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Alfa Laval is launching the first premium separator system for single-use biopharmaceutical processing

The biopharmaceutical industry has seen a major shift toward more flexible cell culture production systems that rely on smaller facilities with single-use processing equipment. However, the primary harvest step of these materials has long posed a major challenge to manufacturers designing single-use processing lines. Alfa Laval has developed a new flexible solution using proven technology. The company is now launching the Alfa Laval CultureOne™, which is the first premium separator system for single-use cell culture processing.

“There have been several drivers for single-use technology in the industry,” explains Doug Osman, Director for Food & Life Science Technology at Alfa Laval. “It makes it easier for our customers to design and construct new facilities, and it allows them greater flexibility to go to market faster. And just like with the use of single-use syringes in doctor’s offices, single-use equipment in manufacturing offers the best assurance of patient safety with no risk of cross-contamination between batches.”

To date, the disc-stack centrifuge – a critical piece of equipment used for harvesting proteins – has not existed in a single-use format, making it difficult for biopharmaceutical manufacturers to make the transition to “full-single-use.” This gap has forced manufacturers to choose between alternatives that provide inefficient separation with low-quality and inconsistent results.

Traditional full-scale centrifuge technologies, such as Alfa Laval’s Culturefuge range, therefore remain the preferred choice for many manufacturers. These units offer efficient and reliable separation performance with increased yield but are often designed for much higher capacities. They also require greater infrastructure due to the need for cleaning- and sterilization-in-place (CIP/SIP) support systems.

Fixing a market gap with unique innovations

“To solve these challenges, Alfa Laval has tapped into more than 130 years’ experience in separation technologies,” explains Osman. “Starting with the proven innovations within our larger, stainless steel Culturefuge models, our goal was to design a separator system for biopharma single-use processing that offers the same high level of performance our customers are used to. The Alfa Laval CultureOne is the result of these efforts.”

Like the Culturefuge range, Alfa Laval CultureOne is based around Alfa Laval’s unique fully hermetic design concept. This design provides the gentlest treatment of cell cultures to protect against cell lysis. In addition, this approach: 1) ensures the sterile boundary of the system, 2) prevents an air-liquid interface in the separator to ensure optimal material handling for subsequent process steps, and 3) reduces the energy consumption of the separator.

“The key difference with Alfa Laval CultureOne is that we have designed all product-contact

parts as consumables,” Osman says. “We call our unique separation insert technology the Alfa Laval Spinsert™. It includes our latest innovations for improved separation performance, all elements of the disc-stack and all connecting tubing and single-use instrumentation.”

The Spinsert assemblies are supplied sterilized and ready-for-use according to all applicable industry standards for GMP production. Only components included in Spinsert are replaced after each use and are made of recyclable material. Alfa Laval manufactures the rest of CultureOne’s non-product contact components, as well as multi-use instrumentation and automation, to meet industry requirements.

New possibilities and proven results

Without the need for onsite cleaning and sterilization, system turnaround time is greatly improved, and the possibility for cross contamination between production batches is eliminated. Use of the CultureOne also eliminates the need for chemicals, water, and energy associated with CIP and SIP.

“In our development process, we also tried to push the technology even further, to create a platform which addresses both current and future trends in an ever-changing business,” Osman concludes, “We are excited about the possibilities for this new technology and are incredibly thankful for the contributions of a number of key manufacturers in the biopharmaceutical market. We have been able to validate the technology with these customers in field trials to insure a robust, repeatable and reliable process results. We cannot wait to show the market as a whole what can be achieved.”

To learn more about Alfa Laval CultureOne™ and Alfa Laval’s approach to single-use biopharmaceutical processing, please visit: www.alfalaval.com/cultureone

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Editor’s notes

Alfa Laval is active in the areas of Energy, Marine, and Food & Water, offering its expertise, products, and service to a wide range of industries in some 100 countries. The company is committed to optimizing processes, creating responsible growth, and driving progress – always going the extra mile to support customers in achieving their business goals and sustainability targets.

Alfa Laval’s innovative technologies are dedicated to purifying, refining, and reusing materials, promoting more responsible use of natural resources. They contribute to improved energy efficiency and heat recovery, better water treatment, and reduced emissions. Thereby, Alfa

Laval is not only accelerating success for its customers, but also for people and the planet. Making the world better, every day. It's all about *Advancing better*[™].

Alfa Laval has 17,500 employees. Annual sales in 2019 were SEK 46.5 billion (approx. EUR 4.4 billion). The company is listed on Nasdaq OMX.

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