

INDENA EXHIBITS SOLUTIONS FOR COMPLEX MOLECULE MANUFACTURING AND NEXT-GENERATION CDMO SERVICES AT CPHI JAPAN 2026

THE ITALIAN GLOBAL LEADER HIGHLIGHTS ADVANCED MODALITIES, HIGH-POTENCY EXPERTISE, AND STRATEGIC COLLABORATIONS FOR LIFE-SAVING THERAPIES

Milan, April 21st, 2026 – Indena is proud to announce its participation in CPHI Japan 2026, taking place from April 21-23 at the Tokyo Big Sight Exhibition Center. As a beacon of research and development for over a century and a leading cGMP Contract Development and Manufacturing Organization (CDMO) for over 35 years, Indena will showcase its advanced capabilities and innovative solutions that are shaping the future of pharmaceutical manufacturing.

Attendees are invited to visit Indena's booth at Italy Pavillon, Stand IT-9, to explore how Indena's unique blend of integrated R&D and GMP manufacturing within high-containment environments provides an unbroken continuum from early development to full-scale commercial production.

Indena's operational footprint spans multiple GMP-certified facilities, operating under stringent EU GMP guidelines with AIFA approval, and fortified by robust system certifications like ISO 14001 and ISO 45001. This robust framework underpins Indena's commitment to quality, safety, and environmental responsibility.

*"Japan represents a key strategic market for Indena, and we are committed to bringing our advanced CDMO capabilities to support its pharmaceutical industry - stated **Bernard Vianes, Global CDMO Director at Indena** -. Our expertise spans the entire lifecycle of complex molecules, from high-potency APIs with industry-leading 1 ng/m³ containment, to pioneering advanced modalities like ADC payload-linkers for targeted oncology and high-potency NCEs for rare diseases. Backed by sophisticated large-scale processing technologies, including advanced chromatography and high-capacity spray drying, we ensure unparalleled quality, purity, and safety in manufacturing".*

Indena's deep-seated proficiency in handling High Potency Active Pharmaceutical Ingredients (HPAPIs) and ultra-potent compounds is a cornerstone of its service offering. With industry-leading containment solutions achieving an Occupational Exposure Limit (OEL) of 1 ng/m³, Indena ensures the utmost safety and environmental protection for the most hazardous substances. The company provides comprehensive manufacturing solutions across the entire product lifecycle, complemented by diverse sourcing strategies including complex chemical synthesis, precision fermentation, and biomass extraction.

Beyond traditional APIs, Indena is at the forefront of advanced modalities. The company possesses unique capabilities in developing and manufacturing ADC payload-linkers, expertly handling highly potent payloads regardless of their molecular origin – a critical proficiency for targeted oncology therapies. Furthermore, Indena maintains a strategic focus on New Chemical Entities (NCEs) for rare diseases, prioritizing high-potency compounds with molecular diversity to address significant unmet medical needs.

Indena's facilities are equipped with state-of-the-art technologies essential for complex molecule production. This includes advanced chromatography capabilities, offering both conventional and HPAPI capacity with columns reaching an impressive 7,700 liters for the highest purity. Its spray drying excellence is demonstrated through five dedicated systems designed for APIs, including potent compounds, contributing to a substantial total annual capacity of up to 93,000 kg.

Indena's commitment to global collaboration extends to regulatory harmonization. At CPHI Japan, critical discussions will take place regarding the regulatory landscape, which is paramount for the efficient export of APIs to the country. This topic will be specifically addressed in a seminar on April 22nd, titled "Requirements for Stable Supply of Active Pharmaceutical Ingredients." **Eleonora Baioni, Area Manager at Indena S.p.A.**, will be a key participant in this seminar, sharing Indena's insights and contributing to efforts for streamlined processes.

*"Japan stands as a pivotal market for global API manufacturers, and we recognize that navigating the unique regulatory requirements for API exports here can be challenging - commented **Eleonora Baioni** - That's why*

Indena is actively engaging with Japanese stakeholders, exploring and proposing steps to simplify these vital processes. Our collaborative vision includes aligning European and Japanese Pharmacopoeias, facilitating the acceptance of CTD Module 3, establishing clear guidelines for changes, and enhancing digitalization. Such strategic alignment will undoubtedly lead to more efficient API exports, significant reductions in costs and timelines, and ultimately foster stronger global collaborations for the benefit of patients worldwide".

Indena's experts wait for all industry stakeholders and potential partners at CPHI Japan, to discuss collaboration opportunities and learn more about the company's comprehensive CDMO services.

Don't miss the presentation *Expectations for improvements to Japan's pharmaceutical regulatory framework in relation to API exports*, by Ms **Eleonora Baioni**, Area Manager at Indena S.p.A. on April 22nd, 2026, 1:30 p.m. - 3:00 p.m., East Hall 3K-08, Tokyo Big Sight.

Visit Indena at **CPHI Japan 2026**: Italy Pavillon, Stand IT-9, 21st - 23th April - East Halls 1, 2 & 3, 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 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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