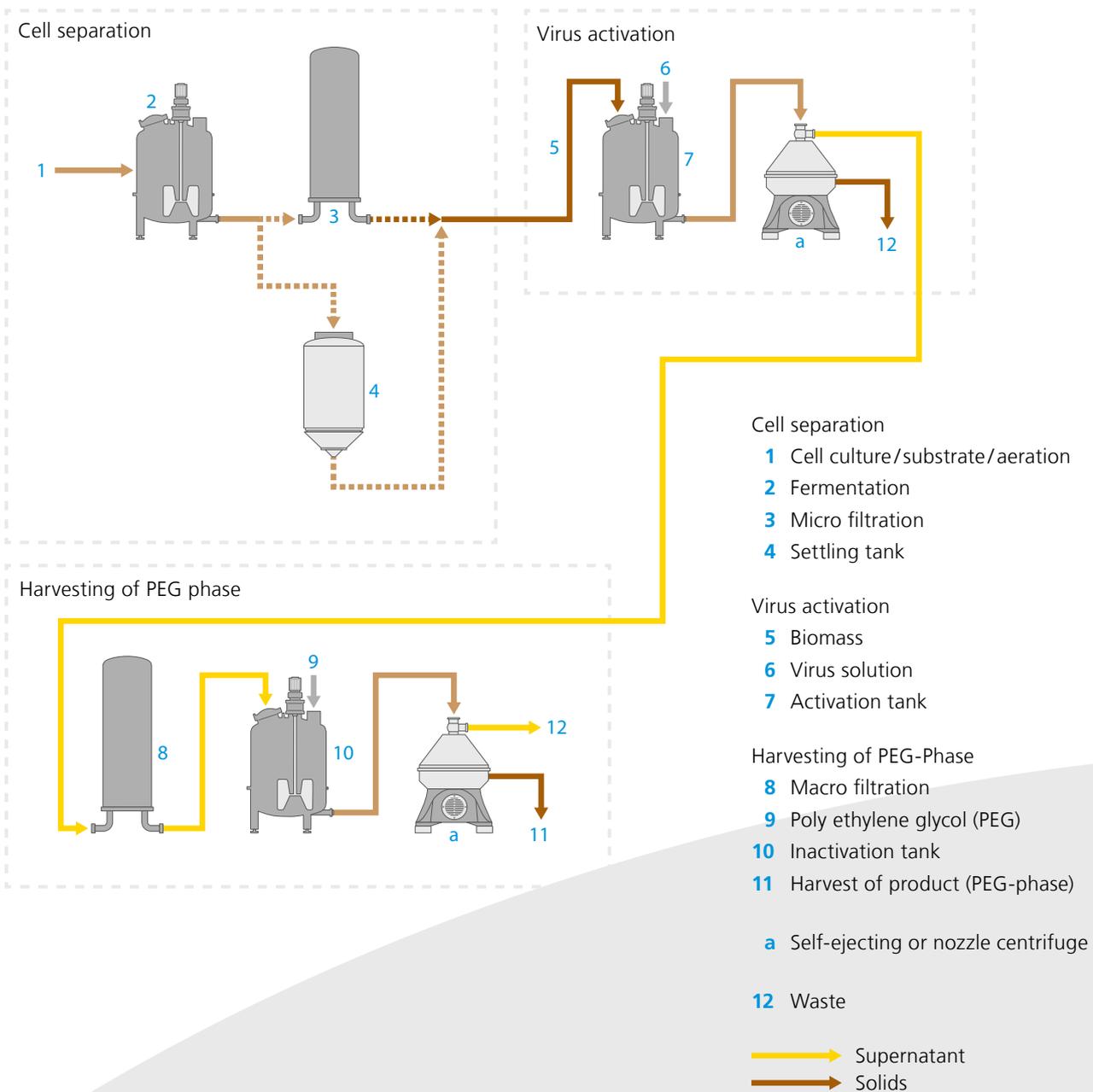
Veterinary vaccines: Protection from active viruses

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 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.

