



# **Biotherapies Days**

**13 & 14 novembre @ Montpellier**

David BALBUENA  
Business Dev Dir.

**#biotherapie  
#bioproduction  
#ADOCC**



# LFB BIOMANUFACTURING: an integrated business unit



- ✓ More than 25 years of experience in the development and the manufacture of *monoclonal antibodies* and *therapeutic proteins*
- ✓ Offering one stop shop CDMO services: from Cell Line Development to GMP manufacturing of drug substance
- ✓ Using flexible technologies with almost exclusively disposable systems.
- ✓ With distinctive customer practice focusing on flexibility and cost efficiency
- ✓ Pharmaceutical expertise and support of the LFB Group
- ✓ Inspected and approved by FDA and ANSM

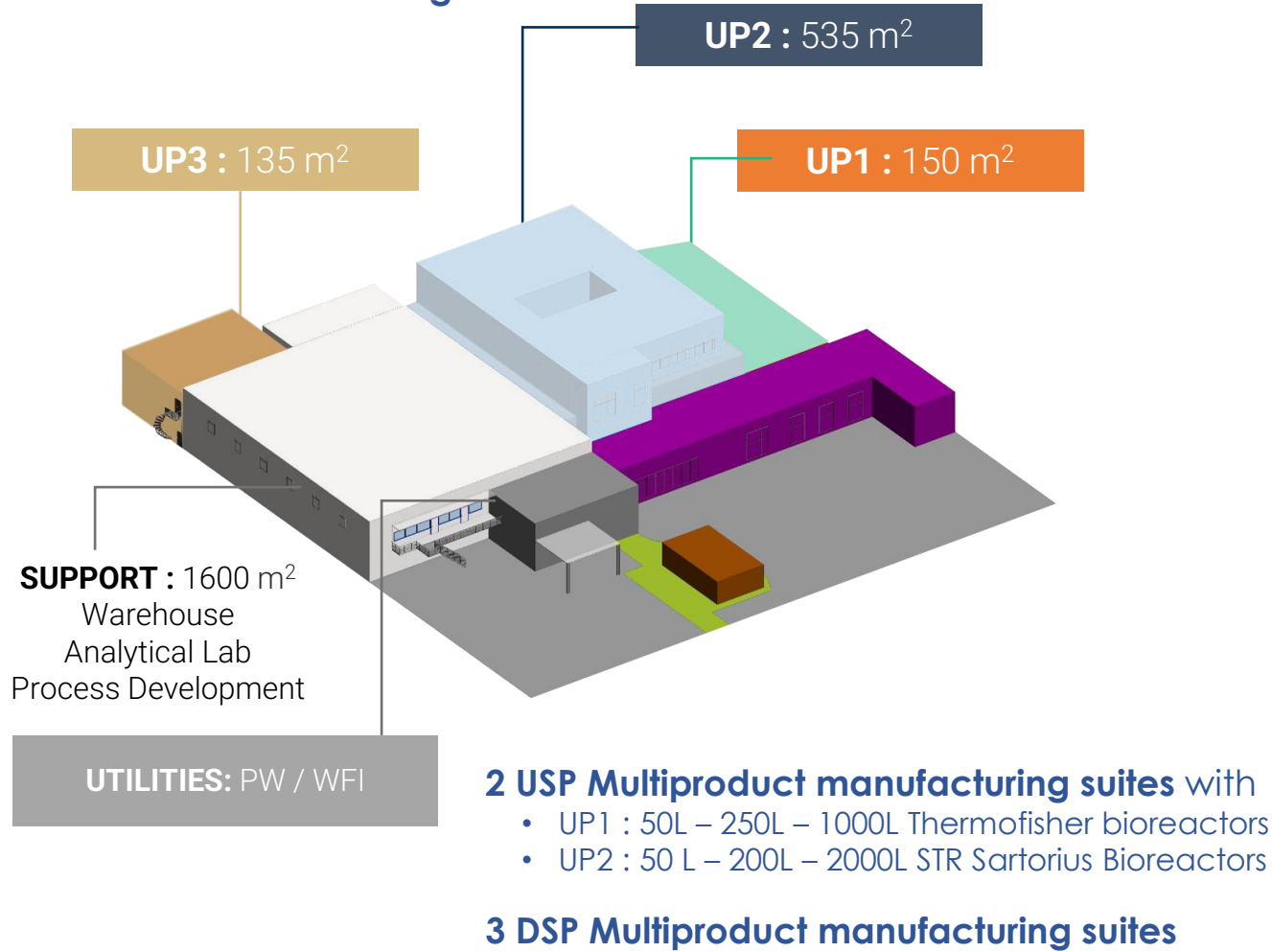


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# LFB BIOMANUFACTURING

## Flexible Process Development and Drug Substance manufacturing Unit



Date de création de l'entreprise : **1997**

Taille de l'entreprise : **ETI** , Filiale du groupe LFB

Nombre d'employés : **85** (sur site)

