

Quality Assurance/Regulatory Compliance

Services

REGISTRAT-MAPI is committed to provide world-class services that meet or exceed our customers' requirements and applicable legal and regulatory requirements through continuous quality improvement.

We conduct studies and registries under the requirements and guidance of all applicable regulators. These include the FDA, international or local regulatory and competent authorities of similar scope and competency, as well as the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and Good Clinical Practices (GCP) guidelines.



REGISTRAT-MAPI's Quality Assurance department oversees regulatory compliance issues and coordinates with the various operational departments to provide guidance and consulting services. REGISTRAT-MAPI personnel work with external and internal clients to achieve regulatory compliance. This includes the use and development of internal communications and processes to ensure compliance and consultation with Sponsors, investigative sites, and regulatory and competent authority representatives on matters of particular importance and relevance to the applicable registry or study.

Quality Assurance System

Activities governed by the Quality Assurance System are continually identified and documented. These documented procedures are controlled and effectively implemented to ensure that REGISTRAT-MAPI products and services meet customer and applicable legal and regulatory requirements.

The objectives of the Quality Assurance System are to:

1. Establish clear lines of authority and responsibility with respect to quality management.
2. Maintain an effective Quality Assurance System in compliance with applicable legal and regulatory requirements and ICH GCP guidelines relevant to the conduct of clinical research studies.
3. Maintain an exceptional level of quality that enhances REGISTRAT-MAPI's reputation in the industry.
4. Maximize internal and external customer satisfaction with the products and services provided by REGISTRAT-MAPI.

The Quality Assurance System is defined in the following controlled documents:

- Quality Manual
- Standard Operating Procedures (SOP)
- Training Records
- Quality Records including specific project-related documents
- Processes

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