

COMPANY PROFILE



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History and Mission

LKF is an independent medical laboratory founded 1991 to support clinical trials of phases I – IV. From planning to completion, the broad spectrum of services covers all aspects of the laboratory part of clinical trials. LKF has considerable experience in a variety of clinical indications, their diagnosis and therapy. Since 2018 LKF is member of GBA Group Pharma, which supports clients throughout the entire drug development lifecycle with Preclinical and Analytical Services, Global Central Laboratory Services, Clinical Trial Supply and Regulatory Services.

Highlights

With an own GBA laboratory in US and a global network of partner laboratories located in Europe, Latin America and China, LKF offers worldwide laboratory services for clinical trials.

Dedicated and experienced project managers are assigned to each study ensuring a long-term consistency within a project. The sophisticated specimen management system ensures full traceability of retrieval, handling, storage and transportation of specimens.

LKF laboratory software complies with international standards (GCP/GLP, 21 CFR Part 11) and is tailored to the client's needs.

The certification according to ISO14001 and ISO 45001 and the EcoVadis silver level rating display our sustainability efforts.



www.bvma.de

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BVMA member since 2010
Audits passed in 2010, 2013, 2016,
2019 and 2022



Member of GBA GROUP PHARMA



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Services

Central Laboratory

- Provision of study specific supplies (manuals, collection kits, forms, packaging material, pre-printed airwaybills, centrifuges, etc.).
- Customized laboratory reports containing reference ranges, individual units (conventional, SI, others), flags (high/low, alert ranges, in-/exclusion) and customized comments sent by mail, email (encrypted) or fax.
- Laboratory testing program accredited according to ISO/IEC 17025.
- Assay development and validation according to regulatory requirements.

Project Management

- Dedicated and experienced project manager for individual studies ensuring proactive communication and long-term consistency within projects.
- Automated and flexible alert system enables timely information of investigators and medical monitors if results are outside of the assigned alert ranges.
- Multilingual communication and laboratory manuals.

Scientific Consultation

- Scientific and medical experts provide guidance on assay selection, pre-analytical requirements and interpretation of analytical results.

Specimen Management and Global Logistics

- World wide shipments of specimens organized by IATA / ADR trained logistical experts.
- Retrieval, handling, storage and transportation of specimens to be analysed by specialized laboratories (e.g. pharmacokinetics, pharmacogenomics).
- Short and long-term specimen storage with permanent temperature monitoring.

Data Management

- Demographic data, analytical data and data on specimen logistics available.
- Timely transfer of clean data in customized data transfer formats.
- Individual data transmission routes, frequencies and security measures.
- Cumulative or incremental data transfer with eCRF support.
- Secure access to laboratory data via internet.



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