

## Alfa Laval in brief

Alfa Laval is a leading global provider of specialized products and engineered solutions.

Our equipment, systems and services are dedicated to helping customers to optimize the performance of their processes. Time and time again.

We help our customers to heat, cool, separate and transport products such as oil, water, chemicals, beverages, foodstuffs, starch and pharmaceuticals.

Our worldwide organization works closely with customers in almost 100 countries to help them stay ahead.

## How to contact Alfa Laval

Up-to-date Alfa Laval contact details for all countries are always available on our website at [www.alfalaval.com](http://www.alfalaval.com)



## Extracting the essence of life

Process solutions and components for the biotechnology and pharmaceutical industries





# Cultivate your investment

Significant investments in time and money are required to bring a drug or vaccine to market. For this reason, pharmaceutical and biotechnology companies are demanding that the process equipment they use meet – and even exceed – their requirements for cleanliness, reliability and performance.

With its leading-edge technologies in separation, heat transfer and fluid handling, backed up by a global service network of highly trained process engineers, Alfa Laval can help you to fulfill the most rigorous requirements of your processes and cultivate your investment.



# Overview

## Layers of experience



Alfa Laval is the world's leading provider of solutions and components for the biotechnology and pharmaceutical industries. Our market position is due not only to the high performance of our equipment, but also to our process expertise, as well as continuous product innovation, pursuit of quality and our global service network.

We are committed to helping you fulfill your most rigorous requirements, from the process and equipment levels all the way down to the cellular level.

### **A long tradition of continuous innovation**

Our customers benefit from a long tradition of continuous product development that started with the world's first centrifugal separators, followed by leaps of innovation over the decades. Our equipment is used in a multitude of industries, providing us with the unique opportunity to share cutting-edge knowledge. The result is a depth of technical expertise and process experience that contributes to the development of future technologies.

### **An unrelenting pursuit of quality**

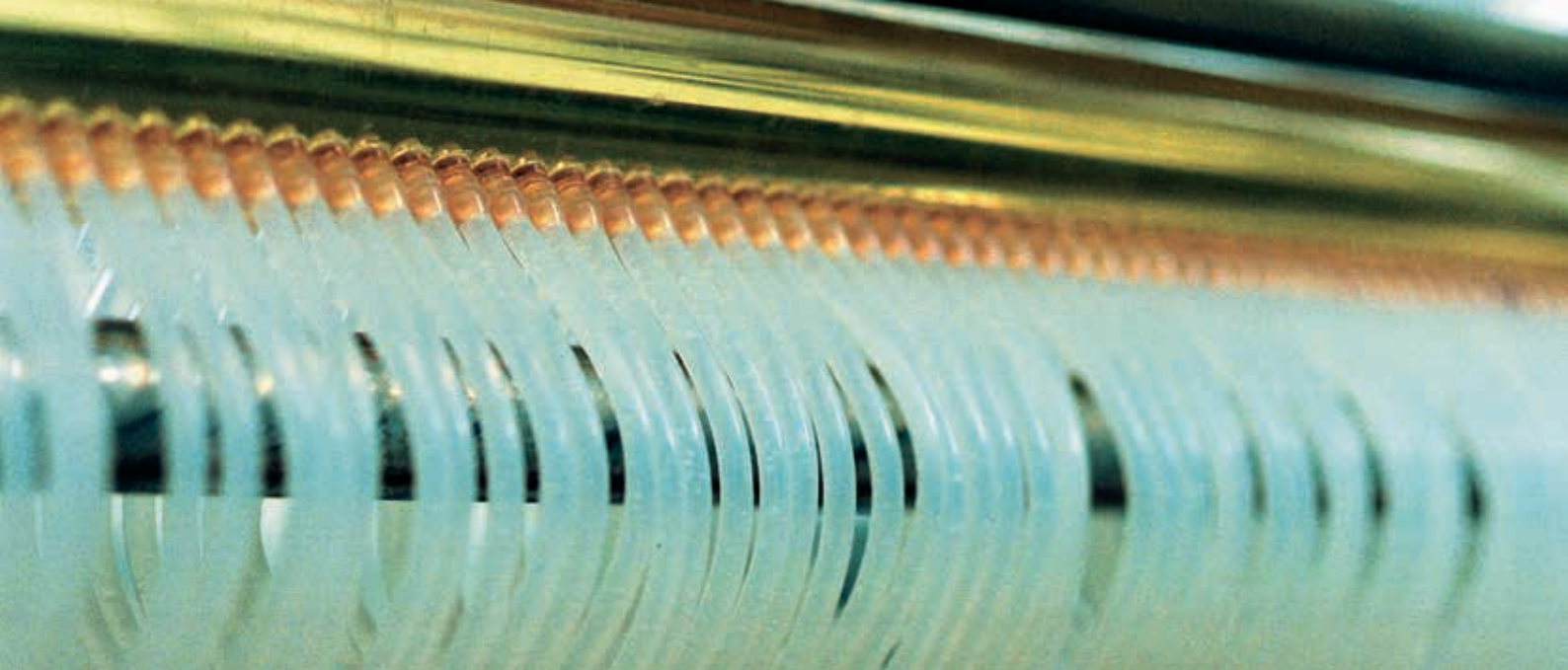
The highest standards of product design and materials combined with high-quality manufacturing and testing methods, are your guarantee of end-product consistency and maximum uptime.

