

@CPhI 2023 ALL THE NEWS ON CDMO AND SUSTAINABILITY FROM INDENA THE IDEAL PARTNER FOR BIOTECH AND MID/BIG SIZE PHARMA COMPANIES IN SPECIFIC INNOVATIVE TECHNOLOGIES

Milan, 24th October 2023 – From the 24st to the 26th of October, at Fira Barcelona Gran Via (Booth 7H40), Indena welcomes clients, partners, experts and the media to share all its news and innovations in the pharmaceutical business and in CDMO (Custom Development Manufacturing Organization) activities, as well as its sustainability vision.

At CPhI 2023 Indena will also relaunch the debate about some traditional APIs which are part of the company most known and successful products: Taxanes, Gloriosa, Saw Palmetto, Cannabidiol.

*“Indena, the leading company dedicated to the identification, development and production of high quality active principles derived from plants, has developed over the years an important expertise in handling molecules requiring high containment – explains **Bernard Vianes Global CDMO Director of Indena S.p.A.** -. The company capitalized its experience in this field by implementing state of the art high containment solutions for high potent NCEs manufacturing, embedding also molecules obtained via synthesis or fermentation processes. Today, through its Custom Development & Manufacturing Organization services, Indena is the ideal partner for biotech and mid/big size pharma companies in these innovative technologies”.*

INDENA CDMO EXPERTISE: A LONG SUCCESSFUL HISTORY

Custom services and strong partnerships with clients have been a company focus since the very beginning and, thanks to a meticulous activity done over the last 30 years, nowadays those represent one of the Indena's key strengths.

Indena CDMO experience starts in 1990s with the first oncological blockbuster drug, Taxol, whose API had to be produced for a pharmaceutical client through a sustainable supply chain, developing a method of insulation under high-containment conditions and an analytical methodology of control according to stringent pharmaceutical protocols in terms of purity and stability.

The solution devised by Indena for Paclitaxel included building a robust supply chain for the biomass through a proprietary Yew Tree cultivations (so avoiding the unsustainable extraction from the bark of Pacific Yew Tree), then developing both a strong industrial method to extract and purify the intermediate 10-Deacetylbaccatin III and a robust and clean analytical frame for the project, complying with the most stringent regulations for pharmaceutical products.

This experience of working with Nature created a totally unique expertise and taught Indena to manage complex molecules of any origin, from both the analytical and the production perspectives. An expertise Indena continues to offer customers over the years, up to the most recent experience with the Australian company Qbiotics, as an example.

*“We're proud to partner with Qbiotics, who relied on us to achieve in an ambitious and challenging project – says **Stefano Togni, Chief Commercial Officer of Indena S.p.A.** -. Our client identified an oncological candidate with a totally innovative mechanism by studying biodiversity and the ecosystem. Then Indena was capable to develop and scale up the lab process to industrialization. A win-win collaboration which allows us to keep exploiting and improving what we learned from Nature for 100 years”.*

A NEW R&D AREA READY BY 2024

Indena manufactures 12 commercial HPAPIs from different origin: synthetic, semi-synthetic and fermentation molecules. This positioning has been achieved thanks to Indena capacity to handle HPAPI with an OEL from 1 Microgram /m³ to 20 ng/m³; the onsite availability of complementary technologies such as GMP microbial fermentation/biotransformation, synthesis and extraction

capabilities and its qualified and cohesive CDMO team. Moreover, 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. These are Indena's major technological pillars securing customized solutions to its partners.

At the beginning of 2024, new HPAPI R&D labs will be ready. In this area, synthetic chemists will handle projects involving highly potent products with OEL up to 20 ng/m³, with the necessary support of qualified analysts.

SUSTAINABILITY FIRST

A cornerstone of Indena is the commitment in sustainability and business continuity.

As regards energy use, which is linked to climate change - one of the most urgent global sustainability challenges - Indena has been working for years in reducing consumption, making energy use more and more efficient and achieving high levels of energy self-production. By the end of 2023, 67% of the energy used by Indena will be self-produced, of which almost 23% from renewable sources.

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

Visit Indena at CPhI 2023: Booth 7H40

24th – 26th October 2023 – Fira Barcelona Gran Via, Spain

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 co-operates 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

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