Interview: Heidrun Katholnigg – Executive Director, Global Clinical Development Europe, Celerion, Austria



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Heidrun Katholnigg, executive director of global clinical development Europe for Celerion, a global CRO that specialises in phase I, II and III clinical trials, discusses the acquisition of Assign Group by Celerion in 2016 and the importance of Austria in managing European clinical operations. Furthermore, she highlights the favourable clinical trial environment in Austria and the outstanding service capabilities of Celerion for current and potential partners.

Celerion acquired Assign Group in 2016. What was the rationale behind the acquisition and how has this affected your activities?

Celerion, a leader in early clinical research, delivers applied translational medicine through global clinical research, data management and biometrics, as well as global bioanalytical services for seamless early drug development. Celerion acquired Assign Group last year with the intention to better support and expand their business in Europe and broaden the scope of their portfolio. Assign's expertise in phase II and III trials across Europe has opened up an array of opportunities. The knowledge transfer between the two companies fits like two pieces of a puzzle, allowing phase I, II and III clinical trials across a large geographical area. Our European expertise will bring guaranteed rapid results, as opposed to Celerion entering the market independently.

Clinical research activities used to be structured regionally, and many multinational companies would ask their local affiliate to search for a partner in the country they were located. In this

regard, Assign developed capabilities across the D.A.CH region that incorporates Germany, Austria and Switzerland, as well as in the Netherlands, Poland, Hungary, the Czech Republic and Slovakia, to satisfy the local demands of the multinational affiliates. This has led to our customers remaining loyal and now we have generated the repeat business demand for our services at Celerion as we had previously.

Despite all the changes, the transition phase is behind us. We have managed to harmonize the standards and procedures in every aspect of our business including IT processes. In a broad sense, the operational standards for our department have remained basically the same as harmonizing mostly consisted of integrating new resources that came along with Celerion’s portfolio of services and internal support procedures.

How have your operations grown since we last met in 2012?

From 2005 until 2011, the company grew rapidly. The global financial crisis affected the entire pharmaceutical industry. As a result of this period we established a business model built around stability. Celerion in Europe is currently diversifying the scope of services it can provide in terms of field of research and this will kick start further growth after this consolidation stage.

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Since last time, we have also implemented internal improvement initiatives due to Celerion’s operational standards; such as, the use of digital methods for analysis purposes to improve overall efficiency and sharing of information to ensure we learn from past experiences.

What significance does Austria play in Celerion´s global operations?

Despite the relatively small revenues we generate in comparison to other lines of service within Celerion, namely the US clinics, we think of ourselves as the most important affiliate within Europe in terms of growth potential. Our activities require fairly basic office supplies; therefore we have exciting potential to grow rapidly as we already have a strong foundation structure to work from.

What is the mandate of the Austrian office?

We have always been very keen about accompanying our partners in their internationalisation, with the Austrian office’s responsibility stretching across the border, managing Germany, Switzerland and most of Celerion´s European countries in our division. We have hired a vast array of native speakers in our Viennese office to help us conduct activities in Belgium, Netherlands, Hungary, Slovakia and Czech Republic in addition to German speaking countries with our own

resources. In some cases, such as Italy, Spain, Portugal, we have chosen to resort to the help of in-sourced local specialists from qualified CRO partners.

Considering many companies perform trials here, what structures are in place to promote clinical trials in Austria?

The regulatory environment of Austria is more favourable to clinical research than in many other countries. Austria contains highly educated scientists that are eager to learn – furthermore – the university hospitals of Vienna, Graz, and Innsbruck as well as the federal hospitals, such as Salzburg, host these experts and are overall genuinely interested in the stimulation of medical care solutions in the country. This, coupled with a world-class research infrastructure and government regulations that facilitate clinical research, creates an interesting market that has the potential to evolve and become a clinical research hub. Additionally, support from national regulatory bodies helps us improve the quality of the trials we conduct, and not only those we conduct within Austria.

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Nevertheless, a portion of the general population has a negative perception of clinical trials as they associate it under the generalised term of testing. In fact, clinical trials are easier to conduct in areas that are not yet covered by the existing range of solutions available as people see their importance. For example, oncology is always viewed positively by the public as they understand this sector still does not have a definite cure. Additionally, in cases where the government supports the products such as vaccines, the general population’s opinion is favourable.

What examples highlight the service capabilities of Celerion in Austria?

Our operations ensure we are capable of working with clients on a long-term basis; in fact, the longest study we ran lasted for about ten years. This oncology experience was in phase II and III, and is quite distinct to phase I research, in which candidates are sometimes tested within weeks or only two months. Furthermore, we conducted epidemiological study including about 5000 subjects. This shows we can maintain a high-level of precision with large quantities of data, a huge challenge for any CRO. Lastly, we’ve proven we can work at an international scale with projects involving the mobilisation of resources in Asia, Australia, Europe, and the Americas (North, Central, South America). Communications across time zones and collating of information was very tricky, but we were successful.

How does Celerion differentiate itself from other CROs in the Austrian market?

We are one of the largest CROs in Austria but most importantly, our employees are office based, allowing us to build a harmonious team environment that communicates efficiently, very different to many of our competitor´s workforce which are mainly home-based or freelance. Our team structure also provides the perfect environment to learn and advance from our colleagues' experience.

Furthermore, if you look at our office, most of our recruits are young and ambitious graduates that we shape for the professional world – in fact – it is pleasant to watch them grow and develop, not only in terms of productivity but also expertise in the CRO domain.

You have worked in clinical research your entire career. How does this experience help you manage your team now?

The team, and especially my vice president, and I form the perfect match to manage the company. My years of experience in the quality department has impacted me significantly in terms of managerial practises as now I am extremely interested in implementing correct procedures and appropriate processes that lead to overall high quality, which benefits the Austrian study participants. I think it is essential to understand where your strengths are and where to improve. I continuously try to learn and the pharmaceutical and biotech industry are never boring as every study has its own unique demands;

All in all, my work now consists of maintaining high standards as a priority within the minds of our people. It is quite nice to explain to colleagues how we are able to monitor patients, discover problems and then find the perfect solution.

What do you want Celerion to have achieved in five years' time?

We want to grow the Austrian affiliates revenue through diversification of study activities and equally Celerion headquarters expect us to grow. Increasing our reach in terms of new clients and broader operations fields does not necessarily mean we will be growing our headcount as we see outsourcing of research operations as a future possibility. I believe it is important that we continue to expand our services and diversify the types of research support opportunities. This ensures that we remain flexible, can adapt to future changes, and further establish ourselves as a cornerstone of clinical research operations in Austria.

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