Interview: Kees Baggerman â?? CEO, Baggerman Farma Consult, The Netherlands

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With almost thirty years of experience in the life sciences sector, local Dutch consultancy firm Baggerman Farma Consult offers a wide portfolio of services to its clients in the pharmaceutical and life sciences industry to meet all of their regulatory needs. Kees Baggerman, CEO and founder, highlights the new Gateway to Europe Access Program which aims to promote the Netherlands as the best location from which to enter the European market and to support international companies looking to enter the Dutch market overcome any Dutch or Europe specific challenges.

As an introduction, could you provide our readers with an overview of Baggerman Farma Consult (BFC) activities and recent milestones?

We are supporting life sciences companies, particularly pharmaceutical companies, with all of their regulatory needs. As regulations govern all aspects of the pharmaceutical industry today, we help our clients with all types of projects such as quality in manufacturing; marketing authorizations for new products; pharmacovigilance and pricing and reimbursement. Promotional compliance is also very important because, quite frequently, one company will sue another company because they think their advertisements do not comply with the law or give an unfair view of the competitorâ??s product.

More specifically, in the last five years, we have developed our Gateway to Europe Access Program to support companies from outside the EU to get their products onto the European market. For this, we have worked with companies from countries around the globe such as Canada, Mexico, South Africa, Indonesia and India. We support these companies throughout the process to deal with the many regulatory hurdles such the importation license. As such, as well as consolidating our regulatory affairs services for Dutch and European companies, trying to really gain ground in non-EU markets has been our focus in recent years.

We are trying to encourage non-EU based companies to use the Netherlands as their gateway to Europe. The Netherlands has a great reputation for the transportation of goods and the majority of the goods which we import will get exported again. There are a number of organizations which support all those transportation companies in their efforts to get transport from outside the EU to go through the Netherlands. We are piggy-backing on those organizations to try and reach pharmaceutical companies considering entering the EU market via Holland to encourage them to choose us as their partner to guide them through this process.

What sets your Gateway to Europe offering apart from other consultancies in this domain?

We have more experience in this domain than many consultancy companies. Moreover, whereas many of these consultancy companies will have a narrower focus and deal either with regulatory affairs or quality, we have a mixed portfolio of vigilance, quality and regulatory affairs and a large variety of products we have worked with.

Many multinational pharmaceutical companies with a presence here see the Netherlands as one of the most challenging EU markets in terms of pricing and ensuring more costly innovative treatments are reimbursed. What is your assessment of the situation?

It is fair to say that we have a tough procedure for getting reimbursement for expensive products; it is a long and drawn out procedure which requires a lot of pharmacoeconomics data. Nonetheless, it is tough in any country. If we compare our pricing reimbursement procedure in the Netherlands to that of the UK, there is not such a great difference.

The problem is that everyone is looking to the national government to improve the issue surrounding market access. However, this is all organized at the EU level. Our Ministry could decide whatever it wanted but it is bound to those European procedures. The area in which the Ministry perhaps has more influence and which it is focusing on is the pricing reimbursement procedures. They recently published a report on how to make these procedures more efficient and to speed them up so they are on top of the situation. I really do not think that there is much they can do at a national level to create a better podium for pharmaceutical companies: it is up to the European bureaucrats to simplify procedures.

Given an increasingly complex environment for compliance and quality, what are the regulatory issues commonly found in the Netherlands for your clients?

The main challenge for companies coming from outside the EU is designing a financial supply chain and then the logistic chain has to follow the fiscal chain. They firstly develop a supply chain driven by the fiscal aspects and then they decide how to organize the logistics. At this point, the questions of import licenses and logistics arise. It is here that we see many companies struggling because huge efforts are required to create the complete chain and to merge the fiscal, logistics and financial components smoothly into one big picture.

BFC boasts a varied clientele, as you are partnering with pharmaceutical companies, medical device manufacturers and healthcare organizations, both in the Netherlands and internationally. What is client breakdown in terms of the size and maturity of companies that you work with?

