WHEN YOU START – START RIGHT

USE IWA CONSULTING

Preparing the eCTD to meet the authorities' requirements is a time-consuming task. IWA Consulting can help you get it right from the very start.

IN THE NEXT couple of years eCTD (Electronic Common Technical Document) will be the mandatory format for submission of marketing authorization applications in accordance with the EU and US eSubmission Roadmap. In the EU marketing authorization applications for CPs and DCPs must already be submitted in eCTD format, whereas the US submission types NDA, ANDA, BLA and Master Files must be submitted in eCTD format beginning May 5, 2017 and US INDs needs to be submitted in eCTD format from May 5, 2018. The new requirements mean more demands on life science companies to set up a valid eCTD.

"Especially for many small companies it will be a challenge to comply with the new requirements. Preparing the eCTD is real handwork and a specialized task to have a valid application that facilitates the Authorities assessment process," says Connie Thestrup, Managing Partner at IWA Consulting, one of Denmark's largest regulatory affairs consultancy companies.

IWA Consulting offers regulatory advice i.e. regulatory strategies and regulatory assistance from the early development phase to the submission of the final marketing authorization application and life cycle management.

"IWA Consulting provides quality, safety and efficacy, both for the documentation but also in the way we work," says Connie Thestrup. "The key to a well-structured eCTD is to get the regulatory aspects in place from the start. We can provide that service through a complete training, providing full insight on eCTD and how a document should be structured. We also pursue the know-how for the regulatory angle on the eCTD. A training session helps companies to get an eCTD mindset for the regulatory documentation from the beginning in order to fulfill all the requirements. We also have the possibility to assist in setting up the eCTD in an easy-to-read format for the assessment," Connie Thestrup informs.

eCTD conference in January

To give further insights, IWA Consulting is arranging an international eCTD conference in the beginning of 2017. The event follows up on the November 2014 conference on the same theme, offering a practical perspective on eCTD. The two-day event will be held at COBIS, the Copenhagen Bio Science Park. The conference will feature presentations and discussions with SME and large company industry profiles and representatives from authorities. Some of the topics that will be highlighted involve submission of your first eCTD, outsourcing of eCTD and discussing the eSubmission roadmap for both the EU and the US.

For more information about IWA Consulting and the upcoming conference, visit www.iwaconsulting.dk.

FACTS ABOUT IWA CONSULTING

- **Founded in 1997. The owners and management partners are Lillan Rejkjær and Connie Thestrup**
- **Currently employs 20 regulatory experts**
- **Offers medical and regulatory services in the EU and US**
- **Offers a complete portfolio of regulatory and medical affairs services to support the development and registration of human medicines, including originators, generics, biotech products and medical devices**
- **Specialized in global eCTD submissions**
- **Quality Management System certified according to DS/EN ISO 9001 since September 2009**
- **Office in Køge and COBIS in Copenhagen**