Arbeitskreis Klinische Arzneimittel Prüfungen
PD Dr. med Seiler GmbH

Contacts:

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Accurate · Key · Professional

Company Profile

AKP was founded in 1996 as a spin-off from IKP (Institut für klinische Pharmakologie) by PD Dr. med. K.-U. Seiler and Prof. Dr. med. P.-W. Lücker. With 16 years experience, **AKP** has achieved a proven record of broad services partnering innovative pharmaceutical companies in managing international and national clinical trials, and non interventional and medical device studies in a vast variety of therapeutic areas.

As an exclusive service provider we partner your company and offer flexible solutions; whether you are looking for us to manage your project from beginning to end or provide customized outsourced services.

Co-operations with other companies and sub-contractors managed through **AKP** (e.g. Data management companies, Laboratories, etc.) allow us to broaden our service portfolio and to offer you even more customized solutions to your specific demand.

AKP's well known engaged services are based on reliable, high quality.
Our work is target-oriented, dedicated and cooperative, scientifically exact, and our flexibility guarantees you cost competitive solutions. **AKP** works diligently to insure compliance with timelines our clients set.

Management

Hilde Huber, Dipl.-Biologist, has been the CEO of **AKP** since 2011. Previously, Mrs. Huber has served as the Co-Chair CEO and Director Clinical Operations.

The former CEO, Priv.-Doz. Dr. med. K.-U. Seiler stepped down in 2011 and is now working as the Chief Medical Officer at **AKP**.

Hilde Huber, Dipl.-Biologist (CEO)

Graduate degree in biology, ECPM diploma in Pharmaceutical Medicine. Extensive experience in clinical trial monitoring and project management for **AKP**, Parke-Davis and Gödecke.

She joined **AKP** in 1997, became Director of Clinical Operations in 2001, and was appointed Co-Chair CEO in 2007. As CEO since 2011, Mrs. Huber is in charge of the monitoring sector, project management, quality assurance and internal training.

Mrs. Huber supports the implementation of the client's project in offering consultation regarding study design, clinical development planning and submissions requirements.

Priv.-Doz. Dr. med. habil. K.-U. Seiler (CMO)

Recognized specialist in clinical pharmacology and internal medicine. Longstanding career at the University of Kiel, Germany. Pharmaceutical industry experience since 1985 as Head of Clinical Research for Janssen (Germany), and later Head of Cardiovascular Clinical Research for Parke-Davis.

Dr. med. K.-U. Seiler is responsible for the internal and external consultancy in medical issues, medical training of **AKP** staff and medical writing of study & submission documents.

Services

A well designed and structered study concept, intensive supervision and guidance of study participants assure **AKP**'s compliance with regulation and directives.

AKP also implements high quality standards of documentation and results - as evidenced by our outstanding audit evaluations.

With our wide range of services we cover activities from protocol development and study management, through the final clinical study report. We guarantee you a cost-effective solution, whether you desire us to provide individual services or completely take over your entire project.

AKP's intensive feedback communication keeps our clients well informed about the current stage of the project's development.

Our services include:

- Medical counselling: used in planning and realization of Phase I – IV trials and non-interventional studies
- Project management: serves as your single point of contact, produces a detailed thorough project, communicates with all parties involved, creates a risk assessment plan, and leads and directs a project team
- Feasibility analysis
- Biometric planning
- Study design
- Development of all study related documents (e.g. study protocol / observational plan, paper based and/or electronic Case Report Forms (eCRFs), etc.)
- Selection of study sites
- Contract negotiations with study sites
- Submissions and notifications to Ethics Commitees, Competent Authority and Local Authorities
- Registrations in public registers
- GCP- and study specific training for study personnel
- Planning and conducting of investigator's meeting
- Patient recruitment support
- Monitoring according to ICH-GCP / FDA and local regulations; Quality assurance for NIS on the basis of § 67 sect. 6 AMG
- Handling of investigator's fees
- Data management
- Statistical analysis
- Medical Writing

Our strengths

… our network – for flexible & customized solutions…

AKP has over 16 years of experience in managing clinical trials. We have built a dynamic network of clinical research professionals and medical specialists working at all levels needed for the successful completion of a study.

This network in addition to our internal experienced clinical research team permits **AKP** to offer flexible and customized solutions according to your individual needs.

Our highly developed resources and our cooperation with other experts enable us to provide all levels of clinical research personnel, whether to support you in specific aspects of clinical trials, or to compile a project team to take over your entire project.

