Interview with Peter van Tilburg, General Director / President, Cambridge Major Laboratories Europe

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It has now been 12 years since you co-founded ChemShop. One of the busiest, but probably most exciting moments in that period must have been the merger with CML in 2007. At that time, now global CEO Michael Major spoke of seamless integration. Was it really that easy in practice?

It was. The entire process, from the initial discussion with Michael Major until the completion of the merger, was only a matter of months. We had the same objectives, goals, philosophy and drive. It seemed like I was talking into a mirror.

Seamless integration basically means that CML Europe and CML US align operating systems and dovetail service offerings: CML Europe focuses primarily on the support of programmes from candidate nomination to proof of concept, whilst CML US focuses on proof of concept through commercial launch. By providing services across the full spectrum of API development we are able to offer real value to our clients. We have also been able to share best practice across the company and in doing so create centres of excellence, where clients know they are getting best-in-class support.

Following the CML merger, significant investments followed into the Weert (Netherlands) facilities. What exactly did this bring and to what extent did it help you to keep CML on the road to success?

The investment was used across all areas of the business: to expand the laboratories, cGMP labs, pilot plant, kilolabs and so on, as well as adding to our most vital asset… our people. We have in

fact been investing continuously from 2008 through 2010: we are in a heavily-regulated industry, and keeping abreast of all regulatory and SHE-related requirements is also vital for the continued growth of the company. We continue to seek better ways to deliver on projects: a good example of this is our recent addition of a crystallization services laboratory, headed by a very experienced solid state chemist. This addition was prompted by our experiences of working with several external “solid state experts: the experience was not always optimal, and we felt that we could do a better job ourselves. So we recruited and invested, and this is already showing great results. We can now add more value to the projects we deliver on, and manage risk better for our clients

Despite being young companies, CML and Chemshop have experienced explosive growth. Is this growth rate also sustainable, as you progress as one entity?

There have been major changes in the pharmaceutical outsourcing model in the last few years, and – if anything – the pace of change has accelerated. The traditional model for big pharma was to focus internal resources on regulatory chemistry, whilst everything else was outsourced. CML Europe grew up as a provider of development services to these companies, using top class science and all our experience to solve complex chemical issues in a safe and competitive way. Now, nearly everything we do is API: we still use our technical skills, but we also have to understand very clearly the regulatory environment around the project – applying a level of GMP appropriate to the clinical development phase of the compound. In fact we are ahead of the game when it comes to such issues, since CML Europe has served clients in the biotech sector for the last 5 – 6 years. The work we perform for big Pharma now mirrors closely that which we perform for biotechs.

Of course, the other big change in the market has been the impact of Asian suppliers. Already many of our big Pharma clients have moved a large part of their discovery chemistry requirements to Asia. This is clearly to control costs. However we are now seeing evidence that the experience in process development may be lacking in many of these Asian partners. Chemistry is coming back to us for the first real scale-up. Of course, as project progress and scale increases, so does the risk – technical, safety and commercial. It may be that there is a re-evaluation of risk and that at this point, the clients feel more comfortable with service providers closer to home, with all the obvious advantages.

Considering all these changes, there are still opportunities to grow. To be able to maintain our historic growth rate we continue to invest in new technologies and in our people to allow us to better serve our changing market. We are still positive this is achievable

Is there a change in mindset needed for the way outsourcing works today?

Yes. More so than ever before, service is at the centre of everything we do. Client requirements can change quickly, so flexibility is critical, but the most important factor is to be close enough to your client to understand the full scope of the individual project. The “generic project” does not exist anymore. We are truly partners to our best clients, effectively embedded in their organizations. In this way we can use our experience to bring maximum value to a project. The dynamics of the pharmaceutical industry are changing so fast and in so many ways that we believe this is the only way forward. However it requires an open and honest way of doing business. Fortunately we have the right people to deliver. I have already touched upon the impact of outsourcing to Asia. Many of the big pharmas have invested heavily in Asia, whilst downsizing research efforts in the west. If you look at the Indian and Chinese population, they are heading towards 3 billion people, while the USA and Europe together have roughly 700 million. India alone already has 350 million below the poverty line. If these 3 billion people aspire to experiencing the same economic growth the West had in the past twenty or thirty years, there will be an obvious and drastic increase in the consumption of medicines. It will not even be a question of “Can we have the best and most innovative medicines?”, but rather “Can we have medicines?”.

India and China are now aggressively trying to get business from the West, by offering extremely low prices for commercial API production. At the same time, big pharma companies are extremely focused on cost-cutting, which is why they close production in the West and find such opportunities increasingly attractive. My fear is that in five years from now, there will be very limited commercial manufacturing and R&D here. At the same time, people will be less tempted to study fields such as chemistry, because of the decrease in jobs. In the end, Western-based companies will be knocking on China and India’s doors, begging for API for medicines.

Of course this is a black and white perspective. Surely, there will always be investment here in the West, and companies will always retain some of their R&D and innovative character in these geographical areas. But especially in terms of commercial manufacturing, the trend to move facilities and processes to the Far East has become impossible to ignore. This also affects service providers because some of the chemicals we used to buy here in Europe have disappeared, simply because many of the European manufacturers were driven out of the market by Indian and Chinese prices.

