Quality and Regulatory Services

Aim

Based on years of hands-on experience in the field of Quality and Regulatory Affairs, QOMNIA has been founded with the aim of providing an integrated service tailored to the GXP (GLP, GMP and GCP) needs of the Pharmaceutical and Parapharmaceutical industry.

Our services are designed both for well-established companies, for which QOMNIA can provide assistance on on-going operations and processes, and for emerging businesses that wish to lay the groundwork for new developments.

Our GLP services

• Support for the management of single- or multi-site pre-clinical studies (safety studies).

Our GCP services

• Support for the management of national and international multicentre studies (from Phase I to Phase IV);

• Management of Third Party services (CRO, Central lab, etc.).

Our GMP services

- IMP Management;
- Design of packaging and IMP labelling according to Annex 13;
- Drafting and reviewing of Quality Agreements;
- Qualification and validation of protocols and instruments;
- Support for the preparation of HA inspections;
- Definition of GMP processes (deviations, changes, CAPA, PQR, etc...);
- Data Integrity Support (from the definition of the validation team to the execution of test script);
- Supplier Qualification.

Our regulatory services

• Support in the preparation of Clinical Trial Applications (CTAs) and related documentation to be submitted to Regulatory Authorities;

• Support in the drafting and reviewing of contracts with clinical sites and local administrations;

• Drafting and reviewing of IMPD and sIMPD for IMPs;

• Drafting and reviewing for Drug Master File;

• Review of Marketing Authorization applications;

• Support in the submission and classification of "essential and non-essential modifications" according to Italian regulations;

•Drafting and review of Validation Master Plan and Site Master File;

• Change management in line with US and EU guidelines;

• Drafting and reviewing of the quality section for medicinal products and medical devices;

Education/Training

National and international regulatory law;

• Quality aspects in pre-clinical (GLP) and clinical (GCP) studies, and issues related to GXP;

• Computer System Validation (in compliance with the current guidelines) for:

- Support in the revision of validation documents;

- Execution of the validation itself with continuous support for the main steps (from the establishment of the validation team to the implementation of tests).

Auditing and Editing

• GLP one site and multi site audit and CAPA Tracking (if required);

• GMP Audit and CAPA Tracking (if required);

• Standard Operating procedures drafting and reviewing .

Other services

• Support in the management of medicinal products for compassionate use;

• Translation of documents from Mandarin and Cantonese Chinese to English and vice versa.