





Cerbios-Pharma SA (hereinafter referred to as “Cerbios”) is a privately held API manufacturer founded in 1994 from the merger of CERNITIN SA (founded in 1975), BIOFERMENT SA (founded in 1976) and SAPEC SA (founded in 1979), located in Barbengo/Lugano in southern Switzerland.

cGMP APIs made by Cerbios cover small molecules (Chemical Division), large molecules and Probiotics (Biological Division) sold worldwide mainly to pharma companies including Europe, USA and Japan.

The Chemical Division has specialized in the past 30 years in **Reduced Folates** (leading position) but also in the manufacturing of **High Potency Active Ingredients (HPAIs)** including a series 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.

On top of that, 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 given 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 that is the supply of all documentation required for a successful registration.

Who we are





With over 30 years' expertise in industrial scale manufacturing of APIs and over 15 years' experience in handling of HPAs according to cGMP, Cerbios is highly qualified in process development of new APIs and HPAs up to commercial production.

During the last few years, Cerbios has made substantial investments in infrastructure to strengthen and extend its activities and services in the field of HPAs, maintaining its large scale API manufacturing facility at the highest quality standards.

Cerbios provides state-of-the-art services for the development and manufacturing of APIs and HPAs according to US, EU and Japanese cGMP standards.

The contract manufacturing services for APIs and HPAs include:

- Technology transfer from our partners to Cerbios
- Chemical process development and scale-up
- Production of cGMP material for clinical trials, registration purposes and commercial supply
- Comprehensive R&D support
- Analytical methods development and validation
- Regulatory expertise for IND, NDA, ANDA, DMF, CEP and Japan-DMF submission

All Cerbios products are manufactured according to cGMP standards only.

Non cGMP key starting materials can be developed by Cerbios' R&D and transferred under confidentiality agreement to selected, reliable and qualified European and/or Far East non GMP manufacturers.

Chemical Services



The facilities consist of the following production units:

- API: 4'000 liter reactors for 10 up to 300 kg/batch
- HPAI: Small scale manufacturing plant for 1 up to 50 g/batch
- HPAI: Kilo plant for quantities up to 1-2 kg/batch

The HPAI production units have the following key technologies:

- cGMP Preparative Chromatography system
- Photochemistry
- Cryogenic capabilities (-60°C)

The HPAI facilities are designed to operate below 1 µg/m³ OEL level (class 3 according to Safebridge) and provide capabilities to operate to Cleanliness Class ISO 7 (Class 10,000).

This allows the safe handling of highly-potent compounds of all categories including cytostatic (not cytotoxic) APIs.

With the latest investments in place in 2009, Cerbios has strengthened its offering with a newly conceived production plant for the manufacturing of HPAs in a modern, flexible and state-of-the-art unit. The multi-purpose plant could be expanded with an additional production line or even with an additional building in a relatively short period of time: the ideal choice for the creation of a unit for your product(s) at interesting conditions.

www.hpai.ch

www.reduced-folates.ch

www.calcium-folate.ch

www.sodium-folate.ch

www.calcium-levofolate.ch

www.folinic-acid.ch

www.calcipotriol.ch

www.calcipotriene.ch

www.calcitriol.ch





Cerbios has over 30 years of expertise in fermentation processes and is a leading company in the production of Probiotics as active pharmaceutical ingredients.

In the field of Recombinant Proteins produced by CHO cell lines & microorganisms, Cerbios is able to offer “full service” including development, starting with cloning of Recombinant Proteins and ending up with process optimization and validation, analytical development and validation, as well as cGMP-manufacturing of biopharmaceuticals compliant with EMEA and US-FDA guidelines. Thanks to its technology, Cerbios has already successfully developed Recombinant Proteins, such as rUK and G-CSF.

The contract manufacturing services in the area of Recombinant Proteins include:

- Development of therapeutic proteins using CHO cell lines or microorganisms
- Upstream & downstream process development
- cGMP manufacturing, analytics and release of biological products
- Cell banking and repository

The choice of suitable media components and correct handling of master and working cell banks are key factors for a reproducible and safe production.

The cultivation media used by Cerbios for its CHO platform are “state-of-the-art”, serum-free, protein-free, antibiotic-free and free of any component of animal origin. These completely synthetic media may be adapted, case by case, to the cell line and the protein to be expressed. This allows for optimization of key parameters including productivity and yield.

Biological Services



The facilities consist of the following production units:

- 100 liter bioreactor unit for Recombinant Proteins
- 2 x 4'000 liter bioreactor plant for Probiotics
- Project for production plant (up to 4'000 liter bioreactors) for Recombinant Proteins

Finishing plant and technologies for our Probiotics:

- Microencapsulation
- Final dosage form production unit including labeling and packaging

From a commercial point of view, one of the most critical key factors is time-to-market. Cerbios has a proven track record for the implementation of a completely new building harboring a new fermentation plant in 18 months from signature of contract to commercial production.

CONJUGATES.

Of particular interest are projects taking advantage of the synergies between the Biological and the Chemical Division of Cerbios, giving the potential for development and manufacturing of small molecules, making use of bioconversion catalytic step technology, or manufacturing of HPAI conjugates with Recombinant Proteins or antibodies.

www.recombinant-proteins.ch

www.sf68.ch

www.urokinase.ch

www.g-csf.ch

www.cernivet.ch





Cerbios quality is a **global concept** managed at all company levels to guarantee full compliance with our Partners' and Authorities' requirements.

The company Quality Policy is aimed to ensure conformity of the products through a strict and efficient quality system. The basis of our system is a constant and careful review of all company activities, oriented to continuous improvement.

Our history of excellent track records gives evidence that continuous investment in personnel training and in system improvement has given the expected results.

Successful audits performed by our Partners and Authorities from highly regulated markets (e.g. Europe, USA, Japan) confirm the validity of our well-established reliable Quality System.

Cerbios is regularly audited by its partners and health authorities:

- Swissmedic: every two years providing cGMP certificate (officially recognized by EMEA)
- US-FDA: for products sold in the USA or under registration
- PMDA: Cerbios site has been granted Accreditation

Quality, Safety & Regulatory



Regulatory support

Cerbios has almost thirty years of experience and knowledge in successfully submitting DMFs for APIs and HPAs to the major authorities world-wide.

Submission of Type II DMFs to the US-FDA, DMFs or CEP documentation to regulatory authorities in Europe and translated DMFs to the Japanese PMDA through Cerbios' agent are common practice and in addition, a service is available for our biotech partners that need this expertise in-house with no need for additional consultancy.

Global regulatory expertise for IND, NDA, ANDA submissions in international formats (USA, Europe and Japan among others)

Health, Safety & Environment (HSE)

In recent years, Cerbios has developed an outstanding Health, Safety and Environment Management System designed to ensure that all aspects of HSE are managed efficiently and to promote continual improvement within company operations.

Our HSE Objectives are: accident, injury and pollution **prevention**; achievement of a world-class HSE performance. This can only be obtained with design quality, risk assessment and continuous training.



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