FACT SHEET

Live Microbial Products Development & Manufacturing

JAFRAL is a European CDMO providing end-to-end development and GMP manufacturing of Live Microbial Products (LMPs). From strain selection and cell banking to fermentation, formulation and QC release, we help accelerate development while ensuring quality, scalability and regulatory readiness.

One European partner, from strain to GMP — across the entire live microbial product journey.

End-to-End Development

Strain selection, cell banking, process and formulation development, analytics and CMC under one roof.

GMP & Non-GMP

Research-grade material, preclinical batches and GMP clinical trial supply in two EU GMP facilities.

Scalable, 2 L – 200 L

Parallel 4 × 1 L DoE development and scale-up fermentation up to 200 L.

30+ Microbial Species

Probiotics, commensals, yeasts and clinically relevant pathogens; GMO and non-GMO, BSL-1 and BSL-2.

This fact sheet summarizes our LMP capabilities across three service tracks: Research & Preclinical Manufacturing, GMP Clinical Manufacturing, and Formulation, Drug Product & Fill-Finish.



Live microbial products — from bulk drug substance to finished capsules.

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Service Tracks

LMP programs move through three service tracks — from research strains and preclinical material to GMP clinical supply and finished drug product. Each track can be engaged independently or as part of a single, continuous development path.

Research & Preclinical Manufacturing

Flexible development and manufacturing for discovery programs, proof-of-concept and non-clinical studies — building a robust, scalable process for your strain from day one.

SERVICES INCLUDE

- Strain selection, characterization & optimization
- Research Cell Bank (RCB) development
- Media optimization & parallel flask screening
- DoE fermentation development (4 × 1 L)
- Formulation development & stability assessment
- Analytical development & characterization
- Material for preclinical studies

TYPICAL APPLICATIONS

- Live Biotherapeutic Products (LBPs)
- Live Bacterial Therapeutics (LBTs)
- Microbial vectors for gene therapy
- Live & microbial-based vaccines
- Probiotics & food supplements

GMP Clinical Manufacturing

EU GMP manufacturing of clinical trial material, with a seamless transition from process development to GMP production in two independent facilities — reducing tech-transfer risk and accelerating entry into the clinic.

GMP SERVICES INCLUDE

- GMP Master & Working Cell Banks (MCB/WCB)
- GMP fermentation, 2 L – 200 L
- Downstream processing (TFF, chromatography)
- QC & release testing (DS and DP)
- GMP stability studies
- Regulatory & CMC support (IND/CTA)

APPLICATIONS

- Infectious diseases & AMR
- Microbiome modulation
- Oncology
- Gene therapy
- Vaccines & preventive healthcare

Formulation, Drug Product & Fill-Finish

From bulk microbial drug substance to final product in its primary container — stability-driven formulation that preserves viability, with flexible filling and packaging.

FORMATS & SERVICES

- Liquids & serums, emulsions
- Lyophilized & spray-dried powders
- Capsules / encapsulation
- Aseptic & non-aseptic filling
- Labelling & customized packaging

KEY BENEFITS

- Viability preserved from harvest to shelf
- DS and DP from one partner
- Shelf-life and stability data for filing
- Animal-free raw materials available
- Formats for oral, topical & other routes

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Capabilities & What We Do

Core Capabilities

Product Types	LBPs, LBTs, microbial vectors for gene therapy (MVGTs), live & microbial-based vaccines
Organisms	30+ bacterial and yeast species · GMO & non-GMO · BSL-1 & BSL-2
Fermentation (USP)	Parallel flask screening, DoE on 4 × 1 L bioreactors, scale-up 2 L – 200 L
Downstream (DSP)	TFF; AEX, SEC, affinity & HIC chromatography; 3 × FPLC, ÄKTA platforms
Formulations	Liquid & serums, lyophilized, spray-dried, emulsions, encapsulated
Quality Grades	Research grade, pre-GMP, EU GMP (human & veterinary, incl. ATMPs)

What We Do — Process Coverage

Process Step	R&D / Preclin.	GMP Clinical	Drug Product	Typical Scale / Output
Strain selection & characterization	✓	✓	–	Up to 10 strains in parallel
Cell banking (RCB / MCB / WCB)	✓	✓	–	200–400 vials per bank
Media & fermentation development	✓	✓	–	4 × 1 L parallel DoE
Scale-up & GMP fermentation	✓	✓	–	2 L – 200 L working volume
Harvest & downstream processing	✓	✓	–	TFF & chromatography
Formulation development	✓	✓	✓	3–5 formulation candidates
Lyophilization / spray-drying	✓	✓	✓	Up to 5 kg powder per batch
Encapsulation & fill-finish	–	✓	✓	Up to 50,000 units per batch
Analytical development	✓	✓	✓	CFU, qPCR, WGS
QC release & stability	–	✓	✓	Stability up to 24 months
Technology transfer	✓	✓	✓	In or out, to/from partner sites
Regulatory & CMC documentation	✓	✓	✓	IND/CTA CMC, US & EU

Table 1: Process coverage by service track, with indicative scale and output.

