Interview: Dr. Marian Gono – Chief Operations Officer; Dr Marian Takac – VP Sales and Marketing, Hameln rds, Slovakia



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Marian Gono, COO, and Marian Takac, VP Sales and Marketing, of Hameln rds discuss the scope of the company's operations in Slovakia, the key milestone of attaining FDA approval just three years after setting up the facility, and the challenges and opportunities of being based in Slovakia.

Could you first provide an overview of Hameln rds to our international readers?

Hameln rds in Slovakia has a long history – though not always under the Hameln name. The roots of the company date back to 1972 when the Ministry of Health set up the Drug Research Institute, as an independent Institution of Spofa, in the town of Hlohovec. The Ministry then named the Institute as VULM a.s. and moved the Institute to Modra, where we are located today. In 2006, German-based Hameln Group acquired 100% of the shares of VULM. We subsequently renamed the company to Hameln rds, with rds standing for research, development and supply chain. Today Hameln Group consists of Hameln Pharmaceuticals in the UK, Hameln Pharma Plus in Germany and Hameln rds here in Slovakia.

We provide a variety of manufacturing and development services for Hameln Group and external customer from all over the world. We began as a regular contract research organization, in the last years we have moved more into the contract manufacturing space and we are looking to extend our service portfolio to become a full contract development and manufacturing organization. We

cater to both our own products and our clients' in terms of API production, laboratory services and also supply chain services for APIs and Final dosage forms. We also offer pre-clinical services in our own animal house facility, as well as regulatory affairs activities.

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Our clients are mainly mid-sized European companies; 95 percent of which are from outside Slovakia and 90 percent from Western Europe. We are also in discussion with several potential Eastern European customers, so we are hopeful to begin diversifying our client base in that sense.

What have been the main successes since you were appointed COO eight years ago?

The biggest milestone was receiving FDA approval within three years of setting up this facility in 2009. This was absolutely critical to our success. Since then, we have passed two more audits: one in 2012 and one earlier this year in 2016. It was a very difficult process because the FDA has its own approach and it is not comparable to the European regulatory requirements. We had to prepare ourselves through customer audits and internal audits.

We are also regularly audited by the country's national authorities: the Slovak National Accreditation Services SNAS for GLP and the Slovak State Institute for Drug Control SIDC for GMP, in addition to client audits of course. In 2014, two of ours API produced in our newly established high potent API facility were granted with the CEP certification.

Fundamentally, we are very proud of our achievements in this regard because we had to build this facility basically from scratch. It was a very old building when we acquired it; to be able to successfully redevelop it in such a short span of time to the requirements of different international regulatory bodies is a huge accomplishment. The proof is in the products that come out of this facility. For one of the substances produced here, there are only two companies in the world that can produce it and one of them is us.

What are the current growth drivers for Hameln Group?

We are focusing on further expanding our API production and laboratory services capabilities. There is always room for improvement and we are hoping to consolidate and further grow our existing portfolio.

A notable initiative is within the laboratory analysis segment, where we are hoping to expand our scope from generics and chemicals to biologics. We will not be the producers of biologics but we would like to offer some analytical services. This will be quite a step-up so we are working hard to

figure out what our customers want. Then we will need to go through potential customer audits and only then can we start talking about commercial orders. To this end, we are integrating a new lyophilisator into our facility along with some new equipment and additional staff training. Ultimately, it will be about our QA process because that is the paramount concern for our clients, and that applies equally to both generics and biologics.

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We have also devoted some money for GMP microbiology to invest in more space, more equipment and more people to bring Hameln rds to a higher level of services and quality, and to improve overall internal processes.

What is the level of your engagement with the broader R&D ecosystem?

We have a variety of partnerships depending on the specific areas of business and projects: academic institutions, academics, pharmaceutical companies, across areas like natural sciences and chemical technology. Slovakia has a strong background in the chemical industry so the production of API is a good match. We actually have a pharmacist employed in galenical development here who also lectures part-time as a university professor. We are also contributing to train and educate the next generation of talent, and we have a couple of students working with us here on work placement.

How is Hameln differentiating itself from your competitors in this market?

It is a tough market because we are facing intense competition, not just from the local market but also from neighboring countries like the Czech Republic. That being said, what differentiates us is that we cater comprehensively to the complete supply chain, up until production of the final APIs: analytic work, development, regulatory affairs. We want to position ourselves as a one-stop shop for our clients. On top of that, we must always bear in mind that we need to consistently provide quality at a reasonable price.

What are the opportunities and challenges of working in Slovakia?

The single biggest advantage we have is being part of the European Union (EU). Many of our services are prepared for third-party countries so we are effectively importing goods into the EU. Access to the EU market is very important for us. There are also many opportunities for partnerships with other companies and academic institutions here. The labor market in Slovakia is very robust and we are able to recruit talented people. We are also fortunate to be able to benefit from EU legislation, most notably the Registration, Evaluation, Authorization and Restriction of

Chemicals (REACH) legislation, which presents another business opportunity for us.

One negative aspect though is that because we are located in the Bratislava region – identified as a relatively well-developed region within the EU – there is not as much EU and governmental stimulus funding available for companies based here compared to more remote parts of Slovakia. Overall this reflects well on the business environment but I must admit that some extra funding would not hurt, and would help us expand further. We currently rely solely on our operating income to generate the profits required to continue investing in our company.

As a service provider, we are fortunate that we rely mostly on the pharma industry for business. Our clients are pharma companies, biotech companies and chemical companies, so we are fairly insulated from the broader policy environment. This independence from the Slovakian system is a good thing as it makes us more secure.

What is your final message to our international audience?

We are a great Slovakian company situated right in the middle of Europe, offering quality services that meet US and EU requirements at a very competitive price! We are your reliable partner without a doubt.

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