Quality Assurance

Rest assured with our insider knowledge

The pharmaceutical industry is one of the most intensely regulated industries globally. In drug development, regulation is aimed at ensuring the quality, safety and efficacy of human medicinal products. Drug development quality management systems encompass GxP, good practice quality guidelines and regulations. The general GxP quality framework aims to ensure quality which is fit-for-purpose and therefore tailored to the specific drug development activity. Consistent quality is achieved with an integrated approach, which combines quality control and independent quality assurance (QA) of products and processes. The Kinesis Pharma QA department leverages intimate knowledge, experience and expertise to serve the quality requirements of sponsors.

Kinesis
Consultants in drug development

The quality requirements of sponsors may focus on in-house or supplier quality. Kinesis Pharma QA consultants are used to performing GAP analyses and audits to assess the state of quality of third parties and the actions required to achieve the sponsor's quality objectives.

What Kinesis offer

- **GLP consultancy**

The Kinesis consultancy services range from supporting a sponsor's organization to improve the level of quality to managing the quality system. Depending on the needs of the organization Kinesis can identify problems by performing a GAP analysis, helping to solve those problems by supporting the sponsor's Quality Assurance Unit, writing Standard Operating Procedures (SOPs), performing audits on studies or facilities and helping sponsors to obtain OECD GLP compliance. Kinesis can also assure independent auditing activities as performed by the sponsor's Quality Assurance Unit. In addition, Kinesis can also help sponsors with the selection of Contract Research Organizations (CROs) or suppliers by performing audits. Kinesis has broad experience with computerized system validation and the coordination of multi-site studies with CROs located in different countries.

- **OECD GLP accreditation support**

With its abundant knowledge and experienced multi-disciplinary team, Kinesis is actively involved in supporting Chinese CROs to acquire OECD GLP accreditation. Various activities are carried out for these Chinese CROs, such as establishing a standard in accordance with the international GLP non-clinical drug safety evaluation platform, focusing on the QA systems in all disciplines relevant for toxicological evaluation of compounds. The services that we offer include writing SOPs, training personnel and providing support in writing study plans and reports. Kinesis performs on-site audits at CROs in China on a regular basis.

One partner, all the brains you need

Key achievements

- Designed and implemented a GLP quality system for several companies
- Maintenance of quality systems for different organizations
- Successful performance of GAP analysis of quality systems including follow-up of required actions
- Complete consultancy on converting an existing quality system to OECD GLP for several Asian CROs
- GLP accreditation since 2003, third consecutive endorsement since June 2009

Why Kinesis Pharma?

- Experienced team of QA consultants
- Close collaboration with in-house non-clinical experts
- Tailor-made QA support
- Broad experience with inspections by authorities
- Committed to sponsors' projects and timelines
- Flexible approach

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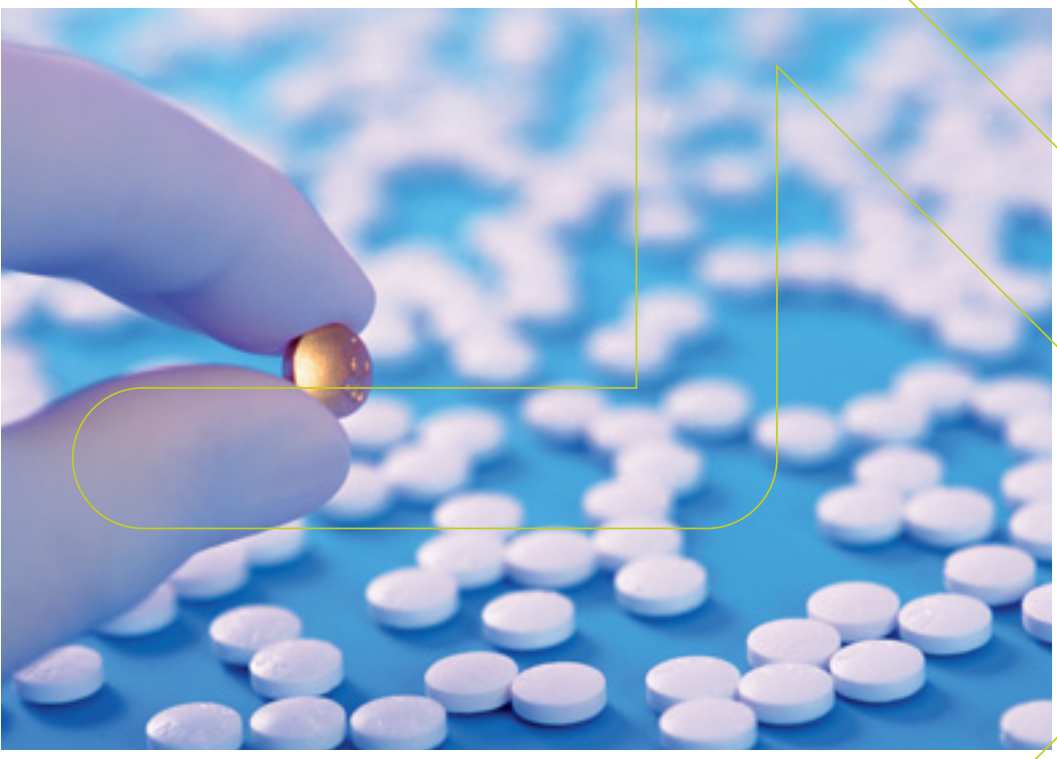

'Quality is the common denominator of success'

About Kinesis Pharma

Kinesis Pharma is an independent drug development organization with headquarters in Breda, the Netherlands. Kinesis Pharma aims to facilitate an efficient and high quality development and registration process for medicinal products and nutraceuticals through consultancy and contract research services. Kinesis Pharma's service offering includes CMC, non-clinical, clinical, regulatory, quality and project management activities for pharmaceutical, nutraceutical and biotech companies.

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