

# eCTD, Stress Free

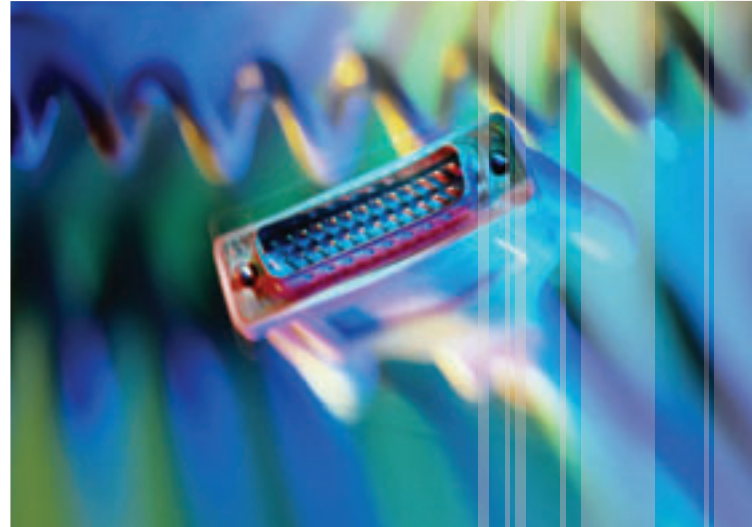
*The importance of thinking electronic ... and paying extraordinary attention to details.*

Recently, a company came to Quintiles because of our technical expertise in electronic submissions. The request was to publish a European eCTD submission, with a paper component of all modules. The customer's documents had been prepared by various authors and were provided for compilation.

## Problems in Translation

Many of the documents had originally been prepared for a paper-only submission, and subsequently scanned to electronic format. The customer indicated that most documents were in PDF format, with bookmarks and hyperlinks added, and were basically ready to include in the submission.

As part of the process, we analyzed the documents against eCTD specifications. We have made a substantial investment in technology that determines whether or not an eCTD submission conforms to all appropriate ICH and regional specifications – and the closer we examined this one, the more challenges we discovered.



Bringing legacy or paper-compliant documents into eCTD compliance can be an unexpected and time-consuming challenge, because the requirements for electronic CTD submissions are far more granular, stringent and detail-oriented.

We adjusted the electronic formatting to make the PDF documents compliant. Despite the challenges – and a tight deadline – we were able to assemble and submit the entire eCTD application a few days ahead of schedule, and produce over 155,000 pages for the required paper component.

## eCTD: You Can't Avoid It, and You May Even Grow to Appreciate It

As our experience grows, we are becoming more and more enthusiastic about eCTD submissions. ►

We have discovered that success is largely a matter of following the same disciplines and utilizing the same technological skills we have refined over the years – since 1997 – working with electronic submission formats. Our regulatory staff has an average of 15 years experience, and our electronic publishing specialists have up to 25 years experience.

One reason for our enthusiasm is the concept of “lifecycle management.” An eCTD dossier consists of distinct sections within modules, rather than a single block, like paper. This enables multiple and quicker turnaround submissions in response to Agency questions for the life of the dossier.

### The Carefully Nurtured Skill of Staying Focused on a Moving Target

eCTD is now the only electronic format acceptable without a waiver for submissions to the FDA CDER division. The EMEA is close behind and moving rapidly toward mandatory eCTD for Centralised Procedure applications by January 2010.

At Quintiles, we’re ready to help you make the transition, through eCTD publishing, document preparation and training. We always think electronic from start to finish, even when working with paper. This makes the transition less complex.

In addition, we stay on top of the constantly evolving details. To stay abreast, we have established a single, global eCTD publishing team that includes representatives from both the US and EU. The global team meets regularly to share new guidances and best practices.

So whether you are working on a US, European or global submission, Quintiles has the technological expertise and knows the latest requirements to make your eCTD submissions less intimidating (and far more routine) than you might imagine.

At Quintiles, *it's all about results.*<sup>TM</sup>

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