

Interview with János Filakovszky, Vice President Therapeutic Delivery Unit, CNS, Quintiles Austria



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How does the Austrian affiliate fit within Quintiles' global structure, and what is the scope of the company's activities here?

Quintiles Austria was established in 1996 and has grown from six employees to 130 as of today. The first scope of the Austrian affiliate was to look at the opportunities in the research arena here in Austria. The Austrian healthcare system is of very high quality and the Austrian regulatory environment complies with the highest industry standards. Austrian authorities are said to be very supportive of the clinical research; a large part of the first group of regulatory processes was established here in the Austrian market and then expanded to other countries as well. The year 1996 was also the time of a very favorable environment which encouraged further expansion into Eastern European countries. The main scope for this region was to support and provide services to Quintiles' customers in the areas of clinical research and drug development.

You have mentioned in previous interviews that the fastest growing countries for clinical research include Russia, Ukraine, and Romania, amongst others, due to large populations and high quality medical infrastructure. How can Austria assert itself in this field in comparison to the growth in other countries?

Austria can contribute with two key factors to the international arena of the clinical research. One is the very favorable regulatory environment and a well-regulated clinical research industry. Austria usually obtains regulatory approvals before most European countries. Austria is highly competitive, and the healthcare services are of very high standards. There are excellent hospitals and university

clinics. Obviously, there are some limitations obviously here as well. In comparison to other European countries Austrian population is fairly small which limits the number of patients interested in or being recruited for clinical trials, as well as the indications and phases of clinical trials. Quintiles Austria has access to patients mainly for the late phase studies.

We spoke to Jan Huber who said that companies look to Austria because physicians, ethics commissions everyone does the job in a timely and professional manner. Do you agree with this?

I do agree. This is the immediate result of the favorable regulatory environment that I have already indicated. Austria is usually one of the first countries to obtain approval to start a clinical study. One of the challenges the industry faces today is to increase the predictability in terms of timelines and costs of conducting a clinical trial and a huge part of that cost is the cost of the startup phase.. If it is possible to accurately predict the startup time and the length of the regulatory approval process, the country becomes very competitive. That is exactly what we observe in Austria .

Do you think Quintiles Austria can serve as a beacon not just to Europe but the rest of the world as a role model?

In terms of the regulatory process and environment, definitely yes.

Michael Klein of Quintiles Indonesia told us that Asia is rapidly becoming the new hub for clinical research. What potential does CEE have in this context?

Eastern Europe plays a significant role in the clinical research for several reasons and these are noted in industry-wide available reports. One of the reports issued by the Food and Drug Administration (FDA), compares the quality of data obtained in the clinical research across the globe.. Eastern Europe is persistently acknowledged as one of the best regions in terms of the quality of the data it delivers.. Additionally, the historically conditioned centralized healthcare system guarantees access to a high number of patients, registries, and patient population in a centralized center of excellence where you can drive high standards and productivity, which is important for drug development, the pharma companies as well as the payers. That is definitely contributing to the success of Eastern Europe.

What do you think spurred on the development and centralization in these countries? Was there a point in time where this took off, or was it gradual?

I believe it is more of a gradual thing. The university education system has always been at a high level. That has definitely had an impact on healthcare service as well. Centralized healthcare has helped to share the best treatment practices around the same patient or disease population. That definitely adds to the success. With the industry present in Eastern Europe since 1995, Quintiles has steadily managed to help develop high industry standards in the clinical research. If you look at

the regulatory environment in Eastern Europe, many governments started implement international ethical committee standards into their national legislation. This started in 1994, and over time Eastern European countries have started to apply the EU standards in clinical research.

Thomas Dewald of Mundipharma mentioned that the synergies between affiliates of Eastern European countries and Austria can learn from each other. What can Quintiles Austria learn from other affiliates in Eastern Europe?

Quintiles has taken the approach to build up the region and ensure physical presence in every country. The company is now present in each country of operations, unlike some competitors who have taken a more centralized approach. Quintiles' strategy from the beginning was to ensure that high level industry standards are completed with the application of the local knowledge, expertise and culture. The role of headquarters in that sense is to obtain knowledge, and apply and share it across the region. Quintiles has always strategized as to how it can apply standards through regulatory bodies across countries such as the Czech Republic, Slovakia, Hungary or Poland. Quintiles worked with the authorities, including Ministries of Health in this region and worked with them to find a way to standardize the process.

