

Interview with Dmitri Pavlovich, MD, Director, Clinical Operations Russia, Quintiles Russia

08.09.2011

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The following is an interview with Dr. Pavlovich, as well as Dr. Sergey Smirnov, Director, Business Development and Operations, CEE, CIS and Russia

Quintiles very recently announced the launch of its first commercial project in Russia, after setting up a local legal entity for the delivery of commercial operations. What is the nature of this project, and how can the existing clinical business serve as a firm base to drive commercial strategies?

Sergey Smirnov: Quintiles Clinical has been present in Russia since 1996. We are experienced in this region, and we know the market very well, including the key opinion leaders, key decision makers, and key stakeholders.

Quintiles's commercial business unit has had success worldwide, and now we are bringing this business to Russia as well. One year ago, we began establishing commercial operations from scratch in Russia, which encompassed everything from forming a separate legal entity to creating all business processes. We implemented these operations on top of our existing clinical expertise.

When we were looking for our first customer for commercial services in this country, we wanted to start with a strong partner and a relatively large project. We found an excellent customer—a well-known, Fortune 15 corporation that operates in pharmaceuticals and fast moving consumer goods worldwide. Our relationship with this organization is both long-standing and multinational.

Quintiles's commercial business has been a successful model worldwide. At the same time, we know that a solid domestic presence and experience in the local market is essential in establishing commercial operations. We may be very successful in one country, but this success may not be instantly translatable to another market. This is especially true if we are talking about a complex region like Russia and CIS.

We structured our team in Russia to address its unique needs. We now have a sales force of 30 representatives, as well as four managers and one project manager. We also added additional clinical infrastructure to support our commercial infrastructure, so we have a full set of operations in place.

Our next step is to create a strong reporting system, as well as a corporate governance and compliance program that adheres to the highest ethical standards and promotional practices. We are also in the process of consolidating our business so we can deliver the best service possible to the

existing client and attract future clients using our initial business success.

Quintiles has released a statement saying Russia is at a “tipping point.” Why is now the right time for Quintiles to expand in this country?

Sergey Smirnov: We believe in the Russian market at large, and the Russian pharmaceutical market in particular. We are confident that state reimbursement for drugs will develop over time, and we hope to participate in this evolution. Quintiles aims to provide a full range of services to both companies that are already present in the market, and to those that wish to enter for the first time.

This expansion is an implementation of our global strategy to develop a stronger foothold in emerging regions and to reformulate our business approach. It actually happens that our own strategy is fully in line with the domestic governmental strategy, as expressed in Healthcare 2020 and Pharma 2020.

Will clinical operations remain the company’s foundation in Russia? Or will the service mix shift toward a more balanced approach?

Dmitri Pavlovich: Our approach is not to consider either clinical or commercial operations as leading on a country level. Quintiles’s global strategy, and our re-formulization as a company taking on the New Health landscape, dictates that we should follow a multifaceted approach. Clinical is the first stage, but Commercial is a logical continuation of implementing products in the Russian market.

Indeed, John Doyle, Vice President Quintiles Consulting, has said the industry needs to shift away from a model wherein “clinical-medical” and “commercial” operations are separated, and bring them together within what Quintiles calls the New Health. In other words, at the earliest stages, companies should integrate their commercial understanding into product development. How does the Russian affiliate communicate this idea to its clients?

Dmitri Pavlovich: This is a good question, because while globally, Quintiles is united in the New Health approach, each country has its own specificities. It is not always easy to persuade people to think differently in Russia, and a certain amount of time will naturally be required to implement this idea on a local level.

However, we are preparing our investigators, key opinion leaders, and regulatory contacts to operate within this framework. They understand that our approach is now more complex in that it goes beyond clinical monitoring and other clinical research processes. Quintiles aims to provide customers with a full package of services, from initial Phase I studies on a country level, up to registration of new products and market activities.

Over the last year and a half we have had an increasing number of unsolicited requests coming from local pharma and international pharma present here, asking us to provide more than clinical research. It is important, and highly strategic, that we initiated commercial operations in Russia.

To what degree do Russia’s well-known regulatory and bureaucratic challenges, which only seemed to increase after the adoption of the Law on Circulation of Medicines, take away from the attractiveness of doing business here?

Dmitri Pavlovich: Bureaucracy exists everywhere. Perhaps in Russia, the extent is more pronounced; however, despite the difficulties, we are seeing positive trends.

These positive trends are not just abstract, but visible in practical outcomes. We have started to again receive approvals for studies in Russian territory. If we compare the situation that we had in 2010 to the situation today, it is clear that things are moving in the right direction. It is just a question of time.

What role does Russia play in Quintiles' Eastern European, and global, network? How is the territory integrated into this broader base?

Sergey Smirnov: Russia is one of the most important emerging markets for the organization. We look at Russia both as a country with its own opportunities, and as a hub to access other markets. For instance, Ukraine, and other neighboring territories have huge potential.

Nowadays, it has become much easier, and far more strategically important, to aggressively enter and develop emerging markets. In doing so, we are ensuring sustainable growth for the company. It is a common strategy for all of Big Pharma to find new opportunities in emerging markets. Quintiles is no exception.

