

GCP Auditing Operations (QA)

Evaluating and Verifying Clinical Trials from an Independent Standpoint

GCP auditing operations are conducted as part of quality assurance activities in order to improve the reliability of a clinical trial by evaluating and verifying, whether the clinical trial is conducted in compliance with GCP (GPSP), Pharmaceutical Affairs Law, protocol, and standard operating procedures, etc.



Major Services

- Consultation in accordance with GCP, Related Laws, Regulations and Standards
- System Audits
- Audit of Medical Institutions Conducting Clinical Trials
- Internal and External Audits of Individual Contract Services
- Audit Investigator initiated Clinical Trials

ADVANTAGE of EPS

- Our staff, well versed in the concepts of ISO9000 and familiar with clinical trials, are actively engaged.
- Our staff, experienced in audit activities in pharmaceutical companies and other organization, conduct efficient and high quality audits.
- Our staff, with a high level of communication skills, attend to various requirements appropriately.
- We provide services with the goal of continual improvement.

Consultation, Regulatory and Others

Our Experienced Staff and Network Respond to a Variety of Needs

Our experienced staff respond to various needs for pharmaceutical development. Utilizing our network, we also support licensing plans from overseas and clinical development in Europe, USA and Asia.

Major Services

- Consultation
 - Planning of Development Strategy, Clinical Trial Plans, and Various Reviews
 - Consultation for Licensing in and for Clinical Trials in Foreign Countries
 - Regulatory Consultation
 - Other General Consultation for Development of Drugs and Medical Devices
- Activity Support
 - Support for Organization and Operation of Standard Operating Procedures (SOPs)
 - Support for Consultation with the Regulatory Authority (Pharmaceuticals and Medical Devices Agency)
 - Support for Protocol Development and Development of Informed Consent
 - Representative Service in Regulation and Support for Regulatory Applications
 - Act as In-country caretaker
- Others
 - Support for Studies in Humans on Health Food and Health Supplements
 - Support for Investigator-Initiated Clinical Trials, Large-Scale Epidemiological Studies, etc.
 - Support for Bioequivalence Studies on Generic Drugs and Applications

ADVANTAGE of EPS

- We are able to provide consulting services specialized in various therapeutic areas such as carcinoma diseases, cardiovascular diseases and central nerve system diseases.
- We are flexible to your needs, from representative service in regulation to pharmaceutical and medical device consultation.