



It seems that even within the rigid infrastructure of the global pharmaceutical industry, you can still — metaphorically — teach an old dog new tricks! So says **Ken Phelps**, President and CEO of Camargo Pharmaceutical Services. **Dr Kevin Robinson** met with Ken during a recent visit to Cincinnati (Ohio, USA) to discuss the company's offering in the drug development sector and find out more about how they use their practical knowledge of science and business strategy to streamline the path-to-market for both new drugs and old.

Ken Phelps describes himself as a chemist by training. "I have more than 30 years of experience in the pharmaceutical business, doing all kinds of work — from laboratory research, to sales, marketing and even developing a cost accounting system once. It was my time in R&D and regulatory affairs, and so forth, that fully prepared me to start this company." The company in question is Camargo Pharmaceutical Services, which Ken explains is a fee-for-service drug development company. "We develop other people's drugs for them and we specialize in what's called 505(b)(2). In a nutshell, we take existing and currently approved drugs and make substantial changes and improvements to those drugs. Our services span from preclinical trials through to manufacturing and the clinical, regulatory and commercial phases of drug development. We're your strategic partner for drug development."

When asked whether the drug discovery/development sector still thriving in the pharmaceutical industry, Ken is very positive: "At this end, it is for sure! There are so many opportunities out there for drugs that have proven to be good and efficacious for a long period of time, but have some negative side-effects," he says, adding, "There are tremendous opportunities to reduce those side-effects

and take those well-proven drugs and make them even better." So, there appears to be a good pipeline — even in a recession? "A great pipeline," beams Phelps, "more than we can possibly do. It really is a situation of how big can this pot get? In this tough climate, we're in a privileged position; we're one of the very few that can actually thrive."

Cost and Quality

I asked Ken how Carmargo balances the management of speed-to-market versus cost and quality. He told me that they try to focus on just doing the essential trials that are absolutely necessary for approval, which, he says, "separates us from other companies." He adds: "We have a very good understanding of what is required by the US Food and Drug Administration (FDA) to get approved. In fact, we're at the FDA several times a month, which gives us the opportunity to be very current regarding what they need for approval and, as such, we design studies that tend to be smaller and more targeted than most people. As a result, we end up getting things done faster for lower costs ... and our clients appreciate that."

Delving further into the concept of smaller and more targeted trials, I put it to Ken that Phase O is the new Phase I. Not, apparently, in Carmargo's world. "Microdosing and so

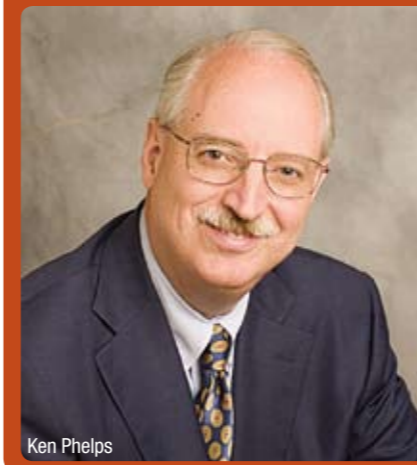
forth?" he laughed, "I can't really comment on that. It doesn't really apply to the kind of work we're doing. Most of our studies are faster and cheaper than the kind of Phase O trials that Big Pharma does, for example. It takes them so long to design their studies that we're usually done and dusted with ours by the time they're still just thinking about it."

To Be or To (b)(2)

Carmargo's website suggests that if you have a drug that has been previously approved by the FDA and are looking to reposition it, then 505(b)(2) may be for you. Ken explained the rationale. "In the USA, for chemically synthesized drugs, we have three rounds of approval. The 505(b)(1) is the most well known. A (b)(1) one is a completely novel drug; it's brand new and one that requires a lot of testing. We're talking 10 years of development and about a billion dollars of investment. Then, there's the 505(J), which is a generic. These are the copycat drugs that are exactly the same as the approved, branded drugs, and the (b)(2) fits in between. A (b)(2) is when you take a drug before it's been approved through the (b)(1) process and make substantial changes to it — so it doesn't qualify as a generic. It has to be promoted in its own right. These submissions have special requirements and our goal is to work with your team to develop

Ken Phelps, President and CEO

Ken Phelps used more than three decades of experience in the health science and services industry to found Camargo Pharmaceutical Services in 2003. As an expert in drug development, specifically the 505(b)(2) regulatory approval pathway, Phelps has aided in the successful FDA approval of numerous compounds. Prior to founding Camargo, his broad background in drug development had led to a number of executive level-assignments in the areas of quality control, project management and regulatory, clinical and medical affairs at Duramed Pharmaceuticals (now Barr Pharmaceuticals). Prior to his work for Duramed, Mr Phelps held a number of positions at Merrell National Labs, which merged to become Merrell Dow and eventually evolved into Aventis. At Merrell, he had global responsibility for quality assurance, quality control and processing technology with an assignment based in Milan, Italy, and later directed IT for multinational manufacturing operations, leading to technical improvements in R&D, accounting and manufacturing operations. He began his career synthesizing, characterizing and performing drug metabolism studies of potential carcinogens with the Eppley Center for Research in Cancer. He also gained early entrepreneurial experience by establishing a laboratory and manufacturing sterile blood collection tubes. Mr Phelps has a BS in Chemistry from the University of Nebraska.



