Fostering Value through Innovation

cerbios

About us

VISION

"To provide excellent services, helping our partners to achieve their core business objectives"

MISSION

"To be a leading company in distinctive chemical and biological API products and services"

With over 40 years in the Pharmaceutical Industry, Cerbios-Pharma SA (from now on "Cerbios") is a privately held company headquartered in Barbengo-Lugano, Switzerland, that specialized in the development and manufacture of both chemical and biological APIs for its partners worldwide.

In addition to the production unit in southern Switzerland, Cerbios offers its APIs from a second plant through its subsidiary GMT Fine Chemicals SA ("GMT"), located in Couvet (Neuchâtel) specialized in the production of Reduced Folates.

Chemical Division

Biological Division

Beyond the development of its product pipeline Cerbios acts also as Contract Development and Manufacturing Organization (CDMO). Exclusive, third-party manufacturing services are provided by the Chemical Division for High Potency Active Ingredients (HPAIs also HPAPIs) and by the Biological Division for monoclonal antibodies (mAbs), recombinant proteins and pharmaceutical probiotics.

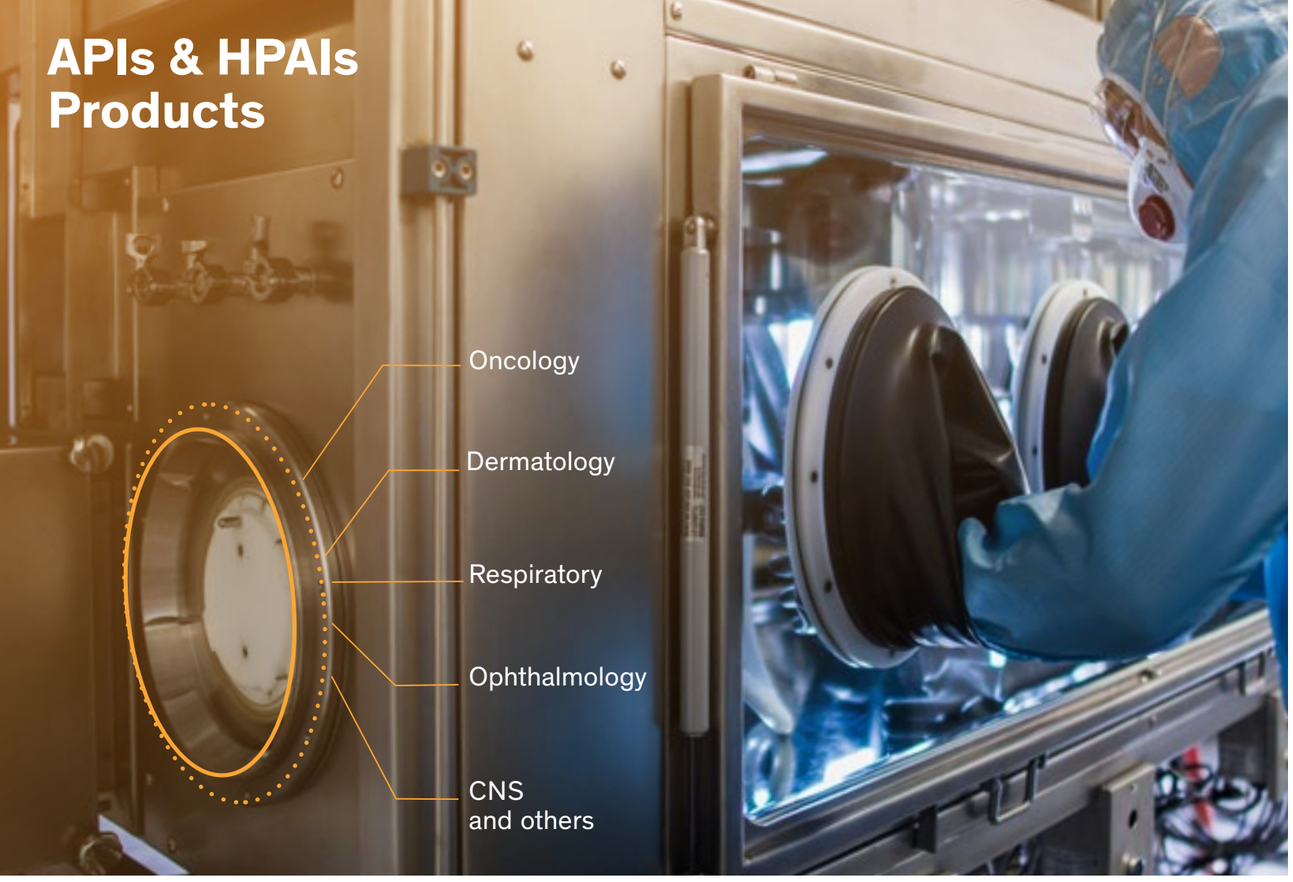
Cerbios offers as well a comprehensive service in the development and manufacturing of Antibody Drug Conjugates (ADCs), including the toxin (payload) and the conjugation steps of the process, combining its know-how in both biologicals and highly potent small molecules. Full CMC support is provided to our worldwide partners, supplying cGMP clinical batches, registration/validation material and commercially manufactured APIs. Paramount to this is the service and experience to supply all the technical documentation and necessary regulatory support for successful registration. Our commercial products are marketed worldwide, primarily in Europe, USA, Japan and India.

