

## Quality Assurance Services

GVK Biosciences (GVK BIO) Clinical Research division has an independent Quality Assurance (QA) unit which conducts audits of services of all business lines within the division on a routine basis to ensure delivery of quality services. The Clinical Research QA staff report to the Director-QA, GVK BIO who in turn reports to the CEO of GVK BIO. In addition to providing routine internal quality assurance support, GVK BIO's QA team also provides auditing services to its clients.

Following are the types of audits we conduct:

- Study specific site audits to ascertain compliance to protocol, GCP and regulatory requirements
- Study specific Clinical Operations audits at start up, ongoing and close-out phases of the study
- Clinical database audits are conducted before the database is moved to production, interim database audit and database audit before database lock
- Biostatistics audits covering quality review of tables, data listings, and study reports
- Project specific medical affairs audits to ensure compliance to protocol, regulatory requirements, client agreements and GCP
- Process oriented audits across different functions and business lines within Clinical Research
- Contract audits on behalf of sponsor/ health authorities at the sites

The Quality Assurance department coordinates training of clinical research staff to ensure continuous improvement and updating of clinical regulations.

### Team Expertise

The QA team has a combined experience of over 20 years. Director-QA, has vast experience in the development of Quality Systems and handling GCP / GLP audits successfully by various regulatory agencies like USFDA, WHO (World Health Organization), AFSSAPS (France), Ministry of Health (Turkey), ANVISA (Brazil) and GCP / GLP audits of multinational companies.

### About GVK BIO

GVK Biosciences (GVK BIO) is Asia's leading Discovery Research and Development organization. GVK BIO provides a broad spectrum of services, stand-alone and integrated, across the R&D value chain.

### Services

- Chemistry Services
- Process R&D and Custom Synthesis
- Biology
- Informatics
- Clinical Research
- Clinical Pharmacology

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