

# QUALITY ASSURANCE

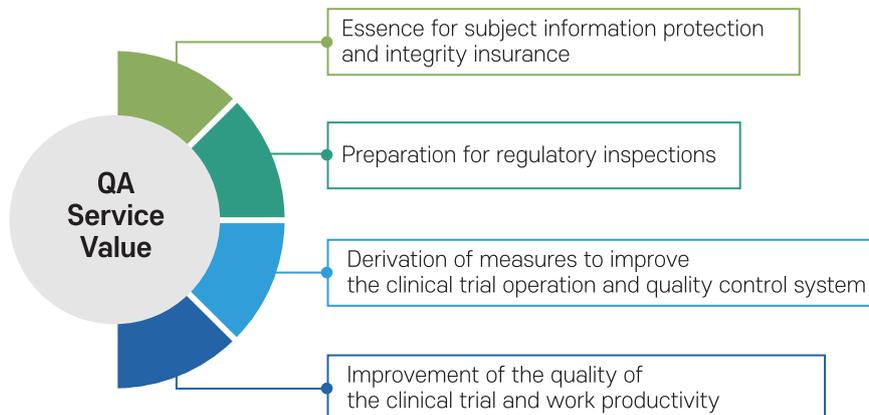
Quality is everything in the pharmaceutical industry

Clinical trial quality assurance is one of the major areas when conducting a clinical trial. Quality assurance will enhance the quality of clinical trial operational organization systems and assure the credibility of the clinical trial result when complied with required regulations.  
**Meet LSK Global PS Quality Assurance service for your stable and successful clinical trial project.**

## About LSK Global PS

- Providing clinical trial services satisfying global standards since March 2000
- One-Stop Full Service CRO that conducts phase 1 ~4 clinical trials, Investigator-initiated trials, post-market studies such as PMS, OS
- Conducted 1,371 clinical trials and post-market studies as of September 2021  
750+ studies for market approval and 150+ global clinical trial experience
- Expertise in internal audit experience for various types of clinical trials
- Many experiences in diverse types of therapeutic areas and pharmaceuticals/  
Clinical Research Organization (CRO) quality assurance audit
- Expertise in conducting external audits which confirms and improves the quality of the clinical trial

LSK Global PS QA service helps to add the following values.



## QA Resource and Audit Experience

### Excellent Trained QA Professionals

Consisted of 4 QA auditors having at least 10 years of experience as CRA, CRM, and PM, with an excellent understanding of clinical trial guidelines and auditing processes LSK Global PS QA auditors ensure the quality of your clinical trial projects.

- 50% of our auditors have more than 7 years of experience in clinical trial audit and quality assurance
- 50% of our auditors have US RQAP-GCP (Registered Quality Assurance Professional) certificates (As of July 2021)
- QA professionals specializing in clinical trial data management and pharmacovigilance audit

### Clinical Trial Research Audit Experience

LSK Global PS QA department has expertise in clinical trial quality assurance from conducting various types of external and system audits.

### Total 100+ External Audit (2016~2020)



## LSK Global PS QA Service Scope

# 01

## Clinical Trial Audit

Audit activities are consisted of Audit Planning/ Audit Conduct/Audit Report and Certificate Issue/ CAPA Follow-Up process upon our client's request.

### GCP Audit

- Confirms the appropriateness of clinical trial quality management system
- Assures compliances of ICH-GCP, local regulations, SOPs, clinical trial protocol when conducting clinical trials
- Regulatory inspection support

### GVP Audit

- Confirms appropriateness of the client's pharmacovigilance system
- Assures the compliance of ICH-GCP, ICH-E2, local regulation, SOPs, study protocol for clinical trial pharmacovigilance activities

### GCDMP Audit

- Confirms appropriateness for clinical data and system management
- Assures the compliance for ICH-GCP, local regulation, SOPs, study protocol during data management

### GCLP Audit

- Confirms compliance for ICH-GCP, local laws/regulations, SOPs, study protocol in central labs, sample management procedures, and sample analysis

### Vendor Assessment / Audit

- Assesses the quality management system suitability and capability to perform services
- Conducts assessment on computer system provider (EDC, PV, e-TMF, CTMS, etc.), Central Lab, Imaging, CRO, SMO

# 02

## Training / Consulting

- ICH-GCP / ISO 14155 / Laws / Education of persons conducting clinical trials training courses with LSK Education Center
- Provides consulting for clinical trial quality management
- Provides ISO 14155 certification consulting to clients

# 03

## SOP Development / Revision

- SOPs consulting and SOPs development & review services for conducting IMP clinical trials and/or, medical devices clinical investigations

The logo for LSK Global PS, featuring the letters 'LSK' in a bold, sans-serif font, followed by 'Global PS' in a smaller, lighter font. A stylized, curved line arches over the 'S' in 'LSK'.

LSK Global Pharma Service Ltd.

97 Toegye-Ro, Coryo Daeyungak Tower 16th Fl. Jung-Gu,  
Seoul Korea 04535

Main : 02.546.1008

Fax : 02.584.9008

E-mail : Quotations: [bd@lskglobal.com](mailto:bd@lskglobal.com)

General Inquiries: [information@lskglobal.com](mailto:information@lskglobal.com)

Website : [www.lskglobal.com](http://www.lskglobal.com)