Anna Lefevre Skjöldebrand – CEO, Swedish Medtech



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Swedish Medtech is Sweden's largest medical technology industry organization, representing more than 180 companies. CEO Anna Lefevre Skjöldebrand explains how patient needs are driving today's medical device industry, analyzes Sweden's unique assets and explains the importance of having a social mission.

You have been at