



# HEALTH IS A JOINT PROJECT

A NEW GENERATION OF CDMO SERVICES



SCIENCE IS OUR NATURE. SINCE 1921

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

Leveraging 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 clients 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 totally synthetic molecules.**

As a highly reliable Western European API producer, Indena displays a **unique capability for Highly Potent APIs** down to 1 ng/m<sup>3</sup> OEL, irrespective of their source.

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



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

Indena understands the critical challenges clients face in bringing innovative pharmaceutical solutions to market. Rising demand for niche APIs for orphan applications and HPAPIs, the need for **scalable and flexible manufacturing**, and a growing emphasis on **sustainability** place unique stresses on pharmaceutical and biotech companies alike. That's why recently, during a strategic meeting at the facility in Settala, the Indena team tackled a pressing question: "How can we **expand our capabilities to better support our clients' needs**, while still upholding the highest standards of safety, quality, and sustainability?"



## UNDERSTANDING CLIENTS' NEEDS

Clients have consistently told Indena that they need more than a CDMO: they need a **partner capable of adapting to their requirements, as well as to an ever-evolving industry**. Whether they are scaling up production for a clinical trial or preparing for commercial launch, they need **reliable solutions that align with strict regulatory standards and tight timelines**. In this scenario, Indena recognizes the importance of being proactive. This means investing in both infrastructure and expertise, to ensure clients can count on a trusted partner at every stage of the product development journey.



## STRATEGIC ASSETS AND INVESTMENTS

- **New laboratories:** the highest efficiency for research and production. Indena has been continuously investing in know-how, personnel, and equipment for its CDMO services for many years. The company has recently invested in infrastructure designed to handle an increasing number of HPAPI projects, ensuring maximum efficiency and complete safety during both analytical research and production. The focus is on **the possibility of studying and producing highly potent molecules, from research and tests on small quantities for industrial scale-up to large-scale production**, in facilities that ensure the necessary segregation between GMP manufacturing and R&D activities.

At Indena's **new laboratories**, numerous highly talented researchers work on different projects carrying out **process and crystallization development** as well as **analytical activities**, using a wide range of techniques including chromatography and spray drying.

Every task is performed in complete safety, thanks to **equipment that guarantees exceptional containment up to 1 ng/m<sup>3</sup>**, namely high-containment hoods and **large glove boxes** for solid product processing.

These new research and development laboratories reinforce the excellence of Indena's CDMO services, which stand out on the market for quality, reliability, and completeness.

- **Expanding HPAPI Manufacturing capacity (OEB 5 – OEB 6).** To meet the increasing demand for **targeted, oncological HPAPIs and ADCs**, in the last few years Indena has completed the **expansion of a new manufacturing line featuring 60-liter reactors, effectively doubling its production capacity.**

Further investments have been made to add **new 100-liter reactors**, enabling the **handling of larger quantities of OEB 5 and OEB 6 products for higher commercial volumes**, while always ensuring the **precision and containment necessary for these highly potent compounds.**

- **Expanding niche API Manufacturing capacity (OEB 1 – OEB 4).** Indena has **expanded its GMP plant** with the addition of a **second facility featuring reactors with capacity of up to 10,000 liters.**

This upgrade enhances Indena's ability to process both natural molecules, requiring semi-synthetic steps, and synthetic molecules at scale, providing clients with unmatched flexibility in production. To further meet market demands efficiently, Indena has **installed a 250-liter hydrogenator in combination with the existing 20-liter model.** This enables the company to better accommodate an increasingly broad range of custom synthesis service requirements.



- **Consolidating particle size engineering expertise (OEB 1 – OEB 4).**

To enhance development services related to **amorphous solid dispersions of APIs from organic solvents**, Indena has installed a **new lab-scale Procept spray dryer to support process development.** This addition complements the existing spray drying manufacturing capacity, which already included the Niro PSD2 and an equivalent of the PSD4 system, further strengthening Indena's ability to meet client needs.

- **Supporting clients with long-term regulatory expertise.**

Indena also offers the valuable support of a **strong regulatory department, which continuously interacts globally with the most important national health authorities** – such as FDA, EMA, AIFA, ANSN, and PDMA.

## 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.

Thanks to the investments in energy efficiency initiatives and renewable energy, during the past few years, Indena progressively reduced its absolute consumption (-6% compared to the 2021 baseline).

The natural gas co-generator at Settala covers over 70% of the plant's electricity needs, and newly **installed photovoltaic panels across the company's European sites** produce sustainable energy – allowing to limit purchases from non-renewable sources.



Thanks to these plants the expectation is to reach photovoltaic power generation of over 4MW by 2026. Moreover, within 2030, the target is to have self-generated electricity equal to 10% of total consumed and 80% of electricity used coming from renewable sources. Furthermore, investments will continue in more energy-efficient machinery in order to reduce CO<sub>2</sub> emissions.

Lastly, all of Indena's European factories are certified according to ISO 14001 Environmental Management System and ISO 45001 Occupational Health and Safety Management System. The plan is to have the Bernett, Settala and Tours factories FSSC 22000 certified by the end of 2025, and 100% of production sites certified according to ISO 45001 by 2028.

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





## DELIVERING RESULTS FOR CLIENTS

By enhancing the company's capacity, upgrading technology, and prioritizing sustainability, Indena is equipped to help clients overcome their challenges – from meeting regulatory requirements, to scaling up production, to complying with tight timelines.

At Indena, we are not just suppliers; we are committed to being a forward-thinking and dependable partner for our clients, delivering solutions – not mere services – tailored to their success.

Together, we can navigate the complexities of the pharmaceutical industry and bring life-changing therapies to patients around the world.

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To find out more:

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