

COMPANY PROFILE



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History and Mission

FGK Clinical Research GmbH is a full service CRO founded in Munich in 2002. Today, FGK employs nearly 250 people and is still owned and managed by its founders: Martin Krauss, a statistician, and Edgar Fenzl, a physician. In addition, the three Senior Directors have become shareholders, allowing the company to continue the reliable and personal service ethos that many small to midsize Biotech, MedTech and even pharmaceutical companies value so highly.

Highlights

Owner-managed medium-sized CRO:

- Tailored customer approach
- Transparent processes and fast response times
- Offices in the EU, operational presence worldwide

Focus:

- Small (start-up) & midsize biotech and medical device companies

Capabilities:

- Full or customized service for all phases of clinical trials
- All major therapeutic areas
- Legal representative services for non-EU clients
- Pharmacovigilance



www.bvma.de

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BVMA member since 2007
Audits passed in 2007, 2010, 2013,
2016, 2019 and 2022



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Services

Consulting

- Drug and device development
- Biostatistical support

Regulatory Affairs

- Development & review of study documents
- CTA with submission to Authorities and ECs/CTIS

Clinical Operations

- Study set-up, project management
- Feasibility, contract negotiations, site management, monitoring etc.

Medical Safety

- Adverse Event (AE) management, assessment reporting, coding
- Medical monitoring etc.

Pharmacovigilance

- Product vigilance, QPPV etc. (fgk-pv.com)

Quality Assurance

- Audits of study site, system audits, internal audits

Data Management

- CRF design and review,
- Data validation, processing and cleaning, external data handling
- CDISC SDTM

Biostatistics and Programming

- Study design, sample size calculation
- Analysis plan, programming and reporting
- CDISC ADaM

eSolutions

- State-of-the-art validated software, in-house programming:
- eCRF with integrated RTSM
- eTMF, CTMS

Medical Writing

- Generation and review of regulatory documents, reports, publications

Legal representative service

- for non-European sponsors conducting studies or seeking MA within the EU/ EEA (fgk-rs.com)



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