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



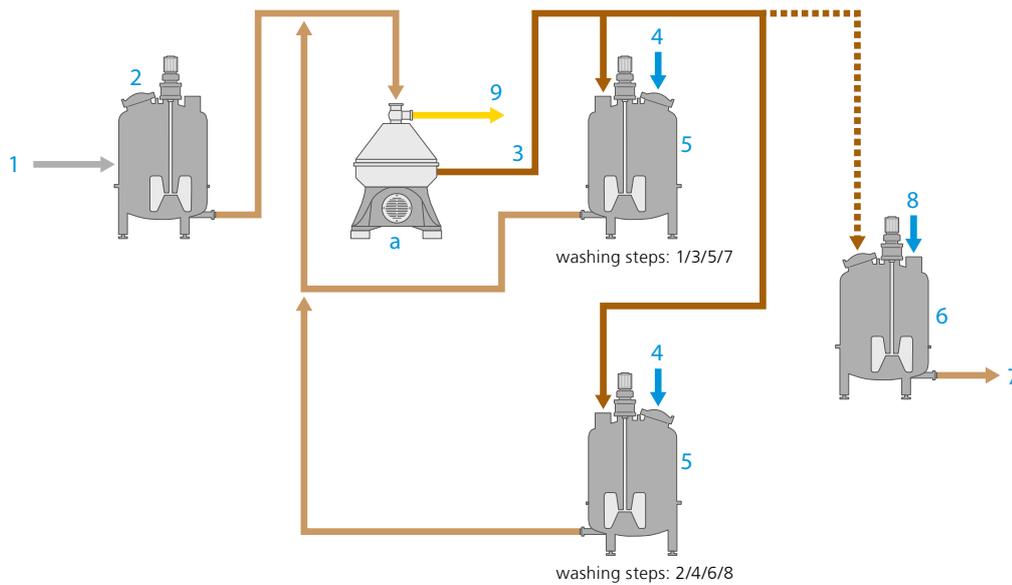
Streamlined production of adjuvants

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 centrifuges, 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, minimizing 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 centrifuges 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 centrifuges by 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

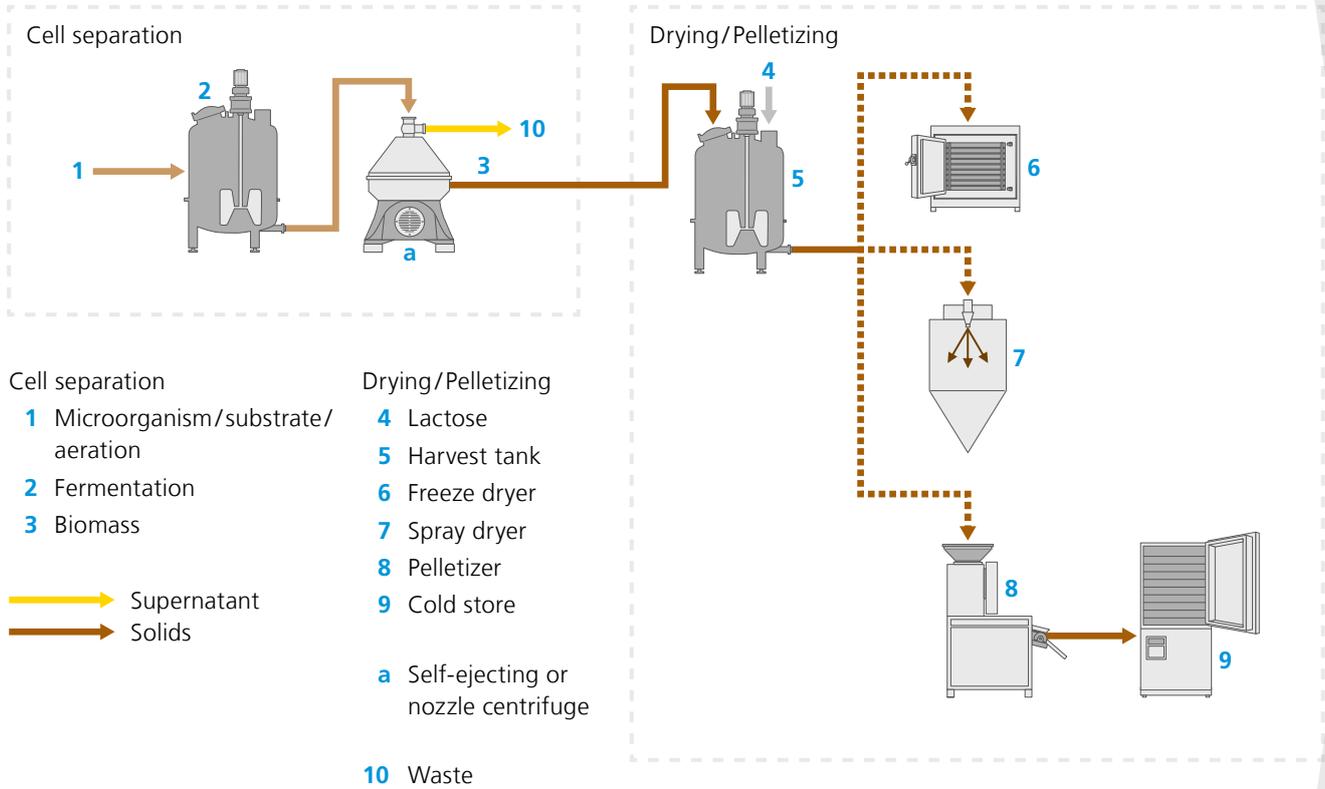
In addition to the CIP routines, nozzle centrifuges from GEA are designed to be sterilized with saturated steam. This safely prevents cross-contamination and ensures the purity of changing product types and batches. The pressure-tight product processing zone of the centrifuge and its drive unit are separated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

