

PAYLOADS FOR ADCs, NEW INNOVATIVE CDMO EQUIPMENT, SUSTAINABLE PRODUCTION OF PHARMA INGREDIENTS DISCOVER ALL THE INDENA'S NEWS @CPHI 2024

Milan, 8th October 2024 – Once more it's time for the exciting opportunity to meet and share all the updates about pharma market @CPHI 2024: from the 8th to the 10th of October, Indena's waiting for its customers, prospects and experts in Milan, the town where its story began more than a century ago and that still hosts its headquarter. The place to meet is **Milano Fair at Rho, Booth C9, Hall 4**: here Indena will present all its news about ADC payloads production, the most recent equipment implemented at its main Italian plant, the sustainable and fully traced supply chain of its novel ingredients **resiniferatoxin, squalene, cytisine** and much more.

*"Indena is truly delighted to welcome its guests to Milan this year – says **Stefano Togni Chief Commercial Officer of Indena S.p.A.** -. This will be a great opportunity to discuss business, share ideas and projects, and talk about innovation and the future of the pharmaceutical sector, particularly of CDMO activities which have always been a priority for Indena. Indena's researchers and managers will be available for customers and prospects to present all the latest updates on the company's facilities, technologies, and solutions for pharmaceutical and biotech companies. For us, working in the CDMO sector means establishing a true partnership, listening to and embracing our client's challenges in order to help them achieve their goals".*

INDENA NEWS AT CPHI 2024

Thanks to more than one hundred years of pharmaceutical excellence applied to medicinal plants Indena today is an undisputed world leader in the identification, development and production of Active Pharmaceutical Ingredients: pure ingredients (molecules isolated from medicinal plants), semi-synthetic (natural compounds, modified through synthesis), standardized extracts and synthetic molecules.

The market for HPAPIs is growing due to the increasing prevalence of complex diseases like cancers, autoimmune disorders, infectious diseases and rare diseases. Indena is at the forefront in addressing the last market challenges, as its capability in HPAPIs production comes from the experience done more than 30 years ago with the first oncological blockbuster drug, Paclitaxel. In fact, during CPHI 2024, one of the main topics are ADCs, and Indena presents its expertise also in this specific area. In this production Indena plays its role being able to manufacture linker-payloads, to support development, clinical and commercial productions: payload-linker process development, scale-up, analytical development, including bioconjugation R&D trials; moving to GMP manufacturing: payload-linker clinical manufacturing and commercial manufacturing; an outstanding analytical development capability. The 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).

*"As known, Antibody Drug Conjugates represent a significant advancement in targeted therapy, holding immense promise for the pharmaceutical industry, and our expertise includes payloads for ADCs, with a backward integration on fermentation for toxins requiring this step and freeze-drying ability in high containment – explains **Pietro Allegrini R&D Director** -. And at CPhI 2024 we'll also tell the news about the production capability of our main site at Settala: we're further expanding our GMP pilot plant so that it will be able 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 down to OEB5), have higher production capacity for products actually made in other departments. And we're also very proud of our CDMO team, where lifelong professional experiences are fused with the enthusiasm and fresh skills of many young scientists".*

Specifically, the upgraded GMP pilot plant will be equipped with more technologies 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 dryers, purification on 2000 Liters low/medium pressure chromatographic columns (up to 9 bars). For hydrogenation, Indena has recently acquired a Biazzi hydrogenator, able to work up to 10 barg.

WORKING IN PARTNERSHIP WITH CLIENTS: A WIN-WIN STRATEGY

Indena's approach to CDMO activities is not only a "service" approach. It means working together with the clients from the very beginning, embracing client's challenges and reaching its goals and success.

At CPhI 2024 **Federico Peterlongo**, Indena's Director of R&D Process Research, and **Paul Reddel**, Executive Director and Chief Scientific Officer of QBiotech, will tell how the two companies successfully developed together the challenging project *From the rainforest to the clinic. Turning a high-potency rare natural product into an anticancer API.*

The project started from the evidence that natural products can be characterized by complex structure, limited availability, and exceptional potency, whose combination makes their development as API a challenging task. Success requires integration of expertise in different areas, including the establishment of a sustainable supply chain for the starting biomass, the capacity to manipulate high-potency products in a GMP environment, and the versatility to strategically complement isolation with semi-synthesis, total synthesis and biotechnology. In this context, mutual thrust between the service provider company and the drug candidate owner is critical, and the successful development of the anticancer drug tigilanol tiglate will give the opportunity to highlight these issues.

RESINIFERATOXIN, SQUALENE, CYTISINE: FROM NATURE TO APIs THROUGH SUSTAINABILITY, TRACEABILITY AND INNOVATION

Working with nature since more than a century, Indena has learned to manage complex molecules of any type, from both the analytical and the production perspectives, and to develop APIs from natural ingredients through an innovative and sustainable way.

It's the case of **Resiniferatoxin** from *Euphorbia resinifera* **O. Berg**, used as a pain killer, for which large dedicated plant cultivations have been set-up and innovative harvesting methods employed by Indena to protect species and support propagation, helping to ensure long-term sustainability. **Squalene**, used as an immunological adjuvant in several vaccines, produced from Amaranthus plant origin respecting the principles of sustainability that could not be guaranteed by animal sources currently used by the industry. **Cytisine**, used as antismoking agent, and made by Indena using plants of *Laburnum anagyroides* **Medik** with a defined origin, a controlled and fully traced biomass supply chain.

SUSTAINABILITY FOR THE BUSINESS

Sustainability is an essential part of Indena way of working. Indena is committed to adhere and contribute to most of the UN's Sustainable Development Goals, starting from raw materials sourcing to production and go-to-market – with a focus on environmental impact, circular economy and a conscious use of energy. For years, Indena has been committed to prioritizing sustainable innovation as a key driver of business strategy. To improve energy efficiency and reduce environmental impact, Indena has invested in cutting-edge technologies, including cogenerations plants and photovoltaic systems. This effort to minimize energy waste and increasingly integrate renewables into our energy sources underscores our long-term vision of sustainability. And sustainability also means reliability in terms of business continuity, working on risk mitigation, the development of dedicated plans, the capability to resume operations promptly, the protection of data, personnel, and technology infrastructure.

Visit Indena at CPHI 2024: Hall 4, Booth C9 - 8th – 10th October 2024 – Fiera Milano, Italy

Don't miss the Indena presentation on October 8th, 3:15 pm, Hall5 stand 5B49: ***From the rainforest to the clinic. Turning a high-potency rare natural product into an anticancer API***, held by Federico Peterlongo, Director of R&D, Process Research at Indena and Paul Reddel, Executive Director and Chief Scientific Officer at QBiotics.

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-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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