

COMPANY PROFILE



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History and Mission

TRIGA-S is a contract research organization with own BSL2 laboratory for in-vitro diagnostics and medical devices. Our high quality is certified according to DIN EN ISO 13485 and DIN EN ISO 9001. As an established service provider, TRIGA-S offers tailor-made solutions for many types of studies: from exploratory to feasibility, and performance evaluation studies. Our GCP/GCLP qualified teams work in accordance with IVDR/MDR, national and international regulations. In 2020, TRIGA-S was awarded "Bavaria's Best 50" and currently has 96 employees.

Highlights

Innovative mind-set

- Contributing to IVD product development

Flexible & agile organization

- Fast set-up and conduction of projects for COVID-19 diagnostics during pandemic

Versatile experience

- From working with global corporations, SME's; university spin-offs and start-ups

Regulatory compliance

- Fulfilment of all legal requirements, e.g. EU-IVDD / IVDR / MDR and FDA

Cost-efficiency & transparency

- Lean communication with project stake holders



TRIGA-S e.K. Scientific Solutions

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BVMA member since 2018
Audits passed in 2018 and 2021



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Services

Study Management

- Planning and execution of performance evaluations (IVDR/MDR/CFR-FDA)
- Risk-based planning and surveillance of processes
- Regulatory consulting
- Biostatistical support
- Data Management

Study Monitoring

- Selection of study sites for IVD/MD studies
- Study initiation, monitoring and close-out
- Site training
- SAE-reporting
- Post-Market Performance Follow-Up

Sample Processing

- Sample kit preparation - customized, small to large volumes
- Collections of clinical samples
- Sample Management (LIM-System)
- Pooling and aliquoting

Contract Laboratory

- Biosafety level 2
- Measurements on several platforms for clinical chemistry, immunology, NAT, ELISA and PCR
- Client-specific analytical performance evaluations
- Feasibility testing
- Exploratory measurements

Study Logistics

- Worldwide
- Coordination of sample and material shipments
- Full traceability, barcoding and temperature controlled

Sample Storage

- Long-term storage of human samples and study materials at -80°C, -20°C, 2-8°C, RT, and 37°C
- Temperature monitoring 24/7 and backup systems

Your diagnostics studies in good hands.