Interview: Dr Gerjan Kemperman â?? CEO, ChemConnection, The Netherlands

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Nanomedicine is expected to become the third pillar of drug development following pharmaceuticals and biologics. The CEO of Dutch contract research and manufacturing organization ChemConnection explains how the company helps customers bring nanomedicine drug delivery systems and APIs from discovery to clinic, fast.

Could you please introduce ChemConnection to our readers around the world?

Established in 2012, ChemConnection is a contract research and manufacturing organization (CRO/CMO), offering services in chemical process R&D, cGMPs manufacture of active pharmaceutical ingredients (APIs) and nanomedicines (mostly Drug products). We built the company on two pillars: APIs and nanomedicine, which is, though, where we see our greatest opportunity to innovate. Today we rely on a team of 32 people, encompassing analytical scientists, R&D and manufacturing, and are working for customers based in the US, Europe, and Israel. The area in which we are mostly active in is bringing nanomedicine drug delivery systems from discovery to clinic. We currently have customer products in phase I, Phase II, and Phase III. We rely on the

complete required expertise and licenses from the Dutch Ministry of Health to analyze and produce nanomedicines. Also for APIs, customers approach us to help them bring products from discovery to clinic. Nanomedicine and APIs seem to be very different pillars, but are actually not, as they rely on the same technology: nanomedicine requires chemistry and formulation science, but also new chemical structures, which require GMP production, as otherwise they cannot be used in the final drug delivery system â?? and thatâ??s where our API chemical expertise comes in.

What was the biggest challenge you faced in founding ChemConnection, and how did you overcome this challenge?

Establishing the first customer contracts at the time that ChemConnection was founded was challenging. But also the timing in taking over the former Organon/MSD pilot plant in the then recently established Pivot Park and at the same time in aligning the team of key people to start the company with was very complex. In small team we needed to capture the essential capabilities in R&D, manufacturing and GMP. We succeeded in this because of the open communications we had with the former Organon/MSD colleagues that we wanted to be involved about our steps, progress and challenges. At the moment we launched the company all required people decided to join our team. Thanks to these people and those who joined our team subsequently we have been able to develop the company very quickly from start up to R&D and GMP licensed manufacturing company.

ChemConnection was elected â??Promising Entrepreneur of the Yearâ?• in 2014. What has been the key to this success?

Our story is the result of unusual circumstances. First, the facilities. The creation of the Pivot Park campus in Oss opened up a lot of opportunities for many companies, as in our case. We were able to take over a huge state-of-the-art pilot plant, set up a GMP quality system, and have it running very quickly. Second, and thatâ??s probably the most important aspect, a strong team. Our people have both a good education and strong experience within major pharmaceutical companies. We were able to assemble a team of people, who do not need to be told how to do things. Everyone relies on a solid scientific background, which has allowed us to help customers with very complex problems.

ChemConnection developed its own proprietary Continuous Flow Reactor (CC2NanoÂ®) for the manufacture of drug-loaded nanoparticles. Could you please elaborate on the impact this innovative technology has on the services you can offer to clients?

The CC2NanoÂ® allows us to scale up nanoparticle products very quickly from milliliter to liter scale without affecting product qualities. During traditional batch processes every step has its impact on the product characteristics â?? something that should be avoided if you want to bring a product from delivery to clinic fast. We have been able to demonstrate that we are able to bring a product development from milliliter to multi-liter scale in a matter of months. Although we are still exploring the whole extent of the technology, it has helped us thus far bring for example liposomal product developments from discovery to clinic faster and in a more reliable way than with traditional manufacturing processes.

What types of projects do you feel ChemConnection could contribute to the most in terms of knowledge, experience, and capabilities?

ChemConnection is a scientifically strong company. Over the past few years we have been taking on complex, uncertain projects. We can help with any complex small molecule product or nanomedicine delivery system. Iâ??m pretty confident for nanomedicine delivery systems we are one of the best options for our customers, as companies from Canada and the US have approached us to help them. They would surely look for someone closer before coming to a young Dutch company on the other side of the ocean. Also, besides the contracts we have already signed, we have received visits

from all over the world. Without doubt other companies are doing the same somewhere else, but probably not as many with our same level of expertise in nanomedicine development.

