IDENTIFYING THE COMPETITIVE EDGE

Small enterprises (SME) and start-ups within biotechnology, pharma, and medtech benefit from expert regulatory advice at a remarkably early stage. IWA Consulting act as a local partner for global development, knowing what it takes to take the biotechnological innovation all the way to regulatory approval and the market.

When biotech innovative compounds and products are taken from the laboratory and applied to both quality development and clinical development, there are an abundance of knowledge that needs to be documented and submitted. Preparing for and keeping track of all the documentation to be ready for regulatory submissions, inspections, and due diligences are essential for survival of the projects.

The start-ups and SMEs are mainly driven by scientists and business developers. Regulatory expertise is rarely represented. However, the strengths of working out a regulatory strategy from the very beginning, are tangible. Just think about it, knowing where you are going and what you are aiming at makes quite a difference, says Lillan Rejkjær, Managing Director at IWA Consulting.

What characterizes a regulatory strategy at this very early stage?

Well, firstly it is highly relevant to know what the competitive edge of your lead compound is; therefore, we recommend doing a target product profile. It takes more than an unmet medical need and a molecule with potential to succeed as a biotech company. The data gaps need to be uncovered – and you need to get an understanding of what your edge is compared to competitors, she says and continues:

An outline of this information highlights what is required from the quality, preclinical and clinical development, and notably it is the information from the development phases that any labeling is based on once you make it to the marketing authorization application, says Lillan Rejkjær, and stresses that if the target product profile proves highly unfavorable, the best advice may be to abort the mission.

The best advice is sometimes not to continue with the compound in question. That may not be comfortable news, but if there is no competitive edge, then the company is better off knowing it from the beginning. Most importantly you need to know how to be competitive and use investments in the most beneficial way with the ultimate aim of improving diseased patients' life.

Electronic clinical trial documentation

Notably, both the European Medicines Agency (EMA) and the Food and Drug Administration (FDA) only accept marketing authorization applications in the eCTD format. Additionally, the FDA only accepts electronic Investigational New Drug Applications (IND). IWA Consulting provides the platform and the regulatory knowledge for building the eCTD in a global format. As it is accepted in the EU to provide the quality part of a Clinical Trial Application (CTA) in CTD format the electronic global format ensures easy preparation of the quality part of a CTA.

There is no longer any ways around doing eCTDs. So, when you start compiling your eCTD, we advise to create a common eCTD from the very beginning which is applicable on both continents, says Connie Lyngbek Thestrup, Managing Director at IWA Consulting.

EU vs US – or both

Often the US market is attractive from an investor's point of view, being much larger and with less restrictions to pricing compared to many European countries.

From a regulatory aspect, there are different ways of working in the US and Europe, and if your business development strategy mainly focuses on the US, it may at first glance seem less relevant to walk the extra mile for a common Dossier. However, the easy solution may not always be the best one, Connie Lyngbek Thestrup says.

Often, the start-ups and SMEs are keen on meeting with the FDA and EMA pushed forward from investors. Lillan Rejkjær recognizes this as a major challenge from a regulatory perspective:

We're in favour of consulting with the regulatory authorities, and we handle this on behalf of both our EU and US clients, however, it is paramount to know your compound in depth. Otherwise, it is not money and time well spent; she ends.

Lillan Rejkjær, Managing Director

Connie Lyngbek Thestrup, Managing Director

About IWA Consulting

- Is a consultancy company with core competences, expertise, and decades of experience within regulatory science
- The company employs 23 regulatory experts
- The IWA Consulting Team provides regulatory science 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
- IWA Consulting is owned by Voisin Consulting Life Sciences (VCLS), a leading global HealthTech product development consultancy company
- Learn more about IWA Consulting at www.iwaconsulting.dk