Nordic Regulatory experts: Improving biotech chances of Success

Why is it that so many biotech companies fail? And what are the tools needed to change that fact?

In order to discuss what to do to increase the chances of success for biotech companies, we met with key experts from LINK Medical, a northern Europe clinical research organization. Joining the conversations was Gunnar Danielsson, Senior Regulatory Advisor in Sweden, along with Lone Dyrby, Regulatory Director in Denmark and Hilde K Holme, Regulatory Director in Norway.

Bringing more value

It is highly beneficial for Biotech companies to partner with a CRO that can take them the whole way. An experienced full-service CRO has an extensive network of experts and has a view on the pharmaceutical drug development with the end in mind. Inevitably, at some point, biotech companies run into regulatory requirements that must be fulfilled so it's crucial to work closely with a strong regulatory team. At LINK Medical, it is important to share knowledge across borders, both geographical and disciplinal.

"Biotech companies have usually a high technical expertise on their product to develop, but often lack the knowledge required in the regulatory aspect. In addition, regulatory requirements might vary in the different countries and regions. It's hard for a biotech company to keep up with the ever-changing regulations in the global market. This is where we can help and really make a difference in bringing more knowledge, value, to our clients," clarifies Hilde K Holme.

"We often ask ourselves; how can we bring more value to our clients? Our goal is always to help them get further in the development of their projects. What we have learnt over the years is that a lot of clients, more than you may think, do not actually have the product or project outline set out beforehand, thus making it very hard for them to know where to start their development," reveals Gunnar Danielsson.

The importance of the TPP

"Most biotech companies fail when it comes to scaling up from research to pre-clinical and/or clinical phases. This is because many employ the trial and error-approach, which is a big risk as it is time consuming and expensive. What they need is a Target product profile, TPP, to steer them in the right direction. A TPP workshop is often a very efficient tool to define the target profile for the product. This is something we have arranged for several clients," says Lone Dyrby, Director Regulatory, LINK Medical Denmark.

Creating a TPP is a task that requires a lot of experience, expertise and knowledge in all areas; including scientific, regulatory, QA and safety, for example. Most small biotech companies lack access to that expertise.

At the same time, keeping it simple is key to success, according to Lone Dyrby and her colleagues Gunnar Danielsson and Hilde K Holme.

"Even though we at LINK Medical have access to large multidisciplinary teams we make a point out of keeping it simple. That is, it should be easy to contact LINK Medical and get the help needed to proceed with early development in any biotech project. We want to be a speaking partner that supports our clients to put plans into action, and at the same time keeping track of how much resources are spent at each stage in the development. We provide a one-point contact responsible for the entire project," says Lone Dyrby.

Regulatory is not one thing but many

Bearing in mind that a drug development project may contain hundreds, or even thousands of steps, all needed to be considered and documented, LINK Medical provides valuable information and support all through the development process.

"Regulatory is not one single aspect – it is ever-present and affects all aspects of the development process. This is why we are so important in our clients' project; we can provide the tools required to successfully bring any project further and on to the next stage. It is all about experience and having access to an extensive network of experts. Just as an example of how complex things can be, a drug development program within the major pharmaceutical industry usually requires the expertise of around 800 people in various functions. Most biotech companies do not have access to those resources, but LINK Medical can through extensive partnerships across the world help in finding these functions," concludes Gunnar Danielsson.

LINK Medical is a full-service contract research organization (CRO) providing product development services for the pharmaceutical and medical device industries across Northern Europe. With one of the largest full-service regulatory team in the Nordics we offer local Regulatory expertise in all Nordic countries. Reaching from early phase development to post-marketing, we provide specialist guidance across every aspect of a project – all from ONE source.

For more information contact us at info@LINKMedical.eu or visit us at www.LINKMedical.eu