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▷ Refine Technology announces record monoclonal antibody titer in a CHO Concentrated-Fed-Batch process using the ATF™ System

Pine Brook, NJ – February 16th, 2010 - Refine Technology, LLC, a manufacturer of novel filtration systems for the biopharmaceutical industry, has announced a record 17g/L titer for an antibody has been achieved in a CHO concentrated-fed-batch (CFB™) process at a global pharmaceutical company.

“What I find exciting about this result is that it was achieved with un-optimized media in an un-optimized process”, explained John Bonham-Carter, VP Sales & Business Development. “Once this process is optimized, we would expect to see a further increase in titer”.

The standard biomanufacturing production platforms are being rapidly revised due to increased pressure on cost of goods, generic competition, and multiple drugs for the same indication. Refine’s ATF Technology means a 1000L reactor could have a similar productivity to a 10,000L. Coupled with single use equipment allowing faster turnaround times, this means a small biomanufacturing facility can achieve a significant yearly output – satisfying all but the largest of market demands. A new Concentrated Perfusion or CFB biomanufacturing facility would require a significantly lower capital cost and, by allowing a decision to be taken closer to market launch, would reduce risk for the manufacturing company.

This result from the CFB process was achieved at the 3L and 55L scale, while scale-up of the process to manufacturing is planned during 2010. The name of the pharmaceutical company was not disclosed.

About the CFB process: (concentrated-fed-batch)

CFB is an exciting novel process to enable extremely high cell concentrations in a bioreactor. The process is simpler to operate than a standard fed-batch process and works with traditional steel fermenters or any single use bioreactor. Refine’s ATF System is employed to help generate the high cell concentrations, and by virtue of concentrating the cell culture and the expressed protein product but yet removing impurities or by-products, a CFB process ensures high viabilities and a more consistent product quality.

About the ATF System

Originally designed to improve continuous culture processes, the ATF System is now used in applications as diverse as cell banking, virus production and microcarrier processes. In a bioreactor, the low shear movement gently separates aggregates often allowing faster cell growth and higher viabilities leading to a more productive process. The Alternating Tangential Flow action allows for a constant backflush or cleaning action to occur, significantly prolonging the life of the filter. The ATF action can also benefit other separation or concentration operations in a similar way.

About Refine Technology

Refine Technology was founded in 1999 with a vision to bring to the biopharmaceutical market cell separation systems that allow for increased productivity of cell derived biopharmaceuticals. Refine soon introduced its patented ATF System which is now being used in the development and manufacturing facilities of many biological and pharmaceutical companies.