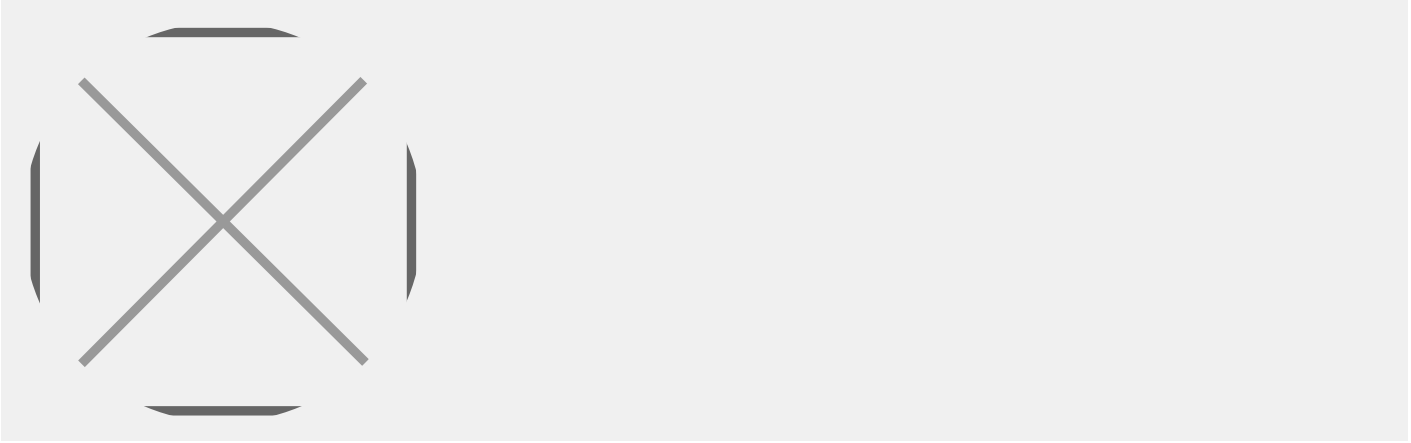
Interview with Marisa Sanvito, Senior Director, Quintiles Brazil



29.07.2012

Tags: Quintiles Brazil

Many international CROs entered Brazil in the past few years, whereas Quintiles made its first move in Brazil in 1996. What was the strategic decision behind entering Brazil at that time, and what does Brazil represent for Quintiles?

Brazil is a top 3 priority right now for Quintiles. The first thing that brought Quintiles to the country is the same as that brings it to anyone's attention, namely, the size of Brazil's population, which can be translated to the size of the market. However, Quintiles started first in Argentina 10 years before, because Argentina at that time implemented legislation abiding to the GCP guidelines. In 1996, Quintiles entered Brazil concurrently with the Resolution 196. This resolution was the first attempt for the country to fall in line with international guidelines.

In our meetings with other big CROs here in Brazil, some claim to be international but with local expertise, while others try to leverage their international network to benefit their local clients. How does Quintiles differentiate itself from the other CROs, both local and international?

Quintiles is truly international in this respect. All our processes are the same. You take the monitors, or any area of the company, in Brazil or Argentina, India, Mexico, Indonesia – they go through the same training, same classes and exams. So the geographic location doesn't matter. What is different, however, is the local tone to accommodate to local needs, not in terms of training but in terms of conducting the business.
Quintiles has the specificity of giving local colors into its relationships and business processes that

can always be adapted, to fit local needs.
One of the reasons why is that Quintiles has labs and data management, so we have the clinical component, the commercial component, and consulting. And what is unique compared to the others is that we can benefit from this knowledge that the company has in its genes, and we can perfect the process. Quintiles is not afraid to try new and innovative methods. This is done on the local, level but we also have processes on the international level so that this knowledge can be assimilated very quickly.

What have been the main milestones and achievements at Quintiles since its entry to Brazil in 1996?

We have grown so fast, and one of our landmarks is actually exactly what you saw today in our offices: Remodeling and changing.
For the first time, we have people who volunteered to work from home, they represent actually 80% of our staff. Whether part time, or telecommuter or totally home based because the traffic jam in Sao Paulo is horrible. It was basically a request from the employees, to gain productivity. And actually Quintiles Brazil is very productive because we don't lose time in the traffic – we avoid it altogether! We have people working outside of Sao Paulo, in Curitiba, Porto Alegre, Salvador, in the North East, in South East, and this is another differentiating factor. Quintiles needs local people because the relationships are much better, and we don't have to waste time to travel from Sao Paulo to Porto Alegre. It is also a very good example of work-life balance.

Most companies we have met speak to challenges surrounding regulation. Could you tell us more about the main challenges that you are facing in Brazil?

Regulation for sure is one of them, and sometimes it can be unpredictable. One of the problems that we have in Brazil, and it affects the entire economy, it's the logistics at airports and ports. We are dealing with importation, with medications, which are time sensitive by all means; When something goes wrong in the supply chain, we face great challenges. Improving logistics reliability is a concern for both the CRO industry as well the full economies of the region.