Reproducible and scalable results

The separation results with these centrifuges 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 centrifuges to facilitate production control and product development.

STARTER CULTURES



GEA CFI 300 CENTRIFUGE SKID

For high cell vitality and multi-purpose operation: Nozzle centrifuges complete with gentle feed and discharge systems, multiple options for operation and modification, and cooling tank.

Human blood plasma

Fractionation at exact target temperatures

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

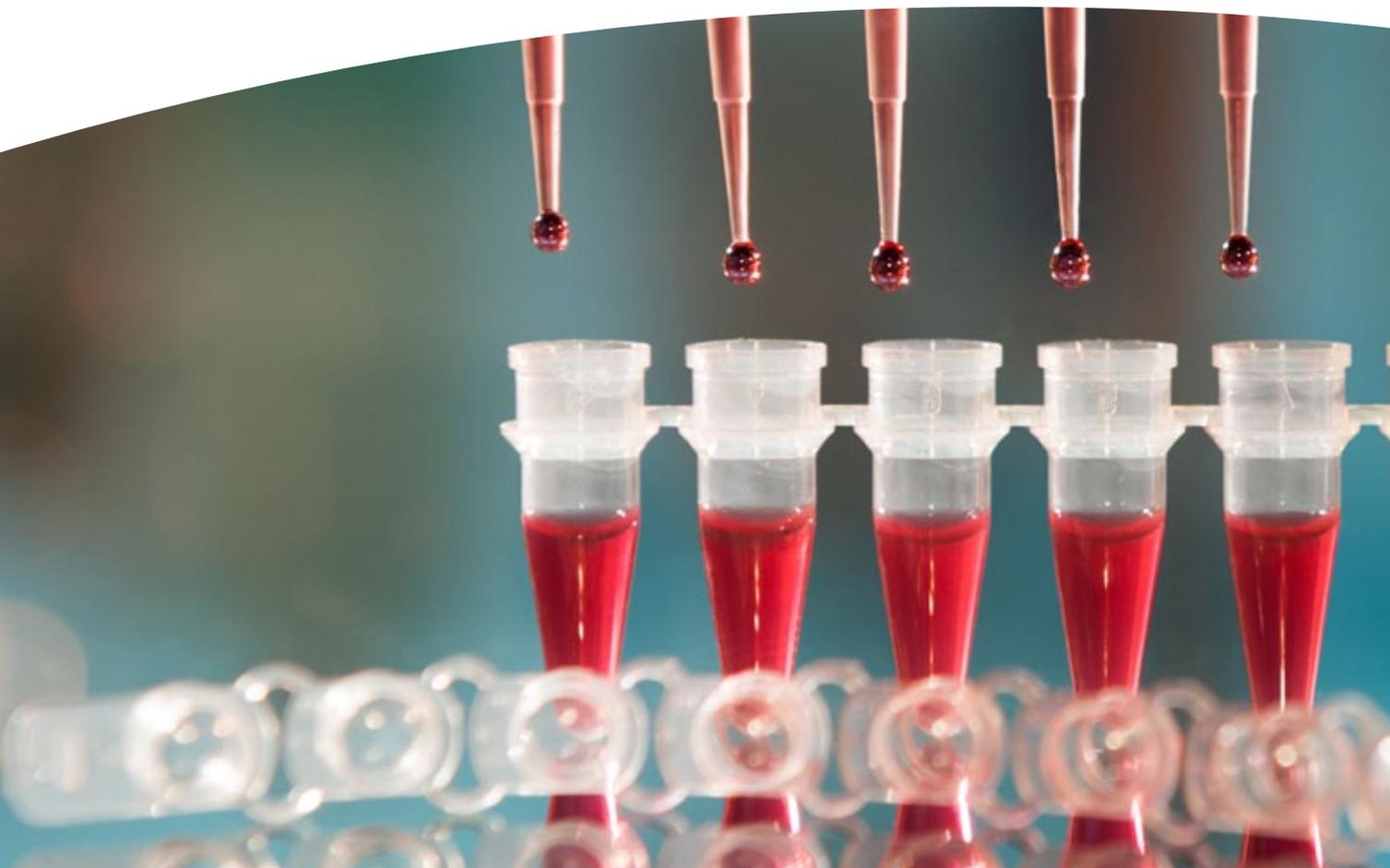
The permitted temperature range for processing blood plasma and plasma components is merely $+2^{\circ}\text{C}$ to -7°C and must be maintained under all circumstances so as not to render the sensitive product unusable. To ensure maximum safety, a direct cooling system is integrated into GEA chamber 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 $\pm 1^{\circ}\text{C}$.

