Pierre Fabre site locations
FRANCE

Spain

Toulouse Dev + Pilot Site (DP)

PAU Commercial Site (DP)

Paris

1h flight

Saint Julien en Genevois Dev + Pilot Site (DS Biologics)

2h drive

Atlantic Ocean

La Manche

Belgium

Spain

Mediterranean sea
1. Biological API (clinical batches of mAbs or ADC)
CDMO biologics
clinical batches of mAbs or ADC

**Upstream Processing**
Starting from your RCB …

- up to 2,000L single-use bioreactors

**Downstream processing**

**Preformulation**

**Fill & Finish**

- … to vial liquid, lyo or PFS

Drug substances sites

1. SAINT-JULIEN-EN-GENEVOIS
   - From Cell Line Development

2. TOULOUSE
   - Lyo Development – Pilot and Commercial

3. PAU
USP: cell culture parameters scale-up process optimization using various expression system

DSP: development of purification and filtration processes, formulation; process scale-up and validation

Analytical transfer, development and qualification

State-of-the-art analytical characterization (DS & DP)

Quality Assurance experts team to support your project (QP in place, IND/IMPD support)
CDMO biologics
clinical batches of mAbs or ADC

ADCs bioconjugation unit

- Up to 100 liters scale (5g - 200 g/batch)
- High-contained environment to make pilot and cGMP batches of ADCs
2. Sterile Liquid and Freeze-Dried Pharmaceuticals
Sterile Liquid and Freeze-Dried Pharmaceuticals

2 sites in France

- PAU Commercial Site (DP)
- Toulouse Dev + Pilot Site (DP)

1h flight
2h drive

Paris

La Manche
Atlantic Ocean

Spain

Mediterranean sea

Belgium
TOULOUSE SITE

💧 A pilot-scale unit dedicated to **aseptic filling** of liquid or lyo products (High Potent or not).

🔨 Sterile Fill & Finish with vials and syringes.

⬆️ 2-m² lyophilizer for scale-up and clinical trial products.

PAU SITE

 لمدة=scale **aseptic production** of pharmaceutical and biological products, in accordance with cGMP regulations and FDA/EMA/PMDA requirements.

🛠️ 10 production units for liquid and lyophilized products: >30 million units produced per year, for >15 worldwide partners (Europe, US, Asia).

🎓 Well trained and skilled experts to support a wide range of fill & finish process for biologics.
Toulouse Site

- Lyo surface 1-2sqm
- Vial from 1mL to 40mL
- Isolator technology, A/C

- Labelling and Packaging services (Pilot Scale)
- EMA Compliant - OEB4/5

- Formulation Development Support (Liquid or Lyo Forms)
PAU SITE

High Containment Technology

Large Range Lyophilisation Capacity

Full Aseptic Processing

All equipment with high level of automation to reduce the need of manual intervention:

→ 3 filling lines equipped with isolators technology (Class A/C)
→ 4 freeze dryers equipped with automatic loading and unloading systems
→ Dedicated cold storage areas for BDS, API and finished product
→ Dedicated product contact parts (tanks, filling parts...)
→ Vials capping under Class A/D
PAU SITE

➔ Visual inspection: fully automatic / semi automatic / manual MIRAGE
➔ Approval by EMA, US FDA, PMDA, ANVISA and other international agencies

Site visits: >20 / year (agencies, partners, audits...)

Manufacturing of ~30 Million units / year
(97 % dedicated to Third Party Manufacturing)

12 partners (Europe, US, Japan)

More than 20 years of Third Party Manufacturing
THANK YOU

Contact us:

pierre_fabre_CDMO@pierre-fabre.com