### **Process and regulatory expertise**

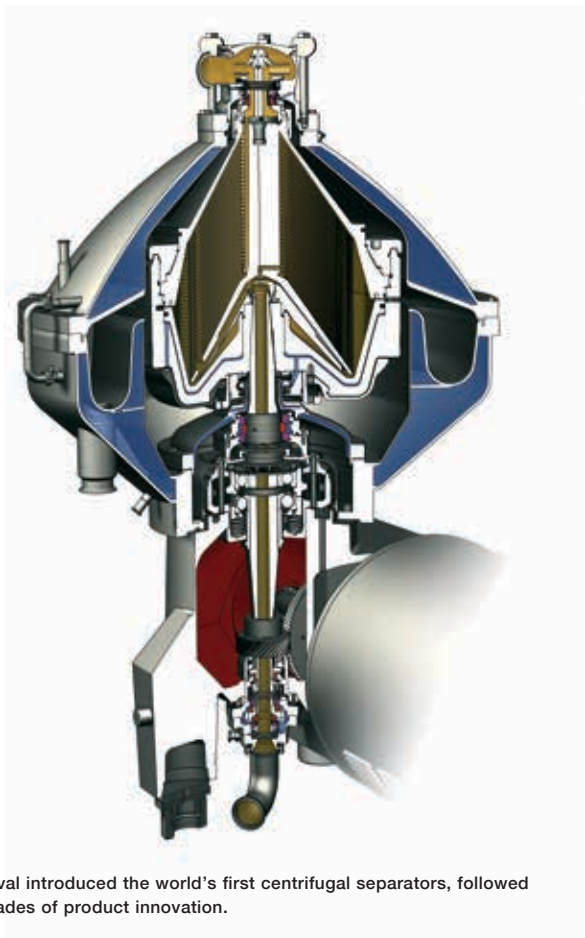
In the biotechnology and pharmaceutical industries where knowledge, verification and reliability are keys to success, Alfa Laval leads the industry in the breadth and depth of our process and regulatory expertise.

### **Global parts and service**

Backed up by a parts and service concept that sets an industry standard, Alfa Laval provides you with round-the-clock global assistance and service and spare parts support through the working life of your equipment.



