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Harvest time!

The latest in bioprocessing

Bioprocessing, especially in the biopharmaceutical arena, demands that companies have a good understanding of both their products and processes. Recent advances in bioprocessing include an increasing popularity of single-use systems and components, enhancements in filters and columns for product purification and improvements in cell-lines and their culture.

Filters and Columns

Sartorius Stedim Biotech GmbH has expanded its array of ultrafilters to include the **Sartocon® ECO** series of ultrafilters. Sartocon ECO ultrafilters have been developed for biotechnological and pharmaceutical purification processes in the industry for the manufacture of vaccines and antibodies. Sartocon ECO is based on Hydrosart® ultrafilter technology that uses stabilised polymer membranes based on hydrophilic generated cellulose. Hydrosart membranes enable especially high yields by minimising protein binding to the membrane and are thus virtually non-fouling. As Sartocon ECO features high stability under strong alkaline conditions and over wide temperature ranges, it is easy to clean but also reusable even after several cleaning cycles, considerably reducing operation costs. In addition, Sartocon ECO filters provide constant process performance, allowing process parameters to be maintained in existing crossflow systems.

Pall Corporation has launched **Supra™ AKS depth filters** for biotechnology and pharmaceutical purification applications. The new intermediate-size cartridges give process developers important new scale-up options when using Pall's line of depth filters featuring Seitz AKS immobilized activated carbon depth filter media. Pall's Seitz AKS filter media incorporates activated carbon within a matrix of cellulosic fibres. The media is coupled with a downstream filter which eliminates carbon particle shedding. Unlike bulk powdered activated carbon (PAC) processing that entails multiple steps, the feed stream is passed through the Seitz AKS sheet filter just once at an appropriate flow rate to achieve the desired adsorptive purification. Scott W Anderson, Global Product Manager at Pall Life Sciences, said:

"Pall's Supra AKS depth filters allow users to purify and decolorise pharmaceutical products by activated carbon adsorption using a modular format. Filters can be quickly installed into standard sanitary-style cartridge housings, and the unique design reduces the risks of downstream contamination."

Dionex has released the **MABPac™ SCX-10 column** that is designed specifically for the exceptionally high-resolution, high-efficiency analysis of monoclonal antibodies and associated variants. This new column's unique nonporous pellicular resin provides unmatched high resolving power, permitting the separation of monoclonal antibody variants that differ by as little as one charged residue. Hydrophobic interactions with the resin are eliminated for very efficient peaks. The column is designed to address the regulatory requirements for biopharmaceutical characterisation.

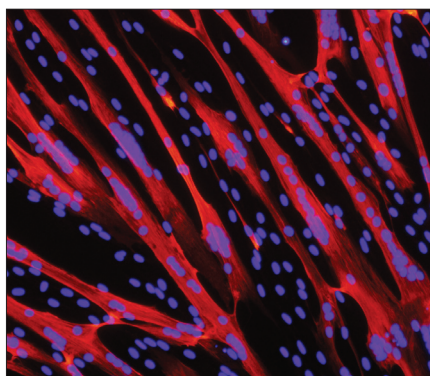
Disposable processing systems and bioreactors

Millipore Corporation has launched **Mobius® Flexible Filtration**, an innovative approach to single-use bioprocessing. Flexible Filtration enables customers to incorporate "lean" principles and continuous process improvements into their single-use manufacturing operations globally. Many companies follow lean manufacturing principles to lower the costs of bringing products to market through waste reduction. Flexible Filtration is uniquely designed to target the seven main wastes identified by lean process initiatives: overproduction, excess inventory, unnecessary transportation, unnecessary motion, waiting, overprocessing and defects.

