

# Interview: Alexander Willemse - CEO, BioConnection BV, The Netherlands

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*The CEO of BioConnection, the leading contract services and manufacturing organization for the development and production of injectable (bio)pharmaceutical products, explains how —thanks to flexibility and quality-driven mentality —the company helps small and medium biotech companies and universities make their products reality.*

**This year BioConnection celebrates its tenth anniversary and you have led the company as CEO since 2008. How has BioConnection evolved over this time period?**

BioConnection aims to be a partner with high-tech, high-end facilities and a one stop shop attitude. Our specialty is to provide tailor-made solutions for our clients by utilizing our best-in class network of development and manufacturing partners. To better understand BioConnection's development we should go back to 2005, the year in which the company was established. Back then Organon, the largest Dutch independent pharmaceutical company, at that time part of Akzo Nobel, opened their new pharmaceutical pilot plant in which BioConnection co-invested. The idea was to help start-up biotech companies by offering them the Organon expertise in production, formulation and analytics through the project management of BioConnection. It was an interesting business model because by co-investing BioConnection did not become owner of any asset, but became part of the

capacity of the plant while also having access to development expertise and assets.

Since then a lot has changed in Oss. In 2007, Organon was sold to Schering-Plough, which later merged with MSD, and, in 2015, MSD decided to shut down its pilot plant facility in Oss. This led to a reexamination of our business model. As a result, we have decided to take on the entire pilot plant in 2016 to ensure that we can cater to all existing customers and expand our capacities. We will focus on the sterile production capabilities at first, but the building also has a full set of solids equipment and is flexible in accommodating other environments like medical devices. This represents a major shift in our strategic direction, moving from a lean-mean company with no assets on the balance sheet and acting as a solutions provider to an organization owning an entire manufacturing site. The basic principle of solution provider will not change; rather, it will be strengthened. Overall, I am certain that this risk will lead to fruitful rewards for the company.

**In what ways was it a challenge to be one of the first real companies operating at Pivot Park and to still be one of the few that are operating commercially?**

A science park, like Pivot Park, should contain a healthy mix of innovative companies and service providers. As “innovation” is led by the startup companies, they should be the majority of the inhabitants of such a park. I think Pivot Park is doing a good job but it takes time to grow and mature.

**How competitive is The Netherlands in the life sciences market and, in particular the contract-manufacturing organization (CMO) market, in a global context?**

The Netherlands stands out from competitors for a number of aspects. We are very open to new customers from different countries; we, being Dutch, are straightforward and direct; and we are good negotiators, as we’ll always come to an agreement. Rumor has it that “You can always talk with Dutch people.” On the other hand, The Netherlands —and Northern Europe overall— is in general not well equipped for low-value/ commodity productions. If a customer is interested in low-value/commodity generics, I doubt we could be competitive. In the middle to high-end value/ high tech segment we are seeing though a lot of productions, as clients are ready to pay for a more quality-oriented manufacture and an environment they can have under control—and that is exactly what we can offer at BioConnection.

**In most of your activities you use active pharmaceutical ingredients (API), which will be filled by your company into vials, ampoules and or syringes so that the API eventually can be administered to patients. The API segment represents according to the Association of the Dutch Chemical Industry represent approximately 50% of the USD 15**

**billion specialty chemical market in The Netherlands. Do you think the quality-driven mentality of Dutch people also applies to production of APIs?**

I would say: YES. The level of education in the Dutch API/chemical industry is very high. Most companies in this segment are highly specialized in complex chemistry and rely on state-of-the-art facilities. Also, an important aspect to consider is the intellectual property (IP) environment, as very often APIs are patent protected — and IP protection in the Netherlands is very high. I think as a country we should be strong in expertise, quality, and integrity and that of course has a price tag

**When you compare BioConnection's business model to lower-cost structure competitors in other markets, in which key areas do you bring the value to justify a higher price?**

At BioConnection, we offer flexibility, experience, and the willingness to think with our customers. Last week I had a discussion with a US customer that contacted us to fill different products in separate vials to be mixed later into one vial for administration. We suggested opting for a syringe for one of their formulations, as it would make the mixing process much easier and therefore safer at the bedside. They were positively surprised, as none had envisioned this simple option before but all were only focused on the question asked. When customers present their problems, we try to find a practical & economic solution for them and not simply take their request as it is — this is highly valued. We like working with customers that are open to discussion. Indeed, it's something easier to co-operate with small companies than with large world wide players.

