INCORPORATING CLINICAL TRIALS IN GLOBAL REGULATORY FILES

A key concept of building a regulatory file is to start it right from the very beginning. IWA Consulting has generated years of expertise and experience within regulatory services specifically aiming at meeting the global demands for regulatory filing of medicinal products.

Lillan Rejkjær, Managing Partner

Connie Lyngbek Thestrup, Managing Partner

Over the past decade the landscape of clinical trials being conducted in the Nordics have changed.

-In the Nordics we tend to see fewer large-scale phase 3 trials and more specialized trials in rare diseases, cancer indications, or phase 1 or phase 2 trials with highly specialized designs, entailing scientific reflections and considerations that drug developers haven't really been used to before, says Lillan Rejkjær, Managing Partner at IWA Consulting.

-The regulatory implications of onboarding this operational change especially in SMEs, is that drug developers meet different challenges during the development process than before. The point is to stay at the forefront of these challenges by understanding the science and starting the documentation right from the beginning by incorporating the documentation into the eCTD format in an appropriate way, she says.

As of 1st of January 2019 submission of marketing authorization applications in the EU is only accepted in the eCTD format.

The FDA also only accepts marketing authorization applications in the eCTD format; further this is also a requirement for the Investigational New Drug Applications (IND) as of May 2018.

-There is no more paper documentation, so if you want to avoid delays in the regulatory and get-to-the-market process the best way is to start the collection of documentation, using a global platform that applies to both the European regulatory processes as well as the American, Lillan Rejkjær explains.

Local operations with global outlook

Connie Lyngbek Thestrup, Managing Partner at IWA Consulting, seconds her colleague and stresses the thinking around developing and bringing a medicinal product to the market with renewed mindsets.

-Unfortunately, we often see that the scientists, the clinical developers, and the regulatory departments have individual understandings and processes, that tend to collaborate too little across departments. However, it is our experience that the way to success is shorter when you understand building the regulatory documentation for a marketing authorization and start the eCTD in a global format with contributions from all sides, Connie Lyngbek Thestrup says.

IWA Consulting provides the platform and the regulatory knowledge for building the eCTD in a global format.

-Time is of essence in drug development. And starting the documentation right – in the right format from the beginning in all departments of the company is by far the shortest and quickest way to success, Connie Lyngbek Thestrup ends.

About IWA Consulting

- Is a Consultancy Company with core competences, expertise, and decades of experience within regulatory affairs
- The company employs 20 regulatory experts
- The IWA Consulting Team provides regulatory affairs specialists expert services to international private and public clients
- The IWA Consulting Team assists biotech, pharma, and medical device companies in achieving major regulatory milestones timely
- Learn more about IWA Consulting at www.iwaconsulting.dk