



**MENARINI**  
**BIOTECH**

# Welcome to Menarini Biotech

Your IND-enabler

*Fast. Flexible. On-Time. Every Time.*



# Who we are

- ❖ Established in 2003
- ❖ Independent legal entity, affiliated to Menarini Group
- ❖ Located in greater Rome area, Italy
- ❖ 80 employees
- ❖ Biologics Custom Services: from gene to vial.
- ❖ Process and Analytical Development & GMP Manufacture for mAbs, BsAbs, fusion proteins, enzymes & more.
- ❖ AIFA/EMA approved, FDA planned
- ❖ Capability and Scalability: across 6 orders of magnitude, max 5x step
- ❖ Full flexibility on Cell-line choice, incl. BSL-2

- ❖ Female/Male (60:40)
- ❖ 90% with academic degree
- ❖ Different nationalities, cultures, and languages
- ❖ Various backgrounds (biopharm, biotech, CDMO)

# Diversity is Key



# Mission and Vision



Being a reliable, innovative and agile partner enabling you as a customer to bring life saving biotherapeutics to patients by applying our expertise in drug development.

From lab to production, our cutting-edge technology accelerates processes, optimizes yields, and ensures precision at every stage.

Our role is to bridge the gap between cutting-edge science and scalable, sustainable products.

**MISSION**



Invent and apply innovative technologies to deliver scientific breakthroughs and meaningfully contribute to finding cures for difficult-to-treat diseases.

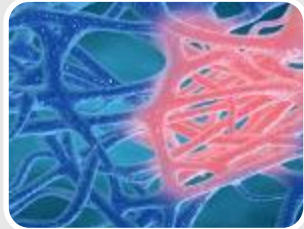
From pioneering research insights to seamless clinical phase development, our commitment to precision and innovation is the bedrock of your biotech triumph.

**VISION**

# Why Work with Menarini Biotech



**Oncology**



**Inflammation**

**Cardiovascular**



- **rapid transition** from discovery to delivery (tech transfer)
- 20+ years of **track record**
- Customer-centric
- **Partners** of innovation
- Provide **expertise, infrastructure, and flexibility** to bring your complex biopharmaceuticals to market quickly and efficiently, without compromising on quality.

- ❖ 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

## Inspection Record of Menarini Biotech (MBH), Pomezia site, Italy

Health Authorities: AIFA (L'Agenzia Italiana del Farmaco)

*AIFA Entity 1: Drug Substance manufacturing and controls*

*AIFA Entity 2: Drug Product quality controls*

Date	Purpose	Entity
19-21 Jun 2024	Periodic Inspection	2
12-14 Dec 2023	Periodic Inspection	1
20-21 Oct 2021	Follow-up of previous Inspection	1
3-5 May, and 27-29 Apr 2021	Periodic inspection and authorization for phase III COVID-19 mAb project Manufacturing	1
17-19 Feb 2021	Activation of Menarini Biotech site for Investigational Medicines Quality Control	2
10-13 Oct 2016	Periodic Inspection	1
03-06 Dec 2013	Periodic Inspection	1
04-06 Oct 2011	Periodic Inspection	1
04-06 Jun 2008	Periodic inspection and authorization for phase III mAb project Manufacturing (Abagovomab)	1
21-23 Mar 2005	Activation of Menarini Biotech site for Investigational API Manufacturing	1

# Key Performance Data

*Support your next Batch Release*

30  
days

Batch  
Review  
Leadtime

5%

Human  
Error

25  
days

Deviation  
average  
Leadtime

90%

Deviations  
closed on  
time within  
30 days

# Customer-centric approach. We are partners in innovation.

## Relationship

- Financially stable (family owned)
- Intimate customer relationship – we care.

## Culture

- Start-up friendly culture: flexible, agile
- Matching start-up mentality: similar size and ways of working
- Based in EU
- Leverage in-house (Menarini Group) R+D expertise



## Your Molecule

### Timelines:

- Fast Timelines (Execution, Responsiveness)
- Short lead times to start project

### Cost: (Your budget matters!)

- very cost competitive, using manufacturing platforms

### Technical Know-How:

- Unprecedented analytical capabilities and drug development track record
- Cutting-edge clinical manufacturing



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# Our consolidated experience spans various classes of biologics



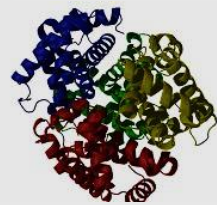
*Robotics, incl. high throughput screening*



*Advanced analytics*



*Single-use technology*

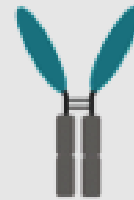


**Enzymes**  
(Esterases, plasminogen activators)

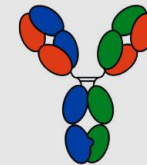
Glucocerebrosidases  
anti-Trypsin/trypsin inhibitor)



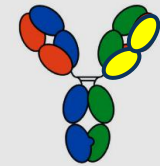
**IgGx,**  
various isotypes



**Fc-fusion**  
proteins



**Common Light Chain BsAbs**



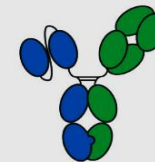
**BsAb,**  
2x half IgG



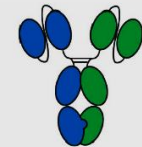
**ADC**



**BsAb,**  
BITE



**ScFv-BsAb**



**ScFv-BsAb, KH**

*Drug development is the process of bringing a novel drug from “bench to bedside”.*