You pursue a very aggressive policy in that sense; within Austria there are many small biotech companies starting up, many of which do not yet have a product on the market although they are very promising. Quintiles is involved with some very big projects but are there any that are too small for Quintiles? How do you reach out to these smaller companies?

Quintiles' business model involves providing services to help develop compounds and to get these compounds to patients as early as possible to meet patient needs. In that context, we provide knowledge and service to any company where we can see the product coming out. I think that one of the biggest challenges for biotech companies in Austria is to have access to funds for research and products. All the industry players in Austria, including the government, need to look at how to get Austrian biotechnology promoted effectively and ensure funding to get these companies into this highly competitive environment of the EU or even outside. Across the EU, you will see some governments taking a very precise approach to promote the biotech sector as one that is contributing to GDP.

What would you recommend to the authorities in Austria to help get funding for these companies?

I am not an expert on Austria; however, a dedicated approach with focus on the promoted sector to facilitate cooperation between players will definitely be helpful because Austria is historically rich with universities and research centers of very high quality. I think that ensuring funding for this sector and promoting it would really help to boost research.

Quintiles was ranked in 2008 in a study as the number one clinical research organization worldwide. In a competitive environment like Austria, does Quintiles' positioning reflect the group's global performance?

We are very proud. We were recently nominated as CRO of the Year by SCRIP . I am very proud of this and I see it as a recognition of the contribution of Quintiles to the development of the pharmaceutical and clinical industry. It definitely has impact, and the Quintiles brand as such is very attractive, which helps us to be the best also from the employee's point of view. As a recognized employer we have access to the best people in Austria and across the region which is definitely a great benefit.

In terms of the specific role that Quintiles plays as an employer, investor, and service provider, are the objectives you have now in line with what you set out when you first joined the company?

This is definitely the case. Since its inception, Quintiles has helped develop compounds for product development services. The role itself is expanding, no doubt. Quintiles is a thirty year old company and its goal has always been to provide innovative solutions to help the product development process and to push high quality compounds into the market as fast as possible, as well as to help our customers meet their goals. The industry has changed over these thirty years. The pressure for pharma companies is bigger, there are more cost constraints, and the regulatory environment is more demanding. There is a need for innovative solutions. Quintiles is investing in providing these innovative solutions for our customers helping to make the drug development process more robust.

Going into 2013, what do you see as the main growth drivers over the next year for Austria?

For Quintiles Austria and Quintiles Eastern Region, we are very well positioned for clinical research. I expect further growth there. The forecast of the market growth is around 6-7 percent. Obviously this means that any company that provides more productive solutions will get a bigger market share because the budgets are somewhat limited. The company is very well situated, and Quintiles has invested much in the past three years to provide innovative solutions for our customers and we are looking forward to further growth.

You have a very international background. Have you had to tailor your management style?

I have worked for Quintiles for 15 years and have been in the industry for 19. I am a physician, neurologist, and have my background in research and patient care, and I had worked in outpatient and inpatient clinics and in clinical research in Austria, Slovakia and Hungary before joining the industry. While all three countries are within close proximity, I have to say culturally all three countries are different. I had an excellent opportunity within Quintiles to grow, to work on different assignments and positions. It is a very exciting time for all of us in the industry and also at

Quintiles. I have really enjoyed each minute of the last fifteen years working here.

You seem like a very relaxed person. Is there anything that keeps you up at night, or that makes you check your Blackberry on the weekend?

I am a very customer-focused and people-oriented individual, so usually these are the two issues that keep me awake. I am very committed to our employees and our people, both locally in Austria and with the international teams I lead across the globe. The problems of my people keep me awake, as well as anticipating and meeting customer needs. I am relaxed, I have a great family, my wife and two boys are my key supporters and have excellent colleagues.

What can we expect you to have done with Quintiles in the next two to three years, and what would you like to have achieved?

In addition to being the Managing Director for Quintiles Eastern Holdings, the Eastern Europe Middle East region, I have an opportunity to be in a structurally more assertive role. I am leading the CNS therapeutic area globally. This allows me to work with cross functional units and cross geographic teams throughout of the lifecycle of the product development, as well as influence planning, design and the execution of programs and projects. That is very exciting because it leads to the necessity in the industry to accelerate product development in a highly productive manner to meet the patients' needs. This will help our customers gain access to knowledge that has accumulated within Quintiles over the last thirty years.

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