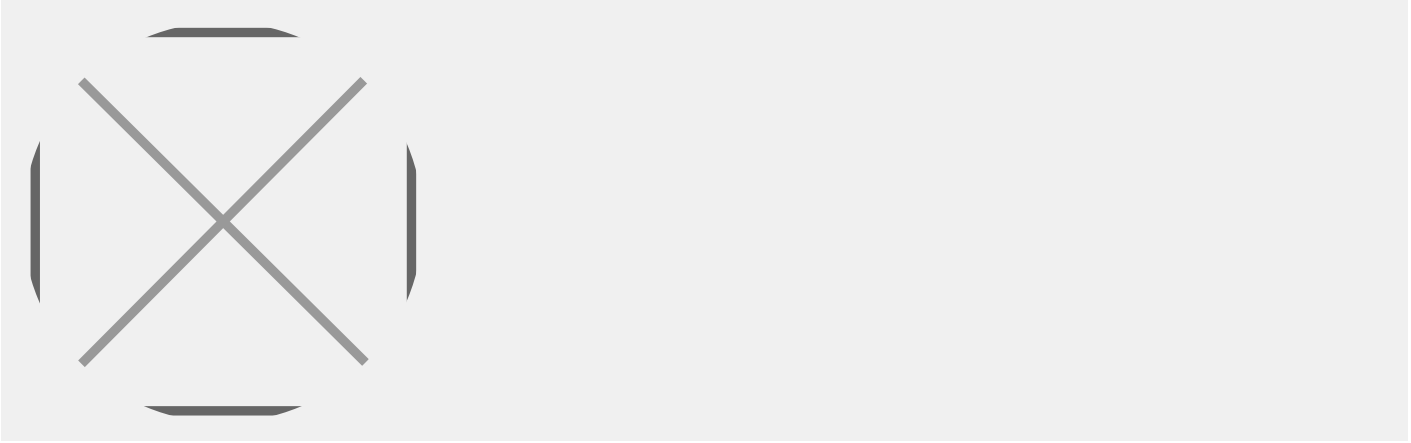
Interview with Anna Filimonova, Associate Director GRO, OSM/GMBA, PAREXEL Russia



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PAREXEL prides itself on improving the time schedule of a product launch. What is the significance of time-to-market in the healthcare industry, and how can PAREXEL expedite the process better than its competitors?

For pharma companies, time is always money—the tendency and drive, therefore, is to get products to market as soon as possible.

PAREXEL is a strong choice to aid in this respect. We are a global company, with a presence that spans over 50 countries around the world. It is always possible, given this coverage, for PAREXEL to select the most suitable clinical sites in the most suitable regions for a given project. Furthermore, the fact that our resources are spread around the globe means that we can start projects at the sites required for any project at any time.

Because of PAREXEL's global presence—including in emerging regions—we are very familiar with local issues. This entails an in-depth understanding of local regulations and local logistics.

PAREXEL works as a global company, with harmonized standards and processes, but can be flexible in performing services and meeting clients' expectations locally, in a wide array of geographies.

So, PAREXEL delivers to its clients the global footprint, with local resources and capabilities, correct?

Precisely.

PAREXEL brings together a range of drug development services along the full continuum of the development process. Is it really feasible for a single company to be a strong choice for both hands-on work like clinical trial management and more hands-off work like consulting?

I would say that we can be and we are.

Again, this is due to our strength as a global enterprise. PAREXEL locations around the world have certain service portfolios, which are integrated at a global level to meet client needs. For example, we have units around the world that conduct a full spectrum of early phase studies. By the same token, there are certain locations that support medical imaging review and data management, for instance. These hubs, work synergistically on a global basis. This endows PAREXEL with the opportunity to be a very adaptable and client-oriented service provider. Capabilities throughout ourorganization complement each other, and we share resources and knowledge.

At the same time, we have global corporate operational procedures. We have global quality standards, and we are oriented toward the same goals and the same vision.

Multinational pharmaceutical companies have historically approached Russia from a limited, marketing-and-sales point of view. Is this scenario changing?

You are quite right. And indeed, the multinational approach toward Russia is changing. One can see this in the evolution of our operations in Russia and the growing demand for a wider range of our services.

