

Seasoned experts, experienced in every aspect of CTD/eCTD preparation

Proven Precision



End-to-End Expertise

Quintiles brings together — under a dedicated project manager — incredibly talented regulatory strategists, medical writers, biostatisticians, and medical, publishing and clinical pharmacology specialists who work closely together to design and implement efficient, effective submissions from beginning to end.

Key team members — including biostatisticians and medical writers — dedicate themselves 100% to CTD/eCTD projects. Our highly skilled regulatory strategists provide valuable regulatory expertise.

Early Submission Planning Helps Accelerate the Entire Product Development Process

At Quintiles, we like to start thinking about registration strategy and planning at the very beginning of a drug development project; that way we can provide critical solutions that facilitate the achievement of regulatory and product development milestones throughout the process. By seamlessly integrating regulatory and key supporting services from the start, we can help accelerate the product development process from beginning to end.

In today's complex and changing regulatory environment, Quintiles' teamwork and in-depth regulatory experience can ensure smooth sailing all the way through to marketing approval and beyond. Contact us today, and see what a difference our experience can make.

Quintiles Experience

- > *Our biostatisticians have an average of 7 years experience*
- > *Our regulatory strategists have an average of 13 years regulatory affairs experience*
- > *Our senior regulatory strategists have from 12 to 30 years experience at the FDA and EMA*
- > *Our medical writers have experience in over 75 therapeutic indications, and an average of 13 years industry experience*
- > *Our publishers have an average of 14 years experience, and we have published over five million pages of regulatory submissions*

Comprehensive CTD/eCTD Services

- > *Integrated clinical development, data management and regulatory submissions*
- > *Pre-submission regulatory authority meeting preparation*
- > *Global regulatory strategy planning and development*
- > *Submission technical section writing*
- > *Clinical data integration, ISSE/ISE analysis and statistical reporting*
- > *Data preparation to CDISC standards*
- > *Submission compilation and assembly*
- > *Paper or electronic submissions*
- > *Author/reviewer training and support*
- > *Submission maintenance*
- > *Post-submission advisory committee meeting preparation, dispute resolution/arbitration and post-meeting issue analysis and responses*

Quintiles is a FDA-registered eCTD provider and a CDISC Registered Solutions Provider.

Contact Us:

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