# Drug development

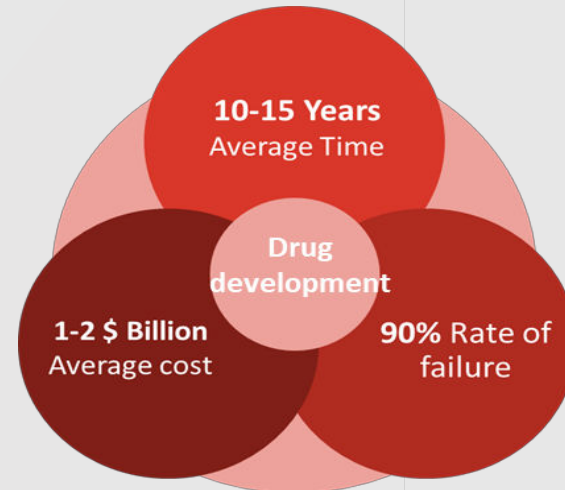
## De-risk

- It can take **10 to 15 years** for a drug to be designed, developed and approved for use in patient
- **Failing is the norm:** average 1 drug get approved over 10.000 candidates
- **Cash-burn** until approval, limited patented period to breakeven and earn

The biopharma industry now: largest & most diverse clinical **pipeline** : 2x unique drugs, from 3,200 (2012) to 6,100 (2022).

Flat **success rate:** ~13% entering the Phase 1 trial stage go on to launch

## De-risk



Sun D. et al, 2022

## De-risk

- Menarini Biotech specializes in **several unique aspects** to accelerate Drug Development



### Need-for-Speed

- Extensive know-how
- Robotics, high throughput, platform-based, single use



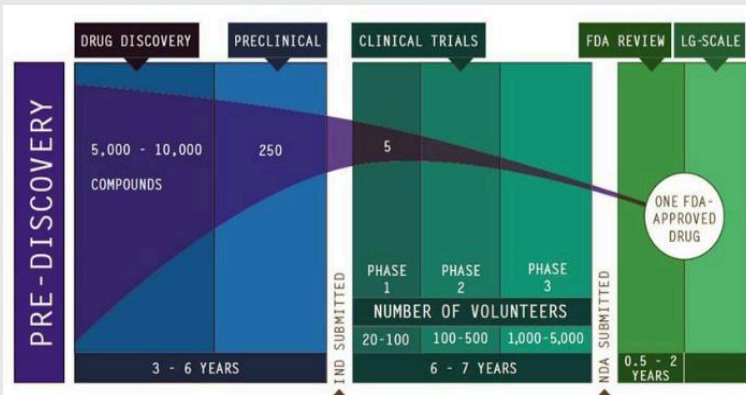
### Step-By-Step

- Cost effectiveness, across 6 orders of magnitude: mL to cubic meter



### Leverage-New-Competences

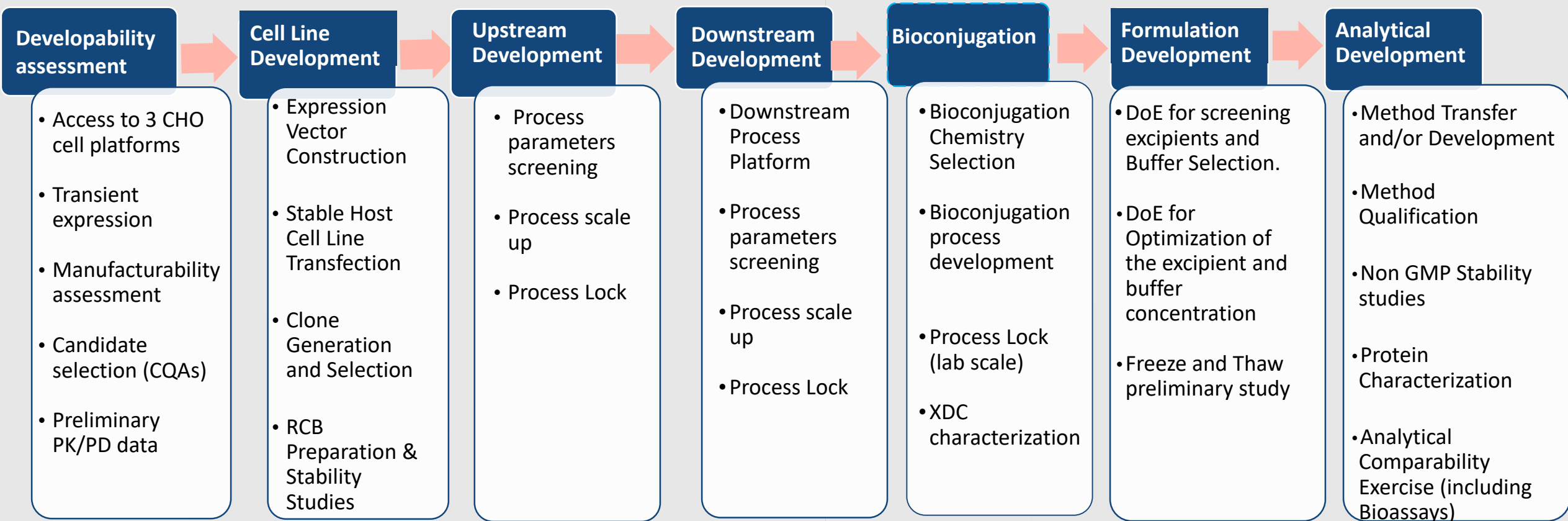
- Guaranteed compliance
- Established CMC expertise
- **Integrated CMC Developability Workflow**



