Interview with Ludek Bazant, Business Development & Regulatory Affairs Director, CEPHA

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Tags: CEPHA

Today, the Czech Republic is widely recognized as a major regional hub for clinical development. How would you compare the current environment to the realities of 1992, when CEPHA was first established, and how has CEPHA developed in the ensuing period?

The Czech Republic has a long tradition of clinical development—even in the communist era, clinical research, as well as the framework of the pharmaceutical industry at large, was already quite developed. Given the favorable environment, the founders of CEPHA chose to establish the company during this period.

CEPHA's establishment built upon the work that the founders were already conducting in their previous positions, and gave us an opportunity to continue in this direction within the framework of a private business. We wanted to develop a CRO entity in the guise of the CRO models we had seen elsewhere in the world.

My colleagues came from academic areas or hospitals where they were involved in clinical research in various therapeutic areas. Personally, after I left academia, I worked at the Institute of Clinical and Experimental Medicine in Prague, a leading hospital focused on organ transplantation and heavily involved in clinical work. My background is in analytical chemistry. I was always involved in the development and use of bioanalytical methods for the determination of drug plasma levels and metabolites—either in PK studies or in therapeutic drug monitoring in hospitals.

In 1991, I took a position at a Canadian CRO. I brought with me my experience in method development and analytical chemistry. On the other hand, this was my first experience working in the regulated industry. This was quite new for me, because previously, although we were working within the standards of Good Scientific Practice, we were far removed from the requirements of agencies like the FDA or Health Canada. I began to understand international-level regulations, and how to work within their confines.

After two years, I decided, along with my colleagues, to establish CEPHA. We formed a group that comprised all of the expertise needed to launch such a company. Our direction was to provide bioequivalence services. We needed to have a pharmacologist, medical staff, statisticians, PK personnel, and, of course, chemists. Six people founded the company—partly physicians, and partly chemists. We then filled the remaining gaps. Today we have 35 full-time employees.

Our early days were quite challenging. Obviously, we had no history, and no reputation. It was very difficult to convince potential clients that we are reliable partners that can provide high quality at a reasonable price. We were happy to finally win two or three initial contracts, and this was our basis to build a good relationship with sponsors and to demonstrate that we can do the job, and do it well.

Once we established our reputation, we were able to expand our reach and offer our services to more clients. Fortunately, the business worked!

Who is CEPHA’s typical client?

We have always focused on bioequivalence studies, and have mostly worked for generic pharmaceutical companies of various sizes. We recruit the majority of our partners from Europe. However, we have also performed studies for the U.S., Canada, Australia, and other world markets.

How does this company manage to compete with the abundance of major international players—including Quintiles, Chiltern, PPD, and PRA—that bring global experience and an established client list to the Czech market?

The difference between CEPHA and the multinational companies present in this market is that many of the MNCs are present in the form of branch offices that work to organize Phase III trials in this country. There are very few major CROs that provide bioequivalence or Phase I studies locally. These companies may win Phase I business here from some potential sponsor—however, they will usually conduct the study abroad in their Phase I units.

CEPHA, on the other hand, has a true local presence and performs studies in-country.

An interesting notion that came out of our interview with Chiltern's Czech manager, Dr. Dariusz Walach, was that CROs are actually performing better in the recession—Dr. Walach explains that as cost pressures rise, pharma companies are now more likely than ever to outsource their work. Have you found this to be the case? Is CEPHA doing well in this recession?

I am not sure that our experience has been similar to that of Dr. Walach. It is certainly true that the financial crisis was one of the major milestones in the history of the last decade. The first milestone was the introduction of the E.C. Directive for Good Clinical Practice that came into effect in 2004. The financial crisis followed this directive, and the final milestone, in my opinion, was the emergence of the CRO market in India.

All of these factors, taken together, shaped the climate for CROs in Europe. CEPHA too faced these challenges. The financial crisis, in particular—in synergy with the growing CRO business in India—drove many pharmaceutical companies to transfer their clinical development to the Indian market. So I do not share Dr. Walach's view: the crisis was a very difficult period for us. The difference is likely that Chiltern is a global enterprise, and CEPHA is considerably more focused. During the crisis, we lost clients, and we lost studies. As far as I know, a number of European-based CROs faced bankruptcy, or even closed their businesses.

Thankfully, CEPHA survived this time, and we now see that sponsors are returning to this region. They are returning for a number of reasons, but, to look at things simply, I would say that the impetus is the fact that the worst period of the financial crisis is over, and the generic pharma business has returned to growth. Furthermore, some companies were not as satisfied with Indian CROs as they expected to be.

Hopefully, the industry's renewed focus on Czech Republic and Europe for clinical trials will be a lasting trend. CEPHA's business is growing today—slowly, but surely.

