

Interview: Ruud Santing - CEO, Sinensis Life Sciences, The Netherlands



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The Netherlands boasts a strong service sector for the life science industries locally and globally. Sinensis Life Sciences CEO, Ruud Santing, discusses his company's history and its offering that covers the whole range of pharmaceutical testing and of small-scale manufacturing of clinical trial materials.

Sinensis Life Sciences was founded in Leiden in 2012. To start, can you please tell us about the company's history?

My background is as CEO of PROXY Laboratories, which was founded in 2001. In 2012, we acquired MicroSafe Laboratories from Merck Millipore, and, later that same year, we merged with our main competition - Bactimm, Farmalyse, and Prolepha Labs - in Zaandam, Nijmegen, and Etten-Leur - to form Sinensis Life Sciences. Sinensis is thus quite new, but our base companies have the tens of years of experience that make us a trusted and reliable independent provider of laboratory testing and manufacturing services to the international life sciences market.

Today, Sinensis stands as a fast-growing sweet orange, with its parts being the different laboratories, all growing and developing. Indeed, our name is derived from the scientific name of the common orange, *Citrus Sinensis*, and was chosen not only because of the Dutch national color

but because of the distinct parts that make up an orange and its appealing nature – sweet and fast growing. As an image, each company within the Sinensis grouping is a discrete segment of the fruit. In the microbiology area, we have Bactimm for basic testing and Micro Safe Laboratories for advanced testing – such as mycoplasma and virus testing – and ProBase Pharma, a joint venture with BaseClear BV, for high-end molecular biology techniques. In the chemical area, we have Prolepha Labs for basic testing, while PROXY Laboratories covers more advanced testing.

In 2014, Sinensis acquired Spinnovation, expanding and strengthening our chemical R&D group given this laboratory's expertise in solid state and liquid NMR, as well as mass spectrometry (MS) and inductively coupled plasma (ICP) spectroscopy analyses. Spinnovation is now thus our chemical testing branch for very advanced techniques.

What interactions exist between these sites, and what synergies do you try to foster?

All our companies started by addressing a niche, and we have decided that all sites will remain in the Netherlands with their own name, their own culture, and their own independent manager. Biology and chemistry labs are extremely different working environments, and staff have quite different mentalities. There is thus no reason to combine them. Furthermore, the Netherlands is home to several life science hubs, and being present in these different hubs means that clients can visit our offices on foot or bike, bringing samples with them.

On a higher level, the sites joined forces, which means that associated functions like IT, HR, or marketing are covered at the group level. This removes a burden, so that our workers can devote themselves to lab tasks they enjoy, rather than administrative tasks. Overall, Sinensis as a larger grouping has a more international posture, being able to act as a one-stop-shop service provider. If you work with business in this sector of the market, we have a 90% market share in the Netherlands.

Interactions do occur in so much as a client first approaches Sinensis for a specific service from one of our companies and, with time, will come to use a broader range. For example, young biotechs are initially only interested in a small portion of our services, but in the next phase of financing, they will need, for example, our manufacturing facilities.

How have you tailored your services to attract more biotech companies?

Our manufacturing facilities have been built simply to address the biotech companies. Crudely speaking, biotechs are comprised of a science guy and a finance guy. These biotechs have a nice product but need to develop methods, determine stability, make standards etc. By the time they

raise significant money, it is sexy to have contracts with big service companies. However, small biotech companies are small clients for these large players and are thus near the end of the row.

We decided that since we had both the facilities and staff accustomed to such an environment, we could also introduce a manufacturing service more suited to biotechs. For a company's first GMP batch, bills totalling a million euros are not uncommon with larger CMOs, while at Sinensis we keep costs low via a more simple procedure. To manufacture a first batch, we use our staff, rather than fancy equipment, to move the batch in a sterile fashion, allowing even the remainder material to be used for analysis. The end result is a much lower price tag and hardly any loss of product, making Sinensis a very economically attractive prospect for clients. It is important to keep in mind that this batch is used by biotechs in their clinical trials and is thus essential to their continued raising of funds.

Furthermore, we have QP services and can undertake all analytics; we can develop methods and establish stability. Unlike other CMO's we have a small manufacturing unit and a very big analytical laboratory. This set-up also means that we are able to attract and assist biotech companies earlier in their life cycles.

You serve over 700 clients worldwide? What is your client breakdown, both in terms of geography and company type?

Sinensis' flexibility, reliability and ability to deliver a high comfort feeling have attracted customers from biotech start-ups to multinational generics manufacturers to big innovative pharma players. The nice thing about being located at Leiden Bio Science Park, Pivot Park in Oss or in Nijmegen, is that we go along the entire life cycle of companies present locally. As such, when a Biotech neighbour first started here in Leiden, they outsourced all testing to Sinensis. They then raised capital and brought some functions in-house again, but when demand rose, they once again outsourced to Sinensis, and today we test their commercial batches, including the post marketing stability studies. In addition, we also provide services to generics companies, such as commercial batch release testing, and biotech companies, developing methods they could not develop in house.