Cerbios' long-terms partners appreciate our values:

- Committment to open and constructive communication
- Excellence in working together
- Professional project management system
- Partner focus
- Respect for people and the environment
- Innovation and creativity

Last but not least, a sustainable strategy, intended as a balanced approach to long-term financial, social and environmental value creation, is deeply integrated in the company business model.

APIs & HPAIs Products



As a leading company with over 40 years of experience in Reduced Folates and in the development and manufacture of Highly Potent Active Ingredients

Cerbios is specialized in high quality cGMP manufacturing of APIs and HPAIs for clinical and commercial supply in different therapeutic areas.

We hold:

- **2 production lines**
  for non potent APIs
- **1 small scale production unit**
  for non potent APIs and intermediates
- **3 HPAI production lines**
  for Highly Potent Active Ingredients

Cerbios is continuously working on the expansion of its product pipeline in the therapeutic areas where it has always been present and developing at the same time its presence and services in new areas. It is in its scope to be a leading supplier of HPAIs that have specific pharmacological activities at very low dosages (<1 mg) or high containment requirements (Category 4 SafeBridge).

Therapeutic areas include:

- Dermatology
- Oncology
- Respiratory
- Ophthalmology
- CNS and others

Reduced Folates

Reduced Folates were first developed by Cerbios in 1979 and are now manufactured both in Lugano and in Couvet. Over the years, its expertise led Cerbios become the leading supplier in the field of Reduced Folates, selling its products worldwide, including USA, Japan, Europe and BRICS. We offer the most extended pipeline of different therapeutically used Reduced Folate derivatives.

In our life, Folates are crucial for proper brain function; for the production of DNA and RNA, especially in infancy, adolescence and pregnancy and for the production of red blood cells. A proper intake of Folates by the mother in the prenatal phase can be a good prophylaxis against the risk of birth defects like spina bifida and language delay in children. A correct Folates consumption may help to prevent heart disease, age-related macular degeneration and depression.

As pharmaceutical products, Folates are normally prescribed in (1) Oncology and (2) Womens't health and pregnancy.

Vitamin D Derivatives

Cerbios has been manufacturing and commercializing HPAIs since 1993 and is continuously working to develop new products in this area and improve their quality.

In general, Vitamin D helps the body to absorb and use Calcium. Vitamin D deficiency can cause several problems including:

- Osteomalacia
- Osteoporosis
- Rickets

For example:

Calcitriol regulates the concentration of calcium and phosphate, for the healthy growth and remodeling of bone.

