



LFB BIOMANUFACTURING

**YOUR CDMO PARTNER
FOR MABS AND RECOMBINANT PROTEINS**



LFB BIOMANUFACTURING COMMITMENT AND FLEXIBILITY

LFB BIOMANUFACTURING is a medium-sized CDMO offering Bioproduction services, from an industrial facility in Alès (South of France). More than 15 years of experience have granted LFB BIOMANUFACTURING with the ability to address complex projects, with a successful track record in cell line and process development, scale-up and GMP manufacturing of various biopharmaceuticals, mainly monoclonal antibodies and recombinant proteins.

LFB BIOMANUFACTURING benefits from its integration within the LFB group, a major player in biologics, with respect to industrial and pharmaceutical expertise, Analytical Methods for Protein characterization and Quality Control, Protein Formulation, Viral Safety, Regulatory and Industrial Project Management.

key assets



Successful track record for cell line development, process scale up and DS manufacturing



Multidisciplinary integrated project team for each project



Integration within the LFB group with key support in pharmaceutical expertise



Proprietary EMABling® platform for optimized antibodies



State-of-the-art equipment and flexible facility (Single Use Technology)



Frequently audited by customers and inspected by regulatory authorities, for clinical and commercial manufacturing

STRENGTHS & SERVICES OF A UNIQUE ONE-STOP SHOP



Process Development and Scale-Up

Upstream (USP) and downstream process (DSP) optimizations executed with state-of-the-art methods and equipment (DOE¹ & Ambr15™ for USP). Industrialization/ scale up assessed with disposable bioreactors such as Wave or Single-Use Bioreactors (SUB) systems.

(1) Design Of Experiment



Analytical Services

Our labs support development, technical transfer, optimization and validation of analytical methods as well as stability studies for clinical and commercial products.



Cell Line Development

Proven mammalian cell line development capabilities, with CHO-S and YB2/O host cell lines. We assist clients with cell line selection, stability assessments and cell line characterization.



GMP Manufacturing

In a GMP multi-product manufacturing facility, we are producing DS* batches since 2003. Buffers and cell culture media are prepared under GMP conditions in dedicated production suites using single-use technologies.

*DS: Drug substance



Quality Assurance and Regulatory Affairs

Our Quality Units ensure that all aspects of drug substance manufacturing fulfill regulatory requirements. Services include tech transfer, GMP audits and qualification of suppliers and subcontractors.

2003
MAbgène
Production
Unit 1

2007
Integration
into LFB group

2009
Disposable
bioreactor
implementation

2011
Site extension/
support services

2016
Capacity
extension
Production
Unit 2

2017
FDA inspection
N° FEI:
3011292311

LFB BIOMANUFACTURING
EMABling® PLATFORM

Enhanced ADCC/ADCP activities of monoclonal antibodies

EMABling® is a LFB proprietary technology for the development and manufacture of recombinant monoclonal antibodies having an enhanced antibody-dependent cellular cytotoxicity and phagocytosis (ADCC/ADCP) activity due to a specific glycosylation pattern.



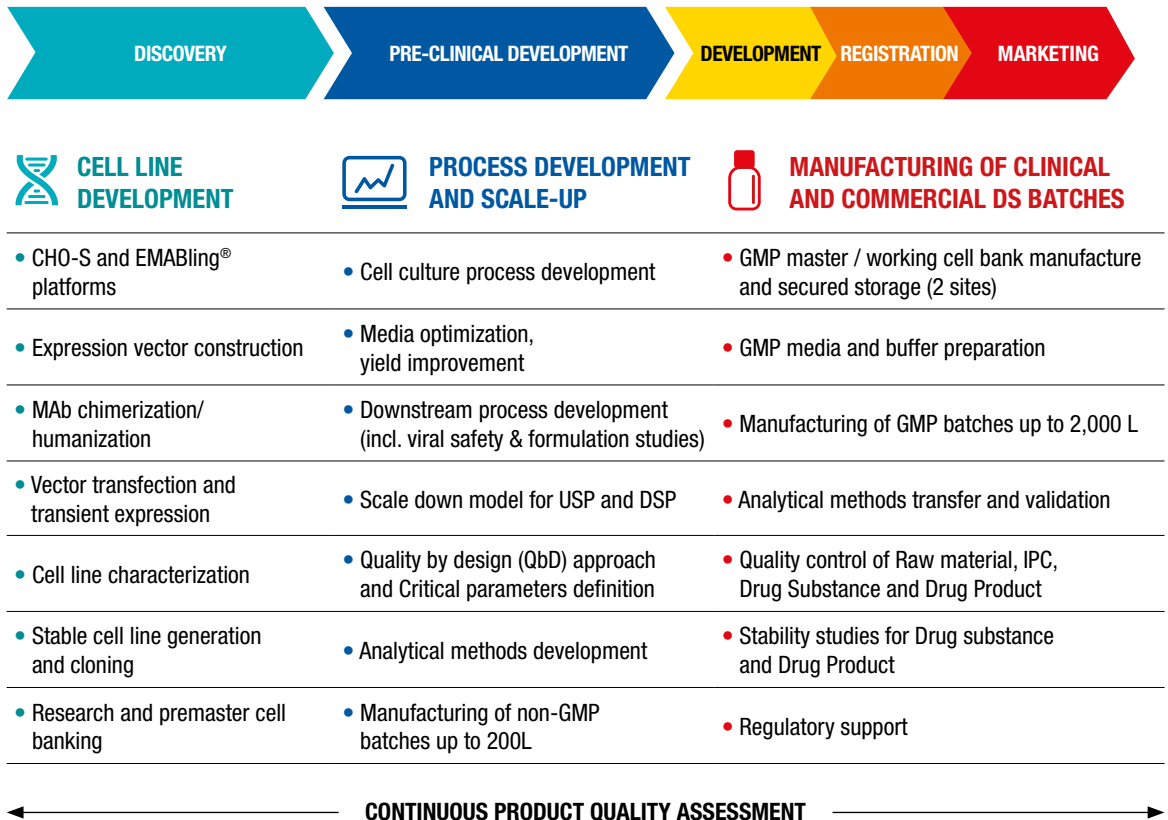
LFB's research in this area has been based on the study of structure-function relationships for monoclonal antibodies and has raised the importance of post-translational modifications (role of glycans) in the functional activity of the antibody

Combined with the host cell line YB2/O-E, specifically optimized expression vectors and cell culture medium (EMABPRO), a powerful clone selection process (including the use of ClonePix™ cloning robot), the EMABling® platform covered by know-how and patents, leads to gram-per-liter producing clones.

EMABling®
is an LFB Patented
technology

US	7,931,895
US	8,409,572
EP	158864
EP	2341078

LFB BIOMANUFACTURING CONTRACT BIOMANUFACTURING SERVICES



PILOT FACILITIES AND EQUIPMENT

- Mammalian cell line development platform
- Quality control laboratory
- Roller bottle, shake flask and Ambr™ systems
- 25L Wave system
- 50L & 200L Single Use Bioreactors
- Downstream process equipment (chromatography, ultrafiltration/diafiltration, nanofiltration)

GMP MANUFACTURING CAPABILITIES

- Production Unit 1 (125 m²) for early stage clinical manufacturing with
 - up to 1000L (single use bioreactor)
- Production Unit 2 (535 m²) for late stage clinical and commercial manufacturing with potential capacity of up to 6 X 2000L (single use bioreactor)
- Industrial clarification/UF-DF/ nanofiltration and chromatography systems



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