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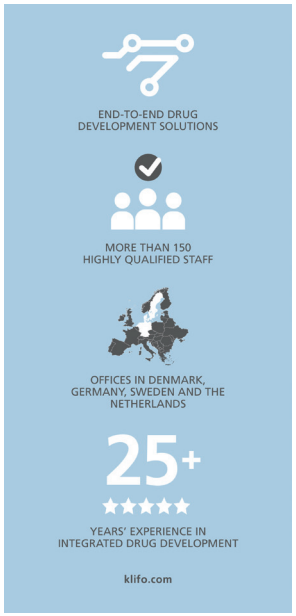
History and Mission

KLIFO, established in 1994, is an integrated drug development consultancy with offices in Denmark, Germany, Sweden and The Netherlands. From our office in Munich, we offer consulting and operational services for strategic drug development, CMC, QA, regulatory affairs and clinical trial management. **Our ambition is to support our clients to accelerate the progress of their drug and medtech development project effectively.**

Highlights

Developing from a CRO into an integrated drug development consultancy, KLIFO's concept is end-to-end support throughout the entire drug and medical device development process.

KLIFO´s Unique Selling Points:
- Dynamic network of experts, adaptable to the client´s needs
- Adjustable scope of services and support
- Strategic expertise & advice
- Strong and flexible in-house resources to support complex and early phase clinical studies
- Part of PSN Research: a worldwide operating CRO (www.psnresearch.com)



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BVMA member since 1996
Audits passed in 2000, 2003, 2006, 2009, 2012, 2015, 2018 and 2021

www.KLIFO.com

Services

As an **integrated drug development consultancy,** KLIFO is a one-stop-shop and provides all services around your drug and medtech development journey.

Clinical Operations Solutions:
- Clinical Project Management
- Clinical Monitoring and Writing
- Data Management and Biostatistics (CDISC, project-adjusted EDC systems and statistical solutions)
- Broad range of indications
- Focus on early phase
- Primarily covering DACH, Benelux and (Northern) Europe

In addition to these clinical operation services, we also offer following solutions:

Clinical Trial Supply
- Packaging & labelling activities for IMP & euphoriant substances
- Temperature controlled packaging: ambient, cold & frozen (-20°C, -80°C)
- Importation support & global distribution network

Pharmacovigilance
- Safety Management Plan, Surveillance & signal detection
- Medical Monitoring
- Safety database, SAE handling

Regulatory Affairs
- IND, ODD, PIP, CTA, IMPD, IB
- Regulatory strategy, approvals and scientific advice in EU & US
- eCTD and CTIS readiness

Drug Development Counselling
- Development, planning and execution of drug and medical device development projects
- Strategic advice

CMC Development
- CMC strategies and plans
- CDMO identification, evaluation and collaboration
- Due diligence conduction
- Analytical method development

Quality Assurance
- GCP, GDP, GMP, GVP
- Onsite and Remote Audits
- International Site Inspections
- QMS gap analysis and set up