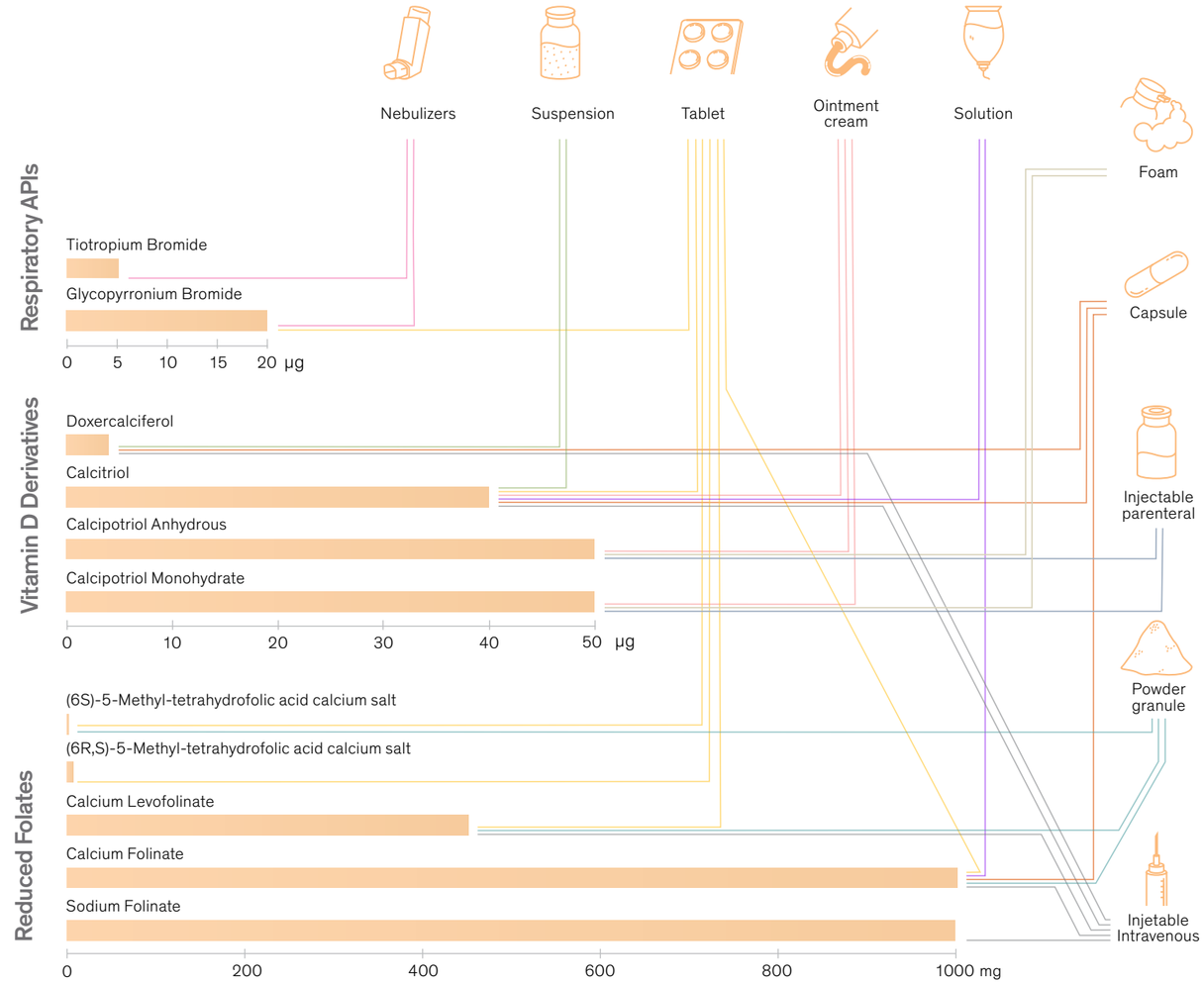
Calcipotriol is used in the treatment of psoriasis.

Respiratory Active Ingredients

We have developed and are developing and manufacturing Drug Substances used in respiratory inhalation therapies that are inherently HPAIs.

Given the strict requirements for inhalators, our strategic commitment ensures a high level of technical and regulatory standards to position the company among the leading suppliers of respiratory Actives.

