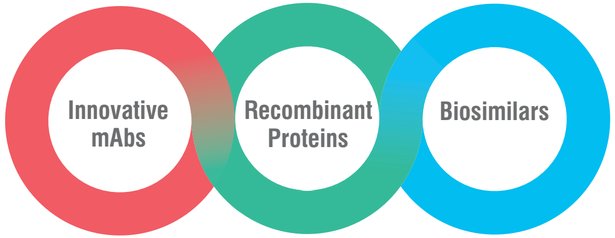
Your partner in biologics production

At Menarini Biotech we provide a fully integrated and personalised service for the production of biologics, ensuring seamless transfer from cell line development through to cGMP production and commercial supply.

We understand that the manufacturing process defines your product, and with our long-established and **proven track record**, broad expertise and **emphasis on quality** - you're in safe hands.

- Dedicated mammalian and microbial facilities
- Expression system & cell line development
- Comprehensive analytical services
- Process scale-up
- cGMP manufacturing
- AIFA (Italian Healthcare Authority) licensed for clinical supply for human use
- Quality assurance and regulatory support
- EMEA and FDA cGMP compliant

MENARINI BIOTECH



Innovative mAbs
Seamless transfer from process development to production with stainless steel at every step. Clinical batches in nine months or less

Recombinant Proteins
Proven track record of success across a wide range of recombinant proteins including difficult-to-produce fusion proteins

Biosimilars
World class process development and analytics combined with extensive knowledge of regulatory requirements

Experience

Menarini Biotech is part of the Menarini Group, Europe's fastest growing biopharmaceutical company. We have **over 25 years' experience** of developing biotechnology products, so have the perfect blend of expertise and experience from which our partners can benefit.

Lab to Pilot to Production. No capacity reservation fee.

CORE SERVICES

- Master and working cell bank production, storage and validation
- Pilot scale production for pre-clinical studies
- Bioburden controlled biologic APIs for clinical supply
- Comprehensive analytical services

CONTACT US

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MENARINI BIOTECH

CONTRACT DEVELOPMENT & MANUFACTURING

WE'RE WITH YOU **ALL THE WAY**

BIOSIMILARS

Biosimilars are particularly sensitive to changes in the manufacturing process which means you need a partner with a trusted track record.

With dedicated project managers with you each step of the way, and our strong emphasis on process development, analytics and comparability testing - you can plan for success.

Our comprehensive facilities - including stainless steel bioreactors – and excellent quality and regulatory experience, means that Menarini Biotech can support you throughout the whole process to ensure **seamless transfer from phase I direct to phase III.**

- Compliance with EMEA and FDA cGMP
- Regulatory expertise in biosimilars
- Dedicated facilities for mammalian and microbial production
- Strong expertise in tech transfer and comparability studies
- Extensive analytical capabilities in process control, release and product characterisation
- cGMP scale up to phase III clinical and commercial production

"Plan for success with seamless transfer to phase III production"

"Cost-effective production of clinical batches in 9 months or less"

INNOVATIVE MONOCLONAL ANTIBODIES

If you need a rapid and cost-effective manufacturing process for your innovative mAb, without production capacity or purification limitations - then please contact us.

We can develop clinical batches in 9 months or less from large scale production (1500 L stirred tank), rapidly progressing from process development to toxicology studies and on to clinical trials supply. With excellence in quality and flexible to your needs, we work with you to deliver to your timelines – and **provide real value at all stages.**

- Clinical batches in 9 months or less
- Stainless steel bioreactors in development and production
- Experts in mAb development and tech transfer
- Cell growth optimisation and process development
- Rapid production of materials for toxicology studies with various reactor volumes, from 2-300 L (microbial) or 5-75 L (mammalian)
- Established expertise up to phase III clinical batches and process validation at maximum scale of 1500L

Get in touch to find out more:
see back page for contact details

RECOMBINANT PROTEINS

When dealing with complicated recombinant protein development you need an experienced partner with a track record of success.

We have successfully developed many recombinant proteins and have a unique level of experience and expertise so you can rest assured.

One of our successes saw the development of a very robust process for production of a fusion protein that was particularly prone to self-digest under non-controlled conditions. Our process yielded high quantities of undegraded product along with valuable know-how and experience. **We offer confidence based on established success.**

- Broad range of recombinant proteins including:
  - Cytokines
  - Fusion proteins
  - Enzymes
- Success in developing non-standard processes
- Dedicated project managers
- Emphasis on quality assurance and analytics
- Seamless scale-up

"Proven track record of success with expertise in non-standard process development"