cerbios
High Quality & Reliable Services

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Cerbios Pharma successfully passes a general GMP inspection

It is with pleasure that we announce that on Thursday evening, September 30th 2010, Cerbios-Pharma SA successfully passed a general GMP inspection.

Originally, the inspection was scheduled to last four days with two inspectors.
Due to the excellent results, the inspectors decided to close the audit at the end of the third day, without issuing a 483.

"We have reached an important milestone by successfully passing the FDA inspection considering the fact that the last FDA inspections was held in 2000 (also with no 483) and that products were marketed in the USA in the past ten years. This validates the high standards and good manufacturing practices at our company", said Dr. Gabriel Haering, CEO.
The general GMP inspection covered all areas of the organisation and systems involved in the production of Active Pharmaceutical Ingredients.

Both inspectors were very experienced (over 30 and over 20 years with the FDA as inspectors) and complimented the company for the excellent practical work (linked to the relevant SOPs) observed during the inspection in the production unit and quality control laboratories. This confirms that our investments in continuous training are important and rewarding.

Today's milestone highlights that Cerbios' strategy to pursue high quality at all levels, from manufacturing production units to quality systems, is the right choice.
This has also been authenticated by our partners that recently participated in a customer satisfaction survey.

About Cerbios-Pharma SA
Cerbios is a privately held company located in Lugano (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).

The Chemical Division has specialized in the past 30 years not only in Reduced Folates (leading position), but also in the manufacturing of High Potency Active Ingredients (HPAIs) with long-term experience in the field of Vitamin D derivatives requiring sophisticated production units with high containment levels.

The Biological Division has specialized since 1976 in the research, development and production of Probiotics as active pharmaceutical ingredients, pharmaceutical finished products and feed additives.
In addition, in the last 15 years, Cerbios has acquired a vast experience on Recombinant Proteins from mammalian cells (CHO) based on a state-of-the-art platform.

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

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