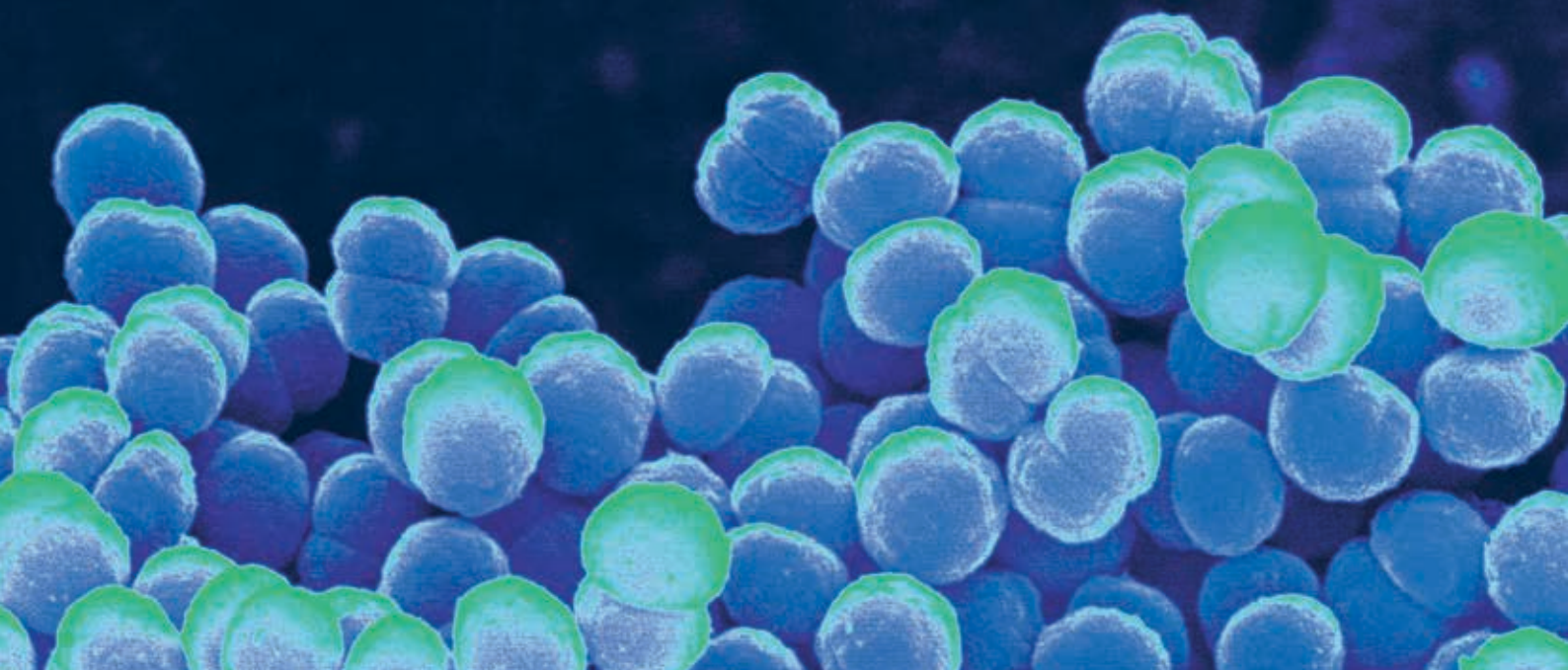
We are committed to helping you fulfill your most rigorous requirements, from the process and equipment levels all the way down to the cellular level.



Alfa Laval introduced the world's first centrifugal separators, followed by decades of product innovation.

#### Systems and components from Alfa Laval

- A wide range of high-speed centrifugal separators for cell harvesting, broth clarification, precipitated protein recovery and separation of cell debris
- Membrane filtration systems ideal for whole broth clarification of antibiotics, amino acids and organic acids as well as for concentration of dextrans
- A complete range of brazed, fusion bonded, gasketed and fully welded plate heat exchangers for cooling and heating of liquids, condensation and media sterilization
- Hygienic tubular heat exchangers for applications such as Water-For-Injection (WFI) and Purified Water (PW)
- Extensive range of pumps, valves, tubes & fittings and other fluid handling components, all certified and documented for hygiene, accuracy and safety
- Advanced tank cleaning components that eliminates product cross-contamination



## Separation technology: Striking a perfect balance

Exciting new developments in the field of genetic engineering and cell culture processing have made it possible for the biopharmaceutical industry to develop and produce a wide range of new treatments and therapeutic drugs. Alfa Laval separators have played a crucial role in these technically advanced processes because they provide

exceptional reliability, hygienic standards and performance.

