



QUINTILES REGULATORY SERVICES

...for the Experience



Regulatory Experience Around the World, Across the Board

With offices throughout the world, Quintiles Regulatory Services provides critical strategic and tactical solutions that facilitate the achievement of regulatory and product development milestones for drugs and biologics. Our focus is on strategy, planning, implementation and training for all phases of the regulatory review and approval process.

It's all about seamlessly integrating regulatory services to accelerate the product development process from beginning to end. It's about having experience with the FDA and the European regulatory authorities, so we can explore with you the most efficient route and shortest timeframe to market. It's therapeutic area expertise. It's understanding regulations, such as the Common Technical Document (CTD/eCTD) requirements or the European Clinical Trial Directive. And it's knowing how to design studies compatible with local regulations that can produce globally valid results.

In today's complex and changing regulatory environment, Quintiles' experience can help ensure smooth sailing from the beginning of a clinical trial through to regulatory submission and approval.

At Quintiles, it's all about results.

The Experience to Help You Move Confidently into Electronic Submissions and eCTD

The FDA and EMEA are both encouraging – and in some cases, already requiring – the use of electronic submissions. The FDA will require all electronic submissions to be in the eCTD format after December 31, 2007. Likewise, the EMEA and other European regulatory authorities are clearly moving toward electronic submissions, and eventually the eCTD format.

Many companies are postponing the transition to electronic filing because it requires new infrastructures, procedures and concepts. Extensive retraining of staff will usually be needed.

However, it is far easier to outsource than to build electronic submissions expertise in-house. Quintiles can handle all aspects of preparation, validation, publishing, submission and lifecycle management of electronic applications for you. Our Regulatory team can also provide strategy on global eCTD submissions and training on writing eCTD-compliant documents. That makes the process painless for our customers.

Quintiles is an FDA-registered eCTD provider, and has received EMEA validation for eCTD submissions in Europe as well.



QUINTILES REGULATORY EXPERIENCE 2000 TO PRESENT

55	CTD projects (paper and electronic)
37	NDA/BLA submissions (paper and electronic)
43	IND submissions (paper and electronic)
28	MAA projects
34	Orphan drug applications
77	Briefing packages and attendance at FDA/EMA meetings
400+	IND and NDA/CTD amendments

Product Regulatory Applications Teamwork That Works for You

Quintiles' regulatory applications 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 regulatory applications from beginning to end.

The team will help you to navigate through the complex registration procedures in the US, Europe and across the globe, to achieve the fastest launch to market.



Helping Orphan Drugs Find a Home

The FDA and European regulators support the development of orphan drugs through both financial and procedural relief. However, obtaining the orphan designation requires special filing procedures.

Quintiles can ensure that your applications are complete and accurate in every way, as well as tailored to local requirements. Our regulatory strategists can help you smoothly navigate the protocol issues unique to orphan drug studies.

REGULATORY SERVICES

- > Strategic planning
- > Product development planning, advisement and preparation
- > Preparation of drug or biologic development plans
- > Regulatory assessment and gap analysis (nonclinical, clinical and CMC)
- > Client meeting management with regulators worldwide
- > Risk management assessment
- > eCTD assistance/process mapping
- > Publishing of electronic or paper submissions
- > Regulatory education and training
- > Quality system GMP/GCP compliance
- > Validations
- > Regulatory due diligence
- > Advertising and promotional materials review
- > Product information and labeling
- > Scientific advisory committee support

Biologics

The biopharmaceutical industry is experiencing a surge in the development of new biologics, fueled by recent scientific breakthroughs. Quintiles has responded by forming a dedicated global biologics regulatory team. We understand the significant differences between the regulatory requirements for drugs and for biologics, and stand ready to help you with strategic planning and regulatory submissions for biologics.

REGULATORY APPLICATIONS

- > Electronic submissions (including eCTD) and paper submissions
- > Global trial approval applications and amendments (IND, IDE, CTA/IMPd)
- > Global marketing applications and amendments/supplements (NDA, BLA, MAA, ANDA, 505(b)(2), 510k, PMA)
- > Orphan drug designation
- > Regulatory application procedure management (including fast track, accelerated approval, rolling review, conditional approval)
- > Product lifecycle management (line extensions/label change, variations, renewals)
- > Clinical study protocols and reports
- > Patient narratives
- > Investigator brochures

Case Study

Comprehensive NDA Services – All in a Single Neat Package

A third of the way into a study, the customer decided to switch from paper to an electronic submission. That required a total education of the customer's team on how to organize and format data to meet the FDA's electronic submission standards. We identified a senior programmer who had just the right experience for our customer's needs – and could manage the migration from paper to electronic submissions within the customer's aggressive timeframe.

After many hours of overtime, we met the deadline. Even better, our careful design and analysis led to better labeling than the customer ever imagined. As a result of our performance on this project, the customer chose Quintiles to handle the publishing of four additional studies. Ultimately, we provided this customer with biostatistics, data management and NDA regulatory services for 26 studies in all.

Case Study

Overcoming the Fear of Electronic Submissions

Another customer was not so eager to embrace the idea of electronic submissions. Our medical writers, biostatisticians, and regulatory publishing group were working with the customer on a paper Common Technical Document submission. In preparing portions of the CTD, we were able to convince the customer that it would be far more efficient to prepare a hybrid electronic submission.

The customer was surprised at how smoothly we handled the transition, and as a result decided to pursue a full eCTD submission next time around.

Case Study

Multiple Strategists for a Biologic with Multiple Indications

Sometimes just having the right expertise isn't enough. A project for a biologic IND included multiple indications – and required expertise in clinical, toxicology and CMC, on an extremely tight timeline. The customer was also looking for a company that had experience with a specific division of the FDA. Thanks to our unequaled depth of resources, we were able to meet the very specialized needs of the customer and the timeline by assigning three highly qualified strategists – with over 26 years of FDA experience – to work on the project at the same time.





Quintiles' multilingual regulatory group – consisting of over 200 professionals – has decades of experience working with regulatory agencies throughout North and South America, Europe, South Africa, India, Japan, Australia and Southeast Asia.

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It's all about results.