The portfolio of this category of HPAIs and related derivatives, including innovation on new synthetic routes, chemical processes and polymorphs, enables Cerbios to offer to third parties some exclusive services for NCE in this area (see Chemical Services).



Contract Development and Manufacturing

Cerbios is highly qualified in process development of new APIs and HPAIs for preclinical, clinical and commercial supply

With a long-term expertise in the development and industrial scale manufacturing of APIs and its know-how in handling HPAIs, Cerbios is the ideal and reliable partner for your New Chemical Entity (NCE) from preclinical, through clinical to commercial supply.

Over the years Cerbios continues to invest in facilities, training and technologies to strengthen and extend its services in the field of HPAIs in order to keep the highest standards of quality, safety and efficient manufacturing practices.

Small molecule contract manufacturing services includes:

- Full CMC service
- Analytical methods development and validation
- Process development based on QBD principles
- Production and supply of Drug Substance from clinical trials to commercial supply
- Regulatory proficiency for worldwide DMF submission

HPAIs Development and Manufacturing

Our HPAIs facilities are designed to operate to the highest containment level according to SafeBridge categorization (Maximum level at SafeBridge 4: < 10 ng/m³ OEL). This allows the safe handling of highly-potent intermediates and Drug Substances of different categories including cytotoxic APIs and toxic payloads for Antibody Drug Conjugates (ADCs).

Leveraging on its Biological division on the same site, Cerbios provides full ADCs development and manufacturing services (for more details look at the ADCs chapter).

Continuous Flow Technology for HPAIs

Cerbios provides commercial scale expertise in developing continuous flow chemical processes. Integrated offer is completed with fast and efficient cGMP scale-up within Cerbios manufacturing units employing available micro-reactor systems or dedicating new systems to the partner's HPAIs.

High Pressure Liquid Chromatography for HPAIs

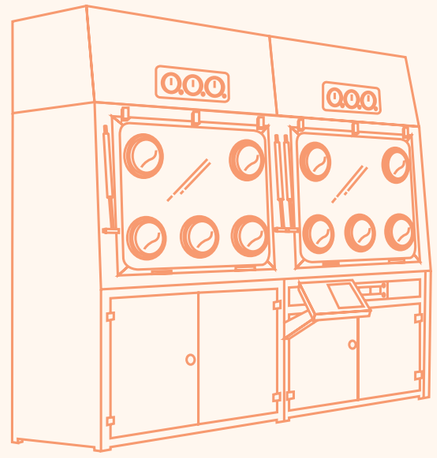
State-of-the-art preparative liquid chromatography units are installed and regularly used in the manufacturing processes of commercial scale HPAIs. The technology allows Cerbios to manage the isolation and purification processes for any kind of difficult to make substances.

Category 3-4* HPAI production units

* According to SafeBrige categorization

5 Units — Fully isolated and contained according to *SafeBridge standards*

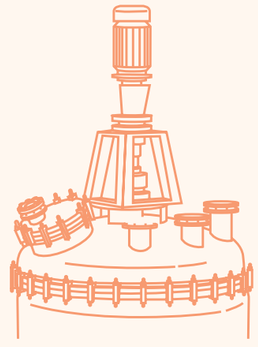
cGMP unit	**10 – 100 gm/batch**
cGMP modular unit	**200 gm – 2 kgs/batch**
*cGMP unit***	**5 – 30 kgs/batch** ** New, operational in 2020
Non cGMP unit	***up to* 50 gm/batch** For Drug Product development
Non cGMP unit	***up to* 100 g/batch** For Drug Product development or Tox studies



Category 1-2* API production units

2 *Large scale Production Line* — **20 – 300 kgs / batch**
For the production of APIs

1 *Small-scale Production Line* — **<5 kgs / batch**
For the manufacturing of APIs and cGMP advanced intermediates



Probiotics: Products and Services

Cerbios is a leading company for Pharmaceutical Probiotics

With over 40 years' experience, Cerbios is renowned to be a worldwide leading company in the field of pharmaceutical probiotics.

