





Pierre Fabre site locations







CDMO biologics clinical batches of mAbs or ADC



Upstream Processing

Starting from your RCB ...



up to 2,000L single-use bioreactors

Downstream processing



Y Preformulation



bioconjugation up to 100L

* Fill & Finish

... to vial liquid, lyo or PFS



from 500 to 80,000units/batch; full aseptic filling

Paris (1h flight) 2h drive 3

Drug substances sites

SAINT-JULIEN-EN-GENEVOIS



From Cell Line Development

Drug products sites

TOULOUSE





Lyo Development - Pilot and Commercial



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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

Conditioning Isolator Purification/Formulation Coupling reactor



- Up to 100 liters scale (5g 200 g/batch)
- <u>High-contained environment</u> to make pilot and cGMP batches of ADCs













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

- Industrial-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

<u>All equipment</u> with high level of automation to reduce the need of manual intervention:

- \rightarrow 3 filling lines equipped with isolators technology (Class A/C)
- ightarrow 4 freeze dryers equipped with automatic loading and unloading systems
- ightarrow Dedicated cold storage areas for BDS, API and finished product
- \rightarrow 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











