Jan Hellqvist – General Manager, KLIFO Sweden



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With almost three decades of experience in the Swedish life science industry, Jan Hellqvist, general manager of KLIFO in Sweden, explains why the country has seen the number of clinical studies from small and medium size companies skyrocket in recent years. Moreover, he discusses the possibilities of opening KLIFO's affiliate and his strategy to position the Danish CRO among the best in the region.

You just joined KLIFO to open the Swedish affiliate last month. What are your first impressions of the company?

KLIFO is a very unique company, it is not a typical CRO. It is more of a house of senior consultants supporting our clients from target product profile to market authorization, and beyond. It is full of experienced people, especially from the Danish pharma and biotech industries. We have consultants with past experience at Novo Nordisk, Lundbeck, LEO Pharma, Ferring, among others. It is a truly Danish company but quickly developing into an international one. The focus clients are early startups, small companies and medium size companies in both pharma and biotech. We do all of the work on the regulatory strategy side, the documents needed to take the drug into a clinical environment, all the way to approval. KLIFO also does clinical planning to understand which types of studies they should do so they can reach the market as quickly as possible. We have a great

number of doctors and medical advisors in that area. Another important aspect to us is the development of the formulation of the drug, whether it is a tablet, cream or injection; that is very unique for a CRO. We support our partners from CMC strategy to market in this area.

KLIFO understands that small companies need knowledge and senior advice on the best route to market for their specific drugs. To date, there is not a Company like KLIFO in Sweden. The company has had great success in Denmark and is now the largest Drug Development Consultancy in the country, working both with large pharma companies and small biotechs. Most of the small biotech companies in Denmark are supported by KLIFO; we support some of them on everything: support for the board, CEO, inventors, and all of the drug development. We can even support them with logistics in the clinical studies to store pharmaceuticals and global logistics for phase I-IV in any country. No other small or medium size CRO is able to provide all of that.

Why did you decide to take on the position as GM at KLIFO?

First of all, I have a long friendship with KLIFO's owner Alejandra Mörck; we have known each other for more than a decade and I saw their success in Denmark. Knowing the Swedish industry, I understood the unmet needs for SMEs; there is no CRO in the country able to match KLIFO's service offering. The unique capabilities of KLIFO attracted me to the company. After almost 30 years in life science, I understand the needs of the clients in Sweden.

Entering a highly competitive Swedish CRO market, what services will you offer to the country's pharmaceutical and medical devices industries?

We offer a complete range of services of KLIFO in Sweden. This includes QA, regulatory, pharmacovigilance, CMC (formulation and regulatory), medical and scientific advice, clinical operations and clinical trial supply. The south of the country is used to collaborating with Danish consultants, which is a plus for us. The aim is to grow the company and the market as fast as possible, but we already have around ten Swedes employed. Our focus at the moment is in the south of Sweden and the Gothenburg area; eventually, we will also expand to the Stockholm and Uppsala region.

What are your priorities to kick start KLIFO in Sweden?

My main priority is to put KLIFO on the Swedish map and get pharma and biotech companies to understand the different ways in which we can support them. We are very different from the typical CRO. I am taking advantage of my network to do as many customer visits as I can to achieve that. We are attending conferences, using internet tools and doing face to face meetings, which I believe have a better effect.

We have visited companies in cancer immunotherapy, which is one of the core areas for KLIFO, and also neurology, endocrinology and other areas in which we have great competence.

How does KLIFO's business model differentiate from other CROs already established here?

The most important priorities for small pharma and biotech companies are the need to develop their clinical planning and the first clinical studies. They must have a regulatory plan in place so they can approach the authorities early on. The companies must decide if they should aim to meet the FDA, EMA or a local agency like the Swedish Medical Products Agency (MPA). The formulation development also requires a detailed plan and we can support them in all those aspects. No other CRO in Sweden can do it, apart from the big multinational ones like IQVIA but in this case without our level of flexibility. KLIFO has the ability to support with good manufacturing practices (GMP), good clinical practice (GCP) and good pharmacovigilance practice (GVP); we have a strong quality assurance department that can set up whatever is needed. Our clients need standard operating procedures, a quality management system, and we can support them in that as well.

KLIFO's CEO Alejandra Mörck mentioned to us that one of the advantages of the company, compared to CRO giants like IQVIA, is that smaller clients will not end up at the end of the list of priorities. What do you say to those small to medium companies looking for a research and development partner?

Being a priority is absolutely a big concern for SMEs. They might have tried one of the global CROs once, but most of them will never do it again because they are not a priority. The large CROs focus more on phase III and phase IV trials. Smaller clients require a high degree of flexibility; KLIFO provides that.

Sweden is the second country in which KLIFO has opened offices in the past year, why do you believe the company chose Sweden as a new market?

The MPA has said that the number of clinical studies in the country has remained fairly stable, but if you talk to the Swedish Association of the Pharmaceutical Industry (LIF), they would say that the number of studies has decreased. That is because LIF is responsible for the large pharmaceutical companies and they are doing less studies in Sweden. SwedenBio, on the other hand, says that the number of trials for small companies is skyrocketing. There has been a shift and KLIFO is well positioned to supply the demand here.

What has driven the increase in clinical studies from SMEs?

We have all been fostered in either Astra or Pharmacia and it has taken a few years for their former employees to reach a certain degree of success. Everything is happening as we speak. There is a large number of interesting startups, for example, two of the most promising drugs in Alzheimer's disease are from Swedish companies like BioArctic and Alzinova. For KLIFO, supporting the startups in Sweden to reach success is a privilege.

SOBI, for example, is thriving thanks to that surge in startups coming from universities. The ecosystem in the country is perfectly set up for them to succeed; we have great universities, incubators and funding to take the drugs into a clinical setting. Vinnova, the Swedish Governmental Agency for Innovation Systems, does a very good job to add to that infrastructure. I hope that more pharmaceutical companies will be formed and that this becomes a trend. Sweden needs more pharma companies to develop pharmaceuticals.

Considering that one of the Sweden's most important assets are the Quality Registries, how will you take advantage of them to produce better outcomes for KLIFO's partners?

In clinical studies where you cannot have a placebo arm, for example, you can use registry data to compare yourself to a clinical outcome. That is increasingly being approved by authorities. The Nordics, and especially Sweden, is the place to go for registry data. When I was at Stryker, the Swedish hip registry was used globally as the way to evaluate hip surgery. The endocrinology registry is also used around the world. The only downside is that it takes a long time to obtain the information, but I know that LIF and SwedenBio are trying to work together with the government to accelerate the process.

You have a long career in different global and local pharma, medtech, diagnostics and CROs. How will you leverage your vast knowledge of the industry in Sweden to make KLIFO succeed?

The challenge is always finding the right client with the need for the services KLIFO can provide. There is high number of them, so the future looks enormously promising. Looking towards the future, I expect KLIFO to open an office in Gothenburg and Stockholm or Uppsala to have a strong grip in the region. The opportunities to grow are really good right now.

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