COMPANY PROFILE

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History and Mission

KLIFO is an integrated European drug development consultancy with significant experience in partnering with pharmaceutical and biotech companies. We provide strategic advice and operational end to end expert solutions across all drug development areas, incl. strategic project management, regulatory affairs, clinical development, clinical trial supply, QA, CMC development, non-clinical development and pharmacovigilance.

Highlights

KLIFO´s expertise covers most therapeutic areas, including advanced therapy medicinal products, immuno oncology, central nervous system and gastroenterology therapeutics. Our experts can also navigate your drug-device combination projects.

Whether your organisation is challenged on time, resources or expertise, we can assemble a team of relevant expert consultants to assist you.

Our tailor-made solutions are based on close collaboration with you and your colleagues so that we harness our combined expertise and ensure proper project implementation.

- **END TO END** DRUG DEVELOPMENT SOLUTIONS
- **MORE THAN 200** HIGHLY QUALIFIED STAFF
- OFFICES IN **DENMARK, GERMANY, SWEDEN AND THE NETHERLANDS**
- **25+ YEARS OF EXPERIENCE** IN INTEGRATED DRUG DEVELOPMENT

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

www.KLIFO.com

Services

KLIFO offers strategic advice and operational support across the entire drug development journey:

Clinical Trial Supply
- Packaging & labelling activities for IMP
- Temperature controlled packaging: ambient, cold & frozen (-20°C, -80°C)
- World Wide distribution
- Clinical Trial Supply Management

Drug Development Counselling
- Development, planning and execution of drug and drug/device development projects
- Non-clinical and toxicology consulting
- Strategic advice and due diligence

CMC Development
- All types of drug substances and drug products
- CMC strategies, plans and project management
- CDMO identification, evaluation and collaboration

Regulatory Affairs
- IB, IMPD, CTA, IND, ODD, PIP, MAA, NDA/BLA
- Regulatory Strategy, Scientific Advice EU/US
- eCTD and CTIS readiness
- Biotech EDMS Solution

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

Clinical Operations Solutions:
- Clinical Project Management & Writing
- Clinical Monitoring & Site Management
- Data Management and Biostatistics
- Particularly strong in oncology, GI, First-in-Man, haematology, diabetes and rare diseases
- Primarily covering DACH, BeNeLux and (Northern) Europe

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