### **The vital importance of cleanliness**

Vital to the success of human therapeutics is the integrity of the process, from harvesting to end product. Alfa Laval meets this challenge with separation systems that are fully contained, easy

to sterilize and can be efficiently and reliably cleaned-in-place.

### **Gentle treatment in processing**

Many of the organisms used for the new generation of drugs and medicines are based on mammalian cell cultures, which require extremely careful treatment to prevent cell wall damage and loss of product.

This requires that any separation process use the most gentle and low shear acceleration possible. At the same time, the equipment used must adhere to the highest standards of hygiene to prevent contamination. Alfa Laval's fully hermetic separator range with its unique hollow spindle are specifically designed for this task.

### **The widest selection**

With the widest range of high-speed separators available on the market, Alfa Laval separators are used in a broad range of biopharma applications, from high and low biomass applications to liquid/liquid duty extractions in hazardous environments, among others.



**Culturefuge is a fully hermetic, high-speed separator developed for applications involving mammalian cell cultures and other sheer-sensitive biological material.**

## Lonza Biologics Handling fragile living cells

To meet the challenges associated with sanitation, quality control and the handling of fragile living cells, Lonza Biologics Portsmouth facility acquired Alfa Laval's BTAX 215 separator, ideally suited for Lonza's needs.

"We were impressed by Alfa Laval, with what they gave us in terms of materials and support," says Gerry Coey of Lonza Biologics. "We don't even consider anybody else now."

Alfa Laval has also developed a customized preventative maintenance plan for Lonza and the separator. This pro-active plan ensures that the separator performs at maximum yield, eliminating any risk of downtime.



A perfect balance between exceptional performance and reliability while maintaining the highest hygienic standards.

### Most experienced in the business

Many biopharma companies require more than standard separation technology for their processes. Working closely with Alfa Laval R&D, some of the most experienced engineers in the business, we can help you develop state-of-the-art solutions that satisfy your most challenging separation requirements.

Our solutions range from small-scale, multi-product pharmaceutical plants to large-scale commercial plants. Utilizing Alfa Laval's knowledge in separation technology, you don't have to reevaluate your process every time you scale up.

### Scale up from lab units to large-scale systems

Our skid-mounted separation systems can be delivered in various configurations, from portable laboratory units to fully automatic, steam sterilizable, large-scale systems for contained operation.

To meet stringent customer protocols, we can provide a rigorous Factory Acceptance Test (FAT) in our in-house

test facility, if required. Additional validation support services can be also provided.

### Culturefuge: the innovations continue

Evidence of our continuing leadership in separation technology is the Culturefuge series, the first and most advanced separator range on the market today designed specifically for fragile cell culture processing.

Our separation technology strikes a perfect balance between exceptional performance and reliability while maintaining the highest hygienic standards and the integrity of cellular organisms.



Mobile MBPX 404 separation unit for R&D and small-scale production.



BTUX 510 separation system for high density fermentations.





## Membrane filtration: As pure as you want it



Alfa Laval membranes can improve the recovery and purification processes.

Alfa Laval's membrane filtration technology is designed to maintain the highest purity levels during processing while ensuring maximum efficiency and productivity. In this case, separation can also take place between dissolved components with differing molecular sizes. However, unlike other solutions, our membrane filtration technology is not intended for the biotechnology industry; rather, it is specifically designed for products produced by bulk fermentation, extraction or hydrolysis, such as antibiotics, enzymes and certain polysaccharides, such as hydroxyethyl starch (HES).

In antibiotics processing applications, for example, Alfa Laval membrane filtration can improve the recovery and purification processes as well as the subsequent concentration and desalting and pyrogen removal.

