Ejvind MÃ¸rtz â?? Co-Founder & COO, Alphalyse

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Alphalyse is a Danish contract research organization (CRO) specialising in protein chemistry, mass spectrometry, and bioinformatics. The firmâ??s co-founder & COO Ejvind MÃ¸rtz outlines its journey since its foundation in 2005, the evolution of the specialist CRO space, and the significance of AI and data integration.

What is Alphalyse and what niche were you trying to fill when you created the company?

In 2005, Alphalyse spun out of a small biopharmaceutical company named ACE BioSciences which discovered and developed novel vaccine candidates and targets for monoclonal antibodies. Alphalyse was founded by Thomas Kofoed and myself and as a daughter company, conducting analytics of the biologics that ACE BioSciences developed.

The objective was to provide protein analysis services to the scientific community. The business model was based on e-commerce, electronic marketing, and email to provide services to laboratories around the world. This required making complex protein analyses into convenient products.

The main customer segment was academia due to their limited needs around simple protein analysis. At one stage we had approximately 350 universities around the world as clients which established Alphalyse as a global company.

Approximately 10 years ago, the focus changed towards companies developing new biologics and protein-based biopharmaceuticals. This is the area that could help people the most and create the most value, however, it required a higher level of expertise in Alphalyseâ??s labs, knowledge of process development for the molecules, and general quality control practices.

Is the pharma industryâ??s embrace of outsourcing the main trend affecting Alphalyseâ??s business today?

Most of Alphalyseâ??s service is based on mass spectrometry analysis which is an advanced scale for weighing complex biologics. The accurate molecular weight of the protein is critical in the quality control of biologics and can lead to investigations into product variants and side products in manufacturing.

This advanced technique requires highly skilled scientists for the analysis to prepare the samples for analysis, operate the complex instruments in the lab, and interpret the data in order to simplify its complexity into understandable reports.

As a result, this level of complexity and the cost of the equipment in makes this niche area ideal for pharmaceutical companies of all sizes to outsource to Alphalyse.

How has the feedback that Alphalyse provides to clients evolved over the lifespan of the company?

The feedback has evolved into an open dialogue with the clients. Alphalyse talks to the client to understand the product and their needs. The laboratory work is then completed on this advanced instrument for a report to be compiled and a draft sent to the client.

Consequently, the dialogue opens to understand the interpretation of the data, the significance of the results for the product, and the next steps in the productâ??s development. This collaboration with clients has changed from Alphalyseâ??s beginnings, when customers would simply purchase the analysis and receive the reports.

What projects does Alphalyse predominantly deal with today?

Alphalyse has invented and developed a world-leading impurity analysis technique by mass spectrometry that can identify and quantify impurities.

As a result, ongoing projects in clinical development require this new technique to avoid compromises in the productâ??s purity and stability. This has lead Alphalyse towards analyses of products in late clinical phases and products approaching commercial status. Currently, Alphalyse is setting up a GMP accreditation to support the manufacturing of biologics for clinical trials.

In terms of the companyâ??s operations, does it still work through remote engagement where the clients post their products to you, you analyse it, and then feedback remotely?

Yes, although today more virtual meetings are involved in initiating a project, discussing it, and setting objectives. Alphalyse will then make a product proposal in writing and potentially modify and improve this proposal before it becomes a real project. Subsequently, the customer ships the samples to Alphalyse, the samples are analyzed, and a report is sent electronically to the client with an additional meeting to discuss and interpret the results for a final conclusion.

How, as a CRO, do you deal with new technology platforms and new science to stay ahead of the game and continue to provide this high-quality feedback?

As a CRO, Alphalyseâ??s methods have to be robust and general to apply to a variety of biologics from multiple biotech clients.

Current trends, such as new gene therapies, have complex manufacturing. Therefore, Alphalyse has adjusted its methods to analyze these gene therapies and cell therapies. The companyâ??s techniques can be used because these products also contain proteins.

Consequently, the advantage of the companyâ??s general mass spectrometry method is that it can be adapted for a variety of biologics, monoclonal antibodies, vaccines, viral vaccines, gene therapy products, and therapeutic proteins made in different manufacturing systems.

Have you seen a rising demand for your services for COVID-19 vaccines or therapeutics?

The pandemic has put a greater focus on developing new biologics and ensuring their purity and safety. This supports Alphalyseâ??s business model through the importance of having safe drugs and good quality controls.

However, Alphalyse has not encountered the same direct business rise due to COVID-19 as other biotechnology or life science companies providing e.g. diagnostics for Covid-19.

How does AI and data play into your operations today and is it more important than it was previously?

The old impurity technique, HCP-ELISA provide a single number for the level of impurity in a product, whereas Alphalyseâ??s mass spectrometry methods specify the entire list of impurities, leading the company to be data focused and data driven.

Alphalyse generates huge amounts of data from the repetition of the same technique for different biologics. Therefore, artificial intelligence is required to interpret these results with bioinformatics experts searching for potential learnings using this information.

Moreover, information automation and data management have become key focuses to generate further revenue by lowering the cost of each analysis. Similar to other Danish organizations at the forefront of digitalization, computers and software robots have been used to automate many workflows in the business.

What is the competitive landscape like today for a unique business model such as Alphalyse?

There are a number of other CROs working in this same space, however, the relatively small size of Alphalyse allows it to be more flexible and faster adjusting to customer needs.

Looking to the future, is there enough talent available locally or will Alphalyse have to look internationally for highly skilled employees?

Alphalyse and its employees are already international. The official language in the company is English and the majority of clients do not speak Danish. Therefore, Alphalyse considers itself to be international and appreciates its growing multiculturalism. Scientists with mass spectrometry expertise are recruited from the the local University of Southern Denmark.

New employees are increasingly focused on quality control and biological development with the skills needed for later-stage biologics development. At this stage, Alphalyse has not had problems finding talent for these positions due to the presence of large biotechnology and pharmaceutical companies such as Novo Nordisk and Novozymes, and their respective manufacturing facilities in the region.

Is the pool of bioinformatics workers available in the region as the work becomes more data driven?

The bioinformatics education in the region is of a high quality and Alphalyse collaborates with university professors to develop new algorithms.

What are your goals in the medium term and how do you hope the company will continue to evolve?

The general trend in making new biologics requires greater control over manufacturing processes and product quality. New techniques developed by Alphalyse such as mass spectrometry help companies create products that are cleaner, safer and more consistent through full control of product and process related impurities.

As these methods grow in demand from both manufacturing and regulatory authorities, Alphalyse will become the key developer for the new analysis of tomorrowâ??s medicine.

What would your final message to our executive audience be?

Alphalyse has transformed itself from basic research in a local university to become a leading support player in the manufacturing and development of new biologics. Furthermore, the company will continue to explore the fields of digitalization, automation, big data, and the opportunities presented by these areas over the coming years.

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