

Avecia leads the way in development and manufacture of yeast-based biologics

Tees Valley, 15 May 2008 : Avecia Biologics has confirmed its position as a world leader in the process development and manufacture of biologics in yeast based systems through completion of over 12 major development and manufacturing projects, including two validation campaigns in recent months.

It is increasingly recognised in the industry that expression of proteins in yeasts such as *Saccharomyces* and *Pichia* can offer a number of advantages over other systems, particularly for more complicated proteins. This means that many of the process and cost-of-goods advantages of microbial systems can be translated into processes for more complex proteins. For instance, yeasts are able to secrete correctly folded protein into the culture supernatant. In addition the use of the methanol-inducible alcohol oxidase 1 promoter (AOX1), in *Pichia* can deliver high levels of heterologous expression under tight control. Use of yeasts also allows post-translational modifications, such as glycosylation.

Developing and operating yeast-based processes has been central to Avecia's biologics strategy for over ten years. The company's extensive R&D capabilities include a wide range of laboratory bioreactors capable of operating high cell density yeast processes with methanol and oxygen supplementation. Their experience using FMEA methods to define Laboratory Process Characterisation (LPC) studies, carried out using statistical experimental design, allows rapid and robust process characterisation, leading to delivery of consistent performance at all scales from 15 litre laboratory to 3000 litre manufacturing scale.

At its development and manufacturing facilities in the Tees Valley, UK, Avecia is able to apply the full range of separation and purification options, including the use of expanded bed chromatography (EBC) which has proved to be particularly advantageous for high-density yeast processes. Their extensive experience of EBC capture and purification provides rapid and efficient scalable primary capture combined with initial purification. Work on a number of

processes has given excellent scale-up data from a 2.5cm expanded bed up to 100cm, including process validation.

Dr Mark Carver, Chief Scientific Officer, Avecia Biologics says “Our extensive experience in developing yeast processes puts us at the forefront of this technology. We have a track record right through the product life cycle, having successfully scaled-up a number processes, including taking them from Phase I through to process validation. We are committed to making strategic investment in technology advances to deliver further improvements in performance, output and cost-of-goods in this field.”

About Avecia

Avecia is a privately owned biotechnology group of companies with recognised leading positions in the process development and manufacture of biopharmaceutical and oligonucleotide medicines. The Group's Tees Valley, UK site has been developing microbial processes and making protein-based biologics to cGMP since 1998. Products currently being worked on include medicines targeted at forms of cancer, heart conditions, stroke, growth and blood disorders. Customers range from some of the world's largest pharmaceutical companies to small innovative biotech start-up businesses.

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