8 things you need to know about eCTDs in China

At the end of 2021, China implemented electronic Common Technical Document (eCTD) submissions to accelerate the review and approval of new pharmaceuticals. eCTDs ultimately benefit pharmaceutical and biotech companies by expediting review times, which means faster approvals and a faster time to market. For the regulatory authorities, eCTDs enable more efficient review processes. Although this is a huge step forward for standardization in the Asia Pacific, there are several important things you need to know before you submit your dossier electronically.

1 Dual language

Chinese dossiers will need to be in Chinese, so if original documents are written in other languages, they must be translated to Chinese, and the original documents must be provided for verification.

2 Paper requirements

During the first phase of the adoption of eCTDs, China's Center of Drug Excellence (CDE) is requesting that paper versions be submitted to supplement the review of the eCTD.

3 PDF e-signatures

The CDE is currently asking for all PDF documents to have an e-signature applied. This will involve adding an electronic stamp to each document at some point in the publishing process.

4 Use of Study Tagging Files (STFs)

Similar to the United States, China is utilizing the STFs for modules 4 and 5. Full ICH E3 formatted reports are strongly recommended, and clinical datasets are required.

5 Accepted date

The CDE will start accepting eCTD applications with their accompanying papers from 29 December 2021.

6 Explanation of unfixed validation warnings

Explanation in a cover letter should provide for any unfixed validation warnings.

7 Dispatch via disc

An electronic gateway will not be available for China in the first phase but is expected to be rolled out in the near to mid future.

8 Use of node extension (3.2.R - Biological Product)

Node extensions will be required to separate out the types of documents to be provided in 3.2.R for biologics only.

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