

Pharmaceutical – QA

Harrison Clinical Research tests new drugs for pharmaceutical companies/take over fantasy

By Helmut Maier-Mannhart

Ever since Bill Gates managed to make a worldwide corporation out of his initial company in the garage, such success stories are synonymous with the American dream of an enterprising career. Such examples, however, can be found in Germany. Men like the 51 year old Francisco Harrison. Born to a Spanish mother and an English father in Spain during the Franco era, he studied medicine in Madrid. As an English citizen, he was not allowed to practice medicine in Spain and moved to England, where he did post-graduate studies in Coventry. At some point, he ended up in Munich, Germany, where he studied pharmacology at Munich University. This brought about the turning point to independence. As scientific assistant at Munich University, Harrison was asked in 1987, by an Italian company, to do a clinical study with a new medication. This paved the way for the Harrison Clinical Research GmbH (HCR), founded in 1989. Today, HCR counts as a leading company in this market segment, which is essential for the development of new drugs.

To understand what happens at HCR, one has to look at how medications are developed. This is not only a lengthy but also a risky process. Before a new medication ends up on the chemist's counter, it takes many years and the costs for the development are, on average, about 800 million dollars. Once the substance has been pre-clinically

tested by the pharmaceutical company, the 4-6 year clinical testing phase in patients begins.

Years ago the regulations for the registration of new medications were not so strict and the test phases were carried out by the pharmaceutical companies themselves. Today, it is far too costly for them to tie up qualified personnel with these tasks. Therefore, these test phases are contracted out more and more. This development was foreseen early by Francisco Harrison and he was able to adjust his services accordingly. His company carries out all the tasks, without which today no drug can achieve registration. Harrison counts 6 of the 10 top pharmaceutical concerns of the world to his regular clients, employs approximately 300 people, of which 180-200 are full-time staff and predominantly medical doctors and he has a yearly turnover of 20 million Euros. According to Harrison, the worldwide market for drug development currently stands at 15 billion Euros. This grows every year by 15-20 percent. The worldwide market leader in contract clinical research is the company Quintiles, with 1600 employees and headquarters in North Carolina.

Harrison foresees no limit to the future growth of his company. On the one hand the outsourcing of clinical studies will still grow substantially and on the other hand there are lots of

pharmaceutical companies seeking strong partnerships and which, therefore, constitute potential take-over candidates. Currently, Harrison is negotiating in the USA. There, around 23 percent of his clients are at home, 15 percent are in Japan and the rest are strewn over the whole of Europe.

The clinical development of medications is divided into three phases, which last between 4-6 years. In Phase I, the safety of the substance in small quantities is tested in a small number of volunteers, this lasts about 6-12 months. In Phase II, which can last for over 2 years, the efficacy of the substance is tested. When this is positively completed, Phase III begins with a large number of patients where the questions to be answered are whether the substance is more efficacious than those available on the market and whether it is really an innovative product. Only then when these questions are satisfactorily answered can the registration of the new product be applied for.

Development of food products

The problems that can arise in each of these three phases, was shown by the spectacular case in London last year, where a half-dozen volunteers were taken critically ill during a clinical study. Tegenero, a pharmaceutical company from Würzburg, Germany, was testing with a London based competitor of HCR, a

new medication for multiple sclerosis amongst other indications. Problems arose when all parties chose the wrong approach for the test phase. Due to the fact that it was a completely new substance, the volunteers should have been dosed at much lower levels, one after the other and not all together.

An exceptional case says Harrison that demonstrates that companies like his have to develop as a sort of quality assurance institution for pharmaceuticals. The quality of his company Harrison ensures through his own dedicated QA department. Around 15 percent of personnel costs are spent on training, he said. Having his own clinic with 36 beds, here in

Munich, where Harrison does Phase I studies, is a further element of his quality assurance as this construction allows for direct and continuous control.

As well as pharmaceutical development, the consumer protection laws have opened up a new, lucrative business area for HCR. It requires that companies in the food industry have to clinically prove certain health related marketing claims for their products. For such tests, Harrison feels well equipped. To maintain or increase his growth rate, Harrison requires additional capital. Up to now, all investments were self-financed but this does not allow him to take full advantage of the opportunities the market

presents. Harrison is looking at ways to open his company to capital investors.

Profile

Name: Francisco Harrison, Chairman
Company: Harrison Clinical Research Group
Location: Headquarters in Munich, Germany
Founded: 1987
Turnover: more than 20 million Euros
Employees: approximately 300
Photo: Harrison Clinical Research

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(The caption for the photo of test tubes on the page, is:)

Large-scale tests for the pharmaceutical industry are the core business of Harrison Clinical Research.