A healthy injection for your business

Improvise or

immunize?

In the biopharm (biotech and pharmaceutical) industry, there's always access to short-term relief. But unless the cause is addressed, even small headaches are likely to return.

Rather than treating individual production symptoms, consider vaccinating your business with the choice of Alfa Laval.

Alfa Laval is the well-known name behind an extensive biopharm offering, including the Tri-Clover® brand and the industry's most trusted separation systems. We supply a full range of separation, heat transfer and flow components – designed and documented for biopharm use.

Our long-lasting solutions are delivered by professionals you can trust, namely Alfa Laval's wide-reaching network of knowledgeable sales and working partners.

Beyond what's prescribe

Alfa Laval does what it takes and more to ensure consistent performance and prevent contamination in biopharm production.

And we have the documentation to prove it.

Alfa Laval Q-doc, our cutting-edge documentation package, shows how our components meet the strictest needs and standards in the biopharm industry. What's more, it includes information that simplifies and facilities the qualification and validation process.

Encompassing all product contact parts, Q-doc describes every aspect from raw material to equipment delivery. By providing full transparency of sourcing, production and supply chains, it allows the slightest change in material or manufacture to be traced – even when it comes to spare parts.

Q-doc is based upon Good Documentation Practice (GDP) and comprises equipment manuals, factory acceptance or performance tests, quality and manufacturing procedures, material certificates, and parts and service information. And for Alfa Laval, the importance of such comprehensive information is clear.

After all, meeting standards is about more than supporting validation. It's about long-term peace of mind.

Assurance of:

- Ease in commissioning and qualification
- Compliance with all relevant standards
- Hassle-free validation of cGMP

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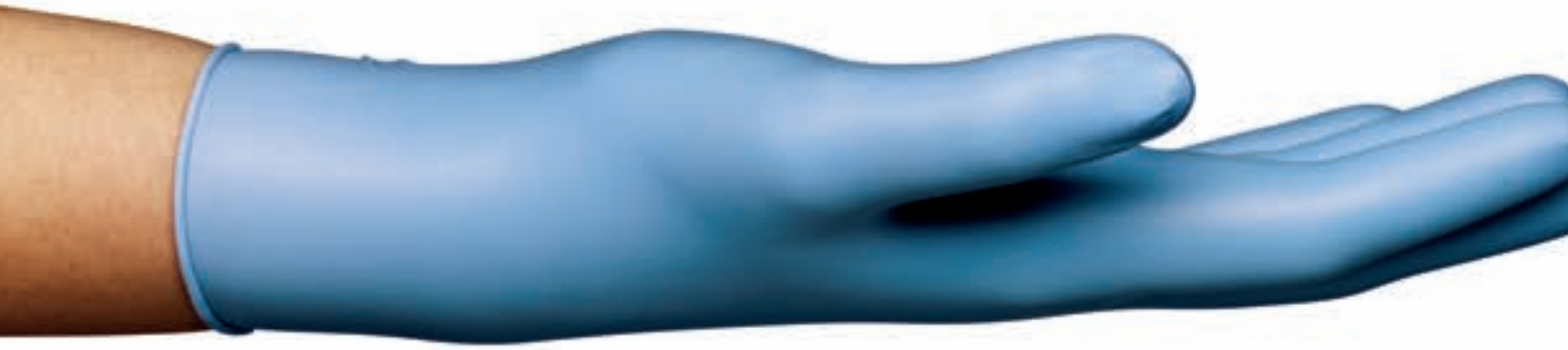


Free from symptoms

Biopharm production demands flawless consistency, not only within a single run, but also from one batch to the next. By optimizing components for unchanging performance, Alfa Laval ensures that what applies at validation also applies down the road.

This optimization begins with design, based on more than a century of experience working with hygienic industries. Alfa Laval design features prevent the contamination of sensitive processes – whether by equipment, by associated media, or by residue from a previous batch.

Many features also protect in other ways, such as our magnetic mixers, whose friction-free, levitating impeller design provides effective mixing down to the very last drop, ensuring no valuable product is wasted.

Our features are backed by robust and inert materials, rigorously tested for biopharm applications and compliant with FDA, USP and other relevant standards. Our product contact materials – including our steel and gasket polymers – are documented and traceable with Alfa Laval Q-doc, which means change control issues leading to revalidation can be avoided.

Performance that:

- Ensures in-batch and batch-to-batch consistency
- Safeguards product characteristics and quality
- Minimizes the need for revalidation

Clean and healthy

Just as proper handling and non-reactive materials are essential in preventing contamination, cleanability is a critical issue.

At times, cleanliness can be maintained through individual features, such as the use of an external rather than an internal spring on the shaft seal of our LKH and SolidC centrifugal pumps. But more often, it depends on the bigger picture.

