BIOTECH
contract
development
manufacturing

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Biopharmaceuticals

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3P Biopharmaceuticals is a Contract Manufacturing Organization (CMO), specialized in the development and manufacture of biologics and cell therapy products for pre clinical and clinical trials and commercial stages in GMP conditions.

GMP certified by the **AEMPS***

API for clinical trials and commercial.

QC and release of medicinal products for clinical trials and commercial.

*Spanish Medicines and Sanitary Products Agency

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WHAT WE OFFER

Development and manufacture of:

BIOLOGICS

Proteins

- Recombinant proteins, native proteins, monoclonal antibodies, fusion proteins.
- Vaccines
- Biosimilars

Other biological molecules

- Peptides
- Lipds
- Carbohidrates
- Complex molecules

CELL THERAPY products

Advanced Therapy Medicinal Products

- Cell therapy products
- Tissue engineered products

Intermediate products:

- Cell culture media
- Biomaterials (scaffolds or membranes)

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RELATED SERVICES

BIOLOGICS

- Generation of protein **expression systems**.
- Development and validation of **analytical methods**.
- Generation and characterization of **MCB and WCB**
- **Cell bank** storage.
- Development of **stability studies**.
- Release of **raw materials, drug substances** and **drug products**.
- GMP and Regulatory **consulting** assessment.
- Fill & finishing.

CELL THERAPY products

- **Isolation, culture (normoxia or hypoxia) and harvest** in GMP and non-GMP conditions.
- Generation, characterization, storage and stability studies of **cell banks.**
- **Autologous or allogeneic** process.
- **Scale up** in different culture systems
- **Analytical development and Quality controls for cell therapy process**
- **Final product formulation** for cell based therapies
- **Logistical** services and shipping validation protocols
- **GMP validation process**

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INTEGRAL SERVICE

POC/ Basic research

- Generation of basic expression system
- Protein Engineering
- Basic development
- Lead candidate selection
- Prolongation of protein half life
- Non GMP small scale production

PC / PC Tox.

- Generation of stable expression system
- Development of scalable bioprocess
- Development of analytical methods
- non-GMP/GMP like production
- Preliminar stability studies
- Preliminar API formulation studies

I / IIa / IIb / III

- Scalability
- Optimization process
- Generation/characterization MCB/RCB
- Qualification of analytical methods
- Raw material release
- GMP production
- Stability studies
- API formulation
- Impurity profiling
- Traces analysis
- Fill&finish
- Generation of CTD documentation
    - Validation of analytical methods
    - Cleaning validation
    - In process control

Registration

- Validation of process
- GMP production
- Formal stability studies
- Generation of CMC-IMPD documentation
- Pilot batches

Market

- Ordinary GMP production
- Stability ongoing studies
- Postmarketing trials

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STATE OF THE ART FACILITY

- Prokaryotic Area: fermentors 10L, 100L, up to 1.000 L
- Eukaryotic Area: bioreactors 50L, 200L, up to 2X200L (disposable)
- R&D Area for full process development
- QC and QA Area

Clean rooms D, C and B

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QUALITY SERVICES

- **GMP certified by the AEMPS** (Spanish Medicines and Sanitary Products Agency)

- **Flexibility and adaptation** to client quality requirements, while maintaining GMP rules requirements.

- **Biosafety level II**

- Wide range of **analytical methods:**
  - Potentiometric methods
  - Spectrophotometric methods
  - High Pressure Liquid Chromatography (RP-HPLC, SEC-HPLC…)
  - HCP determination
  - Endotoxins determination
  - DNA determination by Q-PCR
  - Immune activity assays (WB, ELISA, etc…)
  - Bioassays
  - Isoelectric focusing and SDS-PAGE
  - Microbiological contamination (Bioburden)
  - Others

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R&D ACTIVITY

- Technological platforms for process development of biologics
- Platform for development of biosimilars
- Generation of stable cell lines using the SFV3P system

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TRACK RECORD

BIOLOGICS

- Biological **GMP** production:
  - Phase I (lipids derivatives / recombinant proteins / vaccines). Bacterial and yeast process.
  - Phase II (recombinant membrane proteins). Mammalian process.
  - Commercial stage (fusion protein vaccines). Bacterial process.

