



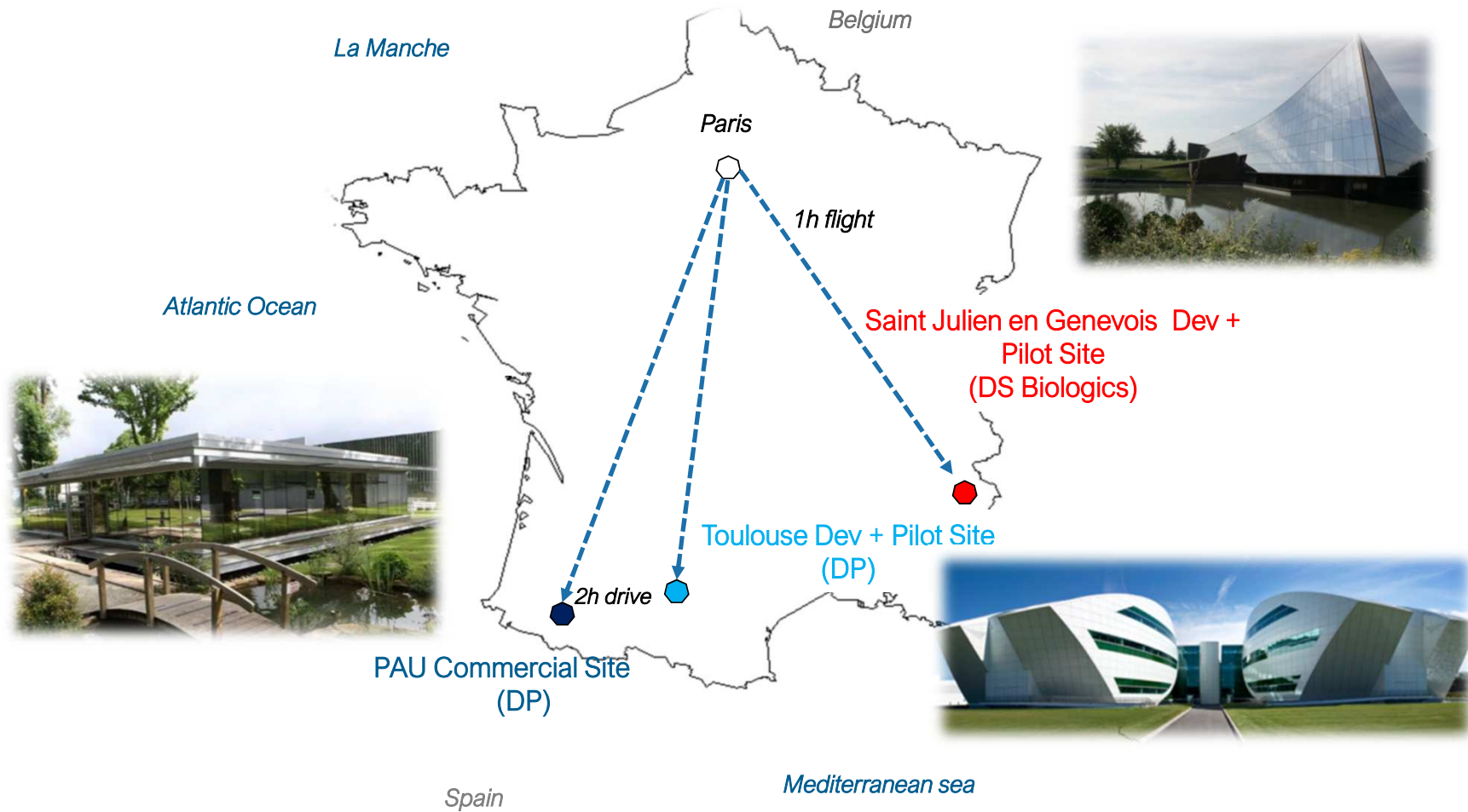
PIERRE FABRE CDMO
Biologics - Fill&Finish activities



Pierre Fabre
CDMO

2019

Pierre Fabre site locations FRANCE





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



bioconjugation
up to 100L

Fill & Finish

... to vial liquid, lyo or PFS



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



Drug substances sites

SAINT-JULIEN-EN-GENEVOIS



From Cell Line Development

Drug products sites

TOULOUSE



PAU



Lyo Development – Pilot and Commercial

CDMO *biologics* clinical batches of mAbs or ADC



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)



