

INDENA SPOTLIGHTS EXPANDED CAPABILITIES AND INNOVATION AT CPHI 2025 FEATURING: NEXT - GENERATION TECHNOLOGIES FOR PHARMA MANUFACTURING, BREAKTHROUGH APIS AND A KEY ADC PROJECT

Milan, 28th October, 2025 – Indena announces its participation at CPHI 2025, taking place from 28th to 30th October at Messe Frankfurt, Germany. The company is pleased to invite customers, prospects, and industry experts at Booth 5.0C102 to discover its latest advancements. Indena will highlight significant upgrades to its main Italian manufacturing plant with new, groundbreaking equipment; present some of its highly effective and innovative APIs; and announce its strategic cooperation with TCG GreenChem for the development of Antibody-Drug Conjugates (ADCs).

"We are delighted to once again be a prominent participant at CPHI 2025, one of the most notable events in the pharmaceutical industry. This year CPHI provides an invaluable opportunity to share with all our stakeholders our latest enhancements, highlighting our specialized facilities — says Daniele Giavini Managing Director of Indena S.p.A. —. We have made significant investments to equip our production sites with efficient and advanced technologies, reinforcing our leadership in CDMO services. For example, our main facility in Settala, Milan, is now equipped with a filter dryer for highly potent molecules, and these upgraded plants are where we develop and produce also our well known and long lasting taxanes. Moreover, we are displaying two recent botanically-derived APIs, Squalene, derived from Amaranthus plants, and Cytisine, sourced from Laburnum anagyroides Medik plants: crafted specifically for the pharmaceutical industry, these products exemplify our unwavering commitment to the highest standards of quality and sustainability.

We look forward to engaging with attendees and discussing how Indena continues to drive innovation and excellence in the pharmaceutical sector."

INDENA NEWS AT CPHI 2025

In 2025, Indena significantly upgraded its facilities, as part of a continuous expansion plan, marking a substantial advancement in the scope, versatility, and reliability of its CDMO services for partners. These strategic improvements primarily focused on its main production site in Settala, near Milan, Italy.

The GMP synthetic plant now features an innovative filter dryer for highly potent molecules, unlocking novel production capabilities and addressing complex client demands while maintaining the highest safety standards. This AIFA-approved facility is fully operational, underscoring Indena's leadership in high-potency molecule synthesis.

The GMP plant's expansion enables large-scale production of HPAPIs (Highly Potent Active Pharmaceutical Ingredients) from synthesis and purification (small molecules up to OEB5). The plant handles diverse synthetic reactions from -80 °C to +150 °C, with infrastructure including stainless steel reactors with capacities up to 10,000 liters, glass-lined reactors up to 3,000 liters, Hastelloy reactors up to 1,200 liters, a 500-liter chromatographic column, and a Hastelloy centrifuge. This setup also supports small-scale commercial productions. For hydrogenation, Indena recently installed a 250-liter. Biazzi hydrogenator, capable of operating up to 10 barg.

Beyond the GMP Plant, Indena's HPAPI kilolabs at the Settala site are another cornerstone. The kilolabs allow safe handling of highly potent molecules, guaranteeing an Occupational Exposure Limit (OEL) of 1 ng/m³. Following the successful integration of a small freeze dryer for HPAPI lyophilization (1 ng/m³ OEL), a larger-scale commercial freeze-drying line is under installation.

"A key advantage of Indena's kilolabs facility is the co-location of laboratories and the production plant within the same building, fostering exceptional process efficiency and secure handling of highly potent molecules - explains **Stefano Togni Chief Commercial Officer of Indena S.p.A. -** Two additional



production lines are planned for highly potent molecules. The first, operational in 2026, will feature 65-liter and 100-liter reactors within glove boxes, and a 40 cm diameter Hastelloy C22 filter dryer, enabling dynamic filtration and drying. A second line includes a freeze dryer with a surface area of 1 m² with a capacity of 10 kg of ice in 24 hours, also located inside a glove box. The same glovebox will also feature a spray dryer, to allow working on HPAPIs, guaranteeing an OEL of less than 1 ng/m³".

Indena's expansion also includes a new 400 sqm R&D laboratory with high-performance, high-containment fume hoods (12 bench-top, 2 walk-in), a laminar flow fume hood, and two glove boxes, providing ample space for scientists. A new industrial GMP line with reactors up to 10,000 L will enable higher-volume API and HPAPI production. Indena's fermentation department for cell-based biotransformation or secondary metabolite production can be leveraged for in-house production of toxins for ADC payloads, ensuring an integrated supply chain. Indena's expertise in GMP microbial fermentation and biotransformation, coupled with high-containment lines, positions it as an ideal partner for precision fermentation HPAPI development.

EXPLORING INDENA'S LEADING PRODUCT SOLUTIONS AT CPHI 2025

Another key area Indena will address is its specialized capabilities in the sustainable and reliable manufacturing of taxanes, essential compounds for cancer therapies: Indena has been a pioneer in the selection and cultivation of highly productive yew breeds and has devised a semi-synthetic proprietary process allowing the obtainment of paclitaxel, docetaxel and cabazitaxel, overcoming yew tree supply issues and ensuring long-term sustainability and stability.

Indena will also highlight other specialized pharmaceutical product offerings: **Squalene**, a key immunological adjuvant for various vaccines, derived from **Amaranthus** plants. It is a responsible, plant-based alternative to animal-derived sources, which often lack comparable environmental and traceability assurances. Also featured is **Cytisine**, an effective anti-smoking agent, derived from **Laburnum anagyroides Medik** plants, cultivated under a strictly controlled and fully traceable biomass supply chain.

INDENA AND TCG GREENCHEM: A STRATEGIC COLLABORATION FOR NEXT-GENERATION ADC TECHNOLOGIES

On 28th October, Pietro Allegrini, Indena's R&D Director, will formally announce a pivotal strategic cooperation with TCG GreenChem, unifying Indena's profound expertise in developing and manufacturing high-potent payloads with TCG GreenChem's innovative approaches in green chemistry and highly efficient process development.

Do not miss the Indena presentations at CPHI 2025:

- 28 October, 1:45 2:10 pm, Hall 12.1 12.1C68: Indena and TCG GreenChem Join Forces to Advance Next-Generation ADC Technologies, held by Pietro Allegrini, R&D Director, Indena and Chris Senanayake, Chief Executive Officer, TCG GreenChem, Inc.
- 30 October, 11:20-12:05 am, Hall 4 4.0G36: *The Impact of Environmental and Social Responsibility on Shaping LATAM-EU Trade Relations Round table*, with the participation of Francesca De Rensis, Marketing Director, Indena.

Visit Indena at CPHI 2025: booth 5.0C102 - 28th - 30th October 2025 - Messe Frankfurt, Germany



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.

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CDMO activities are the priority in Indena's strategic vision. Today, Indena has a multipurpose GMP plant equipped with reactors ranging from 250 lt to 10,000 lt (Stainless Steel, Hastelloy, Glass-lined); several Kilolabs for HPAPIs to offer different capacities for products at the highest containment level (OEL 1 ng/m3 or OEB6) also equipped with freeze-dryers for Payload-Linkers; two spray dryers, large and a mid-size, working with organic solvents; a 20-lt hydrogenator and a 250-liter hydrogenator to satisfy a wider demand for this kind of chemistry.

Find more on indena.com.

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