



**Bertin Pharma**, branch of Bertin Technologies-CNIM group, gathers 4 different entities:

- SPI-Bio & Biotec Centre
- Ellipse Pharmaceuticals & IDPS

No matter the challenge you are facing, a **single project manager** will assist you throughout your whole project **from screening of candidate drugs to manufacturing and distribution of clinical supplies**.

Our services are divided into 2 areas of expertise, **preclinical & clinical supplies and pharmaceutical development & clinical supplies**, and focus on:

Pharmaceutical development & clinical supplies

ADME & Immunogenicity

Biotransformation

Antiviral & Immune Pharmacology  
Biosafety

Biomarkers

**Explore your options with us**



The Regulatory affairs department plays a key role in ensuring that your future or existing product will comply with the permanently updated guidelines and recommendations of the regulatory bodies in France, European Union and United States.

## Full development package

In connection with the **Formulation and Analytical Departments** (*see also service information sheets*), and in relation with well-recognized experts, the technical data is organized in the requested French or English format:

- **Specifications**, in-house monographs and compilation of scientific data related to the **raw materials, active substances, impurities, primary packaging** to perform the writing up of **Drug Substance (S)** part
- Set up of **finished product specifications and internal monographs**
- Compilation of all the documents related to pharmaceutical development, the analytical validation and the manufacturing of pilot batches and process validation to perform the writing up of **Drug Product (P)** part
- Writing up and finalisation of **Module 3** and of **IMPD**
- **Networking with agencies** and recognised experts
- Sum up of **Module 2.3** in connection with well-recognized experts
- **Follow-up dossier filing and questions** from the agencies

## Stand-alone services

- **Evaluation** of pharmaceutical documentation (DMF, NTA, CTD)
- Determination of **technical and document prerequisites** (Pharmaceutical product, OTC, Medical device)
- Modifications of existing dossiers up to **European standards**
- Setting up of **minor or major variations** related documentation
- Management of analytical or formulation studies when and if required
- **CE certification strategy**, writing up of technical and conception dossiers

