

## Chemical Division

## Biological Division

### Who we are

Cerbios-Pharma SA (hereinafter referred to as "Cerbios") is a privately owned company 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 mainly to pharma companies world-wide including Europe, USA and Japan.

The services provided in both areas cover all classical requirements for the registration, launch and commercialization of a product, such as Technology Transfer, process and analytical development, Regulatory Affairs, Patent Services, as well as process and analytical validation required for the production of clinical batches up to commercial production.

### Quality & Regulatory

Our cGMP quality assurance platform is based on international standards (e.g. ICH, PIC).

The quality system supports the registration of NCEs or NBEs with the US-FDA, EMEA, PMDA and other global regulatory agencies by our partners.

Cerbios holds several active DMFs (US, EU, JPN) in CTD format and is regularly inspected by our partners, Swissmedic (last inspection January 2009, recommendations only) and the US-FDA (last inspection in 2000 with no 483).

The site has also received full accreditation from the Japanese PMDA.



### Chemical Division Services

The Chemical Division has specialized for 30 years in **Reduced Folates** (leading position), but also in the manufacturing of **High Potency Active Ingredients (HPAIs)** with a long-term experience in the field of **Vitamin D** derivatives requiring sophisticated production units with high containment levels.

Our specialties:

- **Reduced Folates** (leading company). Most commercialized APIs are offered
- **Vitamin D** derivatives. Extensive expertise in Vitamin D chemistry with support for best synthetic pathway choice
- **High Potency Active Ingredients (HPAIs)** up to class 3

**The services provided for the development and manufacturing of APIs and HPAIs are:**

R&D phase

- Process and analytics development and validation
- Patent searches
- Regulatory support (US, EU, JPN)
- Non cGMP starting material supply chain management optimization

Manufacturing

- From grams to kilograms (HPAIs)
- From kilograms to multi-tons (APIs)
- In different cGMP HPAl production units



### Biological Division Services

Specializing in the research, development and production of Probiotics as active pharmaceutical ingredients, as pharmaceutical finished products and feed additives, Cerbios has also a vast experience with a state-of-the-art CHO platform.

Our specialties:

- **Probiotics** of pharma quality (leading company)
- **Recombinant Proteins** from mammalian cells (CHO)

**The services provided for the development and manufacturing of Recombinant Proteins are:**

R&D phase

- Cloning of the gene of interest
- Upstream & downstream process development
- Process and analytics optimization and validation
- Optimization of synthetic media for key parameters like cell viability and growth, productivity and quality

Manufacturing

- Up to 100 liter bioreactor for Recombinant Proteins
- Project for larger production unit available (up to 4'000 liter bioreactor)

### 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 HPAl conjugates with Recombinant Proteins or antibodies.



# High Quality & Reliable Services

## Our working philosophy

An established product portfolio is complemented by contract manufacturing services for the development and manufacturing of New Chemical and Biological Entities (**NCEs, NBEs**) or future generics on exclusive basis. All classical activities required for clinical supply and successful registration are provided by Cerbios-Pharma SA like: technology transfer, process development, scale-up, validation and regulatory support.

### Chemical Division

Chemistry since 1979

- **Reduced Folates** (leading company)
- **High Potency Active Ingredients (HPAIs)** up to class 3
- Extensive expertise in **Vitamin D** chemistry offering support for best synthetic pathway choice

Manufacturing capacity can vary from few grams up to kilograms in two separate production units for HPAIs or multi-tons for classical APIs in a third production suite.

Over ten years' experience in manufacturing HPAIs.

### Biological Division

Biology since 1976

- **Probiotics** of pharma quality (world's leading company)
- **Microorganism based APIs**
- cGMP Manufacturing of **Recombinant Proteins** from mammalian cells (CHO)

Long-term expertise in upstream and downstream process development includes the optimization of synthetic media composition for best productivity and quality.

Over fifteen years' experience in Recombinant Proteins.

**Conjugates** of HPAIs with Recombinant Proteins: the logical synergy of both our divisions.

[www.cerbios.ch](http://www.cerbios.ch)

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