



# Investigational Medicinal Product Manufacturing & Management



## Advantages

Pierrel Research IMP is a leading global provider of clinical trial supplies. We combine more than 16 years of experience in designing, manufacturing according to GMP and distributing IMPs for worldwide clinical trials.

We take into account the products and procedures unique to each study. We employ our scientific, regulatory, operational, and commercial resources to structure a customized and integrated solution. We help our clients shorten timelines, reduce costs, and optimize IMP preparation.

## Potentials

Our manufacturing facility, EMA approved, is located at Pierrel Research IMP headquarters in Cantù, north of Italy. Services include contract manufacture (packaging, labelling, and certification by QP according Directive 2001/20/EC) and IMP logistics tailored to meet the specific requirements from phase I through phase IV clinical trials.

Pierrel Research IMP provides high quality Investigational Medicinal Products (IMP) services for worldwide clinical trials



## Features

**Manufacture:** We develop trial-specific IMP packaging, blinding, and labelling designs related to clinical indications, patient populations, and compliance behaviours. In everything we do, we strive to help you obtain the most reliable clinical data possible. Together with qualified partnering companies, we supply a full range of drug formulations and packaging in accordance with the highest EUGMP/cGMP quality standards.

**Documentation:** IMP related medical writing, including preparation of IMP section for protocols and IMPD/simplified IMPD or IMP manuals, IMP Distribution Plan, etc., is an integrated component of our services. IMP orders and shipments to investigative sites are fully documented. This guarantees full tracking ability of the smallest shipping unit. We also provide full electronic monitoring of IMP inventory that includes alert notifications of in-stock availability and shelf-life status.

**Analytical:** We set up and validate analytical methods for over-encapsulated study drugs and comparators. We perform the analytical method transfer from other companies and laboratories and we design and execute stability studies.

**Randomization and Pharmacy Management:** Integrated Web-based Randomization & Drug Supply Module (IWRDS), or Interactive Voice Response System (IVRS) tools are offered for managing study drug assignment and resupply.

**Logistics:** Pierrel Research provides warehousing and shipping of IMP with permanent temperature mapping.

Qualified facilities for ambient (15 - 25°C), refrigerated (2 - 8°C), and frozen (-20°C, -80°C) IMP storage are available throughout Europe and North America.

For IMP with strict cool chain requirements, or controlled IMP, we offer direct transport door-to-door using temperature-controlled and secure vans and qualified trained drivers. This guarantees 100 % compliance of shipments with IMP specifications.

IMP orders are dispatched to the investigative sites within 24/48 hours for all countries with Pierrel Research warehouses.

Transportation to locations in non-EU member states is facilitated in less than 72 hours. Green light procedures for critical IMP are implemented according to client requests.

### Bulk Production

- Placebo in capsules
- Over-encapsulation
- Over-encapsulation + filling
- Filling of powders of active in capsule
- De-blistering

### Primary Packaging

- Blistering (PVC/ALU, ALU/ALU) of tablets and capsules
- Bottling of tablets and capsules

### Labelling

- Blisters
- Vials/Bottles
- Boxes
- Re-labelling for "new use by date"
- Secondary Packaging
- Randomization list - Patient Key
- Cartooning of vials/bottles/ sachets
- De-labelling of stickers

### Clinical Trial Supply Management

- Warehousing and storage at different conditions
- Distribution Management
- Return Management
- Clinical Supplies Accountability
- Destruction





## Our Services

- Clinical Trial Manufacture
- Comparator Sourcing and Blinding
- Packaging and Labelling
- Global Distribution and Supply Chain Management
- QP Services
- Stability and Analytical Services
- Configurable IWRDS, IVRS and eCode Breaking Solutions

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