IDIFARMA *is a leading Contract Research and Development Organization for the pharmaceutical and biotechnology industries.*

Based in Spain, and with an increasingly international reach, **IDIFARMA** *provides a full range of services that encompasses: drug formulation, development and validation of analytical methods, quality control and batch release in the EU, Pilot-Scale GMP-compliant manufacturing, ICH stability studies, clinical trial logistics management and regulatory support.*

Our state-of-the-art facility features a purpose-built high containment plant for the manufacturing of GMP-compliant pilot batches in oral solid dosage forms, for both conventional and high potency drugs.

We have ***extensive experience managing clinical trial logistics****, and are able to adapt to the needs of our clients,* ***from individual researchers to multinational pharmaceutical companies****: placebo manufacturing, blinding strategies, labeling and packaging, etc.*

IDIFARMA *also offers* ***comprehensive regulatory support to any pharmaceutical development or clinical trial****, including submission and monitoring of applications to the competent authorities.*

IDIFARMA*'s expertise, capabilities and proven track record make us the perfect partner for the development of your projects.*

IDIFARMA
PHARMACEUTICAL RESEARCH, DEVELOPMENT AND INNOVATION

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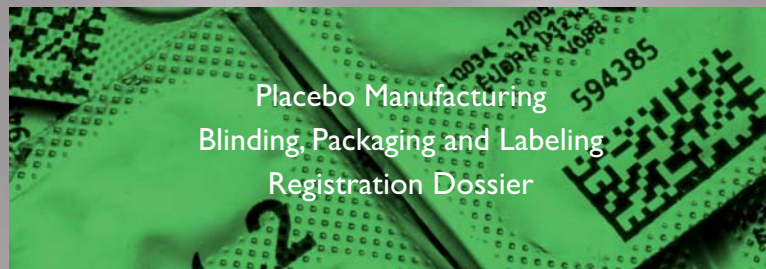
IDIFARMA
PHARMACEUTICAL RESEARCH, DEVELOPMENT AND INNOVATION

Clinical Trial Logistics and Regulatory Affairs



Clinical Trial Logistics Management

We offer to our clients regulatory consulting and logistics management of clinical trials, a complementary service to the activities performed by CROs for clinical research.

We are specialized in advising and collaborating with independent researchers to conduct all types of clinical trials, adapting to the needs of each particular case and providing our experience in regulatory affairs, manufacturing and logistics management to contribute to the success of each project.

Some of the main activities we offer are the following:

- Preparation of the IMPD and Investigator's Brochure.
- Preparation of clinical trials applications to be submitted to IRB/IEC or to competent authorities.
- Management of IMP Product Specification File.
- Design of the IMP labeling according to GMP.
- Strategy design for the blinding/masking of IMP.
- Manufacture of IMP and placebo.
- Labeling and packaging (primary and secondary) of IMP.
- Storage of IMP under controlled conditions.
- Distribution of the IMP among clinical trial sites.
- Management of the return, accountability and destruction of medication used in clinical trials.

Our GMP certified facilities boast a wide range of cutting-edge equipment to ensure the maximum quality, responsiveness and flexibility for clinical trials:

Manufacturing of oral solids:

Oystar Hüttlin Pilotmix 75T single-pot high shear mixer.

Oystar Manesty XL Lab 01 tablet coater, with interchangeable drums.

Fette 1200iC rotary tablet press, fully equipped for formulation development and manufacturing.

Packaging and labeling:

IMA Clinipack blister machine.

Specialized printer for custom design and direct printing on the surface of primary and secondary packaging, which enhances quality and reduces error rate.

Regulatory Affairs

Our experienced Regulatory Affairs Department provides regulatory support to our clients, both during the development phase and in the preparation of reports and specific requests:

- Applications for orphan drugs designation.
- Scientific advice applications.
- Holder of marketing authorizations for medicinal products for human use.
- Marketing authorization applications (eCTD / NEES).
- Expert reports (Quality / Nonclinical / Clinical).
- Submission and monitoring -up to the approval- of applications for marketing authorization.
- Variations of marketing authorizations.
- Translation of product information (SPC, leaflet, labeling).
- Readability Test for leaflet.
- Materials packaging management.