One machine type for all fractionation cycles

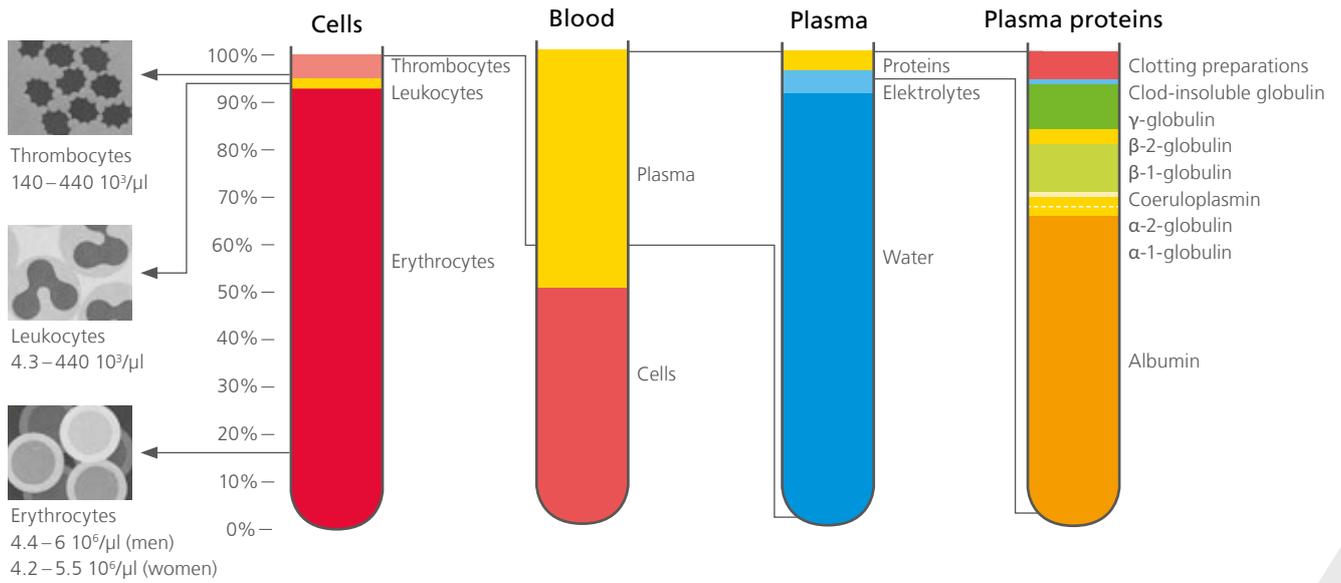
GEA centrifuges for blood plasma fractionation can be applied to all the different steps of the Cohn fractionation process, presenting a particularly economical solution to facilitate efficient plant management as well as future changes in processes or capacities.