Its expertise includes:

- Fermentation
- Drying
- Micro-organisms' stabilization
- Drug Product formulation

Based on its proprietary active ingredient *Enterococcus faecium* SF68® (strain deposit *E. faecium* NCIMB 10415), Cerbios produces in dedicated production lines and commercializes probiotic products for pharmaceutical and feed applications which are marketed under different trademarks in countries all over the world.

Pharmaceutical probiotics

The recent discoveries in the field of the microbiome and its correlation with human health have increased the interest in the development and production of probiotics which is a core competence of Cerbios' Biological Division since 1976.

SF68® has been used since decades in various specialties and is considered as one of the best characterized probiotic with a long history of safe use for solving gastrointestinal disorders.

Feed Additives probiotics

The probiotics produced by Cerbios and used as feed additives are defined as micro-organisms that stabilize the intestinal microflora. They are based on its proprietary probiotic active ingredient *E. faecium* SF68®, and are sold under the trade name Cernivet®. These products are registered in EU (approved by EFSA) and successfully used in broilers, calves and pigs in many countries and in different climatic and rearing conditions.

The various formulations (in the form of granules or microcapsules) of Cerbios' product range meet the requirements of the modern feed industry and have been developed for use in premixtures, milk replacers, water, mash feed and pelleted feed.

Continuous research leads Cerbios to keep developing innovative new formulations and delivery systems to meet more demanding market needs.

Contract Manufacturing Services

We offer Contract Development and Manufacturing (CDMO) services for pharmaceutical probiotic active ingredients. Renowned global companies are relying on Cerbios' services from the selection of raw materials through to manufacturing, quality control and the release of the Drug Substance and Drug Product.

Full service is provided, including : (1) analytical development; (2) medium optimization; (3) process development and (4) commercial scale-up and supply.

Probiotic Manufacturing Capabilities

6.94×10^{18} cfu
of probiotics produced by fermentation per year

3 Mt per week
of microencapsulated probiotics (will be doubled as of 2020)

Probiotic feed additives based on SF68®

Cernivet® LBC G35
Fine granulate

Cernivet® LBC ME20 plus
Microencapsulated

Cernivet® LBC ME10
Microencapsulated

4 mio. of tons per year
of feed supplemented with SF68®

Pharmaceutical finished products based on SF68®

>1.5 billions
TOTAL CAPSULES PRODUCED

More than 70 mio. Patients treated

Biotechnology

Cerbios offers high quality tailor-made programs for biopharmaceuticals and for Antibody-Drug-Conjugates (ADCs)

A competent and flexible team is provided to help our partners to achieve their project timelines and quality objectives. From cloning to cGMP production, Cerbios meets your product development and manufacturing needs for recombinant proteins, monoclonal antibodies (mAbs) and your ADCs.

Recombinant Urokinase

LMW and HMW bioprocess developed and patented by Cerbios

Recombinant proteins and Antibodies

Cell Line Development and Cell Banks Manufacturing:

Cerbios' Cell Line

- Use of proprietary and royalties-free mammalian cell line
- Full and modular service (from DNA sequence to cGMP Cell Banks)

Partner Cell Line

- Tech transfer and optimization of partner Cell Banks
- Tailored Research Cell Bank (RCB) with stable and high yield expression of therapeutic recombinant proteins (including mAbs) for either early development samples or Master Cell Bank (MCB) manufacturing
- Master Cell Bank and Working Cell Bank preparation under cGMP conditions with related regulatory documentation.

Process Development Activities

- Upstream and downstream processes optimization

Manufacturing of cGMP Batches:

- cGMP material is provided with all the documentation required for clinical trials and registration both at process level and at analytical level, following the different clinical phases up to commercialization
- All the manufacturing phases are carried out in a "state-of-the-art" cGMP plant conceived and set up according to international standards (FDA, PMDA)

Antibody Drug Conjugates (ADCs)

With a solid experience for HPAIs as well as for biotechnology products, Cerbios naturally evolved as CDMO for ADCs. Cerbios is one of the front-runners and a recognised partner for startups and pharma companies having ADCs in their pipelines.