PAREXEL first entered the Russian market with the aim of offering clinical site-monitoring services. The main target of our location in Russia was to provide patients in good numbers and good quality data. With the growing research attention multinationals are giving to this market, our portfolio was grown considerably—now, we offer an impressively extensive list of services, which include most of our global portfolio. We continue to expand, as well.In earlier years, multinationals generally brought Phase III and Phase IV clinical studies here. Phase II studies are quite common now. Many companies are now working on yet earlier phases in Russia. There is a full scope of tasks required, from early phase to registration and post-registration studies. Not only local players, but also multinational organizations trust Russian capabilities enough to bring a comprehensive range of product development operations to Russia.

In Russia, what is the link between local clinical development and local market access?

Last year, the Law on Circulation of Medicines was introduced. This law states that a medication can be registered in Russia only after it has been tested locally. The link, therefore, is very direct.

One might say that this clause in the law is not adequately detailed, because there is no quota that states how many patients, and what percentage of patients, should be involved in Russia in order to prove the safety and efficacy of a given product. There is only the mandate that a trial on some level must be conducted domestically.

This demand has both pros and cons. As a CRO, we are happy to seek more business. Conversely, we know that certain companies may be quite minimal in their interpretation of this law. They may select one site, enroll five patients, and, having run this small trial, put their product up for registration. Hopefully the requirement will change in near future.

PAREXEL, as a quality-focused company would try to avoid participating in this type of “formal” clinical trial. I believe that this is the position of most CROs operating on this market—and it is the position of the ACTO association, in which we are members.

It seems paradoxical that despite the fact that the law now stipulates that companies must conduct local clinical trials in Russia, in 2010, the number of domestic trials declined by about 15-25%. What is your understanding of the reasons behind this scenario?

The decline in trials may be in part attributable to new challenges introduced by the regulations in Russia. For several months after the new law came into effect last September, the industry faced significant issues. The Ministry of Health had implemented comprehensive restructuring; they created new departments and agencies; and they created new processes.

The law itself is a positive development. However, it cannot work without supporting procedures, and these procedures were not immediately in place. It took significant time for the structure to solidify to an extent—and still, today, there are some issues that remain, and questions about points like patient insurance.

Of course, this resulted in a decrease in the number of approved trials. The MOH declared timelines for study approval, but these timelines were somewhat difficult to follow because of the restructuring.

Despite an overall decline lead by multinationals, statistics further show that the number of trials sponsored by Russian companies actually increased. To what extent are your services interesting for domestic players?

We work primarily with multinational companies. Most projects we take part in come to us via our global hubs, within the framework of international contracts.

We are beginning to work with more locally-based companies that are seeking to increase their resources and scope. Domestic companies have a desired to reach the same level of standards as the big multinationals. They are increasingly interested in developing their projects outside of

Russia, and therefore they are seeking to outsource trials to recognized, high-quality service providers like PAREXEL. We have many requests from local players, and we negotiate the possibility of collaboration. At times, we find a solution. We anticipate working with more local companies in the years ahead.

Multinational clients have the capacity to work with whomever they want. Why do they choose PAREXEL?

PAREXEL reliably provides a high standard of quality. We havestrong site and patient recruitment capabilities. PAREXEL has a proven track record of providing results within expected timelines and with expected levels of quality.

Would you not say that any CRO would cite ‘quality’ as significant? What does this term entail for PAREXEL that is unique?

PAREXEL has a well-developed system to ensure quality. This includes training, staff selection, quality management, and quality control. It is not enough to train people; it is necessary to keep their knowledge updated, to control their performance, and to recognize good performance. It is very important to capture lessons learned; at PAREXEL, we try to learn from each case. Further, we have standardized global operational practices. Additionally, we have external benchmarks; in the 2011 CRO Quality Benchmarking Report conducted by ISR PAREXEL ranked highest among large CROs for the predictability of its service quality, and in a number of other key categories.

Over the next five years, how will you measure the success of this company?

A key measure of success in Russia will be our clients’ interest in conducting development programs including Russia, as well as in the amount of repeat business we receive. Often, the same sponsors will engage us again—perhaps with the same indication, or perhaps with a different indication. This brings more business, and not only in the areas where we have already been successful, but in other areas as well. What is your final message to the international readers of Pharmaceutical Executive?

I believe that PAREXEL has a great future in Russia. Russia, as a whole, has a great future in clinical trials and vast potential to contribute to the advancement of global healthcare.

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