**Does this mean you prefer to work with smaller companies?**

We also work for leading pharma companies because they take over our customers. The drawback of working with big pharma is that they come to tell you how things must be done even when we have a quality system that was approved by FDA. For big pharma companies we are just only a CMO —maybe a particularly flexible one— but still only a supplier. Indeed our drive and spirit comes from helping young biotech companies and even university professors to bring their ideas from the lab bench to the market.

**BioConnection's website states the company is part of a network of suppliers and can help customers find the service, products and knowledge they're looking for. How would you describe your role within it?**

We are an integrator. It's a small network of companies, and we all know each other. If we cannot help the customer, we recommend them further. We link the whole chain and bring projects to our network partners, they would not have acquired by themselves.

**What are some of the most important product developments you have been involved in in recent years?**

Although there are many, we can only disclose a few. One of our most important projects that we can disclose was Combidex® (a nanosuspension formulation), a revolutionary product by SPL B.V. which was originally initiated by Professor Jelle Barentsz from the Department of Radiology and Nuclear Medicine of the Radboud University Medical Center of Nijmegen. The product represents an important step forward in lymph node imaging to enable earlier cancer treatment. A few years ago we were contacted by the university, as they did not know anyone who had manufactured a similar product before, and within six months BioConnection and ChemConnection, another company in Oss offering services in chemical process R&D and API manufacture, had it up and running. People from the university were very surprised that we were able to develop their product in such a short time. They told us afterwards they would have never expected us to be so successful. The product launch was even on the Dutch media: we were not mentioned, but we knew we were part of its development and were very proud of it. Currently Combidex has evolved in a mature product and is managed and further developed by the enthusiastic people of SPL.

**Can you tell us more about a unique project undertaken by BioConnection that you are particularly proud of?**

One of the projects we are currently running is an orphan drug which we commercially produce for the US and EU market. Most CMOs are not interested in a product that only sells around 10,000 – 20,000 vials per year, but we have access to a small-scale FDA-approved production facility that perfectly matches these niche market products from a quality and economic perspective.

**In this vein, what other types of projects do you feel BioConnection could contribute the most to in terms of knowledge, experience, and capabilities?**

Our unique business model allows us to easily adapt to different customer needs. Furthermore, our state of the art facility in Oss and our network of manufacturing partners allows us to be able to implement customer specific equipment and needs, from clinical scale up to commercial FDA scale. This flexibility, combined with an enthusiastic team is unmet in industry and allows us to take on projects from easy fill and finish or freeze-drying up to advanced nanoparticle formulations.

**Given your involvement in the early stages of product development, what is your overall impression about the start-up and biotech environment in the Netherlands?**

I think we have a lot of talent and people with expertise, but I doubt we have enough entrepreneurs really willing to start a biotech company. It's much easier to join the industry and earn money through the pay-roll rather than starting your own business. It seems it feels not rewarding and it still is difficult to get the necessary funding. Most of our new customers, for instance, are not from The Netherlands, and I think it's mainly because of funding issues and because we are too conservative. In the US, it's very different: if you haven't gone bankrupt at least once in your life, you are not an entrepreneur. We have in Netherlands expertise and bright ideas, and it's a shame too often these are transferred abroad, as in my opinion real innovation comes from the bottom.

**BioConnection stands as an example of Dutch start-up success. As such, do you have any recommendation for upcoming start-ups to get over these hurdles and move towards the path to success?**

My advice would be: "Just do it." I don't have a practical solution, and I feel the money may be there, but it does not reach young entrepreneurs. I think they should stand up and bring out their passion, even if it's economically not justified, as it all starts from the bottom.

**With BioConnection now ten years into its journey, where would you like to have taken BioConnection in five years from now?**

Our business model will remain the same: we'll still be the solution provider, but I'd like to utilize our facilities for "fast track" development of complex formulations and commercial production of niche products and orphan drugs, as we think this market segment is underserved. Currently we cannot provide these services because the production facility was in the hands of the big pharma company MSD, which was limiting our range of services. Logical, as they only needed their own line of products. Today we are only using 10 percent of the capabilities of our plant in Oss, and in the future I'd like to take advantage of the remaining 90 percent. The ever remaining question is: how to reach customers looking for our extended services and how to make sure they reach us. That's the challenge we are taking over for the coming five years. Fortunately my team has at least the same enthusiasm that I have.

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