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,

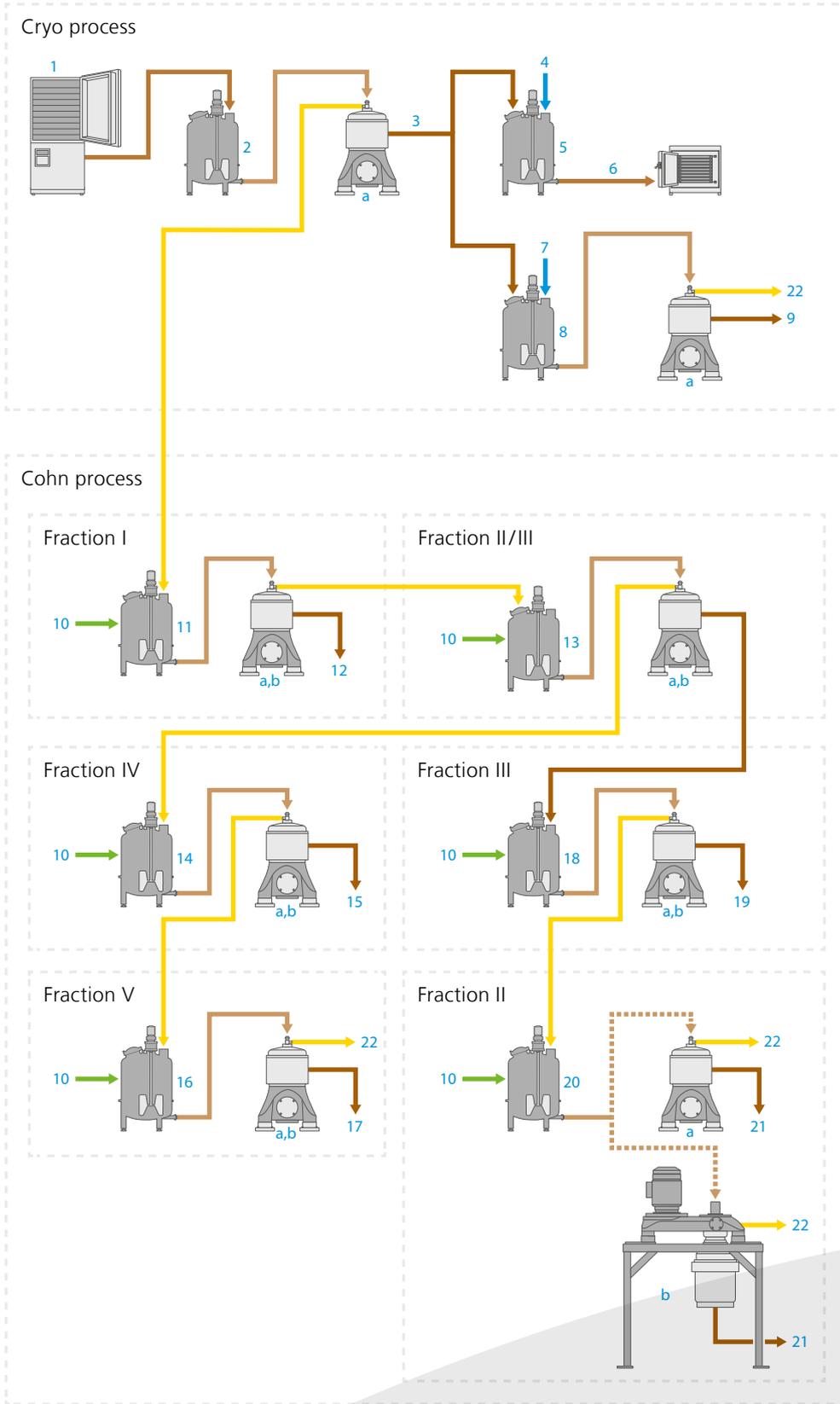


alcohol concentration and pH in order to deliver individual fractions such as fibrinogen, gamma globulin, alpha and beta globulin and albumin.

Thanks to extensive options for adjusting speed, separated particle sizes and discharge volumes, the same type of GEA centrifuge 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)
 - 22 Waste

- a Chamber bowl centrifuge
 - b **hycon** (two room concept with closed solids handling)
- 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.

