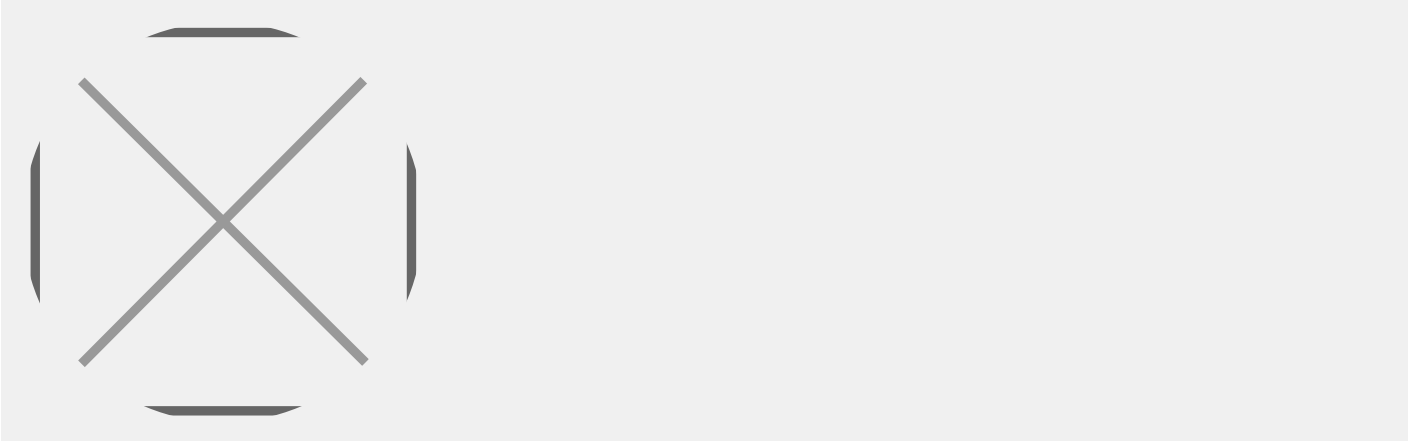
Interview with Michael Klein, Clinicial Operations SE Asia, Quintiles Indonesia



28.07.2012

Tags: Quintiles Indonesia

What role does Indonesia play within Quintiles' Asian operations?

Quintiles has been growing dramatically across the South East Asian Region, which comprises Philippines, Singapore, Thailand, Malaysia, Vietnam and Indonesia as well as Taiwan and South Korea. Indonesia and Vietnam are the two most recent countries of operation, with Indonesia the fastest growing country in this region. Quintiles has decided to invest in clinical research capabilities in this market and we now have the largest clinical research team in the country. Access to patients in a number of therapeutic areas is one of the key drivers of our interest in Indonesia. It is important to have necessary infrastructure to run clinical trials, which includes the regulatory framework. Our interactions with regulators has reassured us that they have the intent to develop clinical research and they are also farther along in promoting this research as compared to some other South East Asian countries. Additionally, Investigator's knowledge and awareness of ICH-GCP is quite high. Many pharmaceutical companies have limited Indonesian research operations as a function of the global economy. These companies have decided to outsource much of the local clinical research, which has enhanced our ability to grow.

There hasn't been a trend of significant net growth in clinical research in Indonesia. What are you doing to un-tap the country's potential?

The pace at which we can develop sites where sponsors are comfortable placing critical projects will determine success in Indonesia. Developing sites includes a number of factors. When we start operations in a country, we initially use a small number of select sites. Over time those sites rapidly

become saturated, and there is a need to expand to new sites. We need to expand both clinical-trial-naive and experienced sites such that overall capacity expansion is maximized. Thus the ability to develop sites is key to determine the pace of growth. We have built out infrastructure to support the influx of project work and now have a sizable team that has the necessary skills and training to manage the ramp-up in project load. Externally, we work with sites, conduct regular ICH-GCP workshops, working closely with regulators and healthcare institutions. We certainly see Indonesia as having huge potential, with access to patients as the primary driver of growth. Surprisingly, low costs provide only limited advantages in this business. The difference in an investigator grant in Malaysia compared to Indonesia, for example, is not significant, although both would offer cost advantages relative to the US Cost is a driver, but not a significant one. Access to patients in multiple therapeutic areas s will fuel growth in Indonesia.

