

INDENA'S CDMO: THE FORMULA FOR CLIENTS' SUCCESS

AT DCAT2023, THE ITALIAN COMPANY, A FULLY-INTEGRATED PARTNER FOR CDMO SERVICES, ANNOUNCES ITS LATEST PROJECT: A NEW R&D DEVELOPMENT LAB FOR HIGHLY POTENT API, READY BY 2023

Milan, 20 March 2023 – Indena is a well-known market leader in botanical derivatives for the pharmaceutical industry, with a know-how developed over a century. In the past few years, Indena was successful to become a reliable Custom services partner in some very demanding technical segments of HPAPI benefiting of its outstanding R&D input. In fact, the technological expansion and diversification of this area have been one of the key pillar of Indena's investment.

At DCAT2023, Indena's experts are ready to present the company's latest project: a new R&D development lab for Highly Potent API.

*"Driven by the increased number of running projects, a major expansion of the R&D building has been planned to respond to customers' demand - explains **Bernard Vianes, Global Director CDMO Indena** -. The expansion program includes the construction of a brand new R&D development laboratory of 400 m² equipped with 12 fumehoods, 2 walk-in fumehoods, 1 laminar flow fumehood, 2 gloveboxes that will be able to host 15 R&D scientists. The project has been authorized in December 2022 and the new laboratory will be up and running by end 2023".*

Indena's CDMO expertise has grown over the last 10 years and today, in a challenging CDMO framework, Indena's projects for customers are very diversified and include botanical research and the development and management of a sustainable botanical supply chain; extraction and isolation of APIs from vegetal materials; fermentation and isolation of HPAPIs and APIs from broths; semi-synthesis and total synthesis of APIs and HPAPIs.

The new multipurpose GMP plant, the HPAPI kilolabs and a PSD2 spray dryer from organic solvents are only examples of the latest investments carried out in the last few years and underlines that the CDMO business area is a top priorities for Indena's strategic development.

*"What Indena has learned in this experience of working with Nature has taught the company to manage complex molecules of any type, from both the analytical and the production perspectives. Nowadays Indena manufactures 12 commercial HPAPIs from various origins: fully synthetic, semi-synthetic and fermentation molecules - adds **Pietro Allegrini, R&D Director Indena** -. 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 its Settala facility, Indena can handle HPAPI with an OEL down to 20 ng/m³".*

With the aim of providing customers with an increasing range of services the company has indeed been investing in the implementation of cutting-edge technologies; the plans for the future are to continue investing by further expanding the capacity for both NCEs and consolidated APIs.

For 2023 and 2024, Indena has planned the expansion of the existing GMP plant, the installation of pilot scale hydrogenator and the expansion of the R&D lab for highly potent compounds.

As well as custom services excellence, Indena pursues a strong commitment to sustainability. Among its actions taken in such field is the smart use of energy in its plants.

At its Settala site, near Milan in Italy, where Indena's CDMO activities are implemented, a natural gas cogeneration plant, operational since 2016, produces 16.6 gigawatt-hours per year, both as electric and thermal energy, and enables a reduction of 1.699 Tons Equivalent Petrol (PET), that means a reduction of 2,500 Tons of CO₂ emissions per year.

Moreover, to implement the largest use of renewable energy, Indena is equipping all its European sites with state-of-the-art photovoltaic panels: the total renewable energy self-production by 2023 will be of 5 gigawatt-hours per year, equivalent to 2,340 Tons of CO₂ saved. In 2023, 67% of the energy used by Indena will be self-produced, of which almost 23% from renewable sources, and 5,177 Tons of CO₂ will be saved.

All the actions taken in favor of sustainability also enable Indena to be fully reliable in terms of business continuity, and therefore to be a solid partner for all its clients.

Indena is the leading company dedicated to the identification, development and production of high quality active principles derived from plants, for use in the pharmaceutical and health food industries. Backed up by a century of botanical experience, the company owns 100 patent families, has published more than 1000 scientific studies and cooperates with the world's most prestigious universities and private research institutions. Indena employs over 900 staff, investing a significant amount of its annual turnover in research, making this activity the key to its success. Headquartered in Milan, Indena has 4 production sites and 5 international branches throughout the world and manages sales in more than 80 countries. The company's experts communicate and interact constantly with the major international regulatory authorities and cooperate on the update of all the main pharmacopoeias.

CDMO activities are the priority in Indena's strategic vision. Today, Indena has a multipurpose GMP plant equipped with reactor ranging from 250 lt to 10,000 lt (Stainless Steel, Hastelloy, Glass-lined); a kilo lab LK2 to offer different capacities for products at the highest containment level (OEL 20 ng/m³ or OEB5); two spray dryers, large and a mid-size, working with organic solvents; a 20-liter hydrogenator being complemented by a 250-liter hydrogenator (ready at the end of 2023) to satisfy a wider demand for this kind of chemistry.

Find more on indena.com

Indena press contacts

bcw-burson cohn & wolfe

Luisa Cavagnera: luisa.cavagnera@bcw-global.com

Ph. +39 3497665890