# Development Services

*Modular, flexible and fast:*

*From Sequence to PoC Studies in <6 Months*



# Execution from DNA to GMP in <9 Months



## Cell Line Development

- Cell construction
- Cloning
- Cell Bank



## Process Development

- Ambr scale (15mL)
- Lab scale (2 - 50L)
- Formulation development

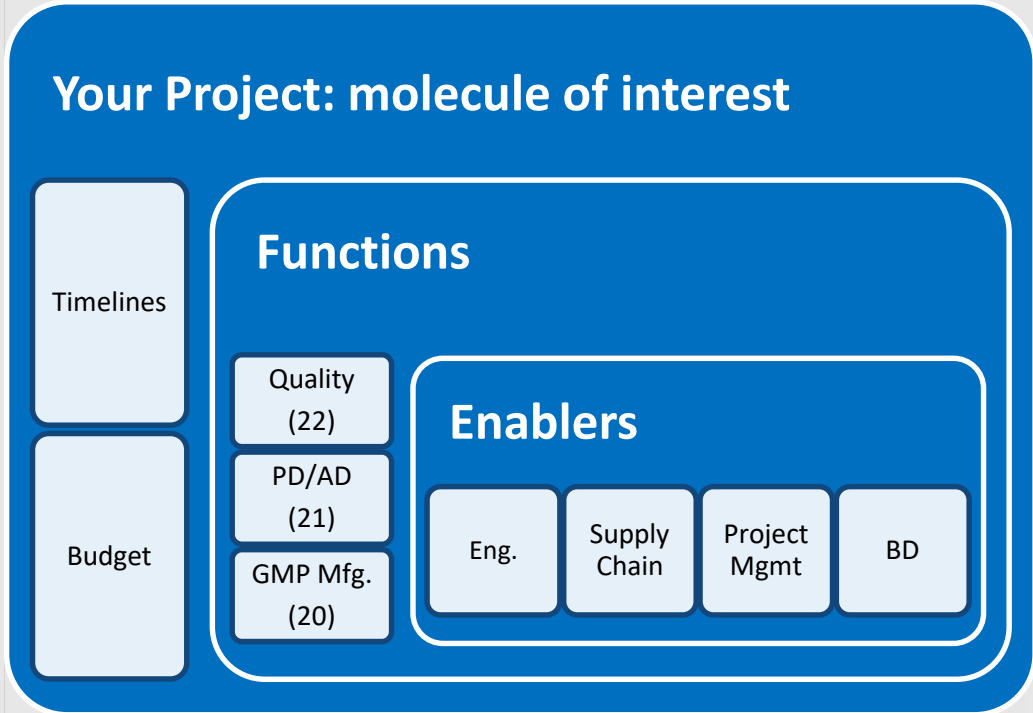
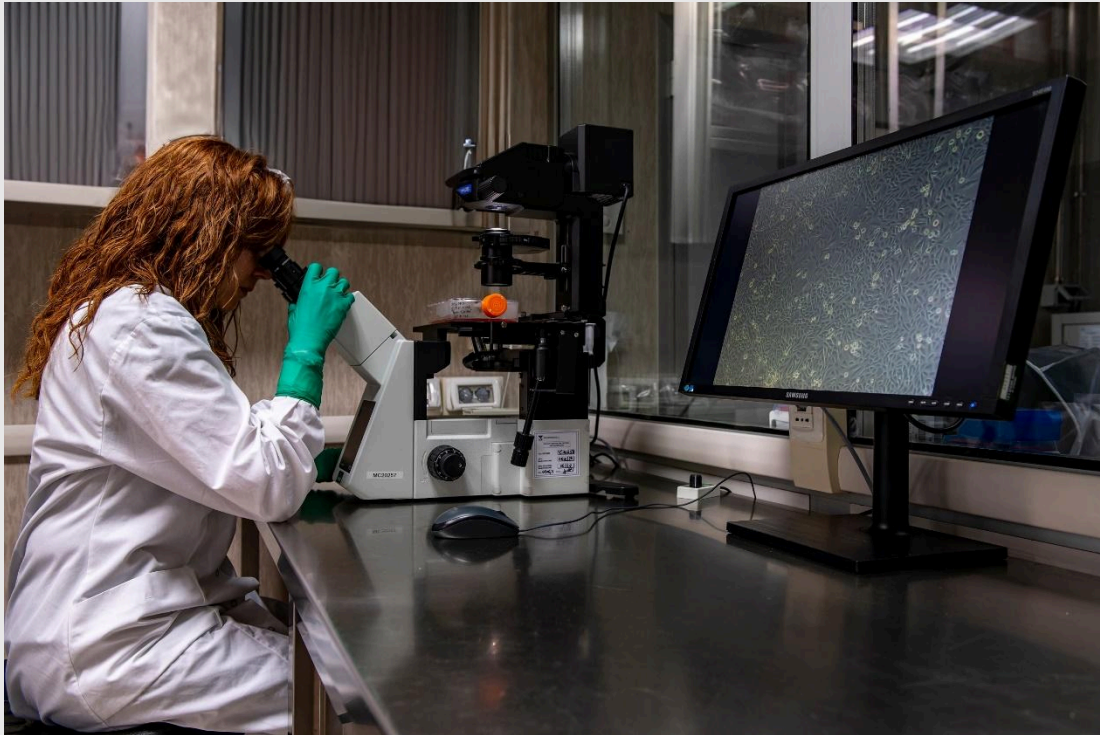