Given that Indonesia's healthcare system isn't reliably available to many segments of the population, how do you ensure you gain a representative cross-section of the population in your trials?

The healthcare infrastructure is an important factor. We are very stringent about our requirements and standards for each institution. For example, simply having an ethics committee isn't enough. It is also necessary for the committee to comply with certain requirements, that they are appropriately constituted and that they have acceptable SOP's. We select institutions that are in areas that are appropriate for a given disease entity. For example, we have done clinical trials in schizophrenia, depression and diabetes in areas where access has not been too challenging and we were able to work in the major urban centers. In time, we anticipate that we will conduct projects in therapeutic areas such as malaria and dengue fever, which will take us to more remote regions. However, the process for selecting institutions will not change. Regardless of whether we are in an urban or rural area, the same controls and processes apply. The only difference may be that existing treatment regimens could disqualify certain institutions. For instance, the protocol may require all patients to be on a certain breast canacer treatment prior to inclusion in aparticular study. This may preclude certain countries and/or institutions if the required therapy is not current standard of care.

What are Quintiles' primary focus areas in Indonesia?

Our sponsors' interest in Indonesia has evolved, even over the three-year period that we have been operating in the country. One area to address is sponsors' general comfort level with the country. Certain negative perceptions persist, some of which might be well founded, but by and large, most of them are not. Bringing stakeholders to the country and working with them here has helped expose many of the negative biases. Thus a key strategic focus is increasing our knowledge of both what exists now and what has potential for the future. If you mentioned clinical trials in Indonesia just a few years ago, red flags would go up. These were often related to security, corruption, and transparency. Quintiles first had to examine these issues internally, and we came to

the conclusion that the issues we face in Indonesia are very similar to those in other developing as well as developed countries, and are thus manageable. We then had to convince our sponsors that this is in fact the case. The only way to accomplish this goal was to build up a track record in Indonesia. We have conducted a number of studies that have gone through the appropriate levels of scrutiny and we have satisfied auditors and multinational clients that everything has been to our expectations. This track record allows us to discuss risk levels with greater level of confidence. Thus, in addition to demographics and infrastructure, perception is a very real a driver of clinical trials in Indonesia. Ultimately, the fact that we have increased our staff from 2 to 20 people in two years proves that we are investing in our belief in the potential of this market.

Given your investment in the country, what are your projections for the growth of Quintiles in Indonesia?

Growth from 2006 to 2009 has been nothing short of phenomenal. We grew our staff from 9 to 20 clinical research professionals in 2008 alone. Revenues in Indonesia, and South East Asia at large, have been supportive of that growth in headcount. We took the decision to ramp up because we believe that the clinical development programs of pharmaceutical companies will reach Indonesia. It's just not possible to overlook a country with a population of 240 million. We believe that Indonesia has all the ingredients necessary to be successful, but there are a couple of other factors that will determine how quickly this growth will occur. One critical rate-limiting factor that we've observed in other countries has been the willingness and speed of regulators to align with global standards and processes. Everything that we have seen coming from the Indonesian authorities (BPOM) is headed in the right direction. There may be changes with the elections in Summer 2009. Thus far we haven't experienced any significant delay in regulatory processes related to clinical trial approval and conduct, or do we anticipate any negative changes The growth trajectory will not change and we don't see the current economic climate negatively impacting this growth trajectory. If anything, outsourcing of clinical research activities has increased, indicating further growth for the CRO industry.

Local companies dominate the Indonesian market with 75% market share. Most local companies manufacture generics, but some, such as Kalbe and Combiphar, are developing innovative drugs. What are your prospects for working with local players?

We don't discriminate between local and global companies. If there is a one-person outfit with a promising compound, we will support that player and help develop their compound. On the other hand, we have aligned our business to service multinational companies at the other end of the spectrum. In the last few years we have seen the biotechnology sector grow in strength. Some of these companies are based in Asia, in particular Australia, and we have done significant business with these smaller players. We have engaged local companies in a number of South East Asian countries, though none yet in Indonesia. This is more a function of our recent entrance into the

local market rather than any strategic decision. Quintiles is excited by our clients' innovative technologies as well as our own innovations regarding the process of clinical development. We have streamlined a number of activities and introduced a host of efficiencies into our processes. We believe we are in a position where we can effectively service global, local and biotech companies.