Ken Phelps

a comprehensive programme, including a timeline with important milestones and costs. What we do at Carmargo is manage every facet of the plan: formulate and test the drug product, conduct clinical studies and submit FDA application submissions."

Looking at the regulatory situation for a (b)(2), Ken explains that the FDA is very comfortable with the concept. "They support the idea because we all know that there are drugs out there that we have come to rely on, but they just have something wrong with them, or could be a little better, that would make them beneficial. We're finding that some of the new drugs being developed have occasional safety profile concerns, so everyone's looking to evolve their

products and overcome these issues. Others are saying that their older drugs just didn't do this or that, so need to be improved. I truly believe that we're meeting an industry requirement based on those needs." In doing so, I wondered what types of companies Ken was working with, generics manufacturers, contract research organizations or Big Pharma? "Most of our clients are neither right now," he said, "They only specialize in the 505(b)(2) area. Generic companies — because of the 'generic cliff' that will affect the industry in 2017–2019 — will need to find something else to do. The very largest of them are thinking, in the backs of their minds, that biogenerics might be the road to follow. But, generics that are biologics will require hundreds of millions of dollars to develop; the vast majority of generics companies just won't be able to do that. They'll need to find something else to do and, quite frankly, 505(b)(2) is something they're all exploring with great interest. By contrast, Big Pharma doesn't like to be left out, not knowing what's going on, so they're willing to dabble in this as well ... just to understand what this is all about."

On the Edge

I asked Ken to explain further about the upcoming generic cliff, how the industry is going to approach it and what's going to happen. He told me that the "generic cliff" is going to happen somewhere between 2017 and 2019 because, at that time, most of the molecules that have been approved in the United States will have had a generic copy made of them by then. "Big Pharma has reduced the number of chemically synthesized drugs coming through the pipeline; they've moved on to biologics. There's much more money in biologics so, therefore, generics companies are abandoning the small molecule copy markets. As such and looking ahead, within a matter of 5 years or so, there will be no more (or maybe only one or two) small molecules being approved each year. There have only been 13 approvals this year, so you can imagine that it will be down even further next year. Eventually, there won't be anything left to copy, so if you're in that market, you'll have to find a new line of business, won't you?" He also commented on the potential migration away from traditional pharma to more natural or functional food products that are becoming more established in the life science sector. "There's always a level of interest in that," he said, "The difficulty in the USA is that 'nutraceutical' is a separate classification and requires virtually no proof. You can make pretty bold claims for your products as long as they don't anger the FDA. We have a few projects

that are going on; we try our best, but it's not as attractive as people would like."

Looking Ahead

Carmargo is in a fortunate position; it seems to be riding out this perfect storm. So much so that the company hasn't really had to make major adjustments to protect itself during the slowdown to keep business buoyant. Ken concedes that they've done certain things in the office to control costs: "We tell our employees every month where we are, so they are comfortable and understand that something could happen. We just don't know, so it's best to be prepared," he said. But the future looks good. The company is very well established in the US, but Ken is looking to expand and break into further geographies. "At this point, we are, I think, globally recognized as the expert in 505(b)(2). We have clients in 25 countries across the world, ranging from India to Japan, throughout Asia and Europe. People know where to come when they need to have 505(b)(2) products developed," he said. "We do need to have a more global vision in terms of our thoughts and services. We think a partnership with someone in the European area would be a great benefit; the European regulatory climate also allows for a hybrid approval procedure, and we think there could be significant cost efficiencies — and perhaps even time efficiencies — if drugs were developed for both markets at the same time. Based on that, we're anxious to work with partners all around Europe to accomplish this."

With that in mind, Ken has an upbeat vision for the company's future. "My forecast for the next few years is that we're going to grow very fast; we'll probably be double this size next year," he says. One of the reasons for that optimism is the tangible results that have been delivered by putting drugs through the 505(b)(2) process. Citing one specific example, Ken describes an injectable product that had to be given to cancer patients four times a day for a "long, long time." The drug was reformulated into a once-a-day tablet. "I think that just highlights what can be done for a patient population that deserves to have anything done, just to relieve the pain and suffering that those people are going through."

For more information

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