

## Cerbios' HPAI manufacturing facility P5 meets control performance within SafeBridge's® Category 4

Last summer, Cerbios-Pharma SA (from now on "Cerbios") commissioned SafeBridge Europe, Ltd. (from now on "SafeBridge") to carry out a surrogate containment performance assessment of three isolators located in P5 manufacturing unit at Cerbios site located in Lugano, Switzerland.

The work was conducted by a SafeBridge specialist supported by Cerbios HSE and Production team.

The isolators were assessed against a Containment Performance Target (CPT) of 10 ng/m<sup>3</sup> using Naproxen Sodium as a surrogate active pharmaceutical ingredient (API).

The objectives of this work were to:

- assess airborne particulate containment performance of the three isolators against a CPT of 10 ng/m<sup>3</sup> during operations.
- assess surface contamination against a target surface concentration of 10 ng/dm<sup>2</sup> following cleaning operations.

The overall results, based on the analysis of more than 200 samples, showed that Cerbios' P5 unit has appropriate containment equipment to handle up to category 4 (SafeBridge categorization system) products.

Proper equipment is only a part of the containment system – Cerbios is also achieving important results at the organizational level.

*"The objective of our company is to comply with state-of-the-art standard in term of safety and quality for all our stakeholders, ranging from our operators to our clients. We believe that this is an important milestone on the way to get full SafeBridge Certification for all our High Potency Active Ingredients (HPAI) production units. These results once more demonstrate Cerbios' commitment in applying best practices to support our partners in their development and commercial phase"* said Gabriel Haering, CEO.

### 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 worldwide.

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 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 availability of all the documentation required for a successful registration.

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