

@DCAT 2024 A NEW GENERATION OF CDMO SERVICES

INDENA DISPLAYS A KEY UNIQUENESS ON HIGHLY POTENT APIS DOWN TO 1 NG/M³ OEL.

THE EXPERTISE INCLUDES PAYLOADS FOR ADCs, WITH A BACKWARD INTEGRATION ON FERMENTATION FOR TOXINS REQUIRING THIS STEP AND LYOPHILIZATION ABILITY IN HIGH CONTAINMENT.

Milan, 18th March 2024 – In CDMO services, Indena acts as a strategic partner, going beyond the mere client/supplier relationship, with full commitment to developing new HPAPIs and APIs, from early clinical stages to commercial-scale manufacturing.

With this mindset, Indena approaches DCAT 2024, where the CDMO team from the Italian company is ready to meet pharma and biotech enterprises offering a full range of reliable and innovative custom services.

Leveraging on 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, analytics and industrialization, encompassing high containment handling and production of HPAPIs from early stage to commercialization.

*“Indena’s positioning is to offer its customers 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 semisynthetic steps and for total-synthetic molecules - explains **Bernard Vianes, Global CDMO Director at Indena** -. As a highly reliable Western European API producer, Indena displays a key uniqueness on Highly Potent APIs down to 1 ng/m³ OEL, irrespective of their source, for which the company is highly skilled and well equipped. This expertise includes payloads for ADCs, with a backward integration on fermentation for toxins requiring this step and freeze-drying ability in high containment”.*

The increasing number of oncology NCEs and antibody-drug conjugates under development, coupled with a growing focus on personalized medicine, is shaping the demand for CDMO services. The HPAPI market is undergoing a shift toward NCEs characterized by higher potency, growing molecular diversity and segmentation for specific populations.

As shown by its long story and expertise, and unlike newcomers in the field, Indena can count on extensive know-how in safely handling HPAPIs, complemented by state-of-the-art equipment and installations.

Within its long-term strategy, Indena has kept ahead of the curve by timely investment in specialized containment facilities that guarantee that both employees and the external environment are safe from exposure, capitalizing on more than 30 years of know-how in high containment.

Nowadays Indena manufactures 12 commercial HPAPIs: fully synthetic, semi-synthetic and fermentation molecules. This is now one of the company’s core areas of expertise. 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 the Settala facility, Indena can handle HPAPIs with an OEL from 1 mcg/m³ to 1 ng/m³

Moreover, Indena has a fermentation department for carrying out living cells-based bio-transformation or secondary metabolite production, which can be exploited for the in-house production of toxins used in ADCs payload, guaranteeing an integrated and independent supply chain. Indena masters GMP microbial fermentation and bio-transformation, and thanks to the availability of high containment lines for the downstream phase, it is the ideal partner for fermentation HPAPI development.

Climate change is one of the most urgent sustainability challenges that people, governments and companies have to face, and this involves a responsible use of energy. Indena has always been oriented and committed to reducing fossil fuel consumption and use, saving energy and achieving high levels of energy self-production. This commitment is mainly achieved thanks to the company’s plant management, starting with its most important plant, located at Settala near Milan in Italy, where Indena’s CDMO activities are conducted.

Another important action for sustainability is the use of renewable energy, and Indena is equipping all its European sites with state-of-the-art photovoltaic panels. Moreover, all of the Indena’s European factories are

ISO 14001 Environmental Management System and ISO 45001 Occupational health and safety management system certified.

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 reliable 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 5 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); two kilo lab LK1 and LK2 to offer different capacities for products at the highest containment level (OEL 1 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 to satisfy a wider demand for this kind of chemistry.

Find more on indena.com

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