- Biological **non GMP** production:
  - Proof of Concept (mAb's / fusion proteins / enzymes)
  - PreClinical (recombinant proteins)

CELL THERAPY products

- Development of cell culture media and biomaterial for clinical use.
- Development and production of stem cells for allogeneic cell therapy. Clinical trial phase I.
- Manufacture of a tissue engineered product for autologous treatment of skin lesions.

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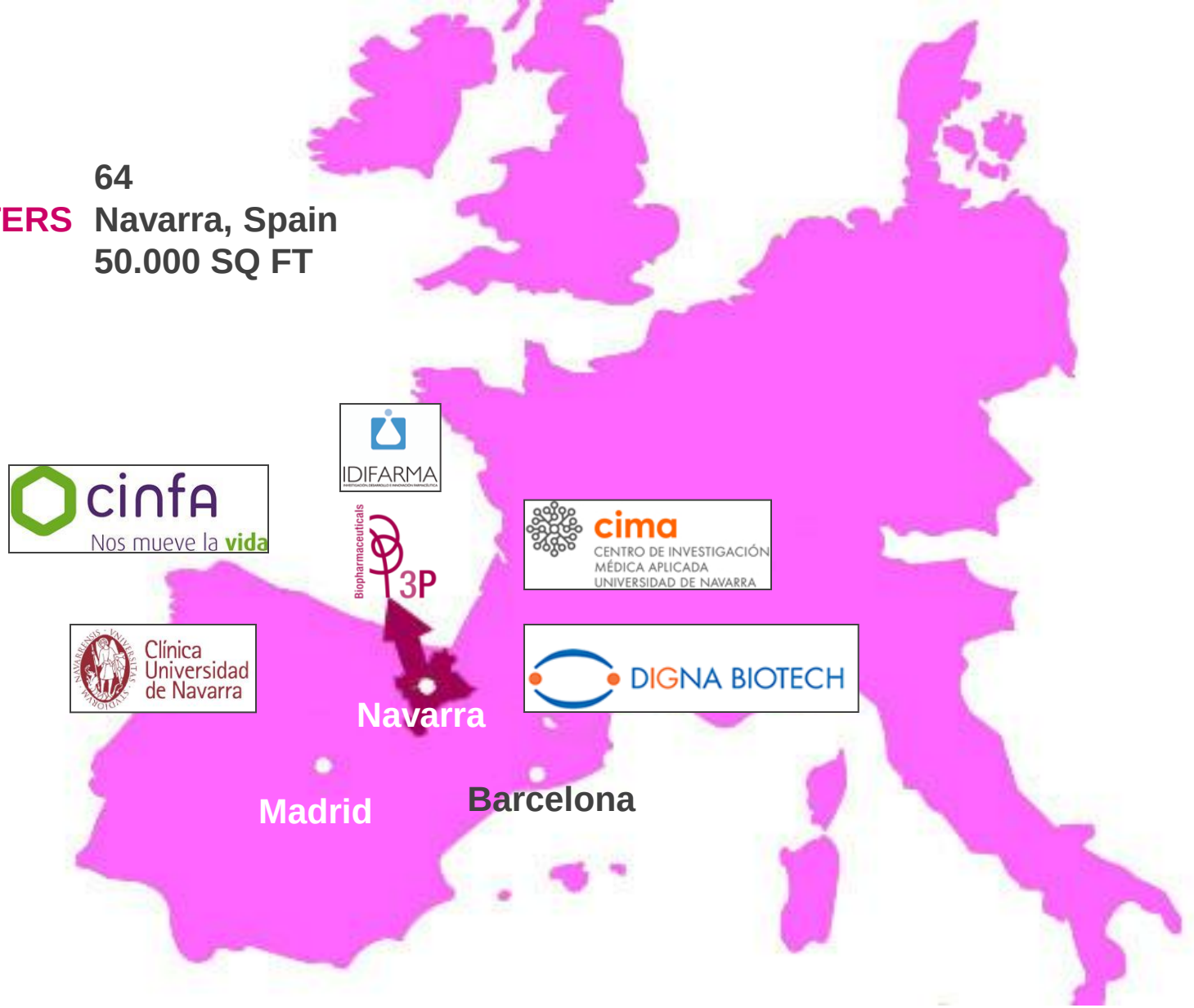
EMPLOYEES 64
HEADQUARTERS Navarra, Spain
FACILITIES 50.000 SQ FT



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