Ultrafiltration membranes can be used in a concentration process. Since they have a defined molecular weight cut-off value, they ensure that only the desired molecules are retained. For example,

with hydroxyethyl starch, the versatility of membrane processing is obvious: selecting the appropriate membrane can produce products based on components with a specified molecular size.

By adding water to the feed in a continuous manner (diafiltration), it is possible to achieve an even greater purity. Once the permeability of the solutes, which are to be removed, is known, it is possible to calculate and optimize the amount of water needed to achieve a specific purity. For extensive processes, the modular design of the Alfa Laval



The membrane flat sheets are available by the metre, as 20x20 cm sheets and for all Alfa Laval plate-and-frame configurations.

## Serumwerk Bernburg Module design a big plus

When Serumwerk Bernburg decided to upgrade the production of artificial plasma, they chose to install two Plate & Frame membrane filtration modules from Alfa Laval. This decision allowed ultrafiltration at high temperatures, preventing the growth of germs – a hugely important criteria for Serumverk’s product.

Sometime later Serumwerk Bernburg purchased more Alfa Laval membranes, with plans for doubling the company’s production capacity. Because of their modular design, it was easy to install Plate & Frame modules in parallel to an existing one, reducing the handling time for one batch by about 50 percent. Consumption of demineralised water for CIP was only increased by about 20 percent.



## Alfa Laval units makes it easy to expand capacity to match increased production requirements.

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### Help you select the right equipment

Alfa Laval’s scope of supply starts with production of the membranes-the heart of the system. Regardless of your product application, we can help you select the most suitable membrane and module configuration at our own state-of-the-art test facilities in Denmark. Or, if preferred, you can choose to rent equipment from a wide range of units.

In both cases, with a full range of lab and pilot scale equipment, our competent staff will work with you to identify and confirm the optimum system configuration and design data for scale-up to your production process.

### A non-destructive technology

Alfa Laval membranes are also ideal for enzyme processing in which the removal of salts or metabolic products is necessary. This is due to membrane filtration’s “non-destructive” technology and the ability to use molecular separa-

tion for purification and concentration.

### Meeting FDA requirements

The ability of our GR membranes to withstand pH values of 1-13 and temperatures aligned with industry standards enables efficient cleaning. This advantage, together with the use of appropriate materials, allows the system to fulfill FDA requirements for pharmaceutical equipment.



LabStak M20, the ideal unit for research and developmental work, quality assurance, as well as pilot plant process optimization and up-scaling.



Spiral membrane plant for yeast applications.



## Heat transfer: Warm it up or take it cool

For the most demanding processes requiring the highest quality performance and hygienic standards, Alfa Laval has the broadest range of heat transfer solutions for both the pharmaceutical and biotechnology areas.

Based on knowledge and experience gained from our separation technology and fluids dynamics, we apply the same principles to our range of heat exchangers, which meet the highest requirements in heat transfer efficiency as well as cleanability and reliability.

### **A leadership position in biotechnology and pharmaceutical**

In pharmaceutical water systems, Pharma-line and Pharma-X heat exchangers are leading the industry in hygienic standards. Pharma-X was specifically developed as a plug-and-play point-of-use cooler of WFI and PW. The heat exchanger is self-sanitized with an extremely short response time and, consequently, generates a low waste of valuable WFI.

The Pharma-line, a state-of-the-art shell & tube heat exchanger, was especially developed to meet stringent cGMP demands of both the pharmaceutical and biotechnology industries. High quality of Pharma-line is due to the critical welding and manufacturing processes are fully controlled and documented.



Gasketed plate heat exchanger with single or double wall plates.



Pharma-X plug-and-play module for efficient point of use cooling.



Pharma-line double tube shell&tube heat exchanger for versatile heating and cooling.

## Merck Compabloc has a compact edge

In 1996, Merck in Darmstadt, Germany installed their first Compabloc condenser. It delivered several advantages in production and maintenance and proved considerably more reliable than the graphite heat exchangers and shell&tube heat exchangers it replaced. Thanks to its compact design, the Compabloc was very easy to install and savings were made in installation costs. In line with increasing demands in the pharmaceutical industry, Merck decided to acquire a new version of the Compabloc with special hygienic features, intended for use in a cGMP compliant production.