Pre-configured skids with fail-safe GEA plasmacool unit

State-of-the-art centrifuge models for blood plasma fractionation, such as GEA BKB 28 or the GEA BKI 45, are available pre-configured and pre-mounted on machine skids with integrated control units and connections. The latest addition to these skids

is GEA plasmacool – a completely independent, dedicated cooling system for the centrifuge that ensures safe product handling at permitted temperatures.

Aseptic GEA hycon two-room concept

In addition to classic chamber centrifuges, the groundbreaking GEA hycon solution is also available for the blood plasma fractionation process. GEA hycon is a two-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 CENTRIFUGE 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.

Recovery of extracellular and intracellular enzymes

Wear-protected recovery at competitive costs

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 centrifuges 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 centrifuges 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 centrifuges.

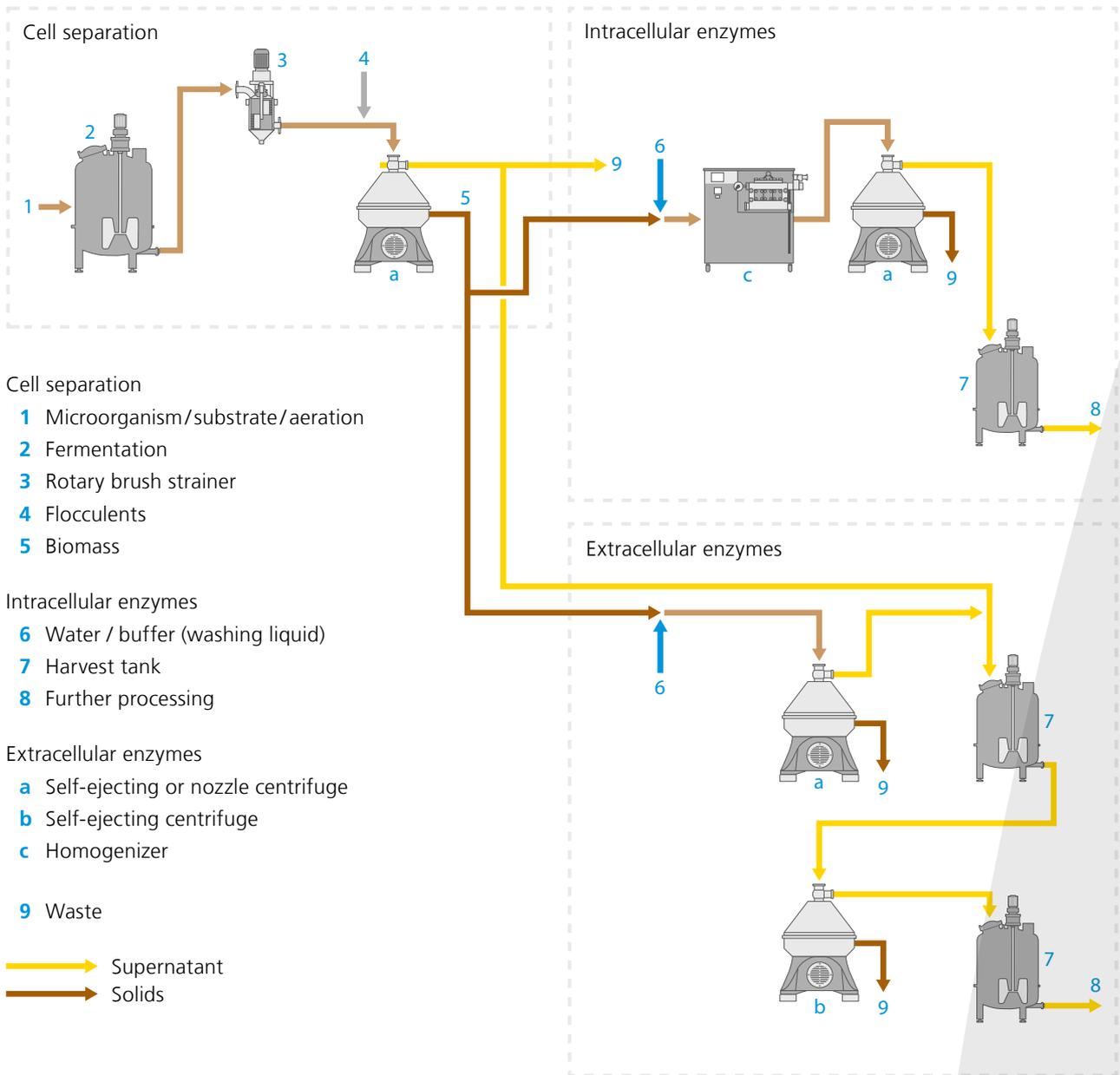
Recovery of extracellular and intracellular enzymes