GE Healthcare has extended its ReadyToProcess™ platform of ready-to-use

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Primary human skeletal muscle derived cells (SkMDC) from Cook MyoSite Inc.

systems with the launch of **ReadyCircuit disposable flow path assemblies** and **ReadyKart**, a mobile processing station for the quick setup of sterile fluid processing systems. All new products are used in the manufacture of biopharmaceuticals. ReadyCircuit's range of over 250 bags, sensors, filtration devices, tubing and sub-assemblies with aseptic connectors enable the user to configure and deploy an optimal bioprocess set-up within minutes. As standard, user configurable sub-assemblies, ReadyCircuit products permit single use processes to be deployed off the shelf instead of requiring weeks like conventional disposable bag sets. Custom assemblies built to user specifications are also available. The disposable ready-to-use format of ReadyCircuit eliminates the need for cleaning and cleaning validation, and thus contributes to reducing costs and enabling the development of biopharmaceuticals, such as vaccines and monoclonal antibodies, with lower capital investment. In addition, ReadyCircuit enables time between batches to be reduced, thereby increasing manufacturing agility.

New Brunswick's recent CelliGen BLU cell culture bioreactor combines single-use technology with the trusted performance and true scalability of a traditional stirred-tank design. CelliGen BLU has been engineered for high-density animal cell culture in research or production, using interchangeable, single-use, stirred-tank vessels in 5.0 and 14.0 liters total volume capacities. A compact controller enables advanced process management for research or cGMP manufacturing. Key benefits include: a single-use vessel which eliminates autoclaving and cleaning providing rapid turnaround between runs and reducing both the risk of contamination and validation requirements. Furthermore initial startup costs are minimised while the, stirred-tank design provides proven performance and scalability. While an integrated control station enables advanced gas management and process control and unique pH and dissolved oxygen (DO) technology makes probe insertion totally non-invasive, eliminating contamination



ReadyCircuit disposable flow path assemblies with ReadyKart from GE Healthcare

risk and making probe autoclaving unnecessary.

A disposable bioreactor representing a new, highly scalable entry point in its line of mixing and process manufacturing systems for the biopharma and biotech industries has been launched by **ATMI Inc.** The **Integrity™ PadReactor™** system accommodates volumes ranging from 20 liters to 1,000 liters. The bioreactor is portable along its entire range of volumes and provides features available on larger, stationary units while offering much swifter set-up times, minimal facility requirements, and the economic benefits of single-use technologies over stainless steel systems. Incorporating key elements of ATMI's industry-leading PadMixer™ technology, the PadReactor system provides enhanced gas exchange, due to its moving sparger. It also achieves low shear mixing due to the vertices of the square tank, which act as natural baffles. These advantages, plus the system's scalability, make it ideal for the production of vaccines, monoclonal antibodies and other secreted proteins.

Media and cells

CDM-HD from FiberCell Systems, Inc. is a chemically defined, protein free serum replacement that permits any basal medium such as DMEM or RPMI to be used without serum. CDM-HD is designed for the culture of cells at high density that can permit growth in a simplified medium. CDM-HD is the first serum replacement optimized for hollow fiber bioreactors from FiberCell Systems. Secreted products such as monoclonal antibodies and recombinant proteins are free of contaminating proteins from the medium and can be purified using simpler protocols, increasing net yield in many cases. CDM-HD provides lot-to-lot consistency and is an economical replacement for serum.

Cook MyoSite Inc. provides **primary human skeletal muscle derived cells (SkMDC)** and complementary culture media and cryopreservation media. SkMDC are isolated consistently, have high purity, high viability, can be expanded reliably, and maintain phenotype/genotype during

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Global Product Manager at Pall Life Sciences

expansion. Cook MyoSite also provides a gene array characterization with each SkMDC purchase to clearly define the starting culture. Cells are categorised on the company's website by donor age, gender, BMI, diabetic condition/insulin dependency, and smoking history, so that the desired cell population can be selected each time an order is placed. Cook MyoSite also offers several varieties of MyoTonic Culture Medium to ensure robust and consistent growth and differentiation of SkMDC.

Companies mentioned in this Product Focus:

ATMI Inc – www.atmi.com
Cook Myosite Inc – www.cookmyosite.com
Dionex – www.dionex.com
FiberCell Systems Inc – www.fibercellsystems.com
GE Healthcare – www.gehealthcare.com
Millipore Corporation – www.millipore.com
New Brunswick – www.nbsc.com
Pall Corporation – www.pall.com
Sartorius Stedim Biotech GmbH – www.sartorius-stedim.com

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