

### News

Lugano, April 27<sup>th</sup>, 2018

## CERBIOS-PHARMA SUCCESFULLY PASSES A GENERAL FDA CGMP INSPECTION

It is with pleasure that we announce that on Friday the 27th of April 2018, Cerbios-Pharma SA (from now on CERBIOS) successfully passed a general FDA GMP inspection.

Originally, the inspection was scheduled to last five days.

Due to the excellent results, the inspector decided to close the audit in the middle of the fifth day, without issuing any 483 observation.



"Since I joined CERBIOS in 2009, this is the third FDA inspection with no 483" says Gabriel Haering, CEO.

"This is the confirmation that our cGMP system is state-of-the-art and compliant with the most recent guidelines and validates our strategy of having an excellent system in place serving our partners world-wide".

The general cGMP inspection covered all areas of the organization and systems involved in the production of Active Pharmaceutical Ingredients.

The inspector complimented the company for the honest approach and excellent practical work (linked to the relevant SOPs) observed during the inspection in the production unit and QC laboratories.

This confirms that our investments in continuous training and personnel motivation are important and rewarding.

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# "Today's milestone highlights that Cerbios' strategy to pursue excellence and innovation at all levels, from manufacturing production units to quality systems and customer care, is the right and winning choice" confirms Denis Angioletti, Chief Commercial Officer.

#### About Cerbios-Pharma SA

Cerbios is a private company with its headquarters in Lugano, Switzerland, specialized in developing and producing active pharmaceutical ingredients (APIs), both chemical and biological, for its clients around the world. Cerbios is a world leader for some generic products used primarily to treat respiratory, dermatological and oncological diseases.

Cerbios also offers its clients an exclusive service to develop and produce highly active pharmaceutical ingredients (HAPIs) and biological monoclonal antibody tablets, recombinant proteins, conjugated monoclonal antibodies (ADCs) and probiotics for pharmaceutical use.

Cerbios is capable of offering a complete service to develop and register pharmaceutical products, tablets supplied for clinical research phases, the necessary regulatory documentation and subsequent marketing supplies. Cerbios products are marketed around the entire world, primarily in the USA, Japan and Europe.

#### For more information please contact:

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