## Tech Transfer and GMP Production

- 3 x 200L
- 2 x 1,000L

*Platform-based: single-use, easy to transfer and scale-up systems and technologies, pre-designed consumables, etc.*

# 80 People Fully Dedicated to Your Next Project



# Upstream Development 2L-50L

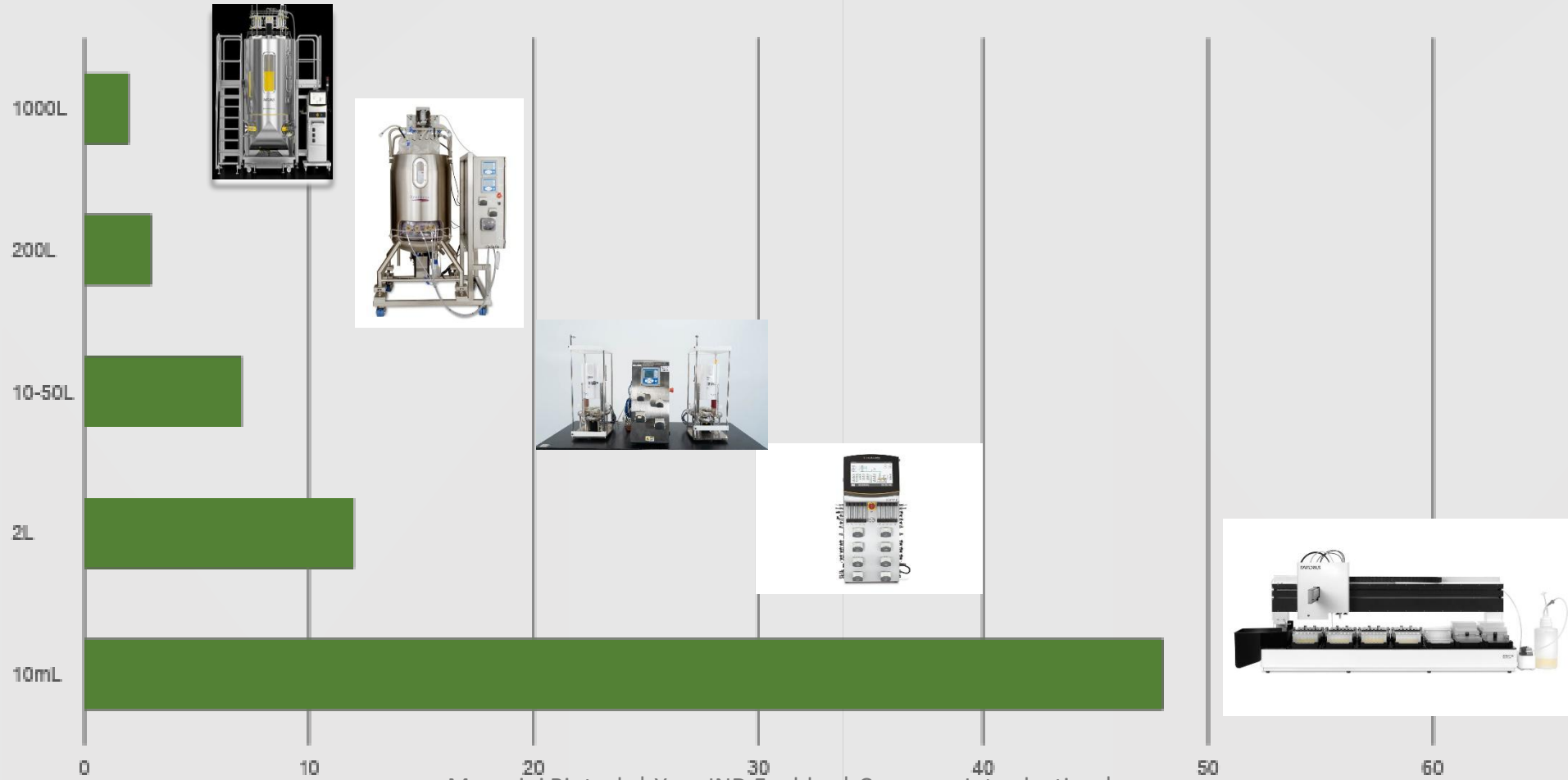
- ❖ Cell Line Development (CLD): experience with e.g. FUT8-knockout CHO, CHO GS, ExpiCHO S, DG44 , hybridoma
- ❖ Basal media screening, selection, and optimization
- ❖ Feed media screening, selection and optimization



