

Our new plant for CHO based mAb or Recombinant Protein manufacturing is ready for the qualification phase.

Cerbios-Pharma SA (from now on "Cerbios") is proud to announce that the construction phase for our new Biotechnology plant is almost concluded.

The "state-of-the-art" biologics plant is dedicated to the production of monoclonal antibodies or therapeutic recombinant proteins based on a CHO platform under cGMP and authorization by Swissmedic for the production of clinical and commercial batches is planned during Q3 / 2013.

This facility will allow Cerbios to strengthen its position as a contract manufacturer for the production of New Biological Entities (NBE) for clinical studies, while until now Cerbios was only supplying material for toxicological studies.

There was a certain delay in the detailed design phase due to comments and observations received from Swissmedic and from our FDA consultant (former FDA inspector for Biotechnology plants audits) during their preliminary reviews.

"I am not frustrated by this delay" confirms Gabriel Haering, Cerbios' CEO. "This delay will be compensated by the fact that Cerbios will now be able to serve its partners for global projects (EU, USA, JPN) like for all our other production units."

In addition, Cerbios has special partnerships in place that will help improve the productivity of the cell lines (at least 3-4 g/liter) received from Start-ups or Universities, including (1) gene synthesis, (2) cloning in an expression vector, and (3) transfection.



For partners already having a cell line with good productivity, the service provided by Cerbios R&D could include (1) cell line optimization, (2) process industrialization, and (3) GMP cell bank manufacturing prior to a move to GMP production for clinical trials.

About Cerbios-Pharma SA

Cerbios is a privately held, self-financed 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 HPAIs for the Chemical Division and mAb, Recombinant Proteins or Pharmaceutical Probiotics 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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