Ioanna Koukli – Owner & Founder, Pharmassist, Greece



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Ioanna Koukli, the owner and founder of Pharmassist Ltd, began the company with a vision of assisting healthcare companies manoeuver through the European regulatory milieu. Today, with Pharmassist established as a full service CRO, Koukli discusses the company's evolution, the potential of clinical trials in Greece, as well as fostering the entrepreneurial spirit in the country to promote investment.

Ms. Koukli, you created Pharmassist 17 years ago to cater to a rapidly changing and demanding pharmaceutical market. The company has now evolved into a full service CRO; could you please provide our global executive readers with a brief background of the inspiration behind starting the company?

Prior to the inception of the company, I had been working in the pharmaceutical industry for eleven years. When I wanted to start my own business, I was certain that I wanted something that differed from the various existing businesses in the field. The opportunity came in the form of the new legal framework in the industry referred to as "regulation 2000", wherein there is more of a standardization of the regulatory environment across the EU. With a single procedure (either centralized or mutual recognition), a company could obtain a market authorization across the entire EU region. Up until that point, the procedures were only performed at national level. I saw this as an opportunity to cater to an unmet need. The company actually began as a regulatory agency, and at that time in 1999, there was no other dedicated regulatory affairs agency in Greece. Though this is not a novel concept worldwide, it was an innovative idea for Greece. Given

the nature of a more uniform regulatory landscape, right from the beginning, we began with international clients as opposed to only local Greek companies. An extroverted business model was also a very innovative concept for Greece at the time, and therefore our differentiation and value proposition was clear.

The business is founded on three main pillars: Competitiveness, Extroversion and Innovation. Could you please explain what each of them entails in brief?

Innovation is a unique and almost independent part of the business at this point, but for the CRO business itself, competitiveness and extroversion are two of the key things that I wanted to have since the beginning. In order to introduce competitiveness, I knew that I needed to have a vast range of services to accommodate diverse needs and more clients. This way, a client can actually collaborate with us throughout a vast spectrum of their CRO needs and this offers us a competitive advantage. Secondly, the expertise and the know-how that we have garnered through the extensive experience we have gained through our collaboration with a wide range of clients, in a multitude of diverse projects (from Rx to OTCs to medical devices and biotech products) as well as the highly scientific background of our employees, ensures the quality of our services. Not only do we boast a range of expertise, but also a range of high-caliber services pertaining to clinical trials, which applies to both interventional and non-interventional clinical studies. We also provide Registry services that most CROs in Greece do not typically cater to.

Your second pillar of extroversion is a unique characteristic in the Greek landscape as many local companies only started looking for business outside the national borders at the onset of the crisis. For yourself, however, this was a defining pillar at the very start, standing today at 30 percent of the turnover being generated from clients abroad. Why was extroversion such an important factor for you?

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I personally believe that extroversion is the key ingredient for success for any company across all industries. In the globalized world today, looking at the national landscape is no longer sufficient because foreign markets can play influential roles. Business decision-makers must always look at the industry at the global level and how they can cater to the whole market, and apply strategies accordingly. Today, there are over 2500 innovative life sciences companies in the Netherlands only and hundreds of thousands more globally, ready to initiate their clinical trial program. In order to be able to access such potential, one must have sound knowledge of strategic locations wherein their businesses can thrive.

In the same vein of being extroverted, Pharmassist opened its first affiliate in the UK on October 2010. Especially given the fact that Great Britain is the cradle of pharmaceutical authorities, how has this decision helped broaden the company's operations?

The rationale was to be able to access non-Greek companies with the aim to further expand our clientele and geographic coverage. As it stands today, 90 percent of our business comes from affiliates of major pharmaceutical companies as well as research and mid-size pharma companies that reside outside Greece. The remaining 10 percent of our business comes from high-caliber Greek clients that have more of an extroverted attitude with regards to conducting their businesses.

Why was it important for Pharmassist itself to have its third pillar as innovation and how have you materialized this?

