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Dedicated to Clinical Trials

LKF – Laboratorium für Klinische Forschung GmbH was established in 1991. After several years of experience in clinical trials in his medical routine laboratory, LKF's founder Prof. Dr. med. W. Junge, M.D. recognized the necessity and advantage of forming a separate and specialized medical laboratory unit exclusively dedicated to supporting clinical trials of phases I–IV. Located in Northern Germany, in the heart of Europe LKF has more than 150 employees and is part of the GBA Group Pharma.

We offer a broad spectrum of services covering all aspects of the laboratory part of clinical trials – from planning to completion. Our team has considerable experience and expertise in a variety of clinical indications, their diagnosis and therapy. LKF has supported more than 1500 national and international clinical trials with some thousand investigator sites in Western and Eastern Europe, the U.S., Canada, Australia, Israel, South Africa and several South American and Asian countries including China. Specimens from approximately 60.000 patient visits are processed annually. To provide fast and high quality global services LKF went into partnership with other clinical laboratories in North America, South America and China. In extensive cross-validation studies the equivalence of methodologies, of reporting formats and of reference intervals within the laboratory network was verified. A continuous quality control program ensures the long-term consistency of analytical results of the laboratory partners.

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Specimen Management and Storage

Post-Analytical and Long-Term Storage, Specimen Management for Third Parties

Post-Analytical Storage

LKF has created a sophisticated specimen retention and retrieval system, which provides various information on each sample. It ensures accurate tracking and enables instant access whenever additional or re-testing is necessary. After completion of the analytical process, specimens are stored frozen as long as the client requests. Specimens are disposed only on the client's written confirmation.

Long-Term Storage

LKF offers long-term storage of different specimen types under certain storage conditions, from liquid nitrogen (–196°C) and –20°C to +37°C. Continuous temperature monitoring, automated alerts and back-up equipment safeguard your samples. Each specimen is tracked individually from accessioning to shipment or disposal. Our sophisticated storage system guarantees a 24h sample retrieval time from request until shipment.

Specimen Management for Third Parties

LKF offers the retrieval, handling, storage and transportation of specimens to be analyzed by a referral laboratory, e.g. for pharmacokinetic or DNA / RNA assays. LKF has established special procedures for the management of DNA samples for genetic testing including a reliable de-identification step to ensure full compliance with data privacy rules.

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Analysis

Analysis

LKF offers a comprehensive clinical laboratory testing program. Whenever possible, the methods and procedures applied are those recommended by international scientific societies, e.g. IFCC, ECAT, or traceable to approved reference material.

Furthermore, LKF has expertise in the development, evaluation and reference interval establishment of new analytical methods. Analyses are performed in a timely and accurate manner. Measurement of routine and safety parameters, including reporting of test results, is usually completed on the day of specimen receipt six days a week.

Although laboratory methods are frequently modified or changed due to technical developments and/or methodological progress, consistency of methodology is provided for the entire period of a trial.

LKF provides analytical services in the following sub-specialties:

- Clinical Chemistry
- Hematology
- Flow Cytometry
- Coagulation
- Endocrinology
- Immunology
- Serology
- Microbiology
- Molecular Biology
- PBMC Isolation
- Pathological Anatomy/Cytology

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Data Management, Reporting and Archiving

Data Management

LKF has developed a data management system dedicated to the requirements of a medical laboratory specialized to clinical trials. Our reliable and flexible software complies with international standards (GCP, FDA 21 CFR Part 11) and is tailored to our clients needs.

LKF's data management system includes the following key features:

- blinding of laboratory data
- electronic archiving of source data, e.g. request forms, hardcopies
- import of external laboratory data
- export of multiple output formats (ASCII, XML)
- accommodation of different data structures (CDISC, OC, SAS or client-specific)
- incremental or cumulative data transfer
- support of eCRF and EDC systems by daily data transfer
- data encryption
- web-based data entry for third party laboratories

Reporting

The laboratory report contains the dates of specimen collection and delivery at LKF, demographic data and reference intervals. Results are flagged according to the specifications defined in the study protocol (e.g. reference ranges, alert values, exclusion/inclusion criteria). Patient results are transmitted as single and/or cumulative reports by fax, e-mail, regular mail or by courier service.

In addition, analytical results are available in a secure area of our homepage (www.lkf-kiel.de). A special report form designed for our clients, the so-called OVERVIEW, is a spreadsheet file representing a compilation of the current status of a study (e.g. demographic data, missing information, site- or country-related visit and enrollment status). The OVERVIEW is available at any time via LKFs homepage or can be transfered automatically on a regular basis.

Archiving

LKF maintains a GCP compliant archive designed and equipped for the secure storage of all study-related documents. Electronic records are archived according to 21 FDA CFR Part 11.

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Bioanalytical Services

Bioanalytical Services

LKF provides a wide range of bioanalytical methodologies supporting all phases of the drug development process. Our highly qualified staff is experienced in the following bioanalytical areas:

Large molecules:

- Enzyme-linked immunosorbent assays (ELISA)
- Radioimmunoassays (RIA)
- Immunradiometrie assays (IRMA)
- Chemiluminescence immunoassays (CLIA)
- Electrochemiluminescence assays (ECLIA)
- Flow Cytometry
- Multiplex immunoassays

Special Services:

- Coagulation assays
- Anti-drug antibodies (ADA)
- Customized assays

Small molecules:

Together with our affiliates within the GBA Group Pharma we are able to offer assays for the detection of small molecules, peptides, plantextracts and polymers in a GCP-certified environment.

LKF is certified according to ISO 17025 and all analytical procedures are in accordance with the relevant regulatory requirements (GCP). Bioanalytical assay development and validation follow the most recent FDA and EMA guidance documents. Our experienced bioanalytical scientists ensure a high quality service based on the „fit-for-purpose" approach adapted to the study needs:

- Exploratory analysis
- Partial validation
- Full validation

All laboratory tasks are specified in study-specific bioanalytical protocols generated during the initiation phase of the project. Analytical data is kept and managed by the use of LKFs GCP and FDA 21 CFR, Part 11 compliant laboratory database. Laboratory results and statistical evaluations are documented in standardized bioanalytical reports.

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