HR is possibly the single most important resource in the CRO business. Yet Indonesia's educational system has been underpowered and finding talented, highly trained employees is certainly a challenge. What is your strategy to attract and retain Indonesia's best and brightest?

Quintiles has been particularly fortunate to attract what we believe are the best and brightest. We rolled out an initiative in 2007 where we batch-recruit trainees and put them through a very rigorous training program that ranges from 12 to 18 weeks. The program has dedicated teams focused solely on working directly with these trainees. Building capacity in the country by investing in these young science graduates has been a key strategy for Indonesia. In a few cases we have been able to attract people with prior experience, which has been possible because of recent restructuring in the local pharmaceutical industry. However, our primary focus is on skills-development, investing in infrastructure, and training fresh talent. We have also brought in experienced personnel from other parts of the world to facilitate this training. We brought in a very experienced Quintiles manager from Eastern Europe to Jakarta and his only responsibility is to work with trainees for 6 months. In 2008 we had employee retention above 92%, across the region. The clinical development group has 450 employees and retention was at 100% in many countries. The fact that we have had such incredible retention rates with such dramatic growth in the industry speaks to very high employee satisfaction. Compensation is probably one element, but data suggests that people often change jobs for other reasons. Relationships with direct mangers are one of the main reasons employees quit. For this reason we have a strong emphasis on building management skills. Work-life balance and growth and development are also very important. Feeling that one is part of a team that cares about its work and each other is also key to job satisfaction. Quintiles is constantly working at building this kind of corporate culture. We have a very clear goal of continuing to be the employer of choice and we have created a 'best place to work' type of environment with a lot of flexibility such as allowing employees to work from home, providing a lifestile allowances, and providing very generous benefits.

Quintiles has received a number of awards for excellence in Asia including Frost & Sullivan's multinational clinical services provider of the year, customer service leadership of the year and multinational laboratory services provider of the year. What do these awards mean for a company like Quintiles and of these awards which are you most proud of and why?

It may be something of a clich? but our most valuable assets are our employees. We don't own products like a pharmaceutical company. Thus the ability to put people in a position that they find fulfilling and rewarding, where they feel their lives are making a meaningful difference and they get excited to get up in the morning and come to work is our biggest reward. Business success flows from there, where engaged employees who feel fulfilled and satisfied will produce great work. The ability to deliver excellence is a byproduct of a happy and engaged employee. We can teach and train all the necessary skills, however, if you have disengaged employees it doesn't matter how great your trainer might be, progress will be far more challenging. Thus, the 92% retention rates in 2008 might not have won us any awards, but it is one of our most satisfying results.

You are on Quintiles' global Council on Research Ethics, with your specialty in clinical research in developing countries. How do you use this expertise to raise ethical standards in the Indonesian market?

Our efforts in Indonesia are no different than in any other part of the Quintiles world. We put a huge emphasis on driving ethical behavior in the organization and in the sites with which we collaborate. There is a system in place that ensures that every single employee has gone through a comprehensive ethics course. We view Asia no differently than any other part of the world. US and European companies can be assured that the same standards that they apply in their home markets also apply in Asia. Quintiles' values drive this focus on ethical behavior.

Dr. Tharmaratnam, you run an organization with 1,700 employees all across Asia. What is your management stile such that you can hold together such a large and dispersed organization?

We work in a very exciting industry and in high growth markets. This industry can also be perceived to be sensitive, thus the number one priority is to ensure we work to the highest ethical and quality standards in the region. Secondly, Asia is a region with tremendous cultural diversity and enormous opportunity. The ability to leverage this diversity to the advantage of the industry, and for Quintiles specifically is an important area of focus. We are leveraging this cultural diversity to deliver high quality clinical research to our customers with the highest ethical standards that one might expect anywhere in the world.

What are your ambitions for Quintiles over the coming 5 years in Indonesia and the region?

In Indonesia in five years you will see an organization with at least 100 employees, working on about 70-80 phase two and phase three global registration clinical trials and recognized as a true partner of choice by the Indonesia government and pharmaceutical industry.

What is your final message on Quintiles Indonesia to your prospective partners, your current partners and the government?

We have demonstrated our confidence in the country by our investment in Indonesia. Sponsors can take it upon themselves to see Indonesia as representing enormous possibilities and tremendous potential. It is also important to note that Indonesia has a high profile at the top management level at Quintiles. The chairman is personally following the progress of the company’s growth in the country.

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