



Hope for Liver Cancer Patients through New Technology

Sirtex is an international life-sciences company that delivers new treatments and hope for those afflicted by liver cancer, and is transforming the market for oncological therapies.

Photography by Armin Höhner

igel Lange, Chief Executive of Sirtex's European division, is based in Bonn, Germany, where he directs sales and marketing for Europe, the Middle East, and Africa. The region is comprised of 20 countries where the company distributes its lead product, SIR-Spheres® (yttrium-90 resin microspheres), to doctors and patients through both whollyowned sales companies and local distributors.

Nigel has a strong background in the healthcare sector, particularly within the pharmaceutical industry. He recently sat down with *The CEO Magazine* to discuss his history with the organisation, plans for the future, and the revolutionary technology Sirtex offers to patients throughout the world.

The CEO Magazine: What is your professional background that you brought to your position with Sirtex?

Nigel: Essentially, I've been involved in healthcare since I graduated from university. I hold two university degrees; one is a Bachelor of Commerce and the other is a Bachelor of Arts. I spent close to two decades in the pharmaceutical industry, but made

the transition to medical devices in 1999. I've been involved for almost 13 years with Sirtex's unique technology, which enables interventional radiologists that we train to deliver millions of potent radioactive microspheres directly to the site of liver tumours. I launched this technology in the US, and following that, I moved to Europe and launched it there at the end of 2003. All of my experience is in medical sales and marketing. I was working in the Asia-Pacific region for six years for a Canadian pharmaceutical company, managing our business in the Far East, prior to becoming involved with this remarkable approach to treating liver cancer that Sirtex has pioneered.

What challenges have you faced since taking up your position?

It was just myself and two chaps from Australia that started the business here in Europe. As I've said, we started Sirtex in the US and then the opportunity came up to take on the challenge of coming to Europe and starting the business here. Since I am Canadian, it is a bit ironic that our first European headquarters were in the former Kanadahaus in Bonn. My family and I did have to overcome a few cultural differences, but overall it's been a very positive experience. Choosing

to locate our office in Bonn, as opposed to London, was a fairly complex business decision, but we wanted to be positioned as a truly European organisation. As it turns out, Germany has become an extremely large and important market for us.

Getting incorporated in Germany raised a few administrative challenges, of course. But without doubt, our biggest challenge was that we were an unknown entity; nobody in Europe had really heard of this technology, so we were really starting from square one. We were walking into very high profile academic institutions, where nobody had heard of the company or its technology.

Getting acceptance for our technology was also complicated because ours is very much a multidisciplinary treatment. SIR-Spheres® microspheres treat liver cancer, but oncologists are not the doctors who administer it to patients. It is their decision to recommend the treatment, but it is administered via a catheter into the liver that is placed by an interventional radiologist. Since SIR-Spheres® microspheres are radioactive, much more so than the radiation therapy that is administered by an external beam, the skills of nuclear medicine physicians are required to prepare >



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the dose. As the therapy is given only to the liver, hepatologists, surgical oncologists and transplant surgeons are often involved. In short, we don't just work with one medical discipline; we are working with several. All of these specialists are kev stakeholders in the use of our technology, and communicating successfully with each of them is a challenge.

Beyond that, the biggest challenge that we continue to face is the challenge of reimbursement in every market. I think what makes this even more challenging in Europe is that the European healthcare market is completely heterogeneous; each country's healthcare system presents its own distinct regulatory and funding issues. In the US, we had a fairly easy launch because we were dealing with a completely homogeneous system. In Europe, you have systems within systems. To be effective requires time and collaboration with reimbursement experts on the ground in each country.

No matter how good a medical technology can be in the clinical setting, no matter how much it can benefit patients, it's always about who's going to pay for it and how much they're going to pay. It's a situation where you're faced with shrinking healthcare budgets, and your product is a medical device that has been supported to date by good but limited data to prove the safety and efficacy of the technology. This is a particular problem when you compare our treatment to chemotherapy and biologicals supported by large pharmaceutical companies with big budgets and longstanding relationships with medical oncologists. All start-ups face challenges, of course, and we have had to overcome our share.

What would you say are the key values of Sirtex?

It's honesty and integrity, it's respect for others and, above all, it's what we do as a company, which is to help benefit the lives of liver cancer patients. It's particularly the



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honesty, integrity, and respect that we show to our customers. Those are our guiding principles. At the end of the day, upholding these values is also what makes our job interesting-we encounter a lot of remarkable patient stories at the different hospitals we work with. We know from the doctors we work with that we are helping people and families that are confronting the serious health challenges of liver metastases or primary liver cancer. It's a rewarding job for all of us in the organisation, and everyone on the multinational team that we have built up over the past decade has played a significant role in impacting the lives of more than 10,000 patients we have treated in Europe.