The idea behind the focus on innovation is to use our own know-how and expertise in innovative product development. This idea started to materialize following our collaboration with the University of Athens for the development of several *in vitro* diagnostics for cancer patients, based on liquid biopsy. The added value in this class of products is the considerably shorter time-to-market, in a field promising to substantially improve cancer treatment in the future.

Clinical trials costs and complexity have continued to escalate in recent years. How have you accommodated to this trend?

The diversity of our services has certainly enabled us to accommodate this need, but the fact that we are operating in Greece is a competitive advantage in and of itself. Greece has a large pool of certified investigators who produce very satisfactory quality of data. This has been complemented the last years with fast and predictable approval timelines. There is a multitude of factors that makes Greece an advantageous place to conduct this type of business, alongside the fact that it has internationally-acknowledged centers of excellence. Being able to achieve all these benefits at such competitive prices is an attractive factor for many companies, especially in relation to the Western European countries, without compromising ethics and quality.

Given the current Greek landscape laden with budget slashing and reimbursement issues, how has this impacted your business here?

This has primarily impacted the non-interventional clinical trial activities, which is a tool of the pharmaceutical company to gain more knowledge with regards to its products, post-authorization.

On the other hand, the interventional trial activities have largely remained isolated from the challenging environment in the country.

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Having begun as a regulatory affairs agency and having grown as a full service CRO, how do you build a rapport with the relevant regulatory authorities in Greece?

Right from the beginning, our relationship with the regulatory authorities has always been based on our profound knowledge of the legislative requirements, as well as a scientific augmentation. This has proven to be very advantageous, especially given the fact that we have also always conducted our business very ethically. We have an open-door approach to dealing with authorities and convey that we are able to collaborate. If you know your subject well and present them with a very good argumentation, it will be well received by the regulatory authorities. This is a philosophy that we do not only relay to our management team, but also to our entire organization and disperse the expertise in order to maintain our reputation as a whole.

We have also developed a strong relationship with the medical community from the ten years of operations and a formidable collaboration with more than 160 opinion leaders in the field. Moreover, all operations are run by very experienced executives with a nexus of expertise in each of their respective fields. We boast executives with background experiences from major multinational pharmaceutical companies.

Clinical trials is an underdeveloped activity in the country with a wealth of untapped potential to bring about further investments into the Greek healthcare landscape. What do you think has been missing in order to develop this landscape?

We need to encourage growth in the market as a whole. I am in accordance with other colleagues' view in the field that there is space for everyone in the landscape. From Pharmassist's perspective, the steps that we are taking is to participate in various international events and promote Greece as a whole as an advantageous clinical trial destination.

In the beginning, our clients' response has been skeptical. However, once the first project had begun, they understoond that there is potential here as the outcomes have been very positive. There had been cases of clients with whom we started off with a small scale clinical trial and we have now turned out to be among their preferred destinations and providers in a number of projects.

On a more personal level, you are also involved in advancing women as business leaders; how would you encourage young women to go into science and have a more entrepreneurial spirit?

I cannot speak for all women entrepreneurs, but I have personally been fortunate enough to have the support of my family and the community. The main thing I found lacking is the incentives available in Greece for all entrepreneurs as a whole in order to propel their businesses. Women are known to take more calculated risks and are therefore very suitable for managerial roles, and I strongly encourage more women to pursue their paths.

What would be your overarching final message to our global executive readers, as a Greek citizen and an entrepreneur, about the business environment in the country, as well as the future potential for Pharmassist?

Firstly, Greece should be considered a very promising destination for clinical trials as it has a very cost-efficient landscape without compromising any ethics and quality. Moreover, in regards with R&D, there are plenty of unpolished diamonds in the Greek landscape with a wealth of potential to elevate our current status in the international sphere.

For Pharmasssist, we are always open for business. Our mission has always been to guide companies with regards to the regulatory environment in Europe and conducting their clinical trial activities. We aspire to be one of the leading companies for conducting clinical trials in Europe.

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