A continuous improvement of its know-how supported by dedicated investments and a strong project management system, positions Cerbios as a CDMO of choice for ADCs.

Conjugation process development

- Early stage process development for the generation of Proof-of-Concept (POC) ADC libraries
- Tailored analytical development
- Process development for scale-up manufacturing (Toxicology and cGMP Batches)
- Manufacturing and supply of batches for IND submission

cGMP Manufacturing

- Manufacturing carried out in a state-of-the-art cGMP plant conceived for worldwide supply
- Supply of cGMP batches for clinical phases and commercial needs

Fully Integrated manufacturing solution on a single site in Lugano

- R&D labs for process and analytical Development
- Payload manufacturing in one of our HPAI unit
- mAb production in the biotech production unit or at a partner designated production site
- Bioconjugation steps and final purification
- QC labs with harmonized IPC and final release on site

In addition, we can provide solutions for Fill & Finish of your ADCs

First conjugation project in **2008**

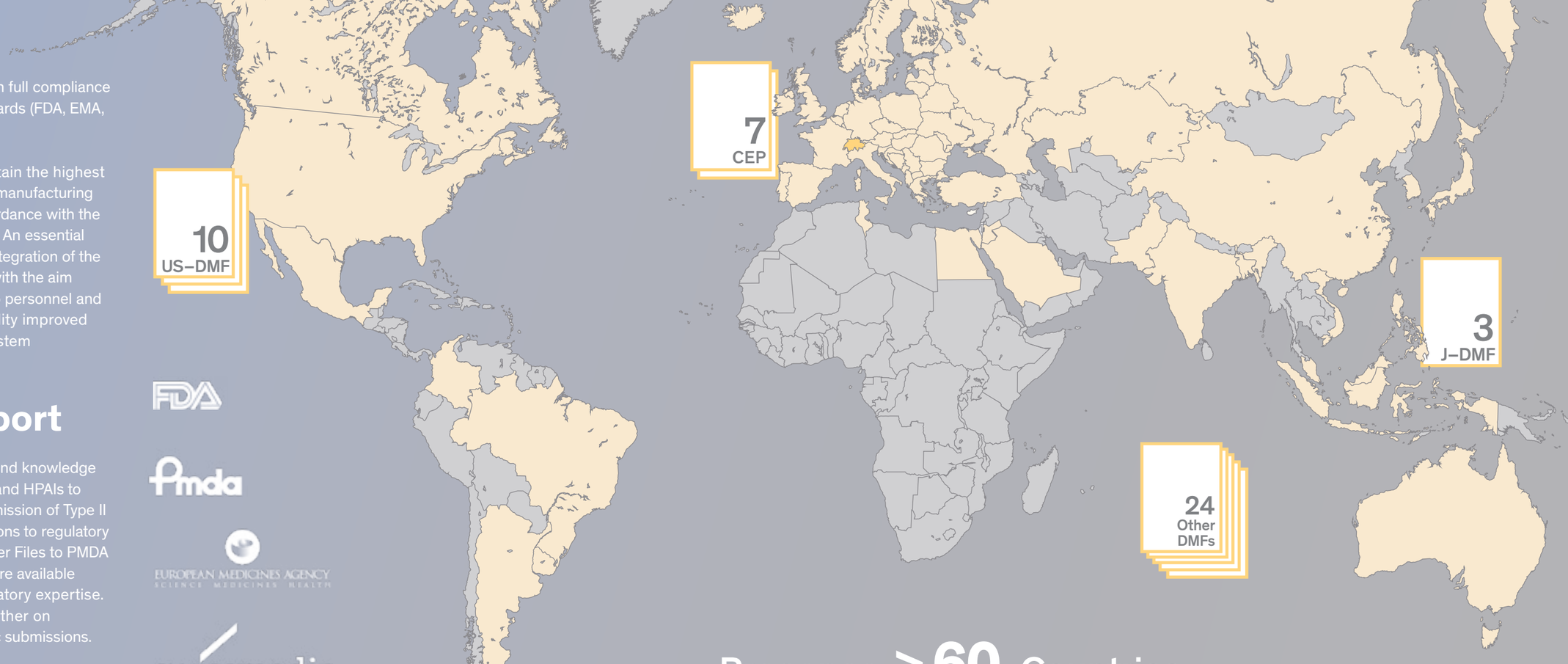
Quality System

Cerbios supports its partners worldwide in full compliance with international quality and safety standards (FDA, EMA, PMDA, OSHA, ECHA…).