Quintiles experienced the different changes in the regulation system and you've been working in the industry at the same time. What is the best system according to you? What is the one that enables the CRO to grow and really develop themselves?

The system for the CROs is the system that is the one that is best for the country. There were many interpretations along the way. It wasn't actually a regulation, it was a resolution, the one that has been released in 1996 and is currently under revision, so we are giving our inputs to the government.
For example, it is said we have to provide the patients for their entire lifetime with the drug there were under even if it was a placebo, if it's the purpose of the drug. That interpretation came from

the idea that we should extend the benefit of the drug. If it's a study drug that's under study, maybe I'm doing more harm than good! So it should be rewriting in a way that make it clear with no room for interpretation.

The question of bureaucracy is also important. It sometimes seems as though the Brazilian government chooses to say "No" by introducing new questions even if the information is already there. We would like to see a faster process, not regulatory changes.

There is also a misunderstanding from the government which believes that we are hiring people with low level of education for our studies, but it's not true. Actually people with a low level of education cannot participate because they will have problems due to the protocol and taking care of the medication. The better the education level, the better the patient in the protocol. Today, we have more people finishing at least high school, more educated people, with greater access to information, but the government treats the entire population as though there is an education and training gap, and which makes things difficult for our industry.

When we met with your counterpart Mister Klein in Indonesia, he mentioned that the first ideas that comes to one's mind when talking about this country is the negative aspect, the questions of "security, corruption and transparency" and as Quintiles we should have knowledge of what exists, is happening and what we could do. When we think about Brazil some negative aspects are the same – security and corruption – so how does Quintiles cope with it and overcome those obstacles with your clients?

Because Quintiles is so dedicated to honesty and transparency in our work, the company mandates that all employees take many courses and classes on security, privacy, anti-bribery. All employees must pass the in order to continue working at Quintiles. They are very strict and vigilant about it.

It goes along with the question of security in IT. Information is encrypted, and all the access is controlled. If it's a client account, we have certified service providers even for transportation because we checked their background. For all areas we have service providers, including payroll and finance, which follow security measures.
Security and privacy of patient and customer data is extremely important to Quintiles. In most instances, we take data security precautions well above what is required by sponsors and regulators. From our senior management, all the way to our CRAs in the field understand the importance of data security. Our leadership makes a point of increasing awareness of how important this security is for the well-being of patients and the success of our customers.

Having been in the country and sector for many years, do you believe Brazil has the ability to become a hub for clinical research?

I think we have the capacity; more than 40% of our patients come from Brazil. I think if we can adapt some regulatory hurdles, Brazil is going to be the Hub. In Quintiles, we are definitively moving toward this.
Our advantages are first the patients. They comply to our studies and are very involved, even if they live far; it's in Brazilian way to bond to their doctors. We are a very warm country.
Doing clinical research is no different; there is a bonding between the investigator and the patient. The patient tends to inform the doctors, they think they have a special treatment, and are therefore really happy to participate to the study.

Having a doctor that you can call at any time for everything and that knows your medical history is a real privilege that even in private medical plan you don't have access to. We don't have primary care like in the UK, with every patient with a general doctor – this doesn't exist in Brazil.
Patients adhere to the protocol, physicians are willing to learn, and they accept new technologies faster than any other country in Latin America. If you give a tablet to patient, they will use it right away.

Most of the CRAs are pharmacists or nurses, so we have a good level of education among our people. The investigators are really interested in the protocol because they realise they can be closer to the pharmaceutical companies, and closer to new drugs and technologies.
We are a young country, so the majority of people in clinical research, they are Generation X or Y. Embracing change is in their nature. People who are working in clinical research were out of college in the 1990s, and that is why it makes Brazil different than a mature market. These different behaviours accumulate to make a real difference.

Among all the companies, COVANCE, Chiltern Intrials, Eurotrials – they all said there were partner of choice. What makes Quintiles the partner of choice?

What makes Quintiles unique? I think that if customers want a company with tradition, breadth of service, from consulting to the whole service, for sure it's Quintiles. Not all of these are done in Brazil, but we remain a one stop shop for clinical development. And bring an unmatched ability to partner with our customers.

I understand when others say they are the partner of choice, because there are different types of sponsors. The market is very fragmented, so there is space for all of us, but if they want expertise concentrated, it's Quintiles.

I would like to say Quintiles is the CRO of choice for all types of companies; we are able to provide services to the smallest companies, the smallest biotech company and start-ups, to the largest pharmaceutical companies in the world.

What is your final message for our international readers, who would be interested in coming to Brazil?

Don’t be afraid of any of these road blocks I’ve mentioned, because at the end of the day Brazil is a very attractive market. However, they have to be patient, a long-term vision, and the right partner to walk through the challenges in logistics, taxes and regulation.

See more interviews