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TEAMWORK
QUALITY
EXCELLENCE

WHO WE ARE

At **Menarini Biotech** we provide a fully integrated and personalised service for the manufacturing of biologics, ensuring seamless transfer from process development through cGMP manufacturing and late stage clinical supply. Menarini Biotech recently established a new entity in the UK located at the Thames Valley Science Park in Reading. The brand new state of the art facility will support process development for late stage clinical programs and supports outsourcing of therapeutic antibodies to contract manufacturing organisations for commercial manufacturing.

Takis has an established track record in drug discovery in Oncology and is recognized for the conception and implementation of a number of innovative technologies. One of the main assets of Takis is the in vivo Electro-Gene-Transfer (DNA-EGT), which can be used for a variety of clinically useful applications, from antibody development, vaccine development to somatic gene therapy. Takis operates worldwide as a Contract Research Organization providing the highest quality and integrated drug discovery solutions, covering all activities from target-to-clinic to meet the industry's need for innovation and efficiency in drug discovery. Takis has established multiple service and discovery agreements with Biotech and Pharma partners.

IBI is an international biopharmaceutical company, FDA approved, that offers services as CDMO for production of injectable forms (solutions and freeze-dried powders) and biotech APIs (monoclonal antibodies and recombinant proteins from CHO cells).
A multipurpose department for GMP production of different finished products (vials and pre-filled syringes), through aseptic filling, is available.
Expert resources address all the phases: from cells engineering, up-stream and down-stream, to analytical characterization and GMP production of APIs and finished products.

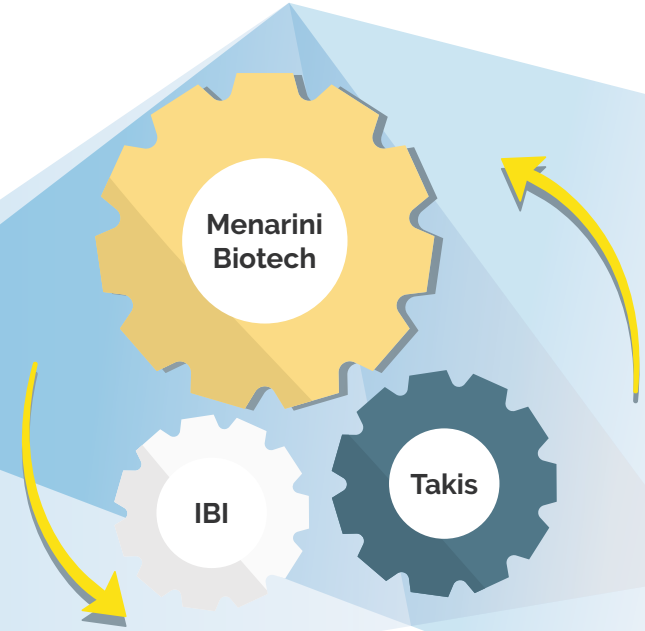
WHAT WE OFFER AND WHY CHOOSE US

As an integrated consortium of complementary biotech companies, we offer streamlined services and full range capabilities to ensure a fast and reliable development, an efficient transfer of projects from preclinical stage to clinical trials and marketing authorization.

*m*AbArt

from target to the patient

Integrated Services for
Biopharmaceutical Companies
From DNA to Drug Product



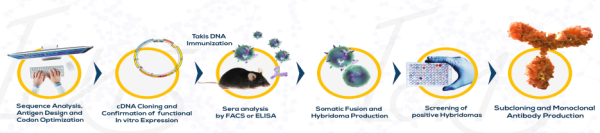
ISTITUTO BIOCHIMICO ITALIANO G. LORENZINI

Fare per Dare

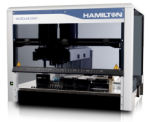
MENARINI BIOTECH

Custom Monoclonal Antibody Development

- Peptide/Protein Immunization
- Genetic Immunization (DNA Electro-Gene-Transfer)
- Antibodies against complex targets (e.g. GPCR, dimers)
- mAb Humanization

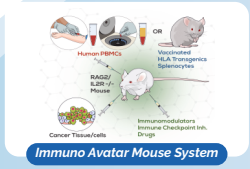


TRIANNI Mouse Platform available to generate human antibodies and derivatives



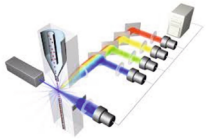
Contract Research Preclinical Services

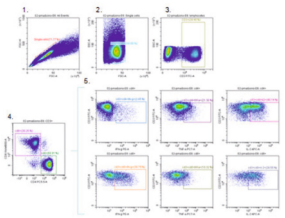
- Oncology
- Immunology
- Molecular Biology
- Animal Models



Immuno Avatar Mouse System

Multiparametric Immunology Assays





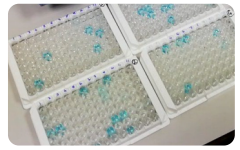
UNI EN ISO **9001:2015**

CERTIQUALITY

SISTEMA DI GESTIONE QUALITÀ CERTIFICATO

Cell Line Engineering

Cloning of GOIs through a licensed, GMP-validated technology platform (CHO-K1 CHOvolution™ cell line from Celonic) Cell Line Development and cGMP Production of Master/Working Cell Banks



Drug Product

- Formulation and Process Development (Injectable solutions and freeze-dried powders)
- Analytical Methods Development
- Stability studies
- Development of innovative delivery systems
- GMP production:
- Dedicated filling line for Phase I / II
- Multipurpose Filling line (Vials, pre-filled syringes) for Phase III and Commercial Scale
- Department authorized for biological IMP

Upstream / Downstream Process Development

- Solaris IO-1000, Wave™ 20/50, XDR-10 bioreactors
- AKTA™ equipment (explorer, prime+, pure)

Product Characterization

- HPLC (IEX, SE, RP)
- CE, Glycans profile analysis (CE-LIF)
- ELISA, Cell-based Potency Assays
- Flow-cytometry, analysis of cell colture metabolites (Nova Flex2™)

cGMP Manufacturing up to 200L

- Class D/C clean rooms, Biosafety level 2
- Wave™ 25 and XDR-200 bioreactors
- AKTA™ equipment (pilot, ready, readyflux) under UNICORN Network

Upstream Process Development

- Ambr 15
- Biostat SUB 2L
- XDR10
- 75 L stainless steel Bioreactor

Downstream Process Development

- High-throughput Janus station
- AKTA Avant
- Akta Explorer
- AKTA Pilot
- AKTA Crossflow

Product Characterization

- Chromatographic techniques (IEC, GFC, RP)
- Electrophoretic techniques (IEF, SDS-PAGE, 2D, CE)
- Receptor binding (Biacore)
- Structural evaluation (Optim)

cGMP Manufacturing up to 1500L

- Class D/C clean rooms
- UNI EN ISO 14001:2004; OHSAS 18001
- Biosafety level 2
- 300 L Stainless Steel
- 1500 L Stainless Steel
- XDR-200 (GE Healthcare) SUB
- Ready To Process Wave Bioreactors
- AKTA Process
- Chromatographic columns several diameters
- UNICORN network
- Buffers preparation
- Viral removal filtration
- QC batch release
- More than 70 GMP lots released