The aim of our Quality System is to maintain the highest quality standard for our production units, manufacturing processes, services and products in accordance with the latest cGMP guidelines and requirements. An essential element of this process is the complete integration of the HSE System (including risk assessment) with the aim of preventing any accidents and injuries to personnel and protect the environment. A culture of quality improved into a Quality by Design (QBD) based system

Regulatory Support

Cerbios has over 40 years of experience and knowledge in successfully submitting DMFs for APIs and HPAIs to the major authorities worldwide. The submission of Type II DMFs to US FDA, ASMFs or CEP applications to regulatory authorities in Europe, and translated Master Files to PMDA in Japan, are common practice. Services are available for our biotech partners that need regulatory expertise. Regulatory dossiers can be submitted either on paper, as eCTD or as non-eCTD electronic submissions.



Presence > 60 Countries

Project Managment

A full Project Management system is paramount to a substantial support to the entire process from development to supply.

Our Project Management Office from development to supply and provides a single point of contact with our partners to ensure rapid and efficient communications. This helps to ensure that projects are delivered on time and on budget, and make sure that Cerbios' partners are continuously informed on progress.

From project evaluation to its execution, Cerbios project management system coordinates multi-disciplinary teams, project related activities and timelines to ensure best possible partner experience:

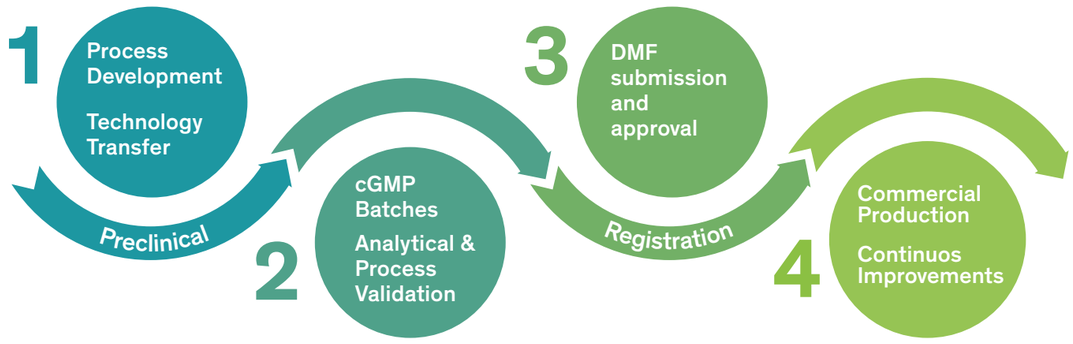
- Dedicated and transparent approach to partner relationship
- Continuous best practices evolution
- Responsive and solution driven
- Flexible and cooperative

> 20h
Person per year
dedicated to PM training

16
Active
Portfolios

120 Current Programs

> 80 New projects per year



Health, Safety & Environment (HSE)

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, gaining the satisfaction of both our partners and regulatory authorities.

With the support of external partners a structured approach is followed in the management of risks, based on design quality, risk assessment and continuous training.