Dmitri Pavlovich: Russia is, of course, a member of BRIC (Brazil, Russia, India and China), and as such, it was always in focus for us. In fact, Russia was among the first countries in which Quintiles began operations in Eastern Europe. The organization here started as one person; now, we have more than 200 employees, and we are continuing to grow. Russia remains a significant part of Quintiles' global strategy.

Speaking of your future ambitions, what is Quintiles' development plan in Russia? Where would you like to be within the next 2-3 years, and how will your offering look?

Sergey Smirnov: Within the next 2-3 years, we want to develop an organization in Russia that effectively delivers all of the Quintiles services that are represented in developed markets like the U.S. and the UK. Quintiles is an integrated service provider, so this is a logical progression of our business.

Dmitri Pavlovich: We have always focused on growth, development, and expansion in the local market. We were actually the first CRO to open an office in the Siberian region of the country, and this fact has also given us a number of advantages.

What do we expect for the next 2-3 years, and even 5 years? First of all, we will build on the significant achievements we have already established. Now that we have started our commercial operations in Russia, the longer-term aim is to provide the global "Four C" services: Clinical, Commercial, Consulting and Capital, and to follow the comprehensive approach the organization has taken on a global level.

You aim to offer services across the whole midstream and downstream life of a product. It seems that drug companies are outsourcing more and more, while service providers are offering more and more services. What is the logical conclusion to this trend?

Sergey Smirnov: Quintiles aims to offer solutions that are tailored to our partners' specific needs, whether they are existing players in the Russian market or new entrants.

For instance, due to the impending patent cliff and the fact that many pharma companies now have huge portfolios, it can be challenging to prioritize products. It is also not easy to manage a sales force—especially in a country like Russia, where your sales force can number in the thousands and still not cover the full spectrum of your target audience.

From this perspective, Quintiles can be of help to existing players. These companies may want to focus on certain products, but to simultaneously develop ancillary product groups. Or, they may want to focus on other core aspects of the business. Whatever their specific needs, Quintiles can offer a solution.

At the same time, you are absolutely right: our goal is to offer, especially to new entrants, full service, including an agency model. For instance, if a company wants to establish a presence in Russia, it can hand over its full portfolio to our team and capitalize on the agency framework. We can offer them full partnership.

Quintiles is unique in that it has local knowledge coupled with international reach and superior quality. Especially in the first steps of market entry, this kind of offering is very attractive.

The future of Quintiles in Russia is very exciting as well, as we aim to broaden our portfolio even further. We will eventually go far beyond simple commercialization of a product and offer brand solutions, patient solutions, patient and doctor education programs, and more.

Having been at this company for 11 years, and less than one year, respectively, what is your advice to your peers about how to successfully manage a CRO in the Russian environment?

Dmitri Pavlovich: I will start, as someone that has had a longer experience in Quintiles. There is no one simple solution that encapsulates how to be successful in Russia. The competitive situation here is fierce. According to my knowledge, there are more than 60 different CROs of varying size across the country vying for position. You have to differentiate yourself to succeed.

The foundation of any good organization is its team. Here within Quintiles, we have a truly motivated, engaged, and experienced group of individuals working in Russia. This, for us, is highly important. We are proud of the talent we offer our customers.

Of course, knowledge is also extremely important. This includes comprehensive knowledge of the market situation, of the regulatory requirements—which frequently change in this environment—and of the domestic logistical realities, which are quite different from those of Western Europe.

Finally, I would cite strategy as an important element. You must understand, from the onset, what you want to accomplish.

I am confident that Quintiles' success to date in this region is a result of our continued focus on each of these areas.

Sergey Smirnov: I would like to add that for us as a commercial organization, quality is crucial to our success. Throughout our business consolidation stage, we must be absolutely sure that our clients receive the superior quality that they have experienced with Quintiles in markets like the U.S. and UK. This is one of our top priorities.

Is it really possible to offer the same kind of quality in today's Russian environment that is available in a Western market?

Sergey Smirnov: Absolutely! In fact, our clinical colleagues would assure you that clinical quality at times even exceeds Western standards.

Dmitri Pavlovich: Indeed, based on our official internal reports, Russian quality in clinical research is comparable to the U.S. and Western Europe, and perhaps even higher in some areas. We are quite

proud of that.

We have access to many patients, and we have many clinical doctors and investigators who are eager to utilize these patients in clinical trials. These specialists are well educated, and they are able to conduct trials at a high level. Again, we return to the importance of a solid team of people: a strong team is not only significant within Quintiles, but within the investigatory pool, as well.

What is your final message to the international readers of Pharmaceutical Executive?

Sergey Smirnov: I think the key message, from the commercial side, is very simple: if you are seeking a partner in Russia, whether it is for existing business or for market entry, think of Quintiles. We are a provider that you can count on.

Dmitri Pavlovich: I agree with Sergey. This is a complex, very unique market, and Quintiles has the experience and knowledge to help these organizations achieve their goals. We are continuing to grow and develop our offerings every day.

Russia also continues to have vast potential for growth, for advancement, and for investment. Russia's government supports this evolution, and the possibilities are endless here.

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