



CYTOTOXICS AND HPAIs

.....CYTOTOXIC AND HIGHLY

Indena HPAIs contract manufacturing 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 Contract Manufacturing** 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 µg/m³ OEL (Class 4).



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 suites



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

LAB SCALE

KILO-LAB

COMMERCIAL PRODUCTION

SPECIFICATIONS

OEL LIMITS

up to 1 - 0.1 µg/m³

up to 0.1 µg/m³

up to 0.1 µg/m³

SERVICES

PROCESS DEVELOPMENT



SCALING-UP



PROCESS VALIDATION



MANUFACTURING OF:

GLP TOX BATCHES



CLINICAL TRIALS BATCHES



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 COGEM FILTER-DRYER WITH DISCHARGING GLOVE BOX
- GLOVE-BOXES INCLUDING:
 - GLASS REACTORS
 - ROTARY EVAPORATORS
 - BUCHNER FILTERS
 - CHROMATOGRAPHIC COLUMNS

ANALYTICAL CAPABILITIES

- HPLC-RID
- HPLC-DAD
- HPLC-ELSD
- HPLC-FD
- HPLC-MS
- UPLC-UV
- UPLC-DAD
- GC-FID
- GC-NPD
- GC-MS
- FT-IR
- NIR
- UV-VIS
- NMR
- HPTLC
- TOC
- DVS
- TG/DTA
- DSC
- SUNTEST
- BIOANALYZER
- MICROSCOPY
- PPSL
- XRPD
- ELISA



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 contract research and manufacturing, 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).

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 4 international branches** throughout the world and manages sales in more than **70 countries**.



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