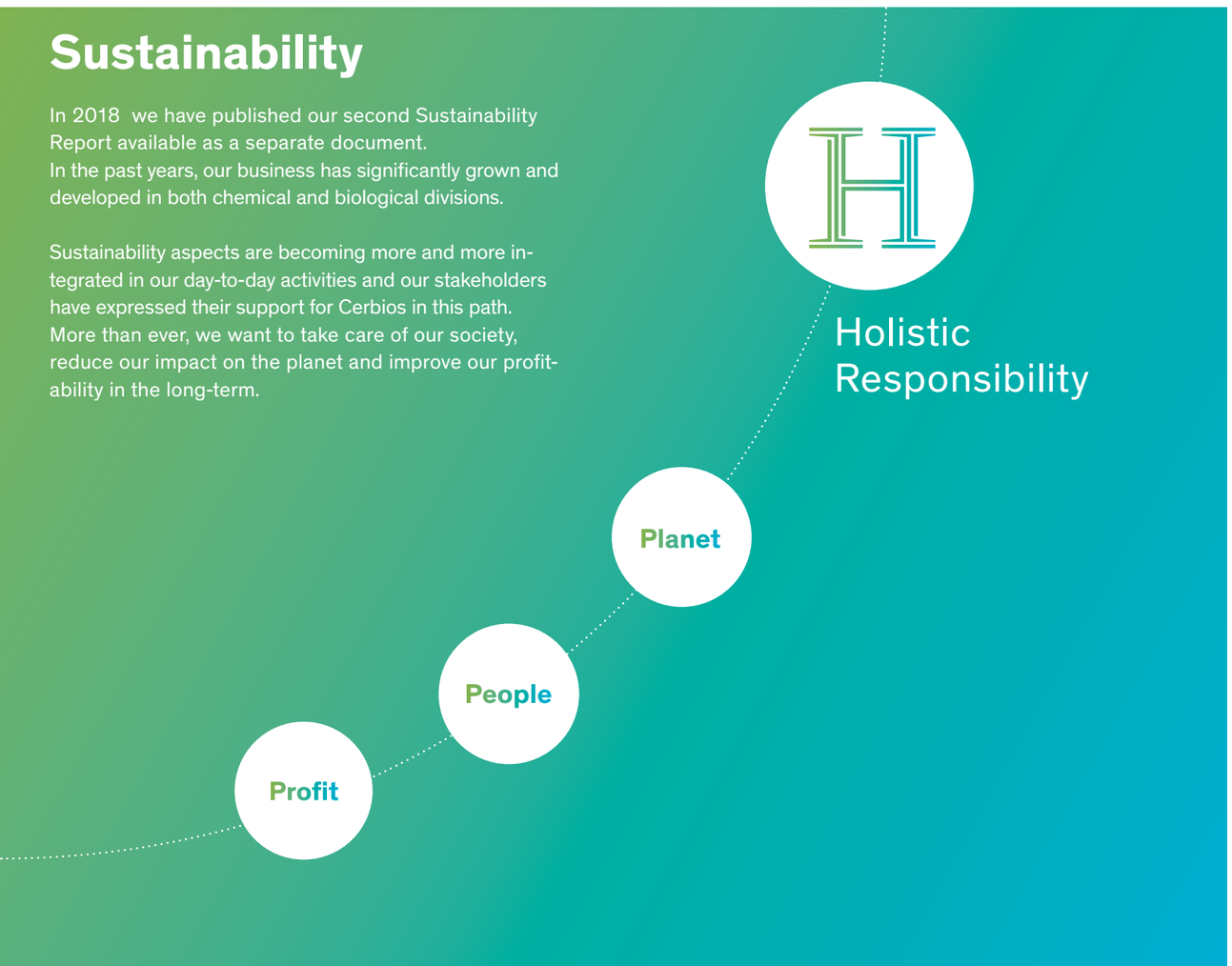
Since Cerbios handles HPAIs with very low OEL, a strict occupational hygiene program has been implemented with the co-operation of SafeBridge Consultants.

The assessment has confirmed the highest containment level suitability for Cerbios equipment: Category 4 (OEL < 10 ng/m^3) for each HPAI production unit.

Sustainability

In 2018 we have published our second Sustainability Report available as a separate document.
In the past years, our business has significantly grown and developed in both chemical and biological divisions.

Sustainability aspects are becoming more and more integrated in our day-to-day activities and our stakeholders have expressed their support for Cerbios in this path.
More than ever, we want to take care of our society, reduce our impact on the planet and improve our profitability in the long-term.



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