Press release

NewLab BioQuality AG subsidiary completes first process development project for a biosimilar

BIBITEC GmbH (Bielefeld), a 100 % subsidiary of NEWLAB BIOQUALITY AG (Erkrath), has completed a five year project involving the process development and production of erythropoietin. The EPO was produced under GMP-compliance and was for use in human clinical trials. EPO is one of the most important hormones for the production of blood cells in humans. The project was sponsored by BIOCEUTICALS Arzneimittel AG, a subsidiary of STADA Arzneimittel AG (Bad Vilbel).

The production system for the EPO was mammalian cells which are one of the best but most difficult systems for the production of recombinant proteins. The fermentation process for the clinical trials was scaled up to 100 liters. An effective purification process involving, among other things, various chromatography steps was also developed. This resulted in a highly purified, active and consistent EPO molecule. It was possible to demonstrate that the EPO was of the highest pharmaceutical standards which are required for human use by employing validated methods as part of the quality control of the EPO. Most of this quality control was performed by NEWLAB.

The entire production and purification process was then successfully transferred to NORBITEC GmbH (Uetersen). This technology transfer was also performed by the

scientists at BIBITEC. NORBITEC has the industrial fermentation capacity to produce the EPO for market supply. This project has proven that NEWLAB is capable of initiating a pharmaceutical project from the earliest development phase throughout to production at the industrial scale.

Background information

BiBiTec GmbH was founded in 2001 by internationally recognized experts in the field of biopharmaceutical process development using mammalian cell culture at the University of Bielefeld. BiBiTec has worked with various pharmaceutical and biotechnology companies since it was founded. The projects have included development and optimization of process for both recombinant proteins and monoclonal antibodies. The fermentation capacity for mammalian cells is 100 liters and the production is CMP-compliant so that the products can be for human use. BiBiTec merged in 2003 with NewLab BioQuality AG in Erkrath.

NewLab BioQuality AG is a leading service company specializing in the quality control of biopharmaceutical substances. The company provides complete service ranging from cell bank testing, purity and safety testing, viral and prion validation studies as well as characterisation of final product, lot release testing and stability studies. In addition, the development of upstream and downstream processes for the production of recombinant proteins and monoclonal antibodies from mammalian cells can be performed GMP compliant up to the 100 liter scale.

NewLab BioQuality AG has been successfully cooperating for the past 11 years with the pharmaceutical and biotech industries. The company is certified according to Good Laboratory Practice and also performs testing to Good Manufacturing Practice. In 2004 NewLab BioQuality AG was successfully inspected by the FDA. The growing company was founded in 1993 and today is one of Germany's largest biotech companies with a staff of approximately 100 people.

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