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



GEA FSI 300 CENTRIFUGE SKID

The economical low-abrasion solution with easy-to-maintain external nozzle: the much-applied GEA nozzle centrifuge for every step in enzyme washing and polishing.

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 directdrive

GEA centrifuges for pharma are equipped with the integrated GEA **directdrive** 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 **directdrive** 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

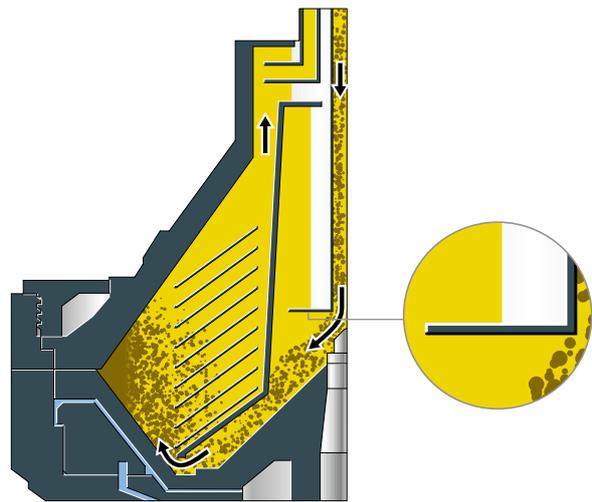
considerably more quietly than an air-cooled equivalent. By integrating sound insulation in the centrifuge, noise levels have been substantially reduced. The operating noise (sound pressure level) of these centrifuges is less than 78 dB (A). External sound insulation measures are not necessary.

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 circumferential speed of the bowl. The patented GEA hydrohermetic inlet has been successfully tested and published on mammalian cell cultures by the University of Bielefeld.



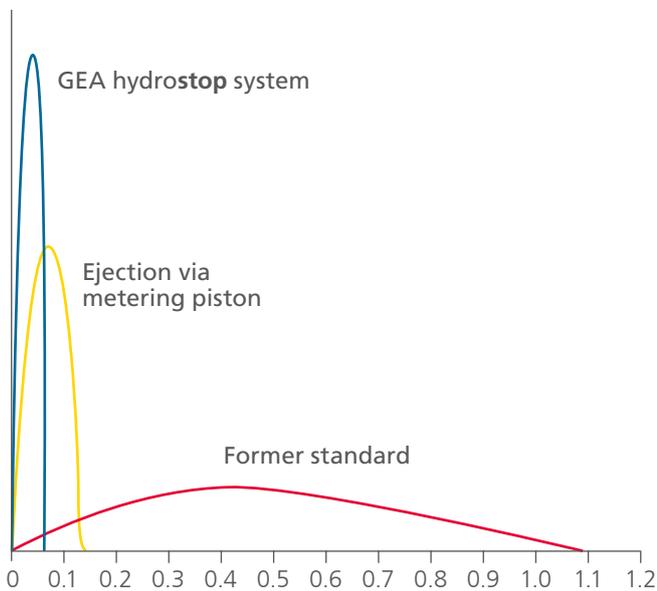
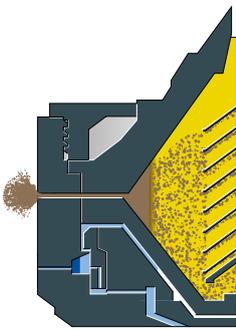
Machine with integrated GEA **directdrive**.



