

Simplifying the move to compliant eCTD submissions



Faced with the challenge of migrating their global ASMF and DMF submissions into eCTD, Qilu Antibiotics (Linyi) Pharmaceutical Co., Ltd., Qilu Antibiotics Pharmaceutical Co., Ltd. and Qilu Tianhe Pharmaceutical Co., Ltd. (Qilu) turned to EXTEDO for help. Using EXTEDO's eCTDmanager solution, they were able to simplify the process of transferring legacy submissions into the eCTD format, reducing errors and saving hundreds of hours of work.

Qilu is an Active Pharmaceutical Ingredient (API) manufacturer based in China. They are widely known for the development and production of active ingredients contained within antibiotics for human use, including Cephalosporins, Anticancers, and Carbapenems. As a global supplier, Qilu have numerous APIs and products registered around the world. For this reason, they are required to comply with many regional regulatory and quality management practices.

Moving to eCTD was a huge amount of work

With eCTD becoming mandatory in most regions around the world, Qilu was faced with the challenge of creating ASMF and DMF submissions in a new standardized format. Their team had limited practical knowledge working with the eCTD standard, and given a lack of trained staff and inherent language barriers, accurately transforming existing submissions into the structure was proving time consuming and challenging. Qilu were already using an alternative eCTD solution, but their team found it complex and difficult to use. They wanted a clear interface that allowed them to setup submissions quickly and easily.

"The updating of forms was difficult as regional variations meant that each document needed to be just a little different," said Lian Qingling, Qilu Antibiotics (Linyi) Pharmaceutical Co., Ltd's RA responsible for international registrations. "Re-checking the data for each region to ensure that we were conforming with latest requirements was a huge amount work".

Finding the best eCTD solution

To establish the best solution to their problem, Qilu performed an extensive market evaluation. They needed not only a partner that was able to help them optimize their processes, but also someone with an in-depth knowledge of creating and managing eCTD submissions around the globe. They evaluated a number of providers based on their ability to deliver, the quality of their service, the usability of their software, and the overall cost.

Their chosen solution was EXTEDO's eCTDmanager. "eCTDmanager was by far the most user friendly, most functional, intuitive and cost-effective solution we found on the market," said Qingling. They were impressed by eCTDmanager's ease of use and simple UI that allowed them to perform time-consuming tasks, such as creating and maintaining hyperlinks, at the click of a button.

Having to manage hundreds of submissions of various APIs and products from different subsidiaries, Qilu Antibiotics Pharmaceutical Co., Ltd decided to use EXTEDO's Attribute Type Descriptor for eCTDmanager. Using the Attribute Type descriptor allows them to assign additional attributes for different levels of



Finished Products and APIs such as Category, Product and Country as well as to set up virtual folder structures. These have allowed them to group dossiers based on the internal subsidiaries that own them, as well as by product group. “We have found this very useful and convenient, especially when there are lots of APIs and finished products involved.” said Li Hongtao, Regulatory Affairs Engineer at Qilu Antibiotics Pharmaceutical Co., Ltd.

EXTEDO offered so much more

At a basic level, eCTDmanager enabled Qilu to simplify the process of transferring their paper, PDF and NeeS formatted submissions into the eCTD format, but EXTEDO was able to offer much more. “Using eCTDmanager, we are now able to perform eCTD validation for all global authorities, for both APIs and finished products, directly with the tool” continued Qingling. “Not only has this increased our work efficiency, but it

also helps us manage the entire lifecycle of the document in a single place.”

Through their regional presence in China, EXTEDO were able to directly support Qilu on-site. The team also found themselves often working remotely too. EXTEDO’s quick responses to support and regulatory questions gave Qilu a confidence which quickly overcame any initial concerns about time-zones and distance. EXTEDO ensured their short-term success and is now providing them with longer-term technical and regulatory advice.

Since deploying eCTDmanager, Qilu has seen dossier production times fall by around 40% and they are now planning on extending their roll-out to other subsidiaries. “We really appreciate solving this most important problem at Qilu. EXTEDO’s eCTDmanager is a very intuitive solution and we are happy for the cooperation with the whole EXTEDO team”, concluded Qingling.

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