



UNLOCK NEXT-LEVEL HEALTH SOLUTIONS

A NEW GENERATION OF CDMO SERVICES



Custom Development & Manufacturing services have been one of Indena's key areas of expertise for more than 30 years now.

Leveraging on its analytical, development and manufacturing capabilities, Indena positions its services in a high added value segment, producing complex molecules requiring both leading technologies and significant expertise in R&D and industrialization, encompassing **high containment handling and production of HPAPIs from early stage to commercialization.**

Indena's goal is to offer its customers the possibility of carrying out **synthetic processes in a wide range of conditions, both for naturally derived molecules** (from botanical sources or from microbial fermentation) **requiring semi-synthetic steps and for total-synthetic molecules.** As a highly reliable Western European API producer, Indena displays a **key uniqueness on Highly Potent APIs** down to 20ng/m³ OEL, irrespective of their source, for which Indena is highly skilled and well equipped.

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This expertise includes **payloads for ADCs, with a backward integration on fermentation for toxins** requiring this step and **freeze-drying ability in high containment.**

Indena has been continually investing in know-how, personnel and equipment for its CDMO services for many years. Its most recent expansion program includes the construction of a **brand new 400 sqm R&D laboratory** equipped with 12 fumehoods, 2 walk-in fumehoods, 1 laminar flow fumehood, 2 gloveboxes able to host 15 R&D scientists.

This laboratory has been **conceived and built specifically to handle Highly Potent APIs** and will be up and running by mid-2024.

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INDENA'S CDMO SERVICES: THE FORMULA FOR CLIENTS' SUCCESS

In CDMO services, Indena acts as a strategic partner, going beyond the mere client/supplier relationship, with **full commitment to developing new HPAPIs and APIs, from early clinical stages to commercial-scale manufacturing.**

In order to always meet its clients' expectations, every year Indena invests in innovative technologies and services. The **quality and efficiency of its equipment and facilities**, however, are only half of the story.

At Indena, it's well understood that **highly qualified, motivated and trained technical staff**, supported by a corporate culture that is strongly oriented toward quality and rigorous HSE policies, is essential to ensure that operations run safely, seamlessly and efficiently.



Indena is also well supported by a **strong regulatory department** that continuously interacts globally with the most important national health authorities, such as FDA, EMA, AIFA, ANSN, PDMA.

The strengths of Indena's CDMO offer are then supported by manufacturing excellence programs, the highest equipment standards and qualified human resources.

THE CURRENT CDMO SCENARIO AND INDENA'S STRATEGY TO MEET MARKET NEEDS

The increasing number of oncology NCEs and antibody-drug conjugates, coupled with a growing focus on personalized medicine, is shaping the demand for CDMO services.



The HPAPI market is undergoing a shift toward NCEs characterized by higher potency, growing molecular diversity and segmentation for specific populations.

As shown by its long story and expertise, and unlike newcomers in the field, Indena can count on **extensive know-how in safely handling HPAPIs, complemented by state-of-the-art equipment and installations.**

Within its long-term strategy, Indena has kept ahead of the curve by timely **investment in specialized containment facilities** that guarantee that both employees and the external environment are safe from exposure, capitalizing on more than 30 years of know-how in high containment.

Nowadays Indena manufactures **12 commercial HPAPIs: fully synthetic, semi-synthetic and fermentation molecules.** This is now one of the company's core areas of expertise. Each substance within Indena is assigned an Occupational Exposure Level and allocated to the proper production line according to the required handling and containment rules. At the Settala facility, Indena can handle HPAPIs with an OEL from 1 mcg/m³ to 20 ng/m³ (with ongoing SMEPAC tests to reach 1 ng/m³).

Moreover, Indena has a **fermentation department for carrying out living cells-based bio-transformation or secondary metabolite production,** which can be exploited for the in-house production of toxins used in ADCs payload, guaranteeing an integrated and independent supply chain. Indena masters GMP microbial fermentation and bio-transformation, and thanks to the availability of high containment lines for the downstream phase, it is the **ideal partner for fermentation HPAPI development.**

SUSTAINABILITY: A CONCRETE COMMITMENT

Indena constantly works to drive progress towards the UN's Sustainable Development Goals, aiming to prioritize sustainability in every phase - **from raw material sourcing to production and marketing** - with a focus on environmental impact, use of renewable energies and a tangible contribution to a more circular economy.

In particular, climate change is one of the most urgent sustainability challenges that people, governments and companies have to face. Recognizing responsible use of energy as a key factor in this context, **Indena has always been oriented and committed to reducing fossil fuel consumption by saving energy as well as by achieving high levels of energy self-production.** Plant management - starting with Indena's most important site, located in Settala near Milan in Italy, where the company's CDMO activities are carried out - plays a pivotal role in this.



Another important action for sustainability is the use of renewable energy, and Indena is equipping all its European sites with state-of-the-art photovoltaic panels. Moreover, **all of Indena's European factories are certified according to the ISO 14001 Environmental Management System and ISO 45001 Occupational Health and Safety Management System.**

All these strategic actions taken in favor of sustainability also make Indena fully reliable in terms of business continuity, strengthening the foundations for long-term, solid partnerships with clients.





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