Microbial Experience

E. coli · *Lactobacillus* · *Bifidobacterium* · *S. cerevisiae* · *Bacillus* · *Clostridium* · *S. aureus* · *P. aeruginosa* · *K. pneumoniae* · *Salmonella* · *M. abscessus* · *C. acnes* · *E. faecalis* · *A. baumannii*

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LIVE MICROBIAL PRODUCTS · FACT SHEET

LBP Focus & Stability Data

Live Biotherapeutic Products (LBPs) are regulated as medicinal products, not food supplements – they need GMP manufacturing, a full CMC package and LBP-specific analytics. JAFRAL supports LBP developers from research strain to the first clinical GMP batch.

Why LBP Developers Choose JAFRAL

End-to-end solutions
Research strain to GMP clinical batch

Scalable production
4 × 1 L DoE to 200 L GMP

Customized manufacturing
Processes tailored to each strain

Fast turnaround
Predictable, coordinated timelines

Research & GMP grade
From preclinical to clinical supply

Comprehensive QC
LBP-specific release and stability testing

Animal-free manufacturing
Animal-free raw materials available

Regulatory support
CMC packages for IND/CTA filings

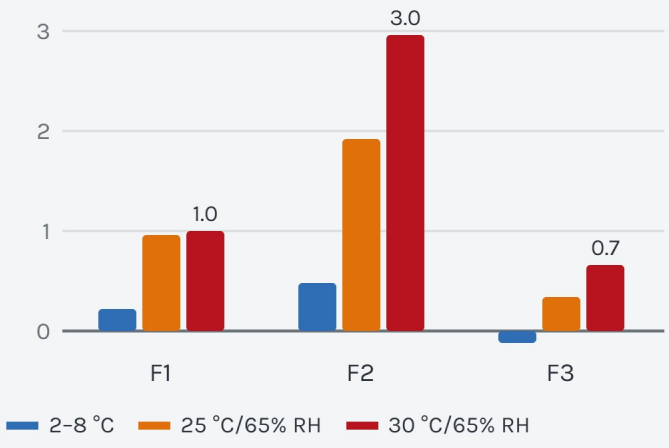
LBP Quality Control Panel

Concentration (CFU) · Identity · Content · Physical properties · Impurities · Safety · Stability · Product-specific tests

Case Data: Lyophilized Formulation Screening

A live bacterial strain from a client WCB was fermented in a 30 L bioreactor, harvested by centrifugation, formulated with three lyoprotectants (F1–F3), lyophilized, milled and sealed in aluminium bags, then stored for 4 weeks at 2–8 °C, 25 °C/65% RH and 30 °C/65% RH.

Viability loss after 4 weeks (Δ $\log_{10}$ CFU/g)



≤ 0.5 log
viability loss for all formulations over 4 weeks at 2–8 °C

≤ 0.7 log
loss for the lead formulation (F3) up to 30 °C/65% RH

2.1 log
difference in viability after lyophilization, driven by lyoprotectant choice

Data: JAFRAL d.o.o., Microbiome Summit 2026 poster. Lyoprotectant compositions are confidential.

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LIVE MICROBIAL PRODUCTS · FACT SHEET

Quality, Timelines & Track Record

Quality & Analytical Capabilities

IDENTITY & VIABILITY

- Strain identification (PCR, qPCR, ddPCR)
- Whole genome sequencing
- CFU enumeration
- Viability & in-process monitoring

PURITY & SAFETY

- Microbial purity testing
- Process-related impurities
- Contamination assessment
- Virulence factor assessment

CHARACTERIZATION & QC

- Metabolic profiling (HPLC, LC-MS)
- Morphology (SEM/TEM)
- Genomic stability
- DS/DP release, stability & shelf life

Two EU GMP-certified facilities (human & veterinary medicinal products, incl. ATMPs) · FDA food facility registration · ISO 14001 · BSL-1 & BSL-2 · GMO & non-GMO.

Typical Timelines

Work Package	Timeline
Strain characterization & RCB	4–8 weeks
Process development (USP/DSP)	8–16 weeks
Formulation & feasibility stability	8–12 weeks
GMP MCB / WCB incl. release	8–12 weeks
GMP clinical batch (DS + DP)	4–6 months
Tech transfer to first GMP batch	6–9 months

Table 2: Indicative timelines by work package.*

*Final timeline depends on strain, product format and program scope.



Applications We Support

- Infectious Diseases
- Microbiome Modulation
- Oncology
- Gene Therapy
- Vaccines
- Preventive Healthcare

60+
microbial and phage banks produced

60+
clinical development programs supported

120+
GMP batches manufactured

3
agencies: FDA, EMA & TGA programs

Let's discuss your strain.

From strain selection to GMP clinical supply — tell us about your organism, product format and timelines, and our team will propose the right development and manufacturing path.

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