ADCs bioconjugation unit

Conditioning

Isolator

Purification/Formulation

Coupling reactor



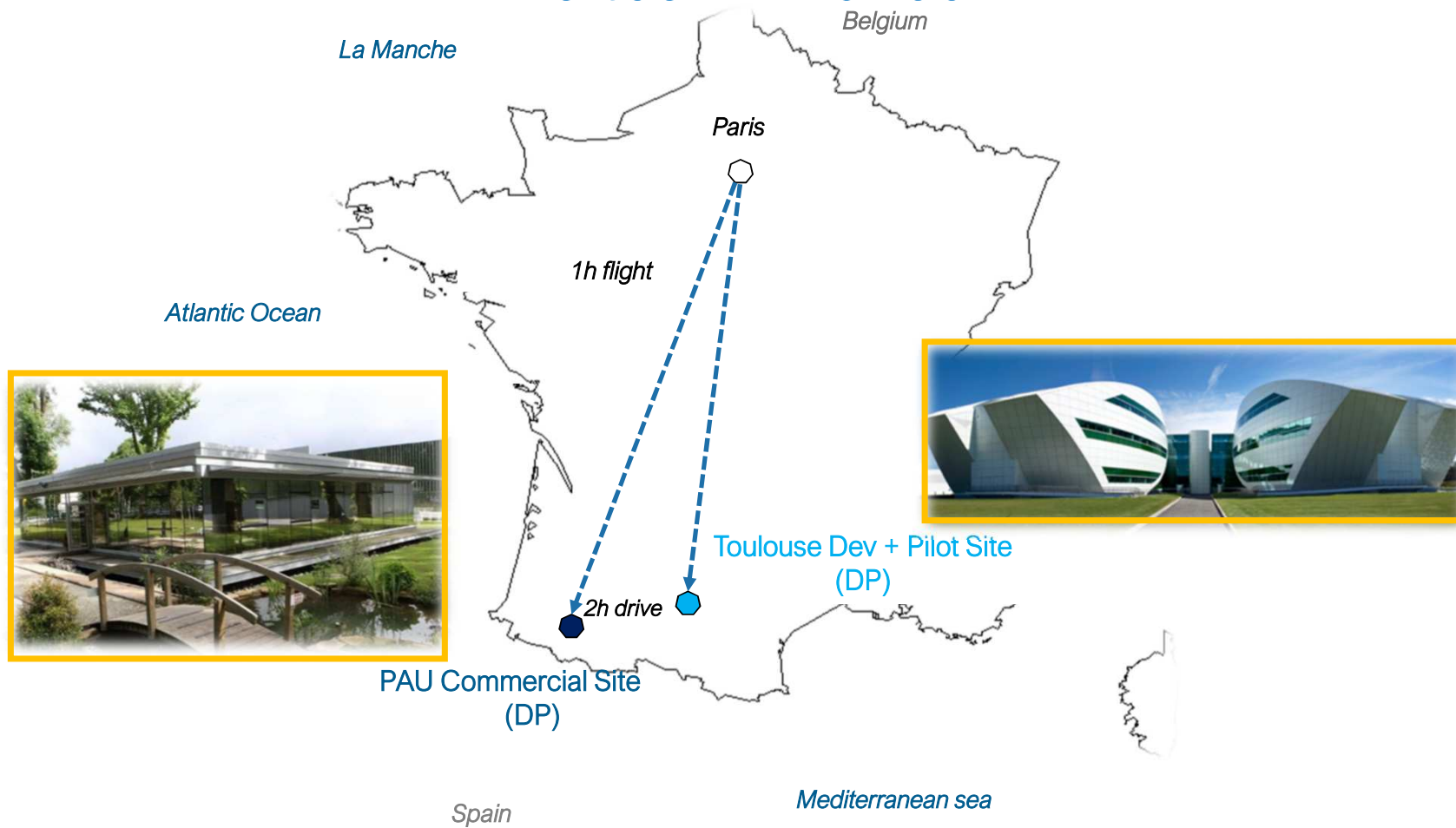
- Up to 100 liters scale (5g - 200 g/batch)
- High-contained environment to make pilot and cGMP batches of ADCs



2. Sterile Liquid and Freeze-Dried Pharmaceuticals



2 sites in France





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



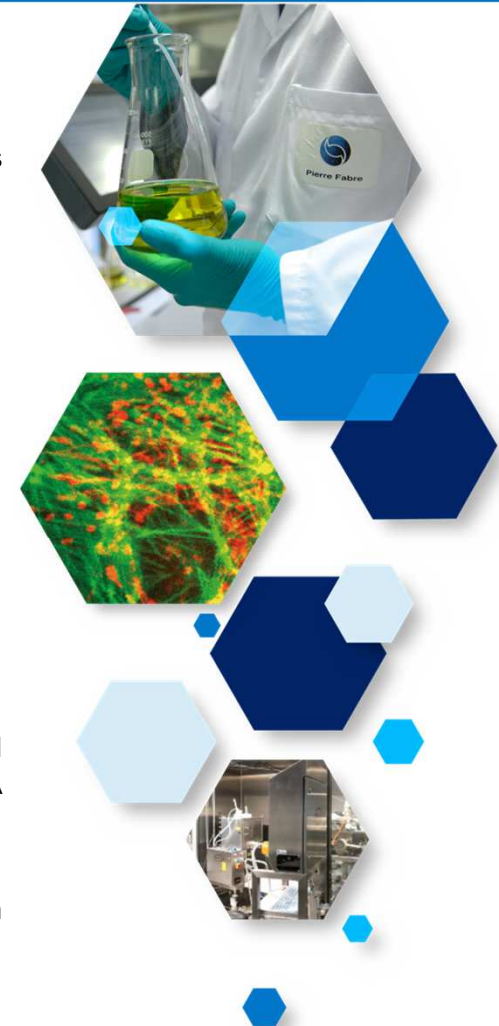
Industrial-scale aseptic production of pharmaceutical and biological products, in accordance with cGMP regulations and FDA/EMA/PMDA requirements.



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

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



A landscape photograph featuring a dense stand of tall, mature pine trees with thick, gnarled trunks and dense, dark green foliage. The trees are set against a clear blue sky with a few wispy clouds. In the foreground, a green lawn is visible. A large, white, downward-pointing arrow shape is superimposed over the center of the image, containing the text 'THANK YOU'. A blue diagonal line runs across the bottom right corner of the white arrow. At the bottom of the image, there is a blue rectangular box containing contact information.

THANK YOU

Contact us:
pierre_fabre_CDMO@pierre-fabre.com