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EUROPE SPECIAL

pharma TECH OUTLOOK

CMO EDITION

Denis Angioletti, CCO

cerbios

Fostering Value through Innovation®

INNOVATING END-TO-END CDMO SERVICES

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The annual listing of 10 companies in Europe that are at the forefront of providing CMO/CDMO solutions and transforming businesses in the region

COVER

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STORY

Dr. Vitor Sousa,
BD Manager

INNOVATING END-TO-END CDMO SERVICES

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TOP 10
CMOs/CDMOs IN EUROPE - 2022

By Stacey Smith

Today, the pharmaceutical industry is riddled with disrupted supply chain processes and evolving regulatory mandates caused by the COVID-19 pandemic. This, combined with the mounting pressures of shrinking timelines and ever-changing market requirements, is leading drug developers and manufacturers to implement tech-driven solutions capable of supporting their clinical trials and subsequent production. As a result, the current pharma landscape is brimming with innovative contract drug manufacturing organisations (CDMOs) offering R&D and production capabilities across all stages of drug development.

However, as most CDMOs only handle specific facets of the overall development and manufacturing of a product, drug manufacturers often have to collaborate with multiple vendors to continue exploring the ever-evolving world of active pharmaceutical ingredients (APIs) and their potentially endless applications. Particularly in process development, scale up, and industrial production of APIs and their derivatives, drug developers find themselves between a rock and a hard place because the current CDMO arena lacks a partner with the proven ability to safely perform chemical and analytical processes on sensitive and costly molecules. The need of the hour is a CDMO that can provide a robust, reliable, compliant, and safe way to handle and process critical API and other pharma ingredients.

Switzerland-based Cerbios was quick to foresee this rise in the significance of offering comprehensive services for APIs across the different stages of drug development, and thus, over its 45-year journey in the pharma space, Cerbios has been investing heavily in API-related R&D, HSE, QA, QC, RA, and manufacturing capabilities. Apart from its breadth of API-related offerings, Cerbios also blends its advanced CDMO services and broad project management expertise to help clients overcome their clinical and/or production hurdles. "Our long-standing history in the pharma space combined with our customer and innovation-driven work culture makes us a unique partner that offers CDMO services on a par with big pharma firms while retaining the ability to make every customer feel special," says Denis Angioletti, chief commercial officer, Cerbios.

Concurrently, the company's core pillars of always delivering safe and sustainable services are evident in Cerbios' focus on prioritising safety and sustainability over merely addressing challenges. For instance, the company is continually striving to implement greener technologies and processes that produce significantly lower hazardous waste material.

Presently, the company's flagship CDMO offerings include its three-decade R&D-backed highly potent API (HPAPI) handling and its leading antibody-drug conjugate (ADC) development and manufacturing capabilities. Apart from these, Cerbios provides services to enhance the rate and efficiencies of all product-related tasks, from early stages through clinical trials to commercial supply. The company also leverages its long-running pharma expertise to help customers always be in lockstep with the latest regulatory mandates and compliance requirements. "Our seasoned team leverages the design of experiment (DoE) and quality by design (QbD) approaches with their professional project management know-how to simplify clients' drug development journey and enhance their go-to-market speed," says Dr. Vitor Sousa, BD Manager at Cerbios.

CDMO Services Backed by Rich History

Cerbios opened its doors back in the early 1930s when the founders envisioned a company to serve the burgeoning pharma sector in Southern Switzerland. Subsequently, in the 1970s, deep biological and chemical process capabilities were added to Cerbios' portfolio. Since then, the company has only grown to expand its offerings in line with the changing pharmaceutical arena, leading Cerbios to focus on the development, manufacturing and commercialisation of HPAPIs and ADCs.

According to Valentino Mandelli, M&S manager at Cerbios, the HPAPI arena has undergone core changes over the years as more stringent regulations concerning the development, storage, analysis, and handling of such molecules emerged. To help its customers navigate this complex minefield of compliance prerequisites, Cerbios leverages its industry know-how and applies precise chemistry, manufacturing, and controls (CMC) following cGMP protocols. The different classes of APIs that the company is actively manufacturing include Cytotoxic molecules, COPDs, payloads for ADCs, Vitamin D derivatives, Reduced Folates, and more. Currently, Cerbios has eight manufacturing units, out of which five units are dedicated to HPAPIs fully isolated and contained according to SafeBridge standards up to Category 4.

On the other hand, Cerbios is one of the front-runners in the ADC development arena owing to

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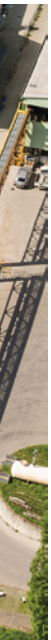
its unique ability to offer the development and manufacturing of ADC and all its components (mAb, toxin/payload, conjugate) in a single site. The company combines process development with manufacturing capabilities to provide a truly end-to-end service that improves effectiveness without compromising the speed and efficiency of clinical trials. Cerbios further expands its ADC services with its PROVEO division that extends the capacity for mAbs (at AGC Bio) and fill-finish services (at Oncotec). From a production standpoint, the company has two fully independent cGMP manufacturing facilities for cytotoxic and non-cytotoxic bioconjugates with 5L-200L single-use reactors, bioburden controlled processes, and dedicated freezing equipment to facilitate effective lyophilisations and drive zero wastage, faster production, and higher cost-savings.



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Delivering Customer Success with Innovation

With such unmatched capabilities, Cerbios has ignited several success stories since its inception in 1976. In a recent case, the company assisted a large drug manufacturer in effectively translating their medicinal chemistry processes into industrial production. To do this, the company assessed the client's findings and, taking advantage of its long-standing expertise, facilitated the creation of manufacturing processes with enhanced yields that aligned with the specified medicinal chemistry and allowed commercial level manufacturing of the end-product. Similarly, Cerbios has also helped customers working with HPAPIs in developing newer process steps capable of helping them improve their yield, minimise their time, and lower operational expenses.

At the heart of the company's success is its ability to align its offerings and delivery approach with the unique needs of a customer and/or the pharma industry at large. Cerbios places significant emphasis on its team's ability to work closely with its clients as a way to gain a deeper understanding of their challenges and find newer and holistic ways to mitigate them. This facet of the company's culture is backed by its drive to constantly invest in emerging technologies that can optimise the discovery, development, and commercialisation of APIs, ADCs, and their components. Another key facet that gives Cerbios a competitive edge is the company's methodical and efficient approach to client projects, which drives better transparency and visibility for all relevant parties.

Towards a Greener and Safer Pharma Sector

Looking ahead, Cerbios is expanding its production and R&D capabilities to attract more clients. "We are investing with the purpose of implementing up to date technologies and increasing the number of manufacturing lines designed on the basis of modern concepts to fulfil the latest safety standards by keeping the maximum flexibility," adds Angioletti. An example of this is Cerbios' use of virtual audits that allow customers to verify that all steps of their product's development, -manufacturing, and analysis are performed as per cGMP standards regardless of their location. This tool has been popular throughout the pandemic as it helped Cerbios' customers quickly overcome the emerging travel restrictions.

From a partnership perspective, the company is currently collaborating with top CDMOs specialised in different sectors to grow its PROVEO division and engaging with global logistics companies to ensure efficient, safe, and timely delivery of sensitive molecule samples worldwide. To conclude, Dr. Sousa reiterates the ethos of Cerbios, "With our core competencies and comprehensive CDMO services suite, we want to continue helping pharma organisations develop innovative drug molecules as a true 'one-stop shop' that addresses all their needs, from development to commercial supply."

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