In order for us to continue to succeed, the honesty and integrity has to remain intact. As a matter of fact, we've had virtually no employee turnover in 10 years. I think that's a testimony to the culture we've built. We tend to build the culture around those values and I tend to think that's why people don't leave; that's why they stay where they are today.

How does your organisation ensure it remains innovative?

One of the things that we have done throughout our company and the European group that has been an integral part of this is to expand the use of our technology by engaging the understanding and support of key medical opinion

leaders. Unless doctors who are leaders in their fields become enthusiastic about SIR-Spheres® microspheres, unless they gain hands-on experience with our technology, the task of diffusing the technology becomes that much more difficult. You need people that work with your technology, not only in the clinical setting but also in interaction with their peers in professional societies and health ministries.

In addition, to help close the data gap between ourselves and the research-based pharmaceutical industry, we are conducting a very extensive clinical trial program that is virtually unprecedented within the medical device industry. We currently have 17 active clinical trials, which have allowed us to strengthen our relationships with the leading doctors in cancer therapy by engaging them in research that could ultimately alter the whole paradigm of treatment for both metastatic colon cancer and primary liver cancer. This is very exciting work for everyone involved. If these studies are successful, the hundreds of doctors around the world who are engaged in them will have a chance to help reposition how our technology is perceived by presenting the results of these clinical trials at scientific symposiums and medical congresses, and publishing them in leading medical journals.

We're also engaged in looking at using our technology in other

solid tumours, which is very important because we haven't exhausted all the possibilities of SIR-Spheres® microspheres. The future appears bright.

How does Sirtex work consultatively with its customers?

We don't view doctors as customers; we view them as partners. Ours is a complex technology because it involves many different disciplines. So we have to agree on a common goal with doctors in all these specialised fields, and that is to ensure the optimal treatment of patients that are afflicted with inoperable liver cancer, whether it's primary liver cancer or metastatic liver cancer. Our goal is to try to improve the lives of those patients. Because of the complexity of our treatment, it's very much a consultative process with each of these doctors. It's a partnership, and they view us as partners because they seek information and advice from us, and they advise us on which patients might respond best to our treatment.

We also offer an in-depth training program, which involves proctoring new hospitals and working side-by-side with their treatment team until everyone involved is comfortable using the technology, and we're comfortable that they are a centre that is going to perform well. It's in the interest of both parties, when you're adopting a new technology, to ensure that you start it off on the right foot. I'm a firm believer that good news travels fast, but bad news always seems to travel faster. We invest considerable financial and human resources to bring every new hospital up to speed with our technology, to mitigate risk to patients and to ensure that all of these hospitals use our technology in the proper way.

What role does collaboration and trust play in your company's key relationships?

Collaboration is particularly important when you're talking about our supply chain. We have a radioactive product; it's a classthree medical device, so you could well imagine the challenges of moving it around the worldflights, ground transport, storage and handling, so collaboration and trust is absolutely key. We rely heavily on solid cooperation with our logistics partners.

When I'm speaking about our supply chain, we always have to keep in mind that at the end of this chain, there's a patient waiting to be treated. In most cases these patients have undergone many other prior therapies. They may have undergone three or four lines of chemotherapy and our treatment may be viewed by patients and their families as a final hope for them in terms of slowing down or arresting their disease. The doctors and nurses who treat these patients know this, and so do we.

We have a full-time medical director on staff, who is a German board-certified interventional radiologist. His presence further ensures that patients will be treated safely, and that only patients who can genuinely benefit from SIR-Spheres® microspheres treatment are selected to receive it. This means that we can maintain high safety standards by offering patients the best possible outcome.

Not every technology or every drug is suitable for every patient who walks through the doctor's door. It's important that doctors get to know which kinds of patients will benefit from the treatment and which kinds of patients will not.

If I tie all of this back to technological development, it's the research efforts and resources we pour back into clinical development that allow us to solidify these relationships that we have with our partners, and ensure that we can continue to develop the technology and make a better life for people that need the therapy.



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for Sirtex?

The future is extremely exciting for us. As I mentioned earlier, we have 17 different clinical trials in various stages of completion. We've just completed a very large trial in metastatic colorectal disease but we are still waiting on the results of that study. That data has to mature before we can draw any conclusions from it, but the study's objective is to demonstrate whether first-line use of SIR-Spheres[®] microspheres with state-of-the art chemotherapy can hold a patient's disease in check significantly longer than chemotherapy alone.

In preparation for potential growth, we've recently commissioned a new manufacturing facility for Europe. We now bring in our product from our manufacturing facility in Singapore, but in terms of positioning ourselves for future growth, we will be manufacturing SIR-Spheres® microspheres in Germany by the end of 2014, to supply both our European and Middle-Eastern markets. There are also opportunities to bring new markets on line; we're not in every country in Europe yet. We've got tremendous growth potential in several key European markets as well as selected ones in the Middle East, which adds further to the very bright future we see. •

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