

Your Challenges Require Smart Solutions.

### About the GBA Group

The GBA Group is one of the leading laboratory and consulting service providers in Europe. Our core competencies: environmental, food and pharmaceutical analysis.

The GBA Group is growing continuously. Currently we are represented at 41 locations. Chemists, food chemists and chemical engineers, biologists and bioengineers as well as pharmaceutical scientists and other fields deliver excellent quality for our customers.

### Our Services in Pharma Analysis

The members of GBA Group Pharma are located in the European Union, have an excellent track record in serving client needs and long lasting experience in handling small molecules, therapeutic peptides, biologics and ATMPs. From early lead optimization and early preclinical stage to global clinical studies, we support you throughout the entire product lifecycle with our central laboratory, GMP Depots, EU GMP manufacturing site for labeling and packaging and QP services, as well as late drug development and analytical services including import testing and QP batch release.

### Our Services in Food Analysis

Our technical equipment and staff expertise enable comprehensive, high-quality processing of your samples and on-time delivery.

In the field of food analysis the GBA Group guarantees fast and reliable transportation and analysis of your samples. Before your samples arrive, questions and uncertainties will be clarified, so the process can be carried out smoothly from the very beginning. Our long-term experience in analyzing samples from almost all kinds of matrices ensures that the results will be calculated and analyzed competently, and that solution-oriented support will be provided.

### Our Services in Environmental Analysis

Environmental analysis at the highest level. Our laboratories for environmental analysis combine swift and competent consulting with the complete range of modern environmental analysis. Our technical equipment and staff expertise enables comprehensive, high-quality processing of your samples as well as on-time delivery. Our competent evaluation of the results and the solution-oriented support that we provide are based on our employees' long-term experience dealing with almost all kinds of matrices.



### Contact:

#### Laboratorium für Klinische Forschung (LKF)

Lise-Meitner-Str. 25-29  
24223 Schwentinental  
Germany

Phone: +49 4307 8276-0  
Fax: +49 4307 8276-79  
bd@lkf-kiel.de



## LKF Central Laboratory Clinical Trial Phase I-IV





### Study Management

LKF has more than 30 years of experience in clinical trials. Dedicated study manager and substitute assigned to each study.



### Laboratory and Analytical Services

LKF offers a comprehensive clinical laboratory testing program and provides a wide range of analytical methodologies supporting all phases of the clinical trial process.



### Lab Kit Supply

Lab kit preparation is done in-house and can be study-specific and/or color coded as requested. Our modern ERP-based production with connection to the warehouse and the obligatory quality check (QC) guarantees the full traceability of the lot number and the expiry date.



### Data Management

Amongst others, our services include blinding of laboratory data, electronic archiving of source data, import of external laboratory data. Export can be done in various output formats e.g. ASCII, XML. Of course we support also eCRF and EDC systems.



### Specimen Management

Post-analytical and long-term storage including sample management for third parties is of course possible with us. We offer different storage conditions (e.g. -196°C, -80°C, -20°C) for your specimens. Central laboratory, GMP Depots, EU GMP manufacturing site for labeling and packaging and QP services, as well as late drug development and analytical services including import testing and QP batch release.

### LKF and Amedon Two partners for one Solution

Amedon is specialized in developing and delivering web-based solutions for clinical research. More than 18-years experience in eCRF, eTMF and SAE Database software development makes Amedon an established and first class service provider for online communication software in the pharma and medical device industry.

Together we developed interfaces to offer combined solutions to clinical trials.

The tracking solution developed by Amedon and LKF enables absolute real time transparency. From the preparation of the lab kits at LKF to the shipment of the samples up to the reporting, all lab kits can be verified at any time.

Bernard Brandewiede (CEO of Amedon):

"No more paper based processes, no more time consuming reconciliation processes.

Amedon provides IT solutions for collecting data, managing data and information as well as documents within clinical trials. In cooperation with LKF we developed solutions to manage the entire process chain, beginning with registration of the Lab Kit, following registration at the Site as well as the logistics in combination with our eCRF solution.

The sponsor and all responsible staff know exactly where the Lab Kit and tubes are and when the analysis is done. Results can be transferred to eCRF to eliminate time consuming manual data entries."

We know every project is unique and every project has specific requirements.

Our strength lies in finding the best solution in cooperation with the customer.

Our tailored IT solution helps you to optimize processes and ensures the validity and integrity of all laboratory data and processes.

### AMEDON GmbH

Phone +49 451 38450-0  
info@amedon.de

## Fields of Expertise

### Preclinical Services

#### PHARMACELSUS

- In-Vitro ADME
- In-Vivo DMPK Studies
- GLP / Non-GLP Bioanalysis

Phone +49 681 3946 - 7510  
info@pharmacelsus.com

- GCLP Bioanalysis
- Services for Biologics
- Biomarker Services

### Clinical Trial Supply

#### ABF

- Labeling & Packaging
- GMP Storage & Global Distribution
- Import & Export
- Storage at 15-25 °C, 2-8 °C, 20 °C, -80 °C, -150 °C, LN2
- CTM and Commercial Services

Phone +43 890120 - 0  
office@abf-pharma.com

- QP Release & QP Services
- Audit Services
- Quality Management
- Sourcing
- Controlled Substances
- PBMC Network

### Central Laboratory

#### LKF

- Safety Analysis
- Bioanalysis
- Lab Kit Supply
- Worldwide Logistics

Phone +49 4307 8276-0  
project@lkf-kiel.de

- Specimen Storage
- Data Management
- Quality Assurance Service

### GMP Testing

#### GBA PHARMA LABS

- Research Development Analysis
- Method Development & Validation
- Quality Control
- Particles and Particles Size Distribution
- Microbiology

Phone +49 89 899229 - 0  
info@gba-pharma.com

- Stability Testing & Storage
- Packaging Material Testing
- Extractables & Leachables Studies
- Elemental Impurities
- ICH Guideline Q3D
- Amino Acid Analysis

### Regulatory Affairs

#### GBA PHARMA LABS

- Homeopathics
- Readability User Test

Phone +49 89 899229 - 0  
info@gba-pharma.com

- Plant-Based Medicines
- Ect Service incl. Submissions