- ❖ 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

# USP: Capability and Scalability

*Across 6 orders of magnitude (<10mL to 1,000L)*



# Downstream Development

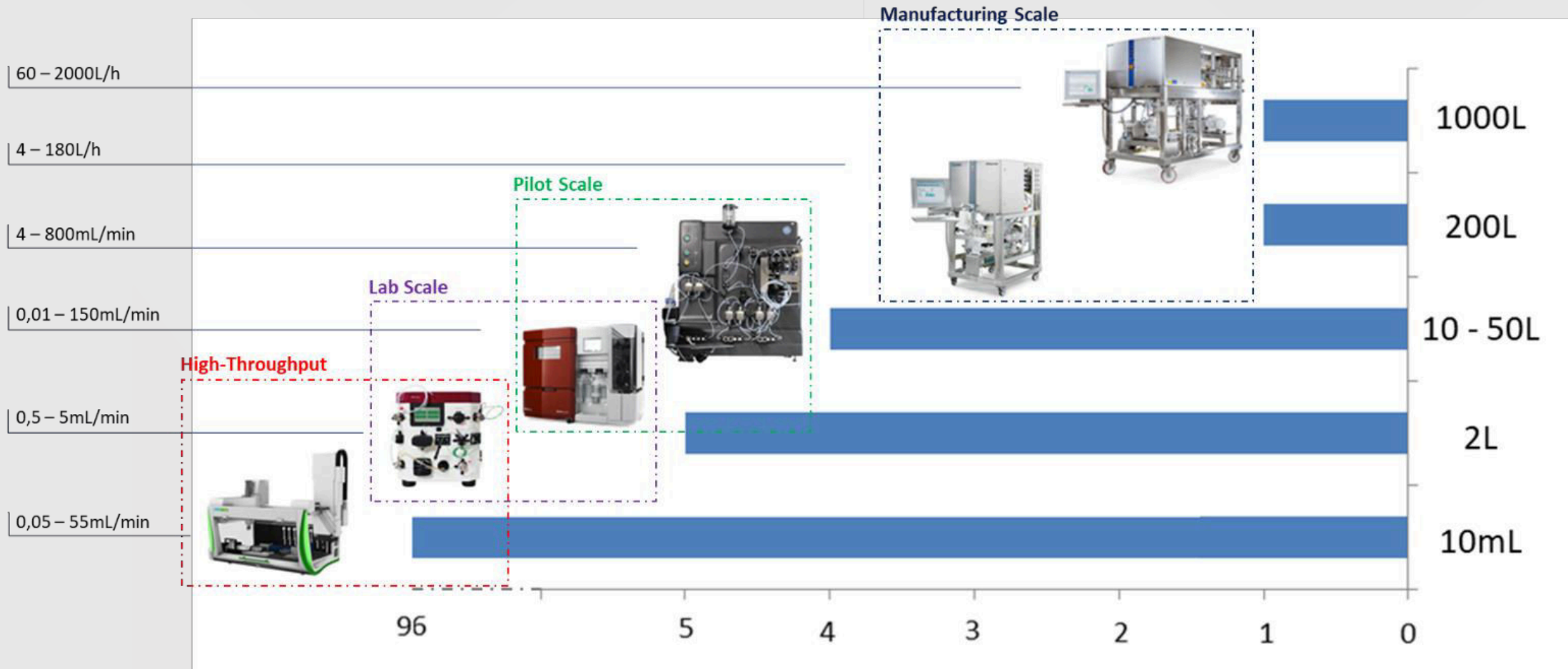
- ❖ ReFiltration (dead end, nano, tangential) screening, selection and optimization
- ❖ Formulation screening and selection
- ❖ Resin screening, selection, and optimization



