TRIALSCOPE SERVICES
Expertise in Regulatory Writing

CITELINE
REGULATORY

Case Study

Citeline Expands Biotech's Bandwidth with Regulatory & Medical Writing Services

The challenge

A mid-size biotech specializing in oncology and rare disease lacked the bandwidth, expertise, and resources to handle its regulatory writing requirements independently and sought a partner to outsource QC and support medical writing.

The client required end-to-end project management and regulatory writing support for timely and accurate regulatory submissions with the challenges of no designated disclosure team and little to no processes/systems in place to support this function

Individual team members had multiple responsibilities and required more hands-on support to manage the project

The team faced very tight deadlines



The solution: Citeline Regulatory & Medical Writing Services

- Providing the client with senior and experienced regulatory writers who could offer best practices for implementation
- Approaching the project with an entrepreneurial mindset, working as project managers to ensure accuracy (QC) and timeliness, taking on disclosure tasks with access to a global team
- Offering a flexible arrangement so the sponsor could scale services up or down as needed

Outcomes & Success

- Met project deadlines
- Ensured high quality and accuracy of regulatory documents
- Received a dedicated lead writer to learn company processes and reduce the burden on resources
- Formed a trusted partnership, becoming the go-to resource that can be counted on every time

"Writers integrated into study teams seamlessly to produce high-quality documents, guidance, project management, and provided support outside of the project scope."

— Senior Director Medical Writing

Learn more about how TrialScope Regulatory Writing Services can help support your regulatory and compliance efforts.

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