Today, Merck has installed more than 100 Compabloc condensers. The company is not only pleased with the performance of the Compablocs but also the support from Alfa Laval's experienced team.



## The broadest portfolio of heat transfer solutions for the most demanding processes

### An advanced pharmaceutical condenser

The Compabloc Free Flow solvent condenser is the result of our long experience from both heat exchanger design and the pharmaceutical industry. It offers a state-of-the-art hygienic design, high performance, low operating costs and easy installation in minimal space. Every detail is designed for patient safety. Compabloc Free Flow fully meets the requirements for installation in stringent cGMP processes.

Cleaning and validating a Compabloc Free Flow is quick and easy. It is fully drainable and the risk of cross-contamination between batches

is minimal thanks to the absence of crevices, dead spots and contact points on the product side. Inspection is easily performed by simply opening the panels, giving full access to all product-wetted surfaces.

Since Compabloc Free Flow is available in highly corrosion-resistant materials, it is the perfect replacement for graphite blocks or shell&tube heat exchangers.



AlfaNova gasket-free heat exchanger.



Compabloc Free Flow, the fully welded plate heat exchanger for condensation duties.



Compact and self-cleaning spiral heat exchanger for a wide range of applications.



## Fluid handling: Keep it clean and safe

Alfa Laval offers a full range of pumps, valves, tank equipment, tubes and fittings for liquid transportation in the biotechnology and pharmaceutical industries. Each of these components set the highest industry standard in terms of maximum integrity in ultra-clean processes combined with durability and reliability that ensure maximum return on investment.

Alfa Laval components are available through a network of about 2,000 authorized distributors and system builders.

### Why choose Alfa Laval components?

Due to their reputation for quality, hygiene and performance reliability as well as their compliance with the guidelines and standards of many countries, Alfa Laval components are installed in systems worldwide. Even the smallest parts are carefully designed to facilitate cleaning, maintenance and operation.

### Ensuring product integrity

To ensure the integrity of your product, we select materials for our fluid handling components that are not reactive, additive, or absorptive. Strict control of substances required for operation, such as lubricants or coolants, is maintained so as not to come into contact with components or in-process materials that could alter the safety, identity, quality or purity of the drug product.

All our components are designed for cleanability to prevent contamination and save cleaning time and costs. For example, our centrifugal pumps with external shaft seals secure easy

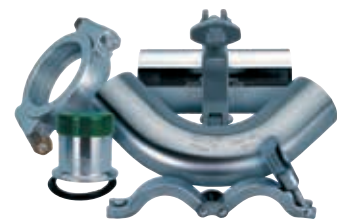
and thorough cleaning. In addition, the crevice-free design ensures that no trapped microorganisms or other residues remain in the pump. This provides security that there is no risk of product contamination.

### Alfa Laval Tri-Clover® sets the standard

The same hygienic principles apply to our Tri-Clover brand of tubes and fittings, which have set the standard for the industry. Smooth, crevice-free, corrosion-resistant interiors and secure, self-aligning joints make installation easy and guarantee hygienic systems that are simple to clean and maintain.



SX rotary lobe pump is noted for its low shear rate.



Tri-Clover tubes and fittings.

## GlaxoSmithKline Quality and performance

GlaxoSmithKline is one of the world's leading research-based pharmaceutical and healthcare companies. At the company's pharmaceutical plant in Belgium, human vaccines are manufactured.

The company chose Alfa Laval pumps for use in the WFI and DIW process loop and for transfer solvents.

GlaxoSmithKline selected these components from Alfa Laval because of their traceability, documented quality and performance, low maintenance requirements and certification.



All our equipment are designed for cleanability to prevent contamination and save cleaning time and costs.

Tri-Clover biopharmaceutical tubes and fittings are available in a wide range of dimension standards and surface finish. All tubes and fittings are in compliance with both American and European hygienic standards and individually capped and bagged to ensure these hygienic standards.

