

It All Comes Down to Experience

Quintiles' seasoned teams have experience with every aspect of NDA preparation.

Quintiles NDA teams bring 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 NDA projects. Our highly skilled regulatory strategists provide valuable regulatory expertise.



Quintiles is an FDA-registered eCTD provider.

QUINTILES' NDA EXPERIENCE

- > Our biostatisticians have an average of 7 years industry 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
- > 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
- > Since 2000, Quintiles has contributed to 37 NDA/BLA submissions, including 10 CTD projects

Early NDA Planning Can Help Accelerate the Entire Product Development Process

At Quintiles, we like to start thinking about NDA 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 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 NDA experience can ensure smooth sailing all the way through to registration. Contact us today, and see what a difference our experience can make.

Quintiles is a CDISC Registered Solutions Provider.

At Quintiles, it's all about results.

COMPREHENSIVE NDA SERVICES

- > Integrated clinical development, data management and regulatory submission
- > 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 (including eCTD)
- > Author/reviewer training and support
- > Submission maintenance
- > Post-submission advisory committee meeting preparation, dispute resolution/arbitration and post-meeting issue analysis and responses

Contact Us:

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