

Interview with Carlos Kiffer, President, GC-2

29.07.2012

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As I was doing research on your company, GC-2, I was unable to find a lot of information since it is a rather new company. Could you bring me up to speed about your company and tell me the story behind GC2 and your role?

GC2 is now on its third year of operation. So it is a start-up company, with most of its shares belonging to Interprax Group, which is a health investment group owning two other companies in Brazil. All three companies share basic infra-structure and administration, being very synergistic with one another. GC2 is the one in the group focused on clinical trials, laboratory and diagnostic solutions. So, GC-2 is a central laboratory solution provider for clinical and also pre-clinical R&D. We are probably one of the first companies in Brazil with Brazilian capital devoted to covering all aspects of pre-clinical and clinical laboratory and diagnostic solutions for pharmaceutical and biotechnological developments. We initiated operations 2 and a half years ago with an R&D unit devoted to pre-clinical lab solutions, where we design and implement the executive discovery and pre-clinical projects of new or incremental products. As a new company, this is our first year of operation in central laboratory for clinical trials, which shares the same model with the R&D unit. GC-2 wishes to partner with clients in order to design and implement laboratory executive projects, focusing on process economy. For this, we operate from this office and from our lab area, which receives and prepares samples for the analytical phase. The lab area is close to the airport and our operation includes a lab coordinator covering all lab phases, from pre to post analytical. We are growing fast though, going into new areas to cover the full spectrum of diagnostic and management solutions for pharma R&D. Next year we will initiate new units focused on bio-

imaging for clinical trials.

Many new trials have been brought to Brazil as of recently? How has this changed since you began working in the field?

That has changed a lot. I started working with clinical trials as a Medical Assistant in a big pharmaceutical company about 16 years ago, where I stayed for around 7. When I first started, Brazil was not as much of a significant player in the pharmaceutical market as it is today, at least if looked at alone. It indeed belonged to a group of countries with potential, but in terms of pharmaceutical market and R&D investment, its significance was smaller, answering for less than 5% share of that market, together with some other countries. Brazil has come a long way in terms of internal development. We couldn't think about having a central lab devoted to clinical trials in Brazil 15 years ago. Now we can. And more than having market for that, we are prepared to do it. We have experienced manpower and intellectual capital to build the necessary environment for pharmaceutical R&D, which includes enough experience for central laboratory work. And of course, the market has grown and has brought investments to the area, both internally from national Pharma companies, as well as from multinational companies. Less than 20 years ago, Brazil and other countries represented 3-5% of multinational Pharma R&D investments, and recent numbers have shown we are around 8%, growing fast to 10%. The country has grown a lot in the 10-15 years. We can say that we already have market for having specialized teams, and hopefully our market is mature enough to support local professional CROs focused on specific support development areas in order to improve both multi-national and national innovation and R&D processes.

You have global partnerships as well?

We have a mix of clients and partners, located in Brazil with local development as well as located elsewhere with international developmental processes. Most of our work is done within Brazil and Latin America, but we are confident we can support clients with lab solutions for the entire continent. Presently we are coordinating projects covering as far in the north as Mexico and Puerto Rico. I can see that in the near future we will increase our participation in Latin America as well as cover other parts of the world, but right now our focus is Brazil and the Latin American region.

Do you find it that national CRO companies have an easier time working in Brazil than the international companies who come from abroad?

No, not really. I think international companies are well prepared and have brought a lot of specialized personnel to Brazil. For both types of companies, struggles are similar. There are many

professionals moving from local to international companies and vice-versa, which allows for experience change. Irrespective of this, situation as a whole is not really different for companies, in term of regulations, laws, procedures, etc. Maybe there is a cultural difference, but as long as they have experienced professionals and mature procedures, this shall not be a problem. I don't really see a difference for the two types of companies operating in Brazil.

What struggles and challenges are the CRO's facing?

The market has grown, as I said. We have a lot of professionalized people now working in clinical trials, but we still have a long way to cover in a few areas. Early clinical trials are still a problem for all of us. Specialized units for early clinical trials such as phase I studies are still a need in the country. The early development phase in the country is also an area which lacks specialized pharmaceutical teams. This still represents a struggle for local and international companies, but with the right set of mind and knowledge, these difficulties may be overcome.

Why are the early trials more difficult?