The Tri-Clover components from Alfa Laval include tubing, bends, tees, reducers, unions, clamp connections, pipe holders and pipe supports.

### Designed for cleaning efficiency

Alfa Laval components are designed to reduce maintenance and cleaning time and facilitate easy and thorough cleaning processes. This means faster cleaning-in-place (CIP) with less downtime between batches, and longer periods between maintenance checks.

Another example is the Alfa Laval rotary lobe pumps designed for optimum efficiency in combination with gentle

product treatment. The multi lobe rotor in our SX pumps, for example, have a proven record of minimizing the shear rate on the product and thereby minimizing the destruction of the product pumped.

Alfa Laval's Toftejorg dynamic tank cleaning devices has saved money and time for hundreds of pharmaceutical companies. These utilize a high-impact, rotating jet-head inside the tank for more efficient removal of residue and bacteria from tank walls – an innovation that cuts cleaning time dramatically. They also reduce the need for cleaning chemicals and rinse water, minimizing any environmental impact.

Alfa Laval tank equipment include manhole covers, tank outlet valves, agitators and Toftejorg tank cleaning devices.

### The Alfa Laval Q-doc package

Alfa Laval has developed the Q-doc package to meet the growing demand for documentation in accordance with legislation and industry standards. Q-doc includes material certificates, test certificates/reports, manufacturing procedures, quality procedures etc. for components and spare parts.



Toftejorg dynamic tank cleaning devices are designed to meet stringent demands for safety, efficiency and hygiene.



# Factory Acceptance Test (FAT)

## Beef up your confidence



Customers and engineers supervise FAT.

Customers acquiring equipment for sophisticated biotechnology processes want to know they are getting exactly what they ordered. For this reason, Alfa Laval offers its customers FAT, a procedure that ensures their equipment will perform as promised.

### Get exactly what you need

FAT lets customers test their equipment at Alfa Laval's facility in Tumba, Sweden, before it is delivered. Engineers install the equipment and connect it to utilities like instrument air, cooling water, steam operating water and then run it on water, demonstrating the equipment's performance and functionality.

This provides customers with an opportunity to verify hydraulic capacity, start time, stop time, discharge function, nozzle locations, pipe slopes, surface finishes, electrical wiring and various documentation and certifications.

Once the equipment is delivered, the customer normally repeats the FAT, now called a site acceptance test or SAT, with all their utilities connected.

### A short-cut to the market

By verifying their processes, customer can get them up and running significantly faster. The learning curve is shorter and the need to make repairs once the equipment is on site is significantly reduced.

In fact, many customers leverage the work done during the FAT in their validation work, some starting the Installation Qualification/Operational Qualifications (IQ/OQ) work as soon as the FAT begins.



## Service and support: Make your investment grow

Even the highest quality of processing equipment runs the risk of failure. Unplanned shutdowns for repairs or maintenance can translate into significant losses in time and money.

That is why customers have turned to Alfa Laval Service, a concept that brings together the industry's best expertise, people and technology to ensure you enjoy the most reliable, problem-free performance.

### **Total coverage**

Purchasing Alfa Laval equipment is only the first step in our long-term commitment to you and your success. Our Performance Agreements, designed to ensure that your processes function as you expect them to, can be tailored to your specific needs.

Our service solutions cover every conceivable service you might need, from upgrading and cleaning, to monitoring and reconditioning. Our approach combines long-term planning and preven-

tive agreement, backed up by the most experienced and knowledgeable engineers in the business.

### **Available 24/7, anywhere, any time**

Your agreement guarantees you access to global network of highly skilled field service engineers. Call for 24/7 technical support, or ask one of our engineers to visit you. With an Alfa Laval regional service center nearby, you always have access to our engineers for hands-on support.

All of our global resources, from parts replacement and equipment maintenance to process consulting and performance improvements, are available to you locally, regardless of your location or the complexity of your requirements.



**The best people, expertise and technology ensure problem-free performance.**