Localisée à **Alès dans le Gard (30)**

3 unités de Production

1 produit Commercial



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# Vos produits / votre techno : 1 ou 2 slides

## DISCOVERY

### Cell Line Development

- > CHO and EMABling® platforms
- > Expression vector construction
- > MAb chimerization/humanization
- > Vector transfection and transient expression
- > Cell line characterization and comparability
- > Stable cell line generation and cloning
- > cell banking

## PRE-CLINICAL DEVELOPMENT

### Process Development and Scale-Up

- > Cell culture process development
- > Adaptation to serum-free media
- > Media optimization, yield improvement
- > Downstream process development
- > Analytical methods development
- > Quality by Design (QbD) approach and identification of product Critical Quality Attributes (CQA) and CPP
- > Manufacturing of non-GMP batches up to 200L

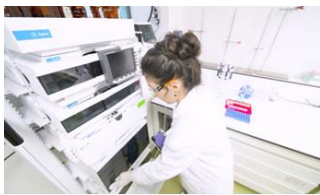
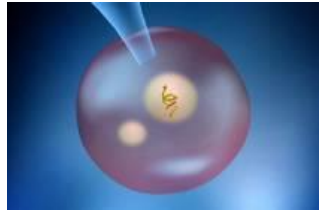
## CLINICAL DEVELOPMENT

### Manufacturing of Clinical and Commercial API/DS Batches

- > GMP Master / Working cell bank manufacture and secured storage
- > GMP media and buffer preparation
- > Manufacturing of up to 2,000L GMP batches
- > Analytical methods transfer and validation
- > Quality control of drug substance, drug product, IPC, raw materials testing
- > Stability studies for API / Drug substance
- > Process characterization and Process validation, Regulatory support

## REGISTRATION

## COMMERCIALIZATION



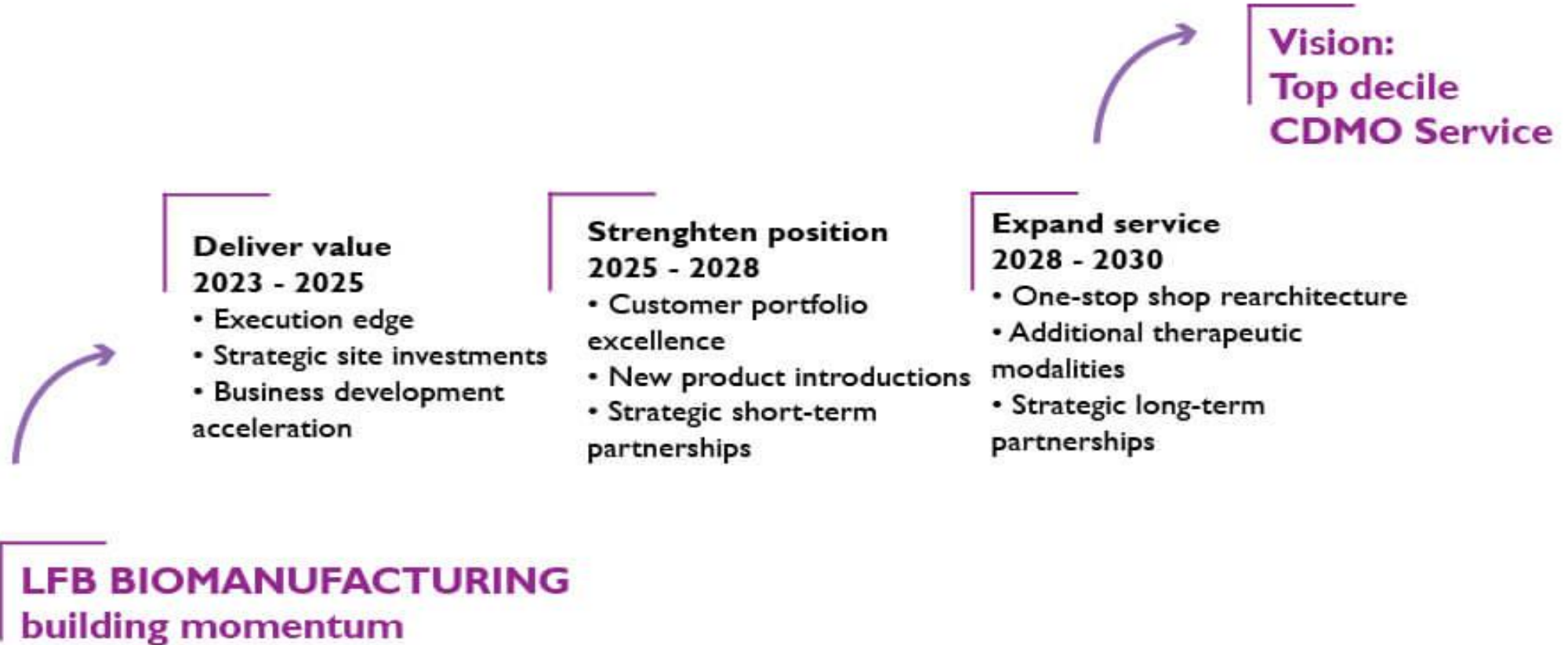
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# LFB BIOMANUFACTURING - ESCAPE<sup>30</sup> – our development strategy

