

HEALTH IS A JOINT PROJECT

INDENA'S NEXT-GENERATION CDMO

 **indena**[®]
SCIENCE IS OUR NATURE. SINCE 1921



Indena's Custom Development & Manufacturing Organization services offer a full range of manufacturing capabilities for pharmaceutical ingredients including Active Pharmaceutical Ingredients (APIs). Such services include the extraction, isolation and purification of natural derivatives as well as the process R&D and manufacturing of **Highly Potent Active Pharmaceutical Ingredient (HPAPI) synthetic molecules**.

The combination of Indena's expertise with state-of-the-art facilities allows the company to deliver products and processes from small-scale orders for GMP batches for clinical use to large commercial manufacturing supplies.

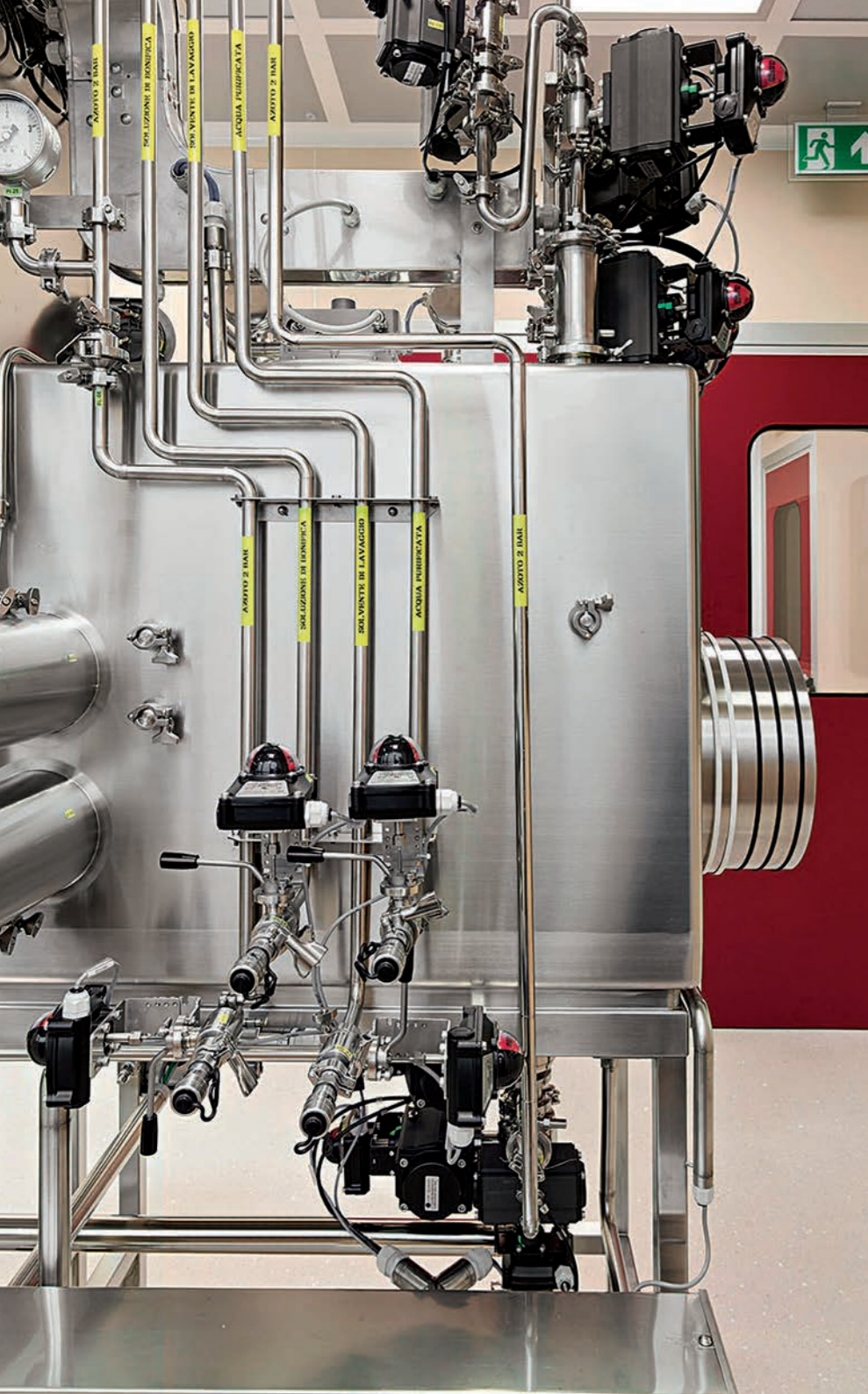
Indena is a full-service provider and a reliable **partner in the cGMP Contract Development and Manufacturing of APIs and HPAPIs**. The company effectively supports both leaders and start-ups in the pharmaceutical and biotech fields, to achieve product success and guarantee patients a healthier life.

