

CERBIOS FURTHER INVESTS IN ITS HIGH POTENCY APIs MANUFACTURING CAPACITY

Cerbios-Pharma SA (from now on “Cerbios”) board of directors has approved the detailed design and budget for the installation in its High Potency Active Ingredients (HPAIs) dedicated building of a new production line able to accommodate larger volumes and batch size.

Cerbios is active in the HPAI arena since 1993 with an established expertise on handling Category 4 SafeBridge (OEL<10 ng/m³) Drug Substances in four different lines: 2 non cGMP ; 2 cGMP.

The P5 building for larger scale cGMP production of HPAIs was originally conceived with empty spaces available for installing an additional production line.

The new production line will be Category 3 Safebridge for batches ranging 5-30 kgs/ batch.

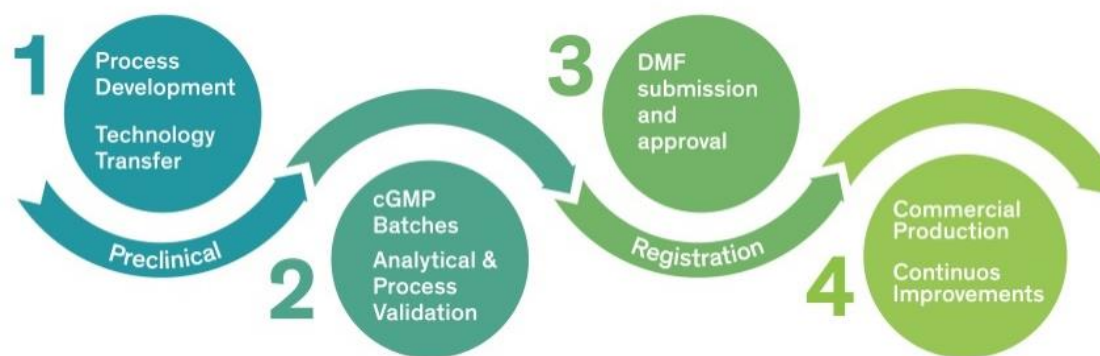
The new unit will be partially occupied for the manufacturing of an HPAI where larger volumes are required thus decreasing the production costs compared to the actual setup. The remaining capacity will be available for our CDMO services and partners.

5 Units		Fully isolated and contained according to SafeBridge standards
cGMP unit	10 – 100 gm/batch	
cGMP modular unit	200 gm – 2 kgs/batch	
cGMP unit**	5 – 30 kgs/ batch	** New, operational in 2020
Non cGMP unit	up to 50 gm/batch	For Drug Product development
Non cGMP unit	up to 100 g/batch	For Drug Product development or Tox studies



“With 25 years of experience handling HPAIs, Cerbios’ reputation for its know-how and proficiency is bringing an increased number of partners’ projects for the development and manufacturing of clinical material as well as commercial production”, confirms Dr. Gabriel Haering, CEO.

“Considering the conjugation suite for Antibody Drug Conjugates ready this summer and this new production line due in the second half of 2020, our offer to our partners will be six HPAI production units in a single site with space available for future expansions if needed”.



In fact, Cerbios supports its partners from the production of non cGMP batches needed for preclinical tests, through clinical to commercial supply applying state-of-the-art Project management system and Quality by Design approach that are paramount to the success of a production campaign and process evolution beyond the registration phase.

For more information please contact:

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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.