MENARINI BIOTECH S.r.l.

Menarini Biotech

For Your Molecule from Gene to Clinic on to Commercialisation

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Who we are

With over 25 years of industry excellence, Menarini Biotech has transitioned from a powerhouse in internal projects to your go-to CDMO for cutting-edge solutions.

Our seasoned team of top-class professionals, coupled with state-of-the-art facilities, ensures that your project receives nothing short of exceptional attention and expertise.

- Established in 2003
- Located in greater Rome area, Italy
- 80 employees
- Custom Services include PD, AD, GMP Manufacture of Biologics #mAbs, #ADCs, #BsMAbs, #fusion proteins … and #more
- AIFA approved
- Background in CDMO, Pharma, Biotech

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Why Work with Menarini Biotech

- Financially stable (family owned)
- Short lead times to start project
- Leverage in-house (Menarini Group) R+D expertise
- Flexible, agile
- Based in EU
- Intimate Customer Relationship – we care.
- Faster Timelines (Execution, Responsiveness) than Your previous CDMO

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Quality First

30 people in
QA, RA, QC, and AD

>30 years of
Experience

Added Value for You:

- 18 years of Successful GMP Inspection
- Authorised for clinical mfg. phase 1-3
- Authorised for QC testing of DP
- Support IMPD/IND filing
- Site documentation, Deviation and Change Control management to go paperless
- CFR 21 part 11 compliant lab software (e.g. Empower-LabX)
- GAMP 5.2 compliant Electronic Validation Protocol

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Key Performance Data

30 days — Batch Review Leadtime

5% — Human Error

25 days — Deviation average Leadtime

90% — Deviations closed on time within 30 days

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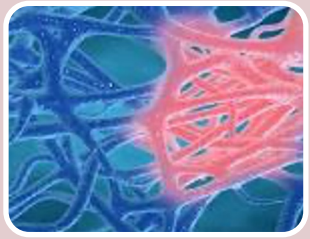
PD: 20+ Years of Track Record Built in Various TAs

Oncology

mAbs including BsAbs, produced in hybridoma and CHO cells;
plasmide vaccines produced in bacteria
Recombinant human apoptosis mediators produced in CHO cells

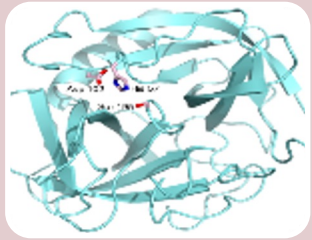
Cardiovascular disease

Recombinant enzymes



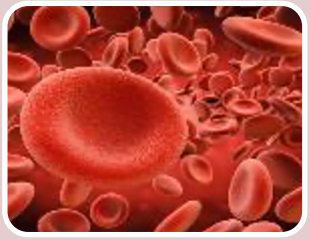
Inflammation

Recombinant enzymes



Enzyme replacement therapy

Recombinant enzymes



Haemopoiesis

Recombinant human cytokines produced in CHO

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Upstream Development 2L-50L

- Cell Line Development (CLD): experience with e.g. Potelligent,CHO GS, Expi-CHO S, DG44 , hybridoma
- Basal media screening, selection, and optimization
- Feed media screening, selection and optimization

- Production bioreactor growth parameter screening, selection and optimization
- Harvest filtration selection and optimization
- We make extensive use of statistics (DoE, PCA, Multivariate Data Analysis) for all development activities

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Downstream Development

- ReFiltration (dead end, nano, tangential) screening, selection and optimization
- Formulation screening and selection
- Resin screening, selection, and optimization

- Intermediate hold studies
- Process optimization and characterization
- Established analytical and DSP platforms

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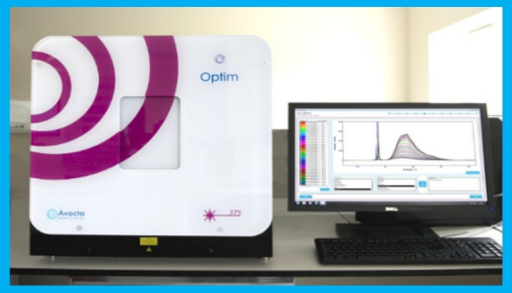
QC: Well-Equipped for Your Next Challenge



SLS/FLR System

- Process-related impurities/Contaminants
- Product-related impurities
- Protein characterisation
- Comparability Study
- Stability Study
- Forced Degradation Study
- Validation of Analytical Methods
- Batch Certification
- Established analytical and DSP platforms

