

CERBIOS-PHARMA SA

Over more than four decades, Swiss-based CERBIOS has built up a reputation as a respected and innovative manufacturer of chemical and biological active pharmaceutical ingredients (APIs) and Highly Potent Active Ingredients (HPAIs). The company's mission is to provide excellent and unique services that help partners to achieve their specific business objectives, based on impressive experience in developing and manufacturing New Chemical Entities (NCEs) and New Biological Entities (NBEs), together with expertise in scale up and optimization of production processes.

Products and Services

CERBIOS has developed a wide range of distinctive chemical and biological API products and related services, guided by an overall vision of proactively promoting product innovation to create options for superior clinical profile through access to innovative technology platforms.

CERBIOS focuses its CMO activities on small molecule, biologics and antibody-drug conjugates (ADCs), serving large, mid-size and emerging pharma companies, innovators and generics manufacturers. The company serves customers in Europe, North America and Japan as well as emerging markets in Central and South America, India, China and South East Asia.

CERBIOS operates in two divisions:

Chemical Division

CERBIOS' Chemical Division offers more than 35 years of experience in small molecules area, with most of its products derived from Vitamin D derivatives and reduced Folates, in which CERBIOS is a world leader. The division applies advanced technologies, including preparative HPLC, Continuous Flow Chemistry, Photochemistry and Particle Engineering for R&D purpose as well as cGMP manufacturing.

Reduced Folate products include Calcium Folate (Leucovorin Calcium), Calcium Levofolate, Folinic acid, 5-Methyl-Tetrahydrofolic acid, Calcium Salt, Sodium Folate, as well as other Folates manufactured exclusively for clients.

Since 1993, the division has also specialized in development, scale-up and commercial manufacturing of HPAIs, and in particular of Vitamin D Derivatives (analogues), such as Calcitriol, Calcipotriol/Calcipotriene, and Doxercalciferol.

Thanks to the unique technologies available, CERBIOS' Exclusive Contract Manufacturer services to third parties has rapidly grown in the past year and in particular in the Development and manufacturing of HPAIs that have specific pharmacological activities at very low dosages (<0.1mg) or high containment requirements (OEL <10 ng/m³, Category 4 Safebridge) from preclinical, through cGMP clinical material to commercial supply.

Therapeutic areas mainly served include dermatology, oncology and respiratory but of course include to all therapeutic areas where HPAI are developed.

Biological Division

CERBIOS Biological is a leading European force in cGMP manufacturing and supply of pharma-quality Probiotic active ingredients.

Its services are based on long-term expertise with Enterococcus Faecium SF68®, capabilities in microencapsulation technology to increase process stability of probiotic feed additives and state-of-the-art CHO platforms.

Biological Division can offer exclusive development and manufacturing of probiotics, recombinant proteins and monoclonal antibodies (MAbs).

CERBIOS portfolio include:

- **Recombinant proteins:** Patented Recombinant Urokinase (r-UK)

- **Probiotic Pharmaceuticals:** Bioflorin product line, APIs and intermediates, bulk pharmaceuticals and finished products on exclusive base
- **Probiotic feed additives:** Cernivet® LBC G35, Cernivet® LBC ME10, Cernivet® LBC ME20 plus, Cernivet® LBC ME5 PET
- Development and manufacturing of **Monoclonal Antibodies** and **Recombinant Proteins** on exclusive basis

Antibody Drug Conjugates and Monoclonal Antibodies

CERBIOS has leveraged the combined experience in HPAs and Mammalian Cell Culture of its Chemical and Biological Divisions to offer CMO services in development and manufacturing of ADCs (Antibody Drug Conjugates).

Conjugation process is performed in a Safebridge Category 4 facility.

Partnering with selected technology-driven companies, CERBIOS offers access to innovative conjugation technologies to increase Cytotoxic Warheads loading on mAbs.

Innovation

CERBIOS holds numerous patents related to particle engineering; bioavailability enhancement and continuous flow chemistry. It has also developed a patented form of recombinant Urokinase (r-UK) as well as its world-beating expertise in *Enterococcus Faecium*, producing SF68®.

Structure and history

CERBIOS was formed in 1994 from the merger of three Lugano-based companies: Cernitin, Bioferment, and Sapec; all three of which had been under the same ownership since the mid 1970s. The CERBIOS name is an amalgamation of the names of the three constituent divisions.

Quality, Regulatory and Standards

CERBIOS operates an internal quality assurance system based on FDA, EMA, PIC/S and ICS guidelines.

Its Lugano manufacturing site is GMLP compliant and is regularly inspected by partners as well as Swissmedic, the FDA, SQS (Swiss Association for Quality & Management System) and Japan's PMDA. A recent FDA inspection involved two inspectors working over four days. The CERBIOS production site has been fully accredited for international manufacture since 2005.

CERBIOS has several approved Drug Master Files (DMFs) active in the USA, EU and Japan and uses eCTD software for electronic submissions.

CERBIOS has developed and implemented an outstanding Management System to provide the framework and tools to manage evolving issues efficiently, while meeting high levels of HSE performance in addition to gaining the satisfaction of both our customers and regulatory authorities.

CERBIOS HSE objectives of prevention of accidents, injuries and pollution and maintenance of world-class performance are achieved through QbD quality design, risk assessment and continuous training.

SafeBridge assessment has confirmed the highest containment level for CERBIOS at Category 4 (up to OEL < 10 ng/m³) for both its small scale and batch production HPAI production units.

Contact

To learn more about CERBIOS products and services and how they can assist your business, please contact the supplier.