We have around a hundred clients, around twenty-five of which are international. Most of our clients are pharmaceutical companies and around 20% have a mixed portfolio including, for example, medical devices. One domain in which we are very active is radiopharmaceuticals. So we have clients in Canada, South Africa, we have even been to Iran. We are also working with several generic companies which are mainly based in Asia. So we are targeting all of these markets but we will, of course, never forget our clients in the Netherlands.

Every consultancy tells us that they are a true partner. What sets your partnership strategy apart from the crowd?

We have had clients whom we have worked with for twenty-five years and others who, as is always the case in this industry, were not satisfied whom we worked with for a couple of months. Normally, if you reach the five year milestone, clients decide to stay with you because of the shared history. Every consultancy, of course, tries to build long-lasting relationships but it does not always work out like that. We, for example, had clients at Organon but it was bought by Schering-Plough. Acquisitions can distort your relationship with the client; they can lead to manufacturing sites or warehouses being closed down; the product portfolio being reduced etc. So there are numerous factors which can lead a company to move on.

If you could pick one project where you were able to help a life science company reach its goals and thus shows Baggerman Farma Consult to the best of its capabilities, what would it be?

A particular success story in our career is IDB Radiopharmacy which was a small Dutch sales organization. We helped them to establish a manufacturing site, get a license, and to take their product, LuMark, through a centralized procedure. This project ran for five years and we went to Italy to buy the manufacturing instruments; we had to plan the building and validation; and, in the end, we had to go to the EMA and tour this exciting centralized procedure.

At the time the company was founded, it was a pioneer in the consultancy field for pharmaceutical production and regulatory affairs. Why did you decide to start this new type of company?

When I started there were around four local consultancy firms serving the industry and from those I think I am the only one that is still active. The reason why made this move was because I am trained as a pharmacist and I had a position in a hospital in Nijmegen which is an hourâ??s commute for me. After four years, I decided this was not a great lifestyle so I jumped into the deep end and tried to build this position as a consultant. I think it was good time to do this because it was all nationally

based and the regulations were far less stringent than they are now. When the company was founded in 1987, products such as radiopharmaceuticals and blood products were not considered to be medicines. Now, however, they are subject to very strict regulations. So it was much simpler when I started out.

There was of course work to be done, for example, all pharmaceutical companies were complete companies in the sense that they had their sales office, at least a warehouse if not manufacturing. Nowadays, however, pharma companies outsource all of their logistics needs to specialized companies. In those days, however, we had many projects where we had to implement quality systems in our clientsâ?? warehouses because that was required by the inspectorate. We have had clients for whom we implemented such a quality system and then, several months later, headquarters in the USA decided that they would close down all the warehouses in favor of outsourcing or centralized logistics. The same also occurred with national regulatory affairs departments.

What is your vision for the company for five years from now?

We would like to expand our European Access Program which is really trying to get a number of projects up and running with companies from countries such as South Africa, Indonesia and Iran. We will also try to improve our base in the USA. Dutch logistics companies are organizing roadshows in the USA to encourage use them when entering the EU. So I will try to take advantage of that to target US life sciences companies which could really benefit from working with us.

As a final message for our readers, what would you say makes BFC the strategic partner of choice for the industry?

Companies should consider our services because we have a lot of experience; we can work with a very broad portfolio of products and can easily accommodate any kind of product the client would need support for. Furthermore, our country is one of the main logistic hubs in Europe and our government and inspectorate are EU oriented. We have a tradition in this country to support the decisions made by the EU and we do not add a local flavoring which can be a big problem in countries like Belgium or France. As such, for operational simplicity, any company coming from outside Europe should really consider the Netherlands as the best location to start their European operations. Of course, if they come to the Netherlands, they should also come to Baggerman Farma Consult, for all of their regulatory needs.

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