

COMPANY PROFILE



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History and Mission

TRIGA-S is a privately-owned CRO, certified according to DIN EN ISO 9001 and a well-established partner for the In-Vitro-Diagnostic (IVD) and Medical Device industry. We offer complete service or tailor-made solutions for clinical studies and laboratory service including analytical and clinical performance studies in our S2 contract laboratory as well as sample processing, sample storage and study logistics. Our teams work according to IVDR, MDR and national regulations.

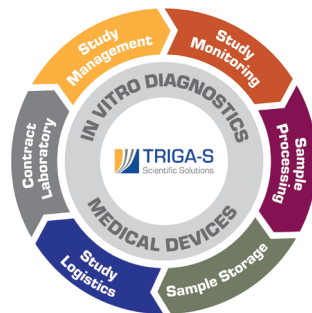
Highlights

More than 20 years of experience in IVD and Medical Device studies. Experts for sample management, processing and testing. GCLP and CLSI Standard, certified according to DIN EN ISO 9001.

S2 contract laboratory for performing In Vitro Diagnostic studies and providing laboratory support.

Study logistics including assembling / shipping sample collection kits and temperature-controlled shipments of clinical samples.

Large area for human sample and reagent storage (any temperature), electronic 24 / 7 temperature monitoring.



TRIGA-S Scientific Solutions

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BVMA member since 2018
Audit passed in 2018



www.triga-s.de

Services

Clinical Trial Management and Monitoring Services

- Project management, study design, conduct of clinical and technical trials
- Analytical and clinical performance evaluations according to GCP / GCLP
- Submission to IRB / EC and regulatory authorities
- Preparation and maintenance of the trial master files (e / TMF)
- Data Management, Biostatistics, Medical writing
- Safety reporting
- Preparation of audits and inspections
- Support in CE certification
- Post Market Clinical Follow-up (PMCF)

- Support for expedited new assay developments by our seasoned team of laboratory experts
- Data management for results and data transfer
- Point of Care Testing (POCT)

Clinical Trial Logistic Services

- Shipping study material and collecting samples worldwide
- Storing samples for short- and / or long-term
- Preparation of tailor made specimen collection kits for clinical studies

Laboratory Services

- Human sample collection, preparation and processing (either tiny or huge, all sample volumes are welcome)
- Application testing and analytical performance evaluation
- Investigational site for exploratory / pilot / performance evaluation and post-launch studies (e.g. clinical chemistry, immunology, ELISA etc.)