

PRODUCTION OF PAYLOADS FOR ADCs, NEW LABS AND EQUIPMENT: ALL THE INDENA NEWS @DCAT 2025

THE COMPANY'S INVESTING BOTH IN TECHNOLOGIES AND IN TALENTED RESEARCHERS,
TO MAKE ITS CDMO SERVICES INCREASINGLY COMPETITIVE AND TO MEET THE CLIENTS' NEEDS

Milan, 17th March 2025 – Antibody-drug conjugates (ADCs) are revolutionizing the treatment landscape for a range of diseases globally, offering targeted therapies with the potential to significantly improve patient outcomes. Indena, the Italian company leader both in the production of high-quality active principles derived from plants and in CDMO services, 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. This expertise includes payloads for ADCs, with a backward integration on fermentation for toxins requiring this step and freeze-drying ability in high containment.

*"In the last year we've been working to add more and more innovative technologies in our main production site, and we're proud of our kilolab LK2 plant recently enhanced with equipment that allows Indena to work with highly potent molecules, guaranteeing an OEL of 1 ng/m³ - says **Bernard Vianes, Global CDMO Director at Indena** -. This is a very significant development, considering that the previous containment level for highly potent compounds was 20 ng/m³. After the addition of a freeze dryer in the LK2 plant, already operational for the lyophilization of HPAPIs guaranteeing an OEL of 1 ng/m³, the next project involves the installation of a larger-scale commercial freeze-drying line in 2026. Indena is then increasingly able to meet clients' needs in producing HPAPIs including payloads for ADCs. Our company is already present on the market with some payloads, as Maytansinoids – DM1 & DM4, entirely manufactured in Europe at the Indena plant including fermentation and synthesis steps, and a GMP Payload-Linker in phase 1".*

Also the Indena GMP plant is being expanded in some steps, starting from a first revamping in early 2024, then with further upgrades at beginning of 2025. This expansion will allow the plant to enlarge the capacity of reactions / chemical synthesis up to 10 times the actual capacity, produce on larger scale HPAPIs obtained both by synthesis and purification (small molecules to OEB5), higher production capacity for products actually made in other departments.

More technologies have been added, for the chemical synthesis and purification of APIs and HPAPIs: centrifugation under containment (reverse bag centrifuge), reactor loading under containment (glove boxes), isolation and drying on filter dryer, purification on 2000 lt slow/medium pressure columns (up to 9 bars) 2x 2500 lts glass lined reactors. For hydrogenation, the company has recently acquired a Biazzi hydrogenator, able to work up to 10 barg.

*"Looking ahead, we're investing to add one further production line, always designed for research and processing of highly potent molecules – explains **Pietro Allegrini, R&D Director at Indena** -. This will be operational in 2026 and will have reactors up to 100-liters, both inserted inside glove boxes, and a 40 cm diameter filter dryer in Hastelloy C22. This configuration allows for filtration and drying under dynamic conditions, and the new equipment integrates with the existing systems in the plant. We're also projecting a second production line which will include a freeze dryer with a capacity of 10 kg of ice in 24 hours, also located inside a glove box. This line will be equipped with a spray dryer inside the glove boxes, which will allow work on HPAPIs, guaranteeing an OEL of less than 1 ng/m³".*

Indena has also invested in a new R&D infrastructure designed to handle an increasing number of HPAPIs projects, ensuring maximum efficiency and complete safety for both analytical research and production. The focus is once again on the possibility of studying and producing highly potent molecules, starting from performing R&D activities on new projects related to HPAPI in a modern, safe and well-equipped lab.

The new laboratories will host numerous highly talented researchers, dedicated only to specific projects. They will work in safe environment thanks to equipment that guarantees high containment, up to 1 ng/m³.

Indena isn't just a leader in APIs industry, but also a company committed in working in the most sustainable way. A concrete case of such approach is Indena's production squalene from a vegetal and sustainable

supply chain. Squalene is a natural triterpene with several health benefits in nutritional, medicinal and pharmaceutical fields. Indena is producing squalene from the *Amaranthus* seeds to be used as vaccine adjuvant and can also guarantee the entire GMP supply chain, during all steps of the manufacturing process: the company will be able to carry out CO₂ extraction of the oil under GMP conditions as well.

This exemplifies Indena's commitment to addressing the critical sustainability challenges facing businesses and individuals alike. By prioritizing renewable energy in its operations and fostering sustainable supply chains, Indena demonstrates its responsibility as a leading force within the industry.

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 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.

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