CDMO services have been a priority for Indena's strategic business development for years.



With the aim of providing customers with an increasing breadth of services, the company has been **investing in cutting-edge technologies** – and mainly in the expansion of its GMP plant and in the upgrade of the spray drying equipment already at the company's plant.

Moreover, with its **highly specialized Quality Assurance system and Regulatory expertise**, Indena is able to fulfill even the strictest requirements set by regulatory agencies.



NEW KILO LAB LK2

To increase and improve its services to customers, Indena has decided to double the capacity of its kilo lab LK2 for OEB 5 products.

The new manufacturing line is capable of practicing Indena technologies on a larger scale, with 60-liter reactors. This expansion completes Indena's production capacity for HPAPIs, allowing the company to offer **different capacities for products at the highest power level (OEL 20 ng / m³ - OEB 5)**.

PILOT SCALE HYDROGENATOR

To face market requests in the most efficient and flexible way, Indena will be installing a **250-liter hydrogenator** which will be ready at the end of 2023. Together with the existing 20-liter hydrogenator, this will allow Indena to satisfy a wider demand for this kind of service.



NEW PRODUCTION GMP PLANT FOR ACTIVE PHARMACEUTICAL INGREDIENTS

In order to meet its client's needs and expectations, Indena has invested to **complement its GMP plant for active pharmaceutical ingredients with a second facility, equipped with reactors up to 10,000 liters**.

This upgrade exploits Indena's technologies at a larger scale, resulting in a state-of-the-art system in line with the sector's best practices from every standpoint: engineering, safety, quality and batch size.

Indena's goal is to offer clients the opportunity to carry out different processes in a wide range of conditions, for both natural molecules that require semisynthetic steps, and synthetic molecules.



MID- AND LARGE-SCALE SPRAY DRYERS FOR AMORPHOUS SOLID DISPERSION

With over 30 years' experience in the spray drying of organic solvents solutions, Indena has expanded and upgraded its mid- and large-scale spray dryers, working with organic solvents.

After the recent installation of the Niro PSD2 spray dryer ATZ5 – which allows an intermediate production scale and guarantees good containment (usable for products also classified as OEB 4 hazard class) – Indena has also revamped a spray dryer ATZ4 already in use for several years. The ATZ4 has 3-4 times the production capacity of the PSD2, allowing services on a larger scale in this specific area and completing Indena's CDMO offer.

VACCINE EXCIPIENTS

Indena has set up a specific suite to produce vaccine excipients from natural origin on a larger scale. This expands a plant that was already active for the same purpose, using preparative and freeze-drying HPLC in a GMP area.

SUSTAINABILITY: A CONCRETE COMMITMENT, STARTING FROM ENERGY MANAGEMENT AT INDENA'S PLANTS

With climate change among the most urgent sustainability challenges that people, governments and companies have to face today, the responsible use of energy must be a key element in any strategy we undertake. And Indena has always been oriented and **committed to reducing fossil fuel consumption, saving energy and achieving high levels of energy self-production.**

These environmental goals are mainly achieved thanks to the company's far-sighted plant management, starting from the most important site in Settala, near Milan in Italy, where Indena's CDMO activities are carried out.

Among the actions taken for a smart use of energy at the Settala site, a **natural gas co-generator plant** has been operational since 2016: it produces 16,566 MWh per year, in the form of both electric and thermal energy, and enables the company to avoid the use of 1,699 metric tons of oil equivalent (TOEs), which translates into **2,500 metric tons of CO₂ emissions saved every year.**





Another important action for sustainability is the use of energy from renewable sources: that's why Indena is equipping all its European sites with **state-of-the-art photovoltaic panels**. The company will self-produce a total of 5,013 MWh of renewable energy per year by 2023, saving the **equivalent of 2,340 metric tons of CO₂**.

All in all, in 2023 67% of the energy used by Indena will be self-produced, with almost 23% generated from renewable sources, and 5,177 metric tons of CO₂ will be avoided.

Finally, all of Indena's European factories are certified according to ISO 14001 Environmental Management System and ISO 45001 Occupational Health and Safety Management System.

In addition to contributing to the planet's wellbeing, these actions in favor of sustainability make Indena more reliable in terms of business continuity, and therefore allow the company to be a solid partner for its clients.

N LOR_4789



SCIENCE IS OUR NATURE. SINCE 1921



To know more:

indena.com



Contact: cdmo@indena.com

_4789

QMLOR_4789

N LOR_4789