However, the general perception is that the Far East has not yet achieved the same levels of quality as some of the Western service providers can offer. What is your Unique Selling Proposition (USP) to convince the pharma industry to rely on CML’s services?

The core business of CML is development chemistry. We continue to invest in our knowledge base, and assess newer technologies – for example flow chemistry. We recently brought in an expert in solid state chemistry to build our internal crystallization team – because we could see that there are real benefits to be able to run solid state work in parallel with the process chemistry, having one inform the other, rather than the two operating independently and trying to tie everything together at the end. Such investments have present tangible benefits to our clients: we can save time and money, we can present options and solutions. I think the key message here is that although chemistry is what we do, the IND or IMPD is what we deliver. What is the value in having a great chemical process if you cannot formulate the API? Hence CML has partnered with a small group of class-leading companies to be able to provide end-to-end solutions for our clients.

So….innovation in our business and in the way we do business.

Apart from speed and cost, what do your clients look for in a service provider?

Advice, reliability, trust and problem solving skills. Development is development – we always have issues to solve! Increasingly, a demonstrated commitment to SHE is important – we've all read the horror stories about contaminations and plant explosions. SHE is at the core of our business, and we have heavily invested in our process safety capabilities, including the addition of a new RC-1.

How do you cope with such a disparate customer base?

It's a global market. Every client is as important to CML as the next one. We know that if we work for a biotech, the next week they may be owned by big Pharma. All get treated as equals! However, it is now a fragmented market, particularly considering the biotech sector, so we are continually looking for companies who are preparing for the clinic, and who will therefore need our services.

In the past you have expressed interest in new services such as microreactor technology. Do you see this widening of your services continuing in the future?

CML Europe aims to offer a "toolbox", as I like to call it. We try to have an open mind as to the best way to deliver a project, and will continually explore new methods to make sure we stay abreast of developments.

"Appropriate Development" is at the heart of what we do: every project has a different dynamic. However we often find that the customer does not really mind how the chemistry is carried out and just wants the right amount, at the right time, made in a reproducible and scalable way. Managing scale-up risk is our responsibility.

Some argue that biotech, rather than big pharma, is the future. Do you see a role for yourself within this playing field?

Absolutely! Because of the size of the big pharma companies, they do not have the innovative power and creativity anymore. This has created corporate cultures where new and innovative ideas tend to suffocate. The big pharmaceutical companies have a lot of difficulties developing new chemical entities that can quickly reach the marketplace. They now rely more and more on innovative bioscience companies to develop a new compound. This is a strategy where they de-risk their pipeline by absorbing these new compounds around the Phase 2B stage. It is an obvious and valid strategy that has proven to work well in the past. Because CML Europe's area of expertise is mostly in Phases I and II, this once again explains how our customer base has been gradually changing towards smaller biotech companies. And it is this change which lead to our collaborations with other service providers serving this sector – now formalized as the Drug Development Cluster.

Working in close collaboration with your customer is obviously crucial to successful outcomes. How do you ensure this on a day-to-day basis?

CML Europe has a very good project management system run by highly experienced managers. It is not unique, but it is an aspect that many Dutch companies are typically very good at. We are able to understand what the customer needs and follow up on that.

While I am sure emerging companies in the Far East will get to that point, so far our communication with Indian or Chinese players has been subpar, or lacking in transparency.

The company's mission is clearly pronounced: "to become the number one western-based supplier of chemistry services to the pharmaceutical and biotech industries". When can we expect to see you there?

This is not something that will happen overnight and will take a few more years. The reason is that CML Europe has the ambition to grow in a sustainable way with the right people. We do not want to be the biggest, we want to be the best. Being the number one does not necessarily mean you are the biggest.

How much do you still feel that this is the original company you started with?

It is a difficult question, because sometimes I feel that nothing has changed. I am still here and neither my drive nor attitude has changed. I still have a lot of ideas and projects I would like to accomplish with the company.

On the other hand, I do notice the organization is becoming increasingly formal. This is not because the parent company forces us to change, but rather because the industry has certain expectations as the company has grown in size. From this point of view, the entrepreneurial aspect of the initial company has changed.

Moving forward, where would you like to bring the company in the Netherlands and what is your final message for the readers of Pharmaceutical Executive?

My goal is to double the company in the Netherlands, not just in size but also in turnover. I think this should be possible without too many problems, although it will require a lot of creativity and innovation. We do not want to wait to adapt to the market. We want to lead the market and remain one step ahead of where the industry is heading in the next couple of years.

The game is changing, and this is why I also set up the Drug Development Cluster, which is the umbrella for a group of companies collaborating in the provision of services to the preclinical development sector. This is a group of class-leading companies, all with CEO-level commitment and – most importantly – the same working principles as CML. Together we are able to manage complete development projects from discovery chemistry to drug product. Client feedback is extremely positive, and really confirms my feeling that there is real benefit when good companies work together closely and understand the common goal. Shorter timelines and better risk-management – results speak for themselves

The message to the readers is that you have to select the service provider you are comfortable with. It is not only about the lowest price. Instead, it is all about added value and quality. A lot of companies forget this, even in biotech

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