Depending upon your specific needs, a project team could consist of:

- Medical Advisors
- Medical Writers
- Project Managers
- Clinical Research Associates
- Clinical Project Assistants
- Data Managers
- Statisticians
- Trainers
- Co-operation with Laboratories, Data Management companies and other CROs

Experience

Our staff is highly experienced and regularly trained in ICH-GCP guidelines, FDA and all national regulations. **AKP** oversees and implements each project as if it was our own. We assure high quality services and results that will meet your timelines and lead your project to success.

AKP has experience in:

- International and national phases I – IV clinical trials
- Non-Interventional Studies (NIS)
- Medical Device Studies (MDS)

and the following therapeutic areas:

- Cardiovascular diseases
- CNS/Pain
- Dermatology
- Endocrinology
- Gastroenterology
- Hyperlipidemia
- Infectious diseases
- Neurology
- Oncology
- Pneumology
- Rheumatology
- Urology

In **Oncology**, experience stretches across the following indications:

- Acute myelogenous leukemia (AML)
- Adenocarcinoma of the stomach
- Bronchial carcinoma
- Chronic lymphocytic leukemia (CLL)
- Colon carcinoma
- Colorectal carcinoma
- Malignant lymphoma
- Mamma carcinoma
- Non small cell lung cancer (NSCLC)
- Pancreas carcinoma
- Prostata carcinoma

Quality & Testimonials

At **AKP** we are dedicated to build quality into all our processes through implementing and maintaining effective Standard Operating Procedures (SOPs).

Extensive training of our hand-picked, experienced professional staff assures the highest proven standard of compliance with ICH-GCP, FDA and local regulations.

Our commitment to customized support guarantees that **AKP** is always up-to-date regarding the status of your study. This focussed, individual service ensures your questions will be answered promptly and with reliable, high quality.

Several audits performed by sponsors and Regulatory Authorities certify the high standard of service quality delivered. Additionally, investigator and sponsor feedback characterizes us as a sustainable, reliable partner.

What sponsors said about us

- "**AKP** delivered very good quality of work: study was audited by the local Authority (Regierungspräsidium) and two GCP site-audits were performed with excellent results."
- "Very good data quality - lowest query rate"
- "**AKP** has a proprietary process in place to do things right the first time, and thus, increase effectiveness and efficiency."
- "It is the merit of **AKP** that the study in total could be completed exactly in time"
- "**AKP** made a very significant contribution to the timely completion of the study, despite several hurdles, and at the same time with very high quality standards."
- "Investigators were satisfied with **AKP**."

What investigators said about us

- "We could always reach a contact person by phone or via e-mail who could provide competent advice."
- "Until today we never experienced such an outstanding support by a CRO."
- "Important medical questions were answered immediately and competently e.g. regarding patient inclusion criteria."
- "The review of documentation at our site was always performed very accurately.

International

In collaboration with our strategic partner, we provide clinical operation services all over Europe.

We maintain a high standard of quality, and we ensure that our standards are met by all our partners through regular quality assurance visits. Senior Management closely supervises all trial related quality activities.

Project Management

Client contact is made and maintained by the Project Management Team. The central Project Management Team, located in Freiburg, Germany, is considered the single point of accountability for the overall delivery of our services, with the special emphasis on quality, ethics and compliance.

The Project Managers (PMs) are committed to completing delivery on time and within the budget by coordinating people across geographical boundaries, with different capabilities and specialisations, and leading the project team within the matrix organisation.

PMs and CRAs with significant clinical experience in various therapeutic areas (e. g. oncology, immunology, respiratory), are trained to ensure high quality clinical data.We believe people matter, and hence strive to find the best fit in terms of PM experience, location, and approach to serving our clients' needs.

Clinical Monitoring

Clinical Monitoring is consistent with global Standard Operating Procedures and in compliance with ICH guidelines. The following countries are covered by **AKP** and our strategic partner:

- **Austria**
- Belgium
- Bosnia & Herzegovina
- Croatia
- France
- **Germany**
- Hungary
- Italy
- Netherlands
- Portugal
- Russia
- Serbia & Montenegro
- Slovenia
- Spain
- **Switzerland**
- Ukraine
- United Kingdom

The CRAs, which have a scientific or medical background (MSc, PhD etc.), are continuously trained by physicians to understand specific diseases and protocol challenges, thereby ensuring protocol compliance and high data quality.

More than 90% of the CRAs are based in local offices, have local knowledge about country-specific customs and regulatory requirements, and monitor sites in their native language. Due to our track record and the remarkable tenure of our staff, our CRAs have strong relationships with the sites, fostering site performance and commitment.