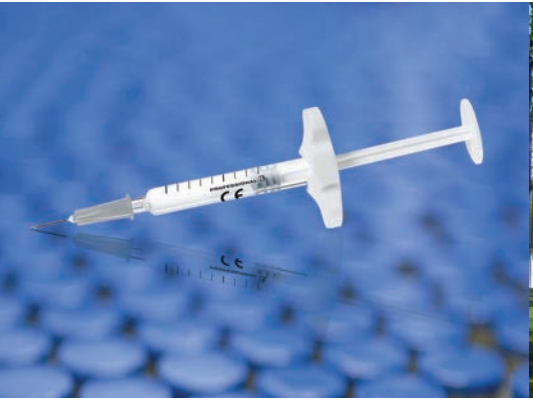
High technology in outsourcing classical and high potent injectables



PIERRE FABRE CONTRACT DEVELOPMENT & MANUFACTURING ORGANIZATION

Pierre Fabre
CDMO

Industrial Expertise & Know how

A WORLDWIDE RECOGNIZED KNOW HOW IN MANUFACTURING INJECTION PRODUCTS

Our production facility of Pau is dedicated to the manufacturing of injection products. Specialized in aseptic processing and isolator manufacturing of anticancer and biotech products in vials, syringes, liquid or freeze dried.

Independent workshops are designed to work in full autonomy (HVAC and Partitioning). They are all connected within a restricted access zone (Grade D).

All our workshops are equipped with a dispensing area in grade A, a compounding area grade A/C under LAF and a manufacturing area grade A/B for conventional products or grade A/C for isolated filling lines.

Our facility is composed of 2 locations representing a total number of 9 workshops specialized in different processes:

- Vials: 4 filling lines; from 1 ml to 40 ml and batch sizes from 10,000 vials to 150,000 vials
- Freeze drying capacity: 5 freeze dryers; automated loading and unloading systems
- Anticancer products: 4 filling lines fully isolated, capacity above 30 million units per year
- QC testing
- Utility production
- Syringes: 2 automated filling line from 1 ml to 30 ml Ready to fill units.
- Conjugated Antibody Production

CUSTOMERS ORIENTATED INNOVATIONS

- Computer adjusted dose control
- Compact loading/unloading systems
- EEx compliance for sterile processing and freeze drying processes
- Washing in Place Isolators
- Sterile capping
- Full automation for higher sterility assurance level
- Custom capping
- Laser printing devices
- No contact waste collection system before treatment