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 hydrostop

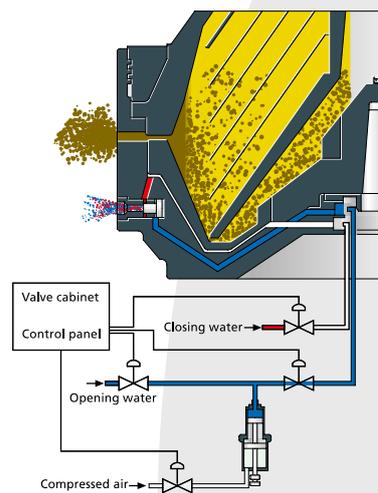
The GEA hydrostop ejection system can be adjusted precisely and reproducibly to specific requirements regarding the concentration of solids. This patented system allows for the shortest possible ejection sequence – less than 1/10 of a second – and also for partial ejection of about every two minutes. 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 hydrostop 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 a riboflavin test, the employment of separators and system components with little dead space such as laser-welded spacers and diaphragm valves, surface roughness of $R_a \leq 0.8 \mu\text{m}$ 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.



Two-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 two-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 two-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.



Special low-temperature solutions

Chamber centrifuges: hundreds in operation

Fractionation by the Cohn process is executed by reliable, cooled chamber centrifuges. GEA blood centrifuges operate in performance ranges from 60 to 1000 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.

The compliance with a narrow temperature range of +2 to -7°C is important for the 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 addressed 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.



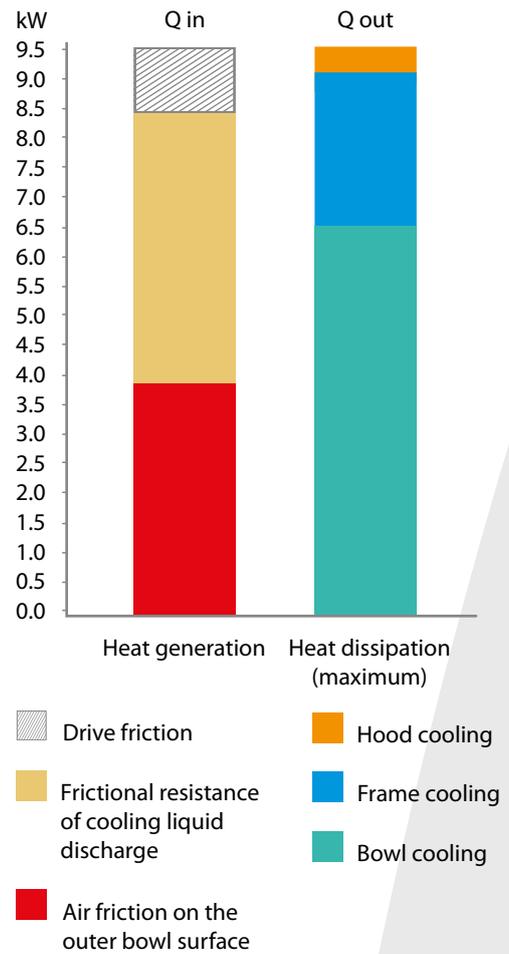
UTMOST SAFETY WITH GEA PLASMACOOL.

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.

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 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 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

Machine range

Machine type	Product throughput depending on the product and process conditions (in l/h)	Applications
Self-cleaning disk stack centrifuge		
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	
PSI 30	500–1,800	
FSI 100*/PSI 100	1,800–3,700	
FSI 170*/PSI 170	3,000–6,000	
FSI 300*/PSI 300	6,000–12,000	
Steam-sterilized, self-cleaning disk stack centrifuge		
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	
CSI 30	500–1,800	
CSI 100	1,800–3,700	
CSI 170	3,000–6,000	
CSI 300	6,000–12,000	
Steam-sterilized centrifuges with nozzle centrifuge		
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	
CFI 30	1,200–2,500	
CFI 100	3,000–6,000	
CFI 170	5,000–9,000	
CFI 300	10,000–20,000	
Chamber centrifuge		
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 centrifuge		
FTC 1*	30–60	Technical centers and pilot plants, human blood plasma
Self-cleaning disk stack centrifuge		
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.



We live our values.

Excellence • Passion • Integrity • Responsibility • GEA-versity

GEA is a global technology company with multi-billion euro sales operations in more than 50 countries. Founded in 1881 the company is one of the largest providers of innovative equipment and process technology. GEA is listed in the STOXX® Europe 600 Index. In addition, the company is included in selected MSCI Global Sustainability Indexes.

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