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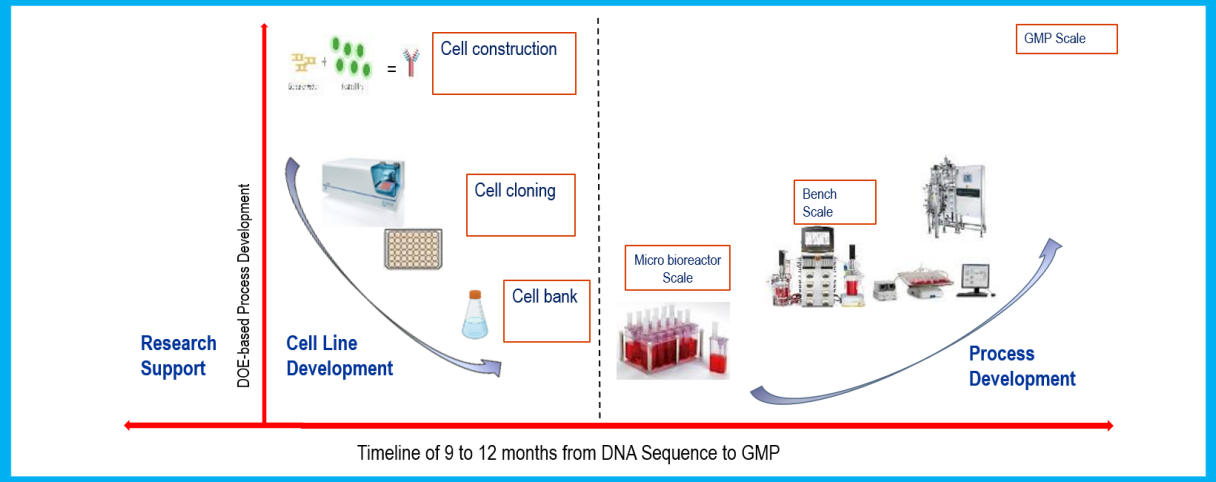
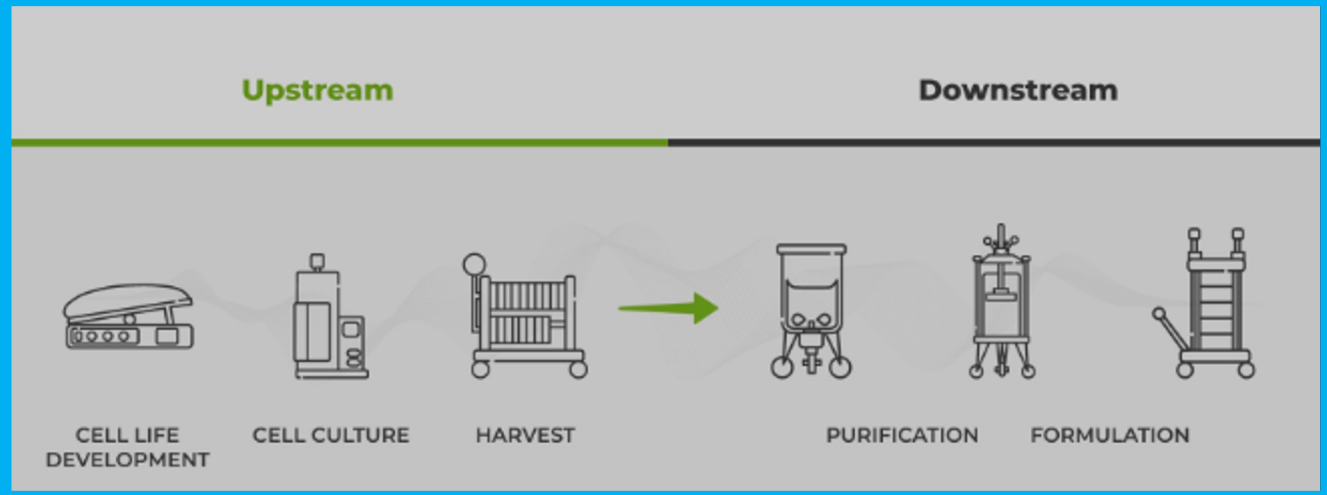
From DNA to GMP (CoA) in 9-12 Months



Simplified Workflows to make Your Molecule on-Time and In-Full

Clinical and Early
Commercial
GMP Manufacturing
In Single-Use Equipment



USP area:
Grade D
390m^2
BSL-2
Media and buffer preparation
3x200L (XDR-200)
2x1kL (STR 1000 3rd gen. SUB)

DSP area:
Grade C
240m^2
BSL-1
Buffer preparation
Column packing
Filling into manifold system bags

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Three Dedicated Workshops for HPAPIs, ADCs, and non-toxic APIs

- Support clinical development ph1-3, e.g. ADC batches (with maytansinoid)
- Highly toxic payloads up to 200g scale
- GMP Mfg.: Two separate facilities for Anticancer and for Standard non-toxic API
- Full SCM including linker technology (incl. mfg. of linker), tech transfers
- Sound knowledge of the current ADC conjugation technology
- Temperature controlled storage of API (controlled 15-25 °c, 2-8 °C, -20°C)
- OEL up to OEB 5

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Pleased to Discuss your next Challenge.

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