## SERVICE

## INNOVATION

## IMPACT



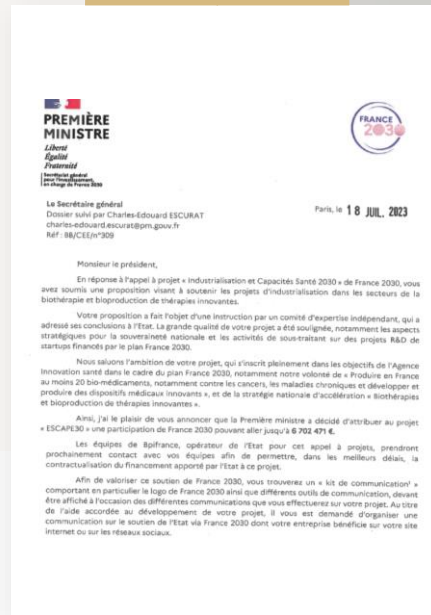
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# Our plan ESCAPE30 Winner of « AAP Capacite Sante France 2030 »

“ In response to the “Industrialisation et Capacités Santé 2030” (“2030 Industrialisation and Health Capacity”) call for projects, the French Prime Minister decided to fund LFB’s project for up to **€6.7 million**. The project, with a total cost of more than **€20 million**, is fully in line with the objectives of the French Health Innovation Agency and the “France 2030” Health component of the 2030 Health Innovation plan. ”

Herbert Guedegbe  
DIRECTEUR DE SITE



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# Our plan ESCAPE30 Winner of « AAP Capacite Sante France 2030 »

## ESCAPE 30 PROJECT

Buffer and media preparation area extension

Analytical laboratory extension to support analytical method development and method validation

Process Development laboratory extension to increase new biological entities development throughput capacity



**Project duration**  
48 months



**Generated turnover**  
38 m€



**Estimated budget**  
20,6 m€



**49 direct jobs**  
by 2026

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## A strategic partnership with Sartorius



SARTORIUS

Through this collaboration, customers will have **access to high-performing Sartorius cell lines and media that support successful transfer and scale-up**, along with an integrated drug development process from LFB BIOMANUFACTURING.

By partnering, the companies are enabling a **one-stop solution that reduces the logistic and administrative efforts involved** when engaging with multiple stakeholders, streamlining development and manufacturing processes.

In time, the collaboration can accelerate time-to-clinic and time-to-market for therapeutic molecules.

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# Remerciements



bpi**france**

## Clients Principaux:



**XENOTHERA**

**OSE**

IMMUNO  
THERAPEUTICS



SpikImm

**FABENTECH**



StromaCare

## Collaborations nationales / régionales :

- Membres de :

FRANCE

**bioblead**



france  
**biotech**  
biotech | medtech | e-santé | IA  
LES ENTREPRENEURS DE LA HEALTHTECH



**mabdesign**  
THE BIOTHERAPY EXPERT

