

## **PRODUCTION**

Indena's main production site is in Settala, just outside Milan.

Built in the late 1960s, it was a model of innovation from the outset, with state-of-the-art facilities and laboratories which have been refurbished and modernised regularly. The Settala plant is today one of the most innovative in the sector for the extraction and processing of botanicals. In addition, further technological expansion has made it possible to manufacture complex synthetic molecules.

About 370 people work in the Settala plant, 30,000 square meters of buildings in an area of some 130,000 square meters. All stages in the production cycle of the botanicals take place here: storage, extraction, concentration, purification and drying. Research and development is also undertaken in the Settala laboratories, in conjunction with over forty research centres both in Italy and abroad.

In addition to the Settala plant, Indena owns production sites in the French city of Tours, Bangalore in India and Palestro in Lombardy, home of the Bernett company which Indena took over in the 1990s. All in all, Indena processes around 20,000 tons of raw material every year in its plants; these come from about 60 countries around the world through sustainable and controlled supply chains.

All production takes place under the banner of maximum safety for those who work there, for products and processes, and for the environment, with the application of HACCP procedures, Good Manufacturing Practices (GMP) and in accordance with ICH international guidelines (Q7). The group's production sites have long held ISO14001 certification for environmental impact management and OHSAS18001 certification for the safety and health of workers.

## **CONTRACT DEVELOPMENT AND MANUFACTURING ORGANIZATION (CDMO)**

One of the business sectors in which Indena has invested heavily in recent years is Contract Development and Manufacturing Organization (CDMO).

Pharmaceutical companies are becoming increasingly interested in outsourcing the production of molecules or extracts which make up their Active Pharmaceutical Ingredients (APIs). This is particularly true for Highly Potent Active Pharmaceutical Ingredients (HPAPIs) which, because of molecule toxicity, require particularly sophisticated and high containment production processes, able to guarantee maximum product safety and quality. It is estimated that some 56% of pharmaceutical and biotech companies now outsource the synthesis of small molecules in the clinical phase, and about a third do so with commercial molecules.

Changes have been made at the Settala factory in recent years designed to make Indena a reliable and trustworthy partner for companies requiring CDMO services.

These changes include: a kilolab created for both natural and synthetic highly-potent products (OEL of 20 ng/m<sup>3</sup>), which is now being doubled in size; a PSD2 spray dryer which can function in the presence of organic solvents (this capitalizes on twenty years of experience in this area and incorporates a large-scale industrial spray dryer used in the intermediate stages); a pilot plant for the preparation of active pharmaceutical ingredients, to bring together all the extractive and synthetic technologies of the group, in which further expansion is underway; a multipurpose fermentation plant capable of handling toxic compounds in quantities ranging from 100 to 20,000 litres.

Natural derivatives remain a fundamental and strategic part of Indena business. The adoption of new technologies however is making it possible to build on decades of corporate know-how in other areas such as fermentation and synthetic molecules.