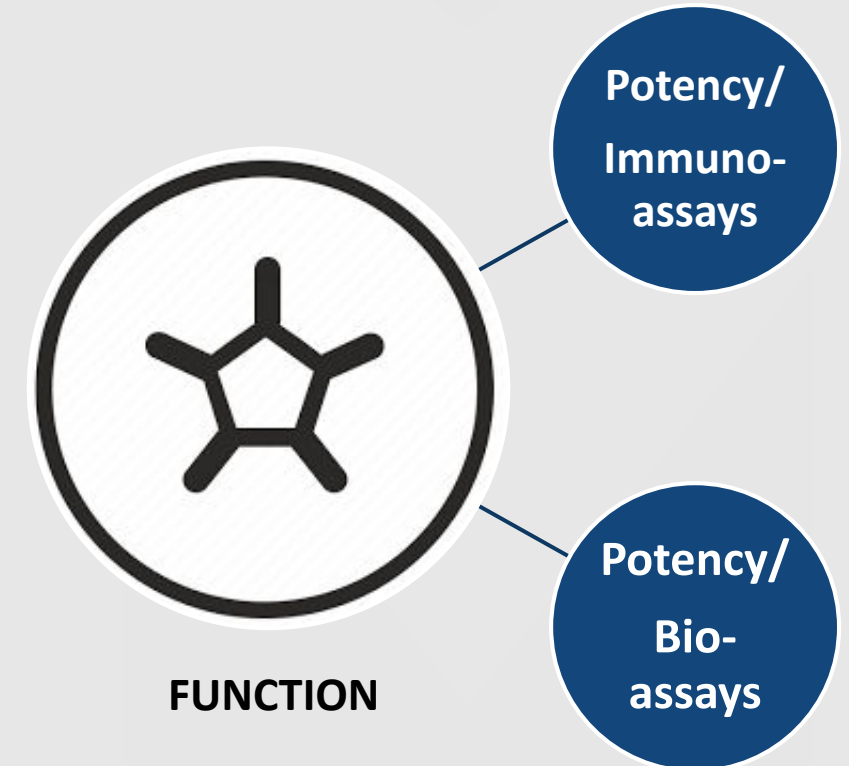
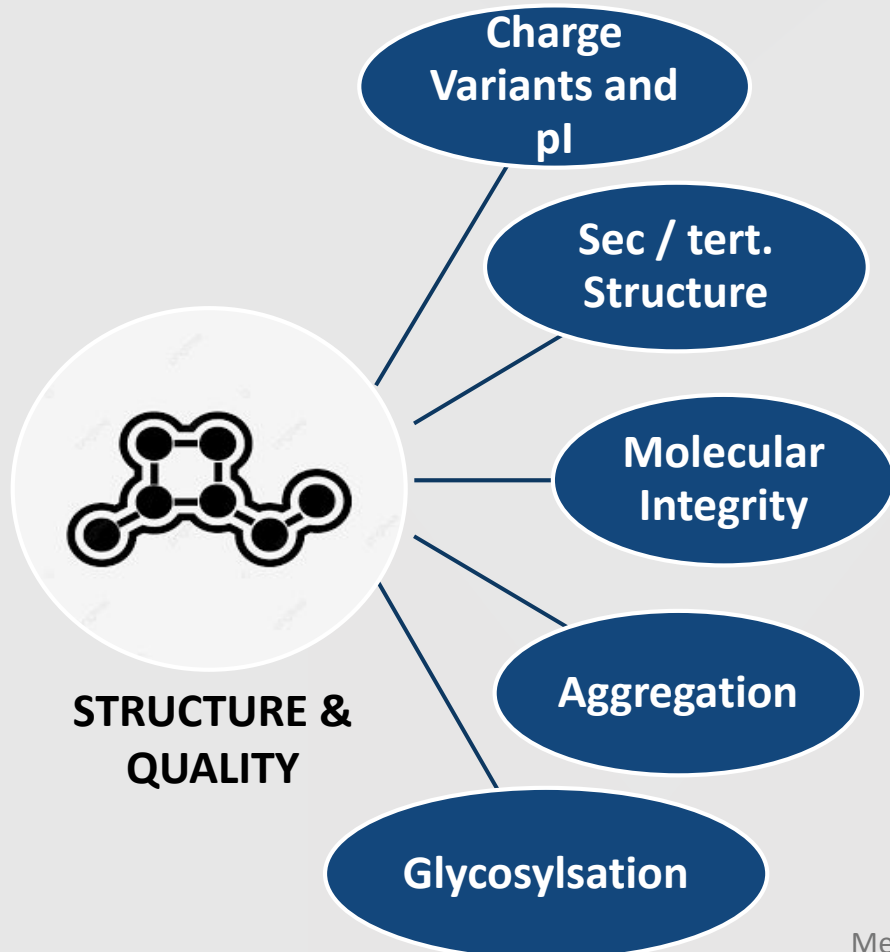
- ❖ Intermediate hold studies
- ❖ Process optimization and characterization
- ❖ Established analytical and DSP platforms