What would you say is the typical profile of your clients? Are you working only with start-ups and small and medium enterprises (SMEs) or are you also working with big pharma?

The majority of our customers are SMEs. We work with some big pharmaceutical companies but nanomedicine is still a field where mostly SMEs are investing. Yet, Iâ??m seeing an increasing number of large drug manufacturers backing them up.

Could you tell us about your role in developing the cancer treatment Combidex and the unique challenges this project presented?

Combidex was a breakthrough product initially developed by a US company that licensed it to the Radboud University Medical Center of Nijmegen. However, the developer decided to cease its production. The medical center had a list of patients waiting to be treated with the product, which suddenly was not available anymore. Hence, Professor Jelle Barentsz from the Department of Radiology and Nuclear Medicine approached us and asked us to produce it. We started with preliminary laboratory experiments: we knew it was going to be complex to control critical elements, such as particle size and composition of the different parts. However, our experience in identifying potential pitfalls meant that we could solve these issues in advance. We started with a 300 ml production, scaled it up to 10 liter in July and August 2014, and in October, had the first 5kg GMP batch that went out to the clinic to treat the first patient in January 2015. Knowing that patients were waiting for the product was a key motivator in our speed of development.

When we heard that Combidex went to clinics and saw this on TV, although ChemConnection was not directly mentioned in the news, we all felt very proud to have been part of this project. People here in the Netherlands personally approached me asking if relatives or friends could benefit from the product. An acquaintance of a former colleague was treated with the product and told me the positive impact the treatment had on his quality of life. For patients itâ??s a major breakthrough, and this makes me very happy about it.

Any other product development you are particularly proud of?

Another development we are particularly proud of is a product of Cristal Therapeutics, a Dutch clinical stage pharmaceutical company developing nanomedicines based on a very innovative nanoparticle delivery platform called CriPecÂ®. This was the most complex product I have ever worked on during my career: we helped the company with the whole supply chain, from the milliliter to eventually a 42-liter clinical GMP batch of nanoparticles, which comprised monomers (eleven chemical steps), polymers (three chemical steps), the drug linker (five chemical steps), and the nanomedicine formulation. Itâ??s a very complex product with many pitfalls and many critical formulation steps, but we have helped them go from discovery to clinic in a very short time frame.

In terms of collaboration, as shown for the Combidex project, you are also working with BioConnection, another Pivot Park company for several projects. What are the advantages of your partnership efforts, and are you looking to develop partnerships with any other companies or institutions in the future?

ChemConnection and Bioconnection have fully complementary expertise and capability and both are required to bring a nanomedicine formulation to clinic. ChemConnection produces the bulk product and Bioconnection turns this into a sterile final product in vials. The expertise and capabilities for making bulk or final product are very different. Therefore our collaboration is highly valuable and it has significant added value that we are located in close proximity, namely both at Pivot Park in Oss.

In May this year you announced that ChemConnection was selected as a partner in a new Horizon2020 program alongside four universities to develop smart carrier systems that deliver drugs to selected places in the human body. Could you please elaborate on the role ChemConnection will be playing in this consortium?

Horizon2020 is a training program for young scientists â??usually PhDsâ?? which is based in different campuses in Europe. We are one of the companies involved: one PhD will start working at our facilities in February next year, and weâ??ll have further PhDs over a period of three-to-five months to work in our labs within the next five years. Our focus is on manufacturability, analytical, and GMP issues related to the production of nanomedicines and the building blocks thereof. The tailoring of new kind of polymers and other type of building blocks, efficacy, and toxicology evaluation will be the main contribution of the academic partners. We are involved in the translation of this science into pharmaceutical products, which are scalable, economically viable, safe, and manufactured under GMP. ChemConnection is very enthusiastic about participating in the program and hope to learn a lot from it.

ChemConnection has already experienced numerous successes since it was founded in 2012. Where would you like to take the company over the next five years?

Obviously I would like to company to grow larger. However, even more important I feel is that we keep on expanding our capabilities in development and manufacture of nanomedicines. While in the beginning the nanomedicine products we worked where generally drug delivery systems of small molecules. We are now working on delivery of peptides and proteins and this requires new expertise both for the process and for the analytical controls. In the next years we will develop our capabilities further into this area to prepare for any kind of products, small molecules and biomolecules that could be better developed into nanodelivery systems.

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