FACT SHEET

# Recombinant Protein Development & Manufacturing

**JAFRAL** is a European CDMO providing end-to-end recombinant protein development and manufacturing services. From expression optimization and process development to purification, analytical characterization and GMP production, we help accelerate development timelines while ensuring quality, scalability and regulatory readiness.

## One European partner, from gene to GMP — across the entire recombinant protein journey.

### End-to-End Development

Gene-to-protein solution: sequence optimization, expression development, purification, formulation and analytical characterization.

### GMP & Non-GMP

Production for research, preclinical studies, clinical development and advanced therapeutic applications.

### Scalable, mg–multi-gram

From feasibility studies and pilot-scale batches to GMP manufacturing for clinical trial supply.

### Animal-Free Manufacturing

Animal-component-free raw materials suitable for biopharmaceutical and advanced therapy applications.

This fact sheet summarizes our recombinant protein CDMO capabilities across three service tracks: Research & Preclinical Manufacturing, GMP Clinical Manufacturing, and Cell-Free Protein Manufacturing.




*JAFRAL's recombinant protein development and manufacturing facility.*

JAFRAL passion for biosolutions

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# Service Tracks

Recombinant protein programs move through three service tracks — from early discovery material to GMP clinical supply, with a cell-free option for speed and difficult targets. Each track can be engaged independently or as part of a single, continuous development path.

## Research & Preclinical Manufacturing

Flexible manufacturing solutions for discovery programs, assay development, proof-of-concept studies and non-clinical testing — rapid, high-quality protein production tailored to your candidate.

### SERVICES INCLUDE

- Expression screening & optimization
- Small-scale fermentation & cultivation
- Protein purification & polishing
- Analytical method development
- Formulation development
- Flexible batch sizes & rapid turnaround
- Delivery-method testing (IV, inhalation & other routes)

### TYPICAL APPLICATIONS

- Cytokines & growth factors
- Vaccine antigens
- Enzymes
- Recombinant antibodies
- Fusion & diagnostic proteins

## GMP Clinical Manufacturing

GMP-compliant recombinant protein manufacturing for clinical applications, with a seamless transition from process development to GMP production — reducing technology-transfer risk and accelerating entry into clinical studies.

### GMP SERVICES INCLUDE

- GMP cell bank generation
- GMP upstream & downstream manufacturing
- Analytical method qualification & release testing
- Stability studies
- GMP batch record documentation
- Regulatory & CMC support

### APPLICATIONS

- Cell & Gene Therapy
- Therapeutic Proteins
- Vaccine Development
- Immunotherapy Programs
- Advanced Biologics

## Cell-Free Recombinant Protein Manufacturing

A powerful alternative to cell-based systems — rapid protein production, simplified process development and access to challenging protein targets, for research, therapeutic and industrial applications.

### KEY BENEFITS

- Rapid protein synthesis
- Accelerated development timelines
- Host-cell-free production, reduced contamination risk
- Difficult-to-express & host-toxic proteins
- Custom protein design & optimization

### APPLICATIONS

- Protein screening & synthetic biology
- Therapeutic protein development
- Enzyme engineering
- Vaccine research
- Advanced biologics development

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# Capabilities & Process Coverage

## Core Capabilities

| | |
|---|---|
| **Expression Systems** | Escherichia coli (E. coli), Yeast expression systems, Cell-free protein synthesis platforms |
| **Production Scale** | mg to multi-gram scale |
| **Purification Methods** | Affinity, Ion-exchange, HIC, SEC and related polishing steps |
| **Quality Grades** | Research grade, Pre-GMP, GMP |

## Expression Platforms

E. coli

Yeast

Cell-Free Synthesis

Our scientists evaluate each target protein's characteristics to identify the most suitable production platform for development and manufacturing success. Additional platforms are evaluated case by case — ask us about your specific target.

## Process Coverage by Service Track

| Process Step | R&D / Preclinical | GMP Clinical | Cell-Free |
|---|---|---|---|
| Process Development | ✓ | ✓ | ✓ |
| Expression System Selection | ✓ | ✓ | ✓ |
| Cell Culture / Cultivation | ✓ | ✓ | ✓ |
| Purification | ✓ | ✓ | ✓ |
| Formulation | ✓ | ✓ | ✓ |
| Analytical Testing | ✓ | ✓ | ✓ |
| Scaling Up | ✓ | ✓ | ✓ |
| Regulatory Compliance | ✓ | ✓ | – |
| Stability Testing | ✓ | ✓ | ✓ |
| Final Product Packaging | – | ✓ | – |

Table 1: Process step coverage across JAFRAL's three recombinant protein service tracks.



*Upstream manufacturing suite — JAFRAL cleanroom facility.*

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# Quality, Timelines & Applications

## Quality & Analytical Capabilities

- Protein concentration
- Identity confirmation
- Purity & homogeneity assessment
- Aggregate analysis
- Residual host cell protein (HCP) analysis
- Residual DNA testing
- Endotoxin testing
- Microbiological testing
- Stability testing
- Potency & functional assays
- Customer-specific analytical methods
- Molecular weight confirmation
- Solubility assessment
- Post-translational modification analysis

Our analytical experts work with customers to establish appropriate QC strategies for both non-GMP and GMP programs. A full method-by-method QC matrix is available on request.

## Typical Timelines

| Production Type | Overall Timeline |
|---|---|
| Research & Preclinical Protein Production | 4–12 weeks |
| Cell-Free Protein Production | 1–4 weeks* |
| Process Development Program | 8–20 weeks |
| GMP Clinical Manufacturing | 4–9 months |

**Table 2: Indicative overall timelines by production type.***

*Final timeline depends on target protein and program scope.



## Applications We Support

- Cytokines
- Growth Factors
- Vaccine Antigens
- Enzymes
- Antibodies
- Fusion Proteins
- Cell & Gene Therapy
- Immunotherapy

### Fast turnaround times

We prioritize efficiency to ensure your projects are completed on time, every time.

### Cost-effective solutions

Our services are designed to deliver maximum value without compromising on quality.

### GMP expertise

From small batches to large-scale manufacturing, we offer GMP-compliant solutions tailored to your needs.

## Let's discuss your protein.

From feasibility to GMP clinical supply — tell us about your target protein and program requirements, and our team will propose the right development and manufacturing path.

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