# DSP: Capability and Scalability

*7 orders of magnitude (0.2mg to 2,000g)*

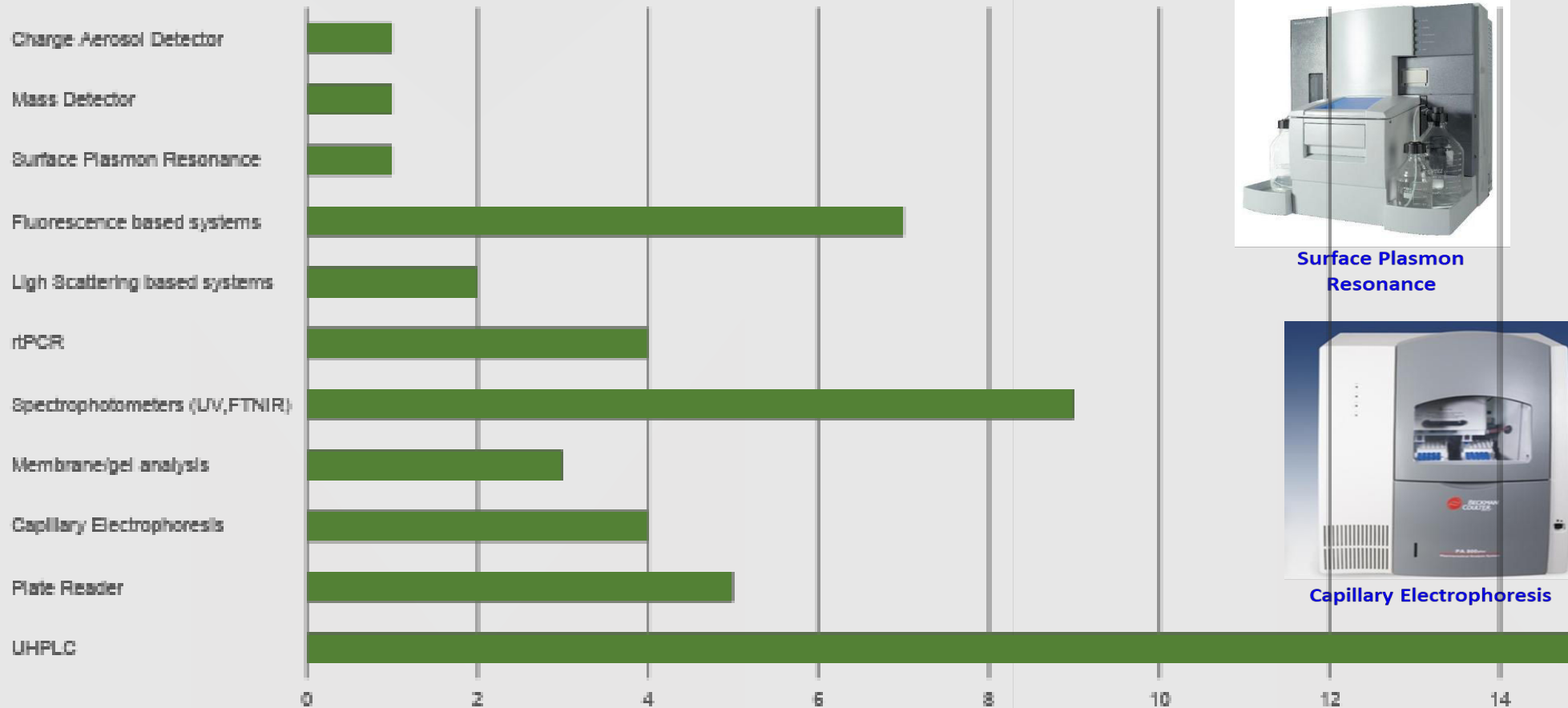


# Unprecedented Analytical Capabilities



# Analytical Capability

*Large Number of Instruments available for you*



**Surface Plasmon Resonance**



**SLS/FLR System**



**Capillary Electrophoresis**



**UHPLC**

# 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 platforms



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# Clinical and Early- Commercial GMP Manufacture