Alfa Laval components are engineered for thorough cleaning, with few parts and smooth, well-constructed internal surfaces. Many are created with Computational Fluid Dynamics (CFD), which is the same flow-modelling technology used in designing aircraft. Besides optimizing product flow, our components enable effective Cleaning In Place (CIP) and Sterilization in Place (SIP).

Joining them are our Toftejorg® tank cleaning devices, which employ dynamic spray heads and jet heads for maximum cleaning efficiency. Rotating in a three-dimensional pattern, these cleaning heads achieve faster and deeper cleaning with far less fluid than conventional static spray balls.

The result is not only production security, but also resources and energy saved in the cleaning process.

Cleaning that:

- Protects the integrity of the finished product
- Combines maximum hygiene with maximum efficiency
- Minimizes water usage and waste handling

Fit for the future

In the long run, achieving consistent results and successful biopharm production means more than protecting processes. It also means protecting uptime.

In that sense, it calls for components that operate efficiently as well as properly. It requires materials that resist unwanted reactions, but which also resist wear. And it demands cleaning options that are not only thorough, but quick and easy as well.

By answering all of these needs, Alfa Laval components let more time to be devoted to profitable production. In other words, they perform longer and require less maintenance and cleaning – which gives them a low cost of ownership.

Even when maintenance is needed, the downtime required is minimal. The small number of parts makes Alfa Laval components easy to clean, but also fast and easy to dismantle and reassemble. Parts and service are readily available through Alfa Laval's partner network, and the traceability of spare parts with Alfa Laval Q-doc ensures a perfect match that avoids product risk.

From the time of validation to production and beyond, Alfa Laval lets you rest assured.

Peace of mind through:

- Maximized uptime
- Ease of cleaning and service
- Reliable access to parts and qualified support

Complete and specific

Alfa Laval has an extensive offering of components and solutions that are specifically suited to the needs of the biopharm industry. Delivered in most cases through the hands of our sales and working partners, they are complemented by additional process solutions, such as our industry-leading separation systems and state-of-the-art plate reactor modules.

The following pages provide a brief overview of our offering, organized into categories.

For a more complete overview and the latest technical details, please visit www.alfalaval.com/biopharm

Tank equipment from Alfa Laval comprises not only our revolutionary levitating magnetic mixer and Toftejorg® dynamic tank cleaning devices, but also a wide range of agitators, access covers, sight glasses, instrumentation and other equipment.

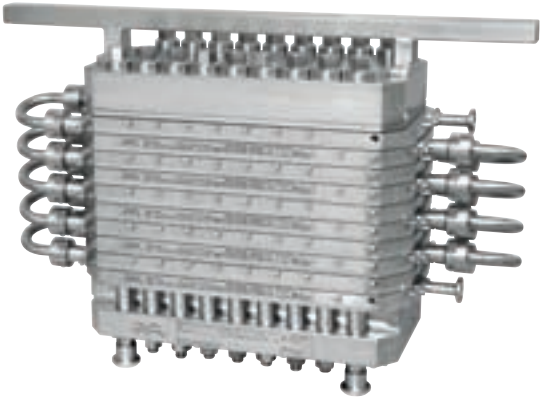
Pumps for biopharm use are available from Alfa Laval in all categories. Our centrifugal pumps, liquid ring pumps and rotary lobe pumps handle the varying viscosities and pressures associated with biopharm production, providing both gentle treatment and high cleanability.

Alfa Laval **heat exchangers** include shell-and-tube models and our unique Pharma-X, a ready-built point-of-use cooler module. We also offer single-wall and double-wall plate heat exchangers in gasketed and welded versions, as well as the unique fusion-bonded AlfaNova plate heat exchanger in 100% stainless steel.

Alfa Laval offers a wide range of **valves** and related automation. Our valve options include diaphragm valves, seat valves in single-seat and double-seat models, sampling valves, butterfly valves, regulating valves and ball valves.

Separation and filtration systems from Alfa Laval represent more than 100 years of leading separation experience. Our centrifugal separation systems, available from laboratory scale to full scale, are complemented by a range of filtration membranes and system solutions.

The **Alfa Laval ART® Plate Reactor** is a continuous flow reactor that combines optimal mixing with efficient heat transfer. In a wide range of reactions, it can achieve increased yield while reducing both solvent use and waste. Its modular and multipurpose design, in which plates with different configurations can be added or removed, enables fast and predictable scale-up.



Alfa Laval can provide a full selection of Tri-Clover® **tubes and fittings.** The whole range exhibits proven, consistent and well-documented quality, and all items are readily available and easy to order.

Tri-Clover®

Alfa Laval in brief

Alfa Laval is a leading global provider of specialized products and engineering 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

Contact details for all countries are continually updated on our web site. Please visit **www.alfalaval.com** to access the information.

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