CEPHA calls itself the leading CRO in the Czech market. By what measure? How does the company quantify its success?

We have few competitors in the Czech Republic. As I noted, the MNCs present in the market conduct the majority of their studies in other global centers. We compare ourselves, therefore, to local players. Our size and volume of business easily exceeds that of our relevant competitors.

You currently have a registered office in Switzerland. Is this indicative of an internationalization strategy?

We actually opened our Swiss office in the mid-‘90s, for a very specific reason. At the time, Swiss regulations required that every company bringing generic products to the market must perform bioequivalence studies with Swiss comparators. There was no such requirement in other European states: companies could, say, performed studies with German reference in order to introduce their product in France or the UK, or vice versa.

Today, there is no longer such a requirement in Switzerland, so the opportunity window has been closed. We have retained our office in the country, but its importance has diminished.

With this said, although our headquarters are in the Czech Republic, I would like to note that we have never been exclusively focused on the Czech market. The trials that we specialize in—bioequivalence, bioavailability, and Phase I—are single-center, short-term studies that are usually performed using healthy subjects. It does not make sense to outsource them abroad, and they are performed locally. There is no real reason for us to establish subsidiaries around the world.

Do you plan on expanding your service portfolio?

During the period we discussed—wherein CEPHA faced the financial crisis and strong competition from Asia—we did indeed enlarge our portfolio. It was during this time that we incorporated Phase I trials into our work; previously, we focused exclusively on bioequivalence and bioavailability. As the Phase I business is quite close to our previous experiences, it made sense to broaden our scope in this way.

It takes time to grow—but we have been successful thus far. We have performed a number of Phase I studies for innovative companies, and we recently opened a new Phase I clinical unit. We will continue to strengthen this area of our business.

What ambitions do you have for the next five years?

We must stay visible in the eyes of our clients. We must retain our reputation as a strong choice for conducting their studies. In recent years, we have seen several huge mergers in the pharmaceutical industry, and the landscape has changed. Due to these mergers, we lost a number of partners. Our continuous task is to stay in touch with the right people.

As companies consolidate and the landscape shifts, are client needs changing as well?

I believe that requirements are indeed changing—but this is largely due to the changing requirements of the regulators. The needs of pharma companies are still the same: to be first to market, and to save as much as possible on cost. Studies conducted by CROs must therefore be

timely and cost-effective.

This environment puts additional pressure on our organization, because we must complete studies quickly, but fulfill a broader range of requirements.

This is another issue that we touched upon with Dr. Walach—it seems that quality requirements are rising and rising, but, at the same time, sponsors demand lower and lower cost from their service providers.

This is definitely true. To be competitive, you have to organize your internal procedures properly. You must conserve resources and compete on price.

How would you describe CEPHA’s culture?

We are essentially a family company. We have a core team that has been in place for many years. All of the founders of the company, for instance, are still here, and many of our key employees have too been with us for a long time.

The company was founded by six scientists—was it difficult to transition to your role as businessmen?

Yes, it certainly was. However, if you make a decision to enter the industry and leave academia, then you have to be ready to serve industry needs and provide support to the company wherever is needed. Personally, I quit the lab and became more focused on business and regulatory affairs. Of course, I missed conducting research—but now, there is no way back. If you want to succeed as a company, you have to be focused on your responsibilities.

What is your proudest achievement in your 19 years with CEPHA?

I am proud of our reputation for quality, and the relationship we enjoy with the majority of our clients. We have over 60 clients at the moment, and most of them come back to us for repeat business. Our clients are confident in our services, and, even after many years, they meet the same staff within the company.

Focus Reports often interviews local success stories, and we have had the privilege to interview some companies that have grown from their modest foundations into truly huge businesses. One such story is Servier. When Focus Reports interviewed Jaques Servier, he remarked that his company—which continues to be a foundation rather than a stock-listed entity—was a product of its time, and could not be established at such a scale in today’s climate. Given current market conditions, could CEPHA be established today?

This is an interesting question. In our case, we also definitely established the company at the right time. In 1992, all the elements were there to successfully build a CRO in the Czech market.

On the other hand, I believe that there is still room in the Czech Republic to launch a CRO today. The environment is stable and predictable. If you have the right business plan, it is feasible to find success.

The most important aspect of our evolution as a company was our focus on quality and reliability. In our industry, there is no room for fraud. Once you make a single mistake of that kind, it’s all over. This is my advice to anyone that wants to establish a business like ours.

On a personal level, what keeps you motivated to stay in this company after nearly two decades of work?

I find my work very dynamic. It changes every day; there is no routine! The environment itself changes very rapidly. We must monitor the developments, implement them, and follow up on the implementation.

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