Menarini Biotech | Your IND Enabler | Company Introduction |  
2025

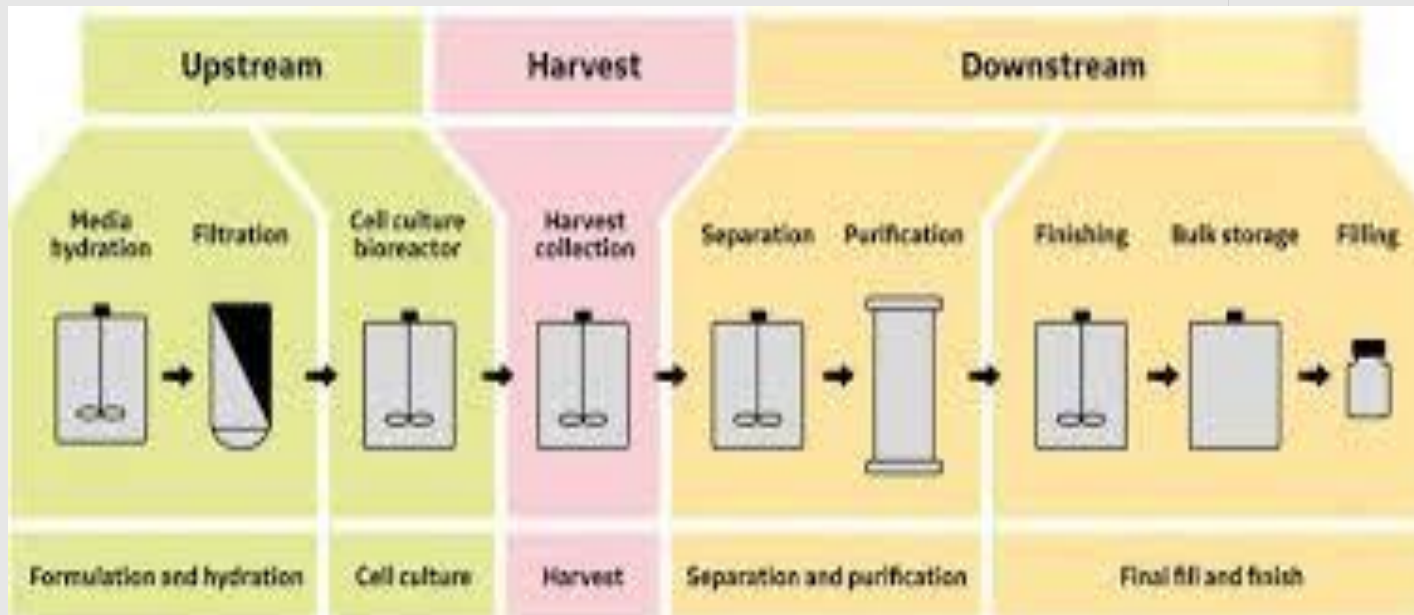




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# Simplified Workflows

*Platform - single-use - easy to transfer and scale-up*



## *USP area:*

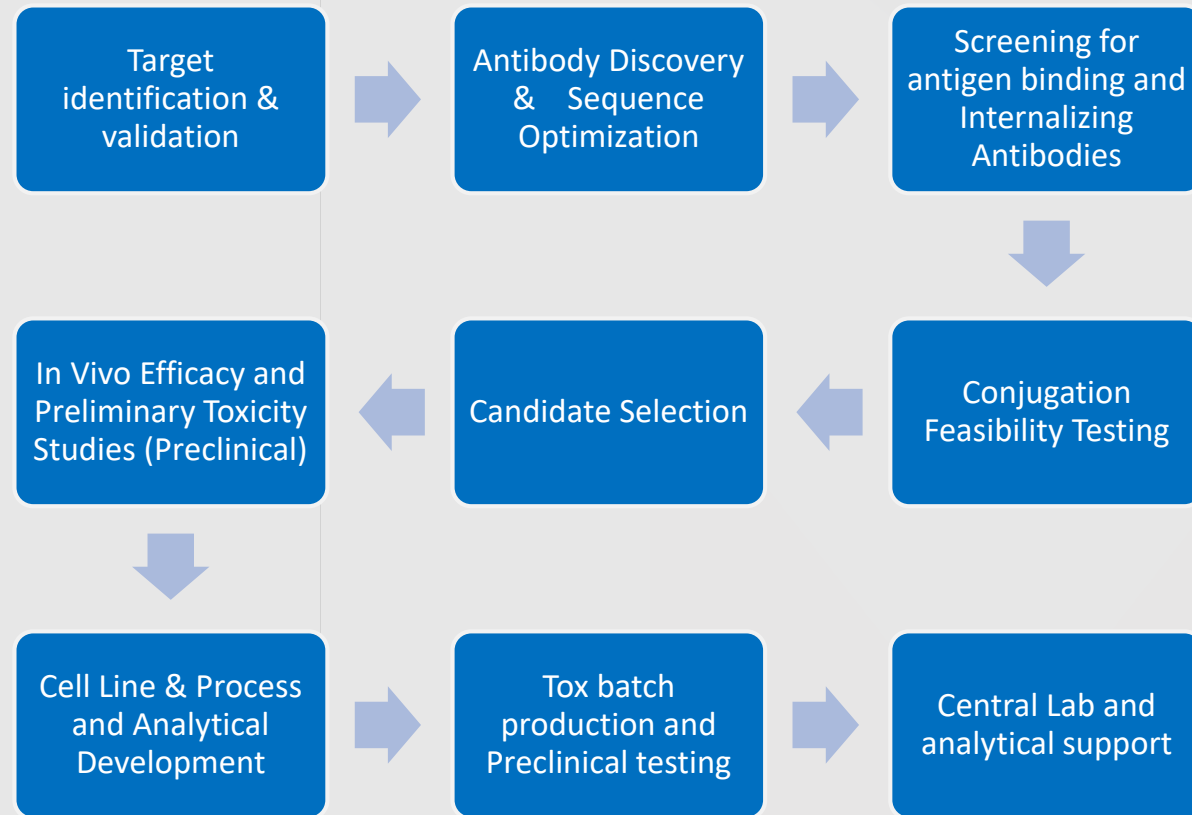
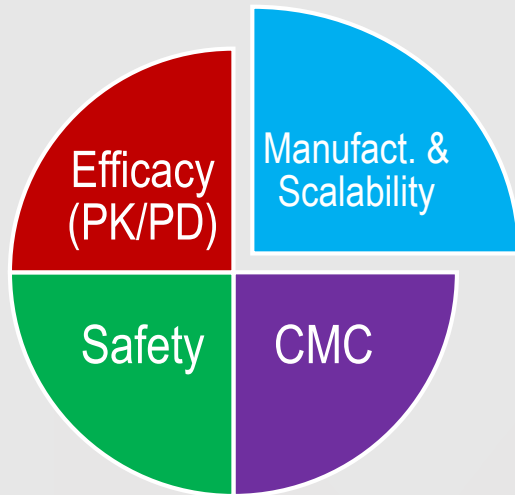
*Grade D, 390m<sup>2</sup>, BSL-2, media and buffer preparation*

*3x200L (XDR-200), 2x1kL (STR 1000 3<sup>rd</sup> gen. SUB)*

## *DSP area:*

*Grade C, 240m<sup>2</sup>, BSL-1, buffer preparation, column packing, filling into manifold system bags*

# Integrated Service Offer: ERBC and MBH



# Summary

## *Who we are and what we do*

### WHO WE ARE



- Small, boutique CDMO
- Fast. Agile. Flexible. Very Competitive
- Established in 2003
- Affiliated to Menarini Group
- Located in Pomezia (Rome)
- 80 employees
- Approved by AIFA/EMA for GMP Mfg

### OUR OFFER



R+D (preclinical) and IND-enabling CMC services, from bench to clinic. Gene to vial.

### OUR TARGET CUSTOMERS



Small to mid-sized biotech companies actively engaged in development and manufacture (CHO and E.coli) of antibodies, fragments, fusion proteins, therapeutic proteins, enzymes

### OUR TRACK RECORD



- > 20years
- (Bs)Abs, produced in hybridoma, CHO cells;
- Recomb. human cytokines produced in CHO;
- Recombinant enzymes (CVD, enzyme replacement therapy, inflammation)

### WHY WORK WITH US



- Faster than your previous CDMO, yet reliable, with no compromise on quality
- Short lead times to start project
- Family-owned: Long-term vision and financially stable

### MADE IN ITALY



- Vibrant life science clusters, e.g. around Milan and Rome, see <http://www.clusterchico.eu/?lang=en#home>
- Strong government support to further grow the life science industry in Italy, see <https://www.investitaly.gov.it/en/sectors/life-sciences>



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# Menarini Biotech

*Equalled by few ...*

*... Surpassed by none*

