

INDENA CDMO WHITE PAPER

Indena's Custom Development & Manufacturing Organization services offers a full range of manufacturing capabilities for pharmaceutical ingredients. Such services include the extraction, isolation and purification of natural derivatives and the process R&D and manufacturing of 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 therefore a full service provider and a reliable partner in the cGMP Contract Development and Manufacturing of Active Pharmaceutical Ingredients (APIs) and Highly Potent Active Pharmaceutical Ingredients (HPAPIs). The company thus effectively supports leading pharmaceutical and biotech companies to achieve product success and guarantee patients' healthier lives.

The CDMO area of business of the company has been one of the priority for Indena's strategic development for some years.

With the aim of providing customers with an increasing breadth of services, the company has been investing in the implementation of cutting-edge technologies, and mainly in the expansion of the GMP pilot plant and in the upgrade of the spray drying technology already existing in the company's plant.

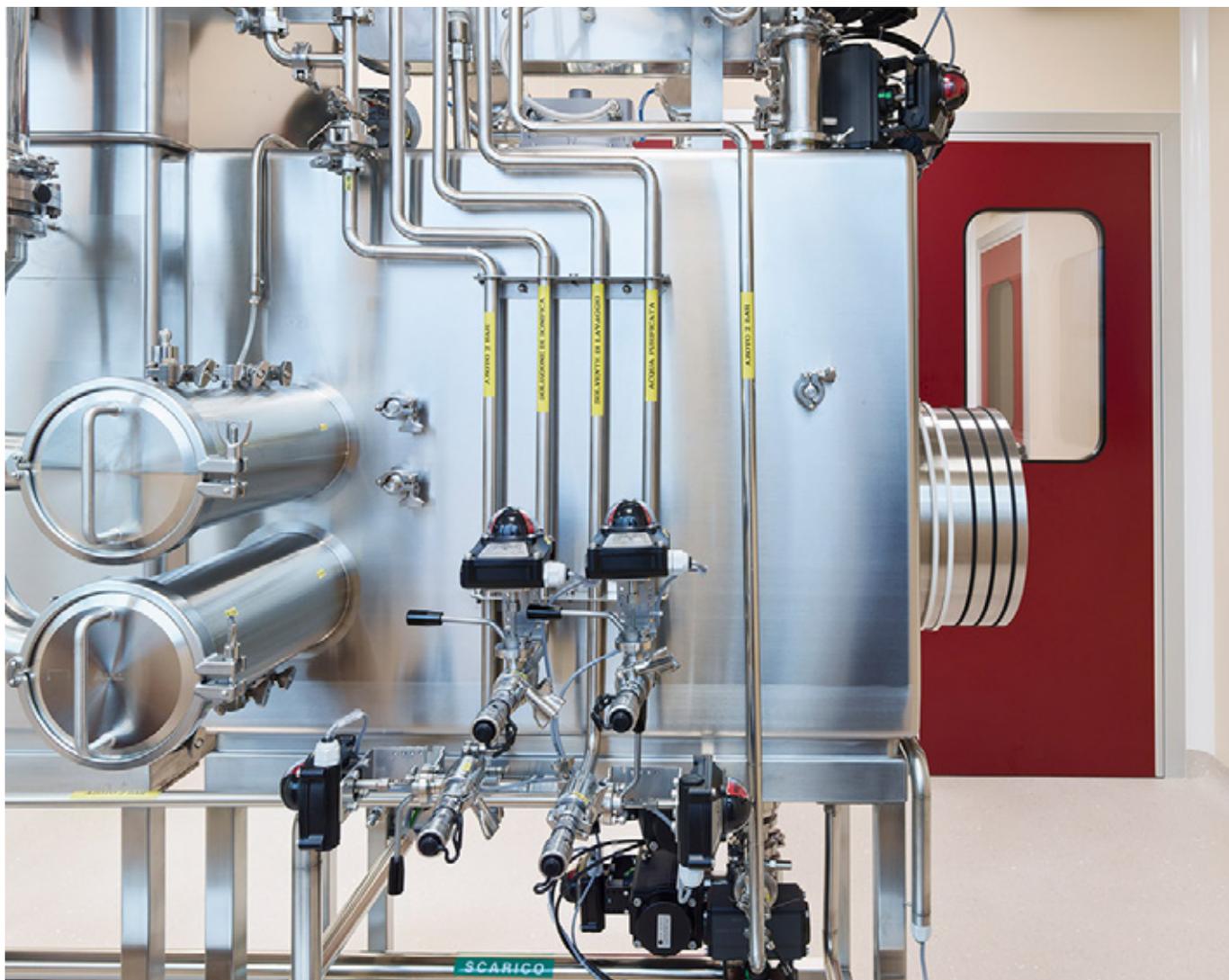
Moreover, with its highly specialized Quality Assurance system and Regulatory expertise, Indena is able to meet the strictest requirements from regulatory agencies.



NEW KILO LAB LK2

With the aim 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 now available and is capable of practicing Indena technologies on a large scale, with 60 liter reactors.

This expansion completes Indena's production capacity towards HPAPIs, allowing the company to offer different capacities for products at the highest power level (OEL 20 ng / m³ - OEB5).



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 2022. Together with the existing 20-liter hydrogenator, the new one will allow Indena to satisfy a wider demand for this kind of service.

NEW PRODUCTION PILOT PLANT FOR ACTIVE PHARMACEUTICAL INGREDIENTS

In order to always meet and surpass its customers' expectations, Indena has been working on complementing its GMP Pilot Plant for active pharmaceutical ingredients, with a second facility equipped with reactors up to 10,000 liters. This intervention takes place with the aim of upgrading the system and exploiting Indena's technologies at a larger scale and obtaining a state-of-the-art system in line with the best practices of the sector from every standpoint: engineering, safety, quality and scale.

Indena's goal is to offer customers the possibility of carrying out synthetic processes even in a wide range of conditions for both natural molecules that require semisynthetic steps, and for synthetic molecules.



MID AND LARGE SCALE SPRAY DRYERS FOR AMORPHOUS SOLID DISPERSION

Backed up by more than 30 years' experience, Indena has been working on the expansion and upgrade of its mid and large scale spray dryers, working with organic solvents.

The recent installation of the Niro PSD2 spray dryer ATZ5, which allows an intermediate production scale and guarantees a good containment (usable for products also classified as OEB4 as a hazard class), has been joined by the revamping of a spray dryer ATZ4, already used in Indena for several years.

The ATZ4 has a production capacity of 3-4 times higher than PSD2 thus allowing services on a larger scale in this specific area and completing the Indena CDMO offer.

VACCINE EXCIPIENTS

Indena is finishing a suite to produce vaccine excipients on a larger scale. It is the expansion of a plant already active for the same purpose, namely the production of vaccine excipients using preparatory and freeze-drying HPLC in a GMP area.



To know more:

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