

CYTOTOXICS AND HPAIs



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Indena HPAIs Custom Services include a full range of high potency manufacturing capabilities for active pharmaceutical ingredients across a wide range of scale.

The combination of Indena's expertise and top class facilities delivers products and processes from small scale GLP batches for toxicology, cGMP batches for clinical trials to larger commercial manufacturing.

Indena's Highly Potent Custom Services site is located in Settala (Italy) and meets US-FDA, ICH and EU requirements. This facility incorporates appropriate room pressurization, airlocks, ventilation and isolators to properly handle highly potent solids and liquids up to $0.1~\mu g/m^3$ OEL.



INDENA HPAIS SERVICES OFFER:

- Extraction, isolation and purification process development, scaling-up and manufacturing
- Process development, scaling-up and manufacturing
- Phase-specific analytical development and validation
- Characterization, certification and control of incoming raw materials and biomasses
- Agronomical development and GACP (Good Agricultural Collection Practices) compliant cultivation of medicinal plants
- QC testing of in-process materials
- Stability studies and impurities elucidation
- Gram to kilogram GLP and cGMP compliant batches for clinical and industrial use
- Commercial production scale in US-FDA and Italian
- Pharmaceutical Agency (AIFA) inspected manufacturing sites





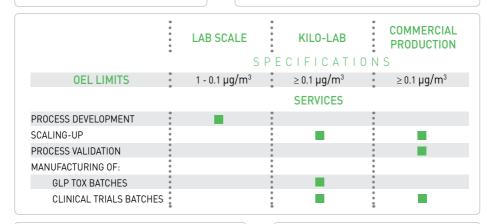
POTENT ACTIVE INGREDIENTS

OPERATIONS

- EXTRACTION
- ISOLATION
- PURIFICATION
- CRYSTALLIZATION
- DRYING
- WEIGHING
- PACKAGING
- ORGANIC SYNTHESIS
- CHROMATOGRAPHY

QUALITY MANAGEMENT

- DEDICATED QA UNITS
- TRAINED AND EXPERIENCED PERSONNEL
- ICH COMPLIANCE
- ISO14001 ACCREDITATION



FEATURES

- NEGATIVE PRESSURE
- HEPA FILTERS
- GLASS REACTORS (20-60 L, -20 TO 100 °C)
- CRYSTALLIZATION
- ROTARY EVAPORATORS (50 L)
- ISOLATORS FOR SOLIDS HANDLING
- WALK-IN AND FUME CUPBOARDS
- STAINLESS STEEL REACTORS
- HASTELLOY REACTOR WITH LOADING GLOVE BOX
- 360 L COGEIM FILTER-DRYER
 WITH DISCHARGING GLOVE BOX
- GLOVE-BOXES INCLUDING:
 GLASS REACTORS
 ROTARY EVAPORATORS
 BUCHNER FILTERS
 CHROMATOGRAPHIC COLUMNS

ANALYTICAL CAPABILITIES





Indena S.p.A. is the world's leading company dedicated to the research, development and production of active principles derived from natural sources.

With its capabilities and expertise, Indena covers food supplements and pharmaceutical areas, producing bulks of active ingredients under cGMP guidelines in AIFA and FDA approved environment, starting from biomasses obtained according to GACP guidelines.

Today Indena opens its **facilities** for custom services, sharing with customers its **innovative research and production capabilities** at lab, kilo-lab and industrial scale, also in the field of Highly Potent Active Ingredients (HPAIs).

More than Ninety years of Indena presence in the pharmaceutical market are a guarantee of high quality standards and reliability, that just a few companies in the world can claim.

Indena is a private Italian company based in Milan (Italy); it employs more than 800 staff distributed on 1 R&D Centre, 5 production sites and 5 international branches throughout the world and manages sales in more than 70 countries.





CONTACT US

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