I personally believe that Brazil has always had for many, many years, a very good experience in the basic science and discovery processes. Additionally, market growth with consequent local investment lines for pharmaceuticals has also offered a boost in local experience of the developmental process. However, Brazil still has a way to cover in terms of going through the basic science and discovery process of pharmaceuticals to the developmental phase. This means that industry-academic partnership mechanisms still need improvement, as well as specialized regulations, public agencies and a more constant investment environment. Apart from that, local Pharma companies still need improvements in terms of innovation portfolio management. As well as multinational companies need to devote themselves to develop local early development expertise. In the past 15 to 20 years, much attention has been given to the late development phases, mostly due to multinational companies investments. With this, a lot has been learned locally, but the same type of decisions and investments need now to focus on the early phases. There were not many international development programs coming to Brazil in the early phase previously and the Brazilian companies were not fully prepared to cover all the process. But we do have the basics with good discovery and innovation environments, the challenge now being to bring these discoveries into products. We are learning, though, and a lot has been covered. One of GC-2 initiatives is our R&D unit, specifically though to help cover that gap.

What has been the most exciting things happening in the CRO industry?

It's the exact same answer. The early development and R&D processes are great news. The fact that the country is starting to devote itself professionally to this area is great. There are now some local Brazilian companies quite well prepared to do this. Additionally, there has been a recent movement which is very exciting – multinational and international companies bringing innovation and early development to Brazil, using local capacities and knowledge. We have seen some multinational projects in the past couple of years partnering with local companies for pre-clinical and early phase development here. Although most are still incremental innovation, there are some radical products. And basically the process is the same, being only a step away from radical innovation. This is very exciting to see.

This would add a lot of credibility to the Brazilian industry if they came out with the next big Blockbuster drug. This is the goal?

It is very exciting to see the process from its birth, from its discovery, to its pre-clinical and early phases, then to clinical and reaching the market. From the R&D perspective, the goal is mastering in the full process with proficiency. And yes, gaining international credibility for that is part of this. As for having a local Blockbuster, I can imagine all industries wish that. However, I'm not sure this is the final goal. Blockbusters will eventually come.

My next question, what do you see as GC2 role in all the new clinical trial coming up?

We will always have the position of being partners for the development process. As part of that, we are in tune with the movement of many companies requiring a new type of a relationship with service providers. We are prepared, and intend to be more and more, to strategic partnerships, since we do believe our knowledge as a company should be part of the developmental process. It is our deep belief that open innovation has come to stay and, with it, comes the need for intellectual capital. And this is exactly the reason why partnerships will be more and more necessary for the developmental process. It is harder to detain all knowledge within a group or person, and collaborative processes tend to be more successful. GC-2 knows the risk of development and wishes to follow this path, to participate in the process from the very beginning, to help design it better from the very early phases, and also to share the inherent risks. That is the way companies should be prepared to go – strategic partnerships. We are already operating this way and expect to expand it in the near future.

Focusing a bit more on you, I have seen that you have published some books and papers. What are you working on right now?

Briefly, I do not have a traditional entrepreneurial career. I am not really considered to be an innate businessman. I have always shared the corporate and academic lives with pleasure. I always wanted to that when I first joined a pharmaceutical company some 16 years ago; although I cannot say that I was fully aware of the impact or consequences by then. I always wanted to keep an academic life together with corporate activities. Now I can see it was a good choice. Probably due to this mixed career, I understand well about what we talked earlier – the need for an everyday build of the relationship between basic research and developmental process. This relationship between basic science and development is more mature in Europe in the USA, and it is not quite as mature in Brazil and Latin America. In a sense, I have been trying to do this link with my career. I am an infectious disease physician and currently hold a position of research at the Federal University of Sao Paulo, focusing on antimicrobial use, mathematical modeling, and epidemiology of resistance, which are, in a sense, all related to the development of new antibiotics.

Is there already an association that is dedicated to this movement...linking corporations and universities?

Some of the specialist societies are trying to form associations. The medical professionals working in pharmaceutical industries are building links between the corporations and the universities, with some examples already in place and functioning. It is a movement and a need for the link is being increasingly recognized. But I cannot really say there is an institution or an organization exclusively dedicated to this movement yet.

Last but not least, if we come back in another 4 years to do another report, what do you expect to be happening in your company and the industry as whole?

With our company I can certainly tell you that there will be a growth. We plan to cover the full spectrum of research and development for pharmaceuticals but always with that specialized look into the developmental process and into areas that we see are needed most; Laboratory, imaging, early phase. Our company belong the diagnostic niche where it will certainly grow in the next few years.

As for the pharmaceutical industry as a whole, I see more investments, hopefully well structured ones, and consequently more innovation projects in Brazil. These projects will be from both multinational companies, coming to Brazil in the early phases, as well as from local companies with incremental and radical innovations. I also see more cooperative development processes and radical innovations occurring in the country with more significant shares. I would also like to think that a new frontier for both local and multinational Pharma companies would be to include their R&D processes performed in Brazil and Latin American in the global market. It means that they

should start thinking of their local R&D development as part of their global strategies.

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