

**Innovation, personalization
and experience in every
project**



coetus
PHARMA

∞mmittment

At Coetus, we offer our technical and business expertise with the commitment to provide high-quality customized pharmaceutical solutions in every project."

Professionals with:

+20 years of experience in the pharmaceutical sector, guaranteeing a technical and strategic approach



∞partner

Coetus is part of the business group **MANA PHARMA** a Spanish pharmaceutical company with more than 100 employees located at different international offices.

Coetus is a member of  **NET-PHARMA** the leading hub in Europe for technological and industrial services in the healthcare sector.

Coetus is a strategic partner of **COVEX** a pharmaceutical laboratory located in Madrid.

∞etus
PHARMA



License and supply



Services



MAH/Local Representative



Pharmacovigilance



Distribution



CMO/
Serialization



Product list

Find the product list Here



- Preparation/compilation of the dossier (Mod 1 - Mod 5) in CTD format.
- Master Dossier revision/update
- Reformatting of the Registration Dossier in compliance with any country requirement.
- Submission of a new marketing authorization application (Nat, DCP, CP, MRP). Documentation support.
- National phase of registration procedures.
- Preparation of mock-ups.
- Elaboration of the deficiency letter response document. Technical support.
- Price and reimbursement request.
- Scientific Advice Reports.
- Due Diligence of registration dossier (portfolio acquisition)
- Master Variations Typification.
- Marketing Authorization Transfer.
- Regulatory strategies.
- Translation of the Master Dossier.
- Revision of L&S agreements.
- Co-development of medicines.
- Clinical Studies (BE)
- Contact with Health Authorities.
- Renewals.

Quality

- Supplier search and Due Diligence.
- Supplier Qualification.
- Auditorias GXP audits: finished product manufacturers, active ingredient manufacturers, warehouses, testing laboratories, carriers, and packaging materials, under EU quality regulations.
- Consulting on GMP compliance
- Preparation for GXP inspections.
- Implementation of Quality Systems.
- Conducting Gap Analysis (AARR).
- Writing of PQR (Product Quality Review).
- Writing of SOPs (Standard Operating Procedures).
- Management and follow-up of deviation.
- GMP, GDP training.
- Manufacturing transfer.



PHARMACEUTICAL LOGISTICS OPERATOR, AUTHORIZED AS A WHOLESALE PHARMACEUTICAL DISTRIBUTION OF HUMAN AND VETERINARY PRODUCTS

- Monitoring of Ambient Conditions 15°C-25°C and Storage 2°-8°C
- Security of installations
- Orderly flows of goods
- Maintenance and Cleaning Controls in the facilities; DDDs
- Recall support



Local Representative

Local representative responsible for the registration and any relationship with the Regulatory Authorities, as well as post-marketing activities. Appointed by the Marketing Authorization Holder (MAH) to represent them in the corresponding Member State.

Pharmacovigilance services

Clinical Safety

- Responsible Person Services
- Clinical Trial Documentation
- Safety Management Plan
- SAE & SUSAR Management

Veterinary Vigilance

- EU-QPPV services
- EVVet Management
- SPOR
- Union Product Database
- Adverse Event Reporting
- Global Literature Monitoring
- Safety writing & Aggregate reports
- PSMF Management
- Signal Management
- Regulatory Intelligence
- Safety Communications
- Benefit-risk, RMPs & REMS
- Local Literature Monitoring
- LPPV & Local Safety Personnel
- Local Case Management
- Drug Safety Physician
- SOP Creation & Review
- Pharmacovigilance training



Pharmacovigilance

- EU-QPPV services
- Eudravigilance Management
- SPOR
- Article 57
- ICSR/AER Management
- Global Literature Monitoring
- Safety writing & Aggregate reports
- PSMF Management
- Signal Management
- Regulatory Intelligence
- Safety Communications
- Benefit-risk, RMPs & REMS
- Local Literature Monitoring
- LPPV & Local Safety Personnel
- Local Case Management
- Drug Safety Physician
- SOP Creation & Review
- Pharmacovigilance training

Cosmetovigilance

- Cosmetic AER Management
- Responsible Person
- Global Literature Monitoring
- Local Literature Monitoring
- Regulatory Intelligence
- SOP Creation & Review
- Cosmetovigilance training



Where we are

- Mexico
- United States
- Central America
- South America (except Brazil)
- Spain
- Portugal
- United Arab Emirates
- Hong Kong
- Korea
- Australia
- New Zealand
- Canada
- Saudi Arabia
- Algeria
- Egypt
- Iraq
- Jordan
- Kuwait
- Morocco



Contact

Coetus Pharma

Avenida Diagonal 571, planta 2

08029 Barcelona

Info@coetuspharma.com

www.coetuspharma.com



Madrid

Edificio NET PHARMA MADRID



Barcelona

Edificio NET PHARMA BARCELONA



+34 910 88 41 88
+ 34 637 825 632