

Cerbios' board approves the investment for upgrading the current plant for CHO based recombinant protein manufacturing

Cerbios strongly believes that Biotechnology will play a more and more significant role in the future of the pharmaceutical industry. This advanced technology is expected to make available more effective drugs and increase the quality of life of patients worldwide.

For this reason, and based on Cerbios' long-term experience in mammalian cells, the Cerbios board has approved the investment of several million Swiss Francs in the modification and improvement of the existing biotechnology manufacturing facility.

This investment will make available to the European market a "state-of-the-art" biologics plant dedicated to the production of therapeutic recombinant proteins based on a CHO platform under cGMP.

This facility will allow Cerbios to strengthen its position as a contract manufacturer for the production of New Biological Entities (NBE).

The facility consists of separate areas for upstream, downstream and critical downstream operations, and is designed with special attention to the optimization of personnel flow and to the reduction of contamination risks. A separate area is dedicated to the storage of the Master Cell Bank and the Working Cell Bank under cGMP conditions. The new structure will occupy approximately 500 m², of which more than 320m² are clean rooms, and it is expected to be fully operational and approved by regulatory authorities for manufacturing by Q3/Q4 2012.

The newly upgraded cGMP manufacturing facility with an advanced high quality infrastructure is designed to accommodate the manufacture of active ingredients based on recombinant proteins and monoclonal antibodies not only for pre-clinical and clinical phases, but also for commercial use. As a first step the facility will maintain its current bioreactor capacity, which is up to 100 liters. This will serve the supply of material for clinical phase I and II. However, the upgraded plant is designed for the quick expansion of the capacity up to 500 liters (stainless steel or disposable technology).

The Cerbios R&D team has over 15 years of experience in the field of biotechnology applied to the production of recombinant APIs from CHO cells. The team's experience includes cloning of the gene in suitable vectors, transfections, clone selections, setting of culture conditions and optimization of culture media for upstream process development, biochemical experience in purifications for downstream process development, scaling up, setting and validation of analytical methods for in process control, stability and release testing. Thanks to its technology and experience, Cerbios has already successfully developed recombinant proteins, such as rUK and rG-CSF. Based on this know-how, Cerbios can offer to its customers full process development starting from a cell line or process optimization after a Technology Transfer. This includes upstream and downstream process development, validations (analytical, process, cleaning), release of the API, stability studies and characterization of the product.



About Cerbios-Pharma SA

Cerbios is a privately held company located in Barbengo (Switzerland) specialized in the development and manufacturing of chemical and biological APIs for our partners world-wide. APIs made by Cerbios cover small molecules (Chemical Division), large molecules and Probiotics (Biological Division).

Services for third parties under exclusive manufacturing are offered in the area of HPAs for the Chemical Division and Recombinant Proteins for the Biological Division. Full CMC support is provided to our partners in order to supply them with cGMP clinical batches, registration/validation material, and APIs from commercial manufacturing. Paramount to this is the ability to supply all the documentation required for a successful registration.

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