Clinical Development Partner

Linical

Linical Regulatory Services

Why Choose Linical

At Linical, we understand and have extensive experience in global drug development, enabling us to provide our clients world-class regulatory consulting services. Our approach is tailored to each unique program, and our strategies help clients successfully navigate the global regulatory process in the most cost effective and quickest to market manner. Through partnering with Linical, clients can:

- Streamline the development pathway
- Avoid unnecessary studies
- Save money
- Shorten timelines to get products to market
- Gain valuable feedback from agency meetings to reach key inflection points and raise funds

While Linical has a global footprint of regulatory team members throughout the world, our regions of focus are North America, Europe, and Japan (part of our APAC offerings along with China, South Korea, and Taiwan). Our experts are ready to assist as our clients plan registrations into the three largest markets for pharmaceuticals in the world.

Comprehensive Regulatory Capabilities

Regulatory Strategy Development Services

for quickest to market path for US and/or global development taking into account other countries and regions for future drug registrations.

Gap Analysis and Mitigation Strategies

Interactions with FDA for CDER, CBER, MFDS, etc.

- Preparing Meeting Requests and Briefing Packages (INTERACT, Pre-IND, EOP1, EOP2, Scientific Advice from EMA or National Authorities, Pre-NDA/BLA as well meeting with PMDA and other regulators)
- Serve as your US Agent

Authoring of Regulatory Documents

- INDs, CTA/IMPDs, IND Annual Reports, IND Maintenance Submissions
- NDAs, BLAs, ANDAs, 505(b)(2) Applications
- CTDs/eCTDs (including summaries, ISS/ISE)
- Fast Track and Orphan Drug Applications
- Periodic Adverse Drug Experience Reports and Periodic Safety Update Reports
- Preparation of DMFs, Annual Reports, Protocol Amendments, and Post-approval Supplements

Post Approval Services

- Review of promotional materials
- Review of labeling changes
- Strategic planning for new indications

Contact Us

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