Innovations & Know How

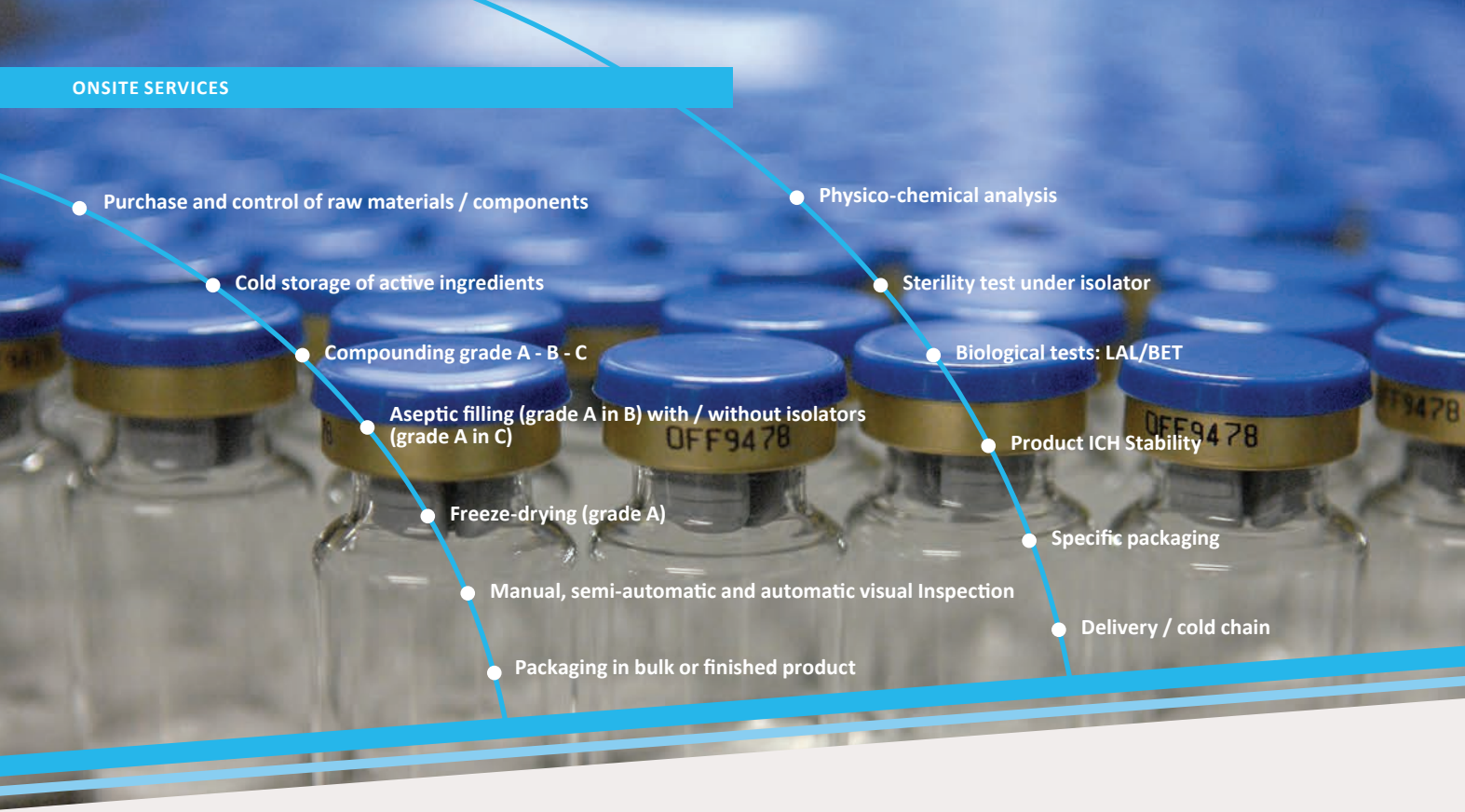
Pierre Fabre CDMO commits to always offer process technology innovations in compliance with regulatory standards for future drug products. Our main objective is to be continuously pionneers in the manufacturing processes.

Our experts are worldwide recognized.
All our facilities comply with main regulatory requirements: ANSM (France), FDA (U.S.A.), PMDA (Japan), ANVISA (Brazil)...

- **Effectiveness warranty:** Our faisability answer will be returned within 24 hours.
- **Confidential warranty:** A confidential Agreement will be in place to cover documentation and oral exchanges.
- **Expertise warranty:** Our experts will be dedicated to your product.
- **Engagement warranty:** Manufacturing and Supply Agreement will be signed in addition to the Quality Agreement to cover our supply partnership.
- **Communication warranty:** Single window person for your team from launch of the project until compliance of Process Validation Batches.

Quality Commitments

With more than 24 years experience in manufacturing injection products for international markets, our team is providing the best know how in aseptic manufacturing of most advanced molecules. Manufacturing large molecules, highly potents in freeze dryed or liquid forms as well as in vials, syringes is our main activity. Trained operators in addition to the latest technologies implemented on site, ensure to our partners successful management of timelines and guaranty right first time process development.


ONSITE SERVICES
Purchase and control of raw materials / components
Cold storage of active ingredients
Compounding grade A - B - C
Aseptic filling (grade A in B) with / without isolators (grade A in C)
Freeze-drying (grade A)
Manual, semi-automatic and automatic visual Inspection
Packaging in bulk or finished product
Physico-chemical analysis
Sterility test under isolator
Biological tests: LAL/BET
Product ICH Stability
Specific packaging
Delivery / cold chain

Pau

Parenteral production facility for conventional and highly potent products

Pierre Fabre Contract Development
& Manufacturing Organization
3, avenue Hubert Curien - BP 13562
31035 Toulouse cedex 1 - FRANCE
Phone: +33 (0)5 34 50 60 00
CDMO_injectables@pierre-fabre.com
www.pierre-fabre.com/en/cdmo