



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**



Ellipse Pharmaceuticals is offering specific services for the development of **parental formulation** from **new chemical entities** to **biotech-derived** products.

Formulation of SVIs (Small Volume Injectable as described in the USP) depends mainly on the drug candidate characteristics, such as solubility, stability and pharmacokinetic properties.

Our competent and dedicated team will assist you for the complete pharmaceutical development of **immediate release** and **long-lasting formulations**.

Focusing on the key parameters

Our pharmaceutical development program addresses key **parameters for injectable products** such as:

- **Pharmacokinetic assessment** of the drug candidate
- **Formulation** (solutions, emulsions, dry solids, freeze-dried or polymeric sustained release systems)
- **Analytical development & validation** (state-of-the-art for NCE and pioneer for biotech)
- **Sterility** (selection of the most appropriate method)
- **Primary packaging selection** (stability and compatibility studies, cost of goods)
- **Regulatory stability studies/In-Use stability** (evaluation of the stability in the process of use: preparation, infusion)

Benefits

- A well qualified team supported by recognized experts
- A dedicated platform with last generation equipments
- A National & European network of pilot and manufacturing sites
- A perfect knowledge of regulatory guidelines & requirements



SPI-Bio, BIOTEC CENTRE, Ellipse & IDPS
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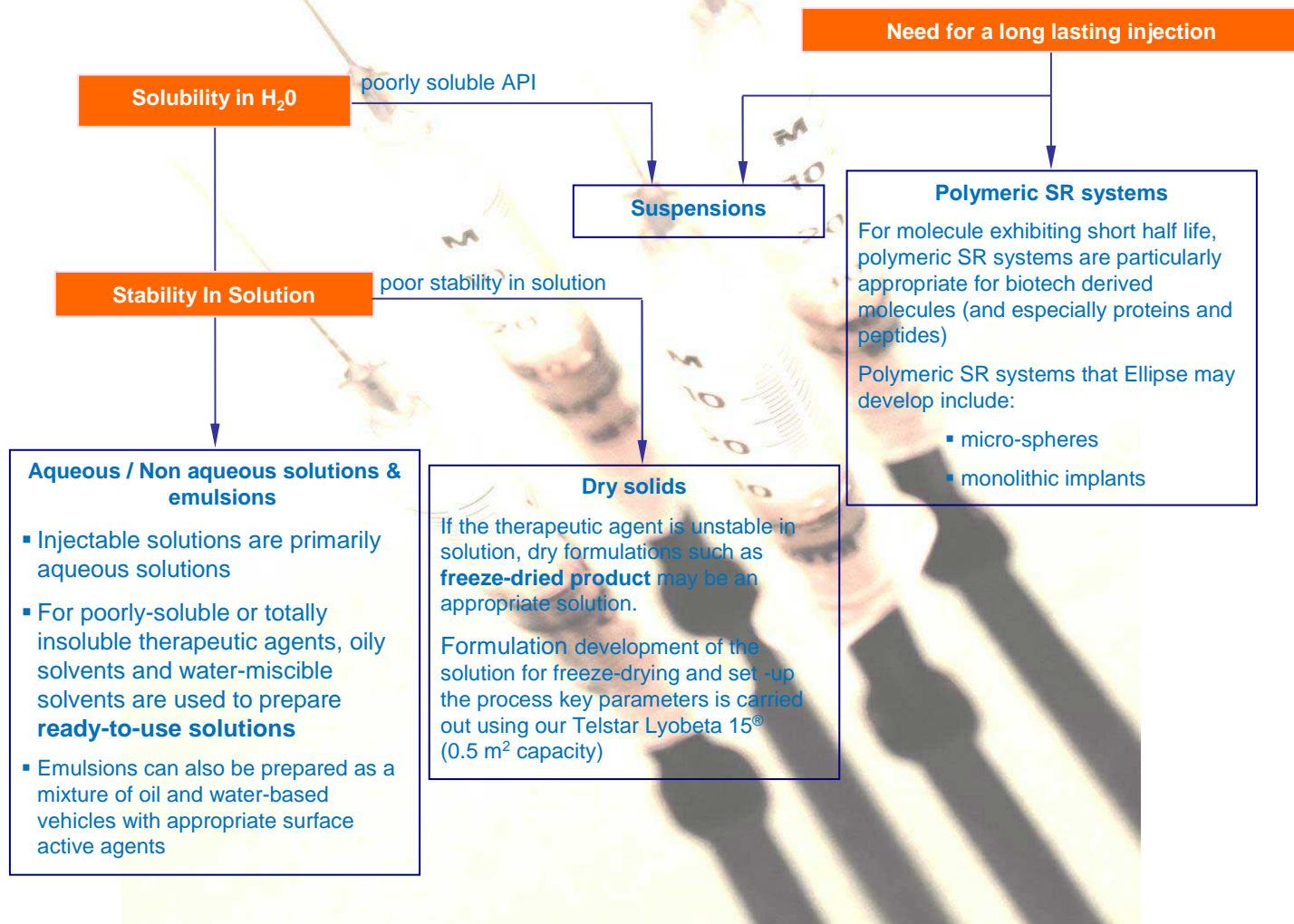
Web: www.ellipse-pharma.com



A comprehensive range of services

Immediate release dosage forms

Sustained release dosage forms



Pharmaceutical development also includes the assessment of key parameters such as:

- Selection of the adequate **primary packaging** including vials, ampoules, pre-filled syringes, cartridges, perfusion bags...
- Study of the **interaction** between the formulation and the primary closure system (extractables and leachables)
- Screening of the appropriate **sterilisation method** (terminal sterilisation, sterile filtering and multi-step process)
- Constitution of the **pharmaceutical documentation** (Module 3 CTD and IMPD)

Related services

Analytical services
 Formulation services
 Pharmacokinetics & bioanalysis

Therapeutic protein-based drug characterization platform
 Extensive biopharmaceutical expertise
 Regulatory affairs