

CDMO SERVICES AND INNOVATIVE PRODUCTS FOR PHARMA INDUSTRY: ALL THE INDENA NEWS @CPHI JAPAN 2025

THE ITALIAN COMPANY STANDS AS A RELIABLE PARTNER FOR PHARMA AND BIOTECH CLIENTS IN JAPANESE MARKET

Milan, 8th April 2025 – Indena is the Italian 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. It will be part of CPHI Japan from 9 to 11 April, at East Halls 4, 5 & 6, Tokyo Big Sight, Tokyo, booth IT 16.

Indena, headquartered in Milan, Italy, has been working in Japan for many years through its Japanese branch, which focuses mainly on the nutraceutical market. On the occasion of the Japanese edition of CPHI, the company is presenting its innovative pharma products and CDMO activities. Indena manages these activities as a strategic partner for pharma and biotech firms, going beyond the mere client-supplier relationship, with full commitment to developing new HPAPIs and APIs, from early clinical stages to commercial-scale manufacturing.

*“Indena’s goal 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 – says **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 1ng/m³ OEL, irrespective of their source, for which Indena is highly skilled and well equipped. At CPHI Japan 2025 we’re happy to share with our guests the main news about the most recent investments in equipment and know-how we made, with the aim of addressing the last market challenges”.*

Over the past year, Indena has strategically invested in advanced technologies at its main production plant. A prime example is the recent upgrade to the kilolab LK2 plant, now equipped to handle highly potent molecules with an Occupational Exposure Limit (OEL) of 1 ng/m³. This represents a major leap forward, significantly improving upon the previous containment level of 20 ng/m³ for such compounds. Following the successful integration of a freeze dryer into the LK2 plant – already operational for the lyophilization of HPAPIs while maintaining the stringent 1 ng/m³ OEL – Indena plans to install a commercial-scale freeze-drying line in 2026. These advancements solidify Indena’s capacity to fulfill growing client demands for HPAPI production, including payloads for Antibody-Drug Conjugates (ADCs). Indena already offers a portfolio of payloads, including Maytansinoids (DM1 & DM4), which are entirely manufactured at its European facility, encompassing both fermentation and synthesis. Furthermore, the company provides a GMP Payload-Linker currently in Phase 1 development.

Moreover, Indena has strengthened its HPAPI capabilities with a new R&D infrastructure. Designed to handle a growing number of HPAPI projects, the facility ensures maximum efficiency and complete safety for analytical research and production. The focus is on studying and producing highly potent molecules, starting with R&D activities on new HPAPI projects in a modern, safe, and well-equipped lab.

At CPHI Japan 2025, Indena will also present two important products. The first is **Squalene**, a natural triterpene with several health benefits in nutritional, medicinal, and pharmaceutical fields. It acts as an antioxidant, anticancer agent, skin care ingredient, drug delivery vehicle, detoxifier, and anti-infection agent. Traditional extraction of Squalene from sharks' livers is becoming increasingly unsustainable. Fortunately, since the last decade, squalene has also been extracted from vegetables like olive oil, walnut oil, rice bran oil, cashews, and amaranth oil. With a strong commitment to sustainability, Indena produces squalene from amaranth seeds for use as a vaccine adjuvant and can guarantee the entire GMP supply chain throughout all steps of the manufacturing process. The company will also be able to carry out CO₂ extraction of the oil under GMP conditions.

Another important product Indena will present at CPHI Japan is **QS-21**, derived from a crude extract (Vet-Sap) obtained from the bark of a South American plant (*Quillaja saponaria*). This product is used as an adjuvant in vaccines undergoing clinical development and is a component that enhances the immune system response.

*“QS-21 is a highly purified product obtained through final lyophilization – explains **Fedrico Debattista Regional Manager at Indena** -. Currently, Indena produces QS-21 exclusively for USA Desert King, who directly supplies the raw extract. We’re working to promote QS-21 in the Japanese market, where the product will be supplied by Desert King in partnership with Indena. CPHI Japan 2025 marks the first opportunity to announce this business development, and we will be glad to engage with our guests during the show to discuss the project’s features in more detail.”.*

At CPHI Japan 2025, Indena will showcase its commitment to sustainability, a core tenet of the company's way of working, to the Japanese market. Indena actively supports and contributes to the majority of the UN's Sustainable Development Goals, integrating sustainable practices across its value chain, from raw material sourcing to production and market access. This encompasses a strong focus on minimizing environmental impact, promoting a circular economy, and ensuring the responsible use of energy.

For years, Indena has prioritized sustainable innovation as a critical driver of its business strategy. To enhance energy efficiency and mitigate environmental impact, the company has invested in advanced technologies, including cogeneration plants and photovoltaic systems. These efforts to minimize energy waste and increase the integration of renewable energy sources underscore Indena's long-term commitment to sustainability. Furthermore, sustainability extends to ensuring business continuity through proactive risk mitigation, the development of dedicated contingency plans, the capability to rapidly resume operations, and the robust protection of data, personnel, and technological infrastructure.

Visit Indena at CPHI Japan 2025: booth IT 16, 9th - 11th April - East Halls 4, 5 & 6, Tokyo Big Sight, Tokyo.

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 liters to 10,000 liters (Stainless Steel, Hastelloy, Glass-lined); a kilo lab LK2 to offer different capacities for products at the highest containment level (OEL 1ng/m³ or OEB5); 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](https://www.indena.com)

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