In terms of geographies, we of course have a wide client base in the Netherlands and across North Western Europe for the UK to France, Germany and Scandinavia, but we also have many clients in developing markets. India is a market of interest where we currently have about 20 clients, and the Middle East is booming for us. As one example, in Lebanon, any company can register, but all companies must have their first three batches tested by WHO certified companies. We are one of

the very few WHO prequalified companies in Europe. Finally, the high-end NMR testing services available under GMP at Spinnovation is quite unique on a global level and attracts many clients from the United States.

What makes Sinensis the partner of choice for your clients?

The most important factor to be a good partner is to know the quality. A further step ahead, we also know what our clients are up to, and, it is thus not always answering a question but rethinking it. Finally, we are very fast and flexible. Our turnaround time for standard analysis is usually twice as fast as the in-house laboratories of manufacturing companies. We thus have clients that do not send samples to their own laboratory but come to us since we can give results more efficiently.

What elements make the Netherlands an attractive eco-system for both testing and contract manufacturing?

We are reliable, do not have any strikes, and transport is very good thanks to both Schiphol airport, which is even closer to Leiden than to Amsterdam, as well as the Port of Rotterdam. You can send your samples by plane and your shipments by container to Rotterdam, so logistically we are a perfect hub. However, the Netherlands is a very small local market, given that everything must be in Dutch for local consumers. Market introductions are usually thus done more often in the UK, Spain, Italy Germany, or France, which are then expanded into the rest of the EU. Many small biotech companies, though, chose to do this in the Netherlands, as registration is easier here than in Central and Eastern European countries for example.

Are you looking to acquire any new targets here in the Netherlands or abroad?

In our sector, chemical or micro testing we already have a 90% market share, so we are looking to expand more in terms of new testing areas such as bioanalytical testing, especially for human bodily fluids, next-generation sequencing testing, DNA testing, and in healthcare testing. We are looking at targets in North Western Europe, where there are many cultural similarities with the Netherlands. There are already significant players in the British market, so we are not looking there, and we have decided not to look for targets in Southern, Central and Eastern Europe.

Last month, Sinensis and ViruSure announced a partnership. How does this partnership strengthen Sinensis offering? Are you looking for more outside partnerships in the near future?

Viral clearance is a typical job that requires a lot of expertise to undertake, such as is present at ViruSure in Austria. ViruSure is a leading player in the field of virus and prion testing service, with

strong expertise in biopharmaceutical biosafety testing based on state-of-the-art technology. The partnership thus allows us to offer an even more complete portfolio of testing to our industrial clients.

Overall, we join forces in general with companies that bring added value but do not want to be part of our group and currently have five to six such collaborations. We are always looking for outside partnerships for areas we do not wish to bring in house.

To look at one specific project in the news as of late, Mr. Kemperman and Mr. Willemse at ChemConnection and BioConnection were extremely proud of the Combidex's 'Nano suspension' project. Can you tell us more about Sinensis' contribution, and the unique challenges this project presented to you?

The Combidex project involved a combination of manufacturing and analysis. The API was manufactured by ChemConnection, and the filling in the vials was done by Sinensis. BioConnection is the broker that brought all collaborating parties together. The final result, a nano suspension, was black. However, one of the sterile requirements of fill and finish is to complete a visual inspection of your vials. How do you do this when the product in the vials is black and contains particles? We thus had to invent a new method for inspection. As such, the project was a case to not simply follow the existing rules but rather to establish them.

"Sinensis: We Provide Solutions." Given your company slogan, can you please tell me about the solution Sinensis has been able to provide over the last three years of which you are most proud of and showcases the company?

One example is a single nasal spray device to deliver small doses of opiates to patients. Such a device should be present in every doctor's bag and can be placed in the nose of a patient in any position, regardless of whether they are anxious or having an epileptic fit, to end symptoms. The trick behind our successful design was to deliver a very small volume (100 microliters) into the device in a completely aseptic manner. I do not think any other company can do this.

Looking to Horizon 2020, what would you like to have achieved in the next five years?

I want to expand into more service areas, such as bioanalysis and medicinal cannabis, a current area of focus. We are finalizing a facility to produce clinical trial material - both placebo and products - for all kinds of medicinal cannabis. Entering this market is quite difficult given both the challenges related to recreational drug use and the current lack of regulation in the medicinal cannabis field. We are thus developing analytical standards and methods for this field to first bring

to European regulators and then share on a global level. To further our efforts in this field, we are working with a company that hosts a GMP facility for producing hemp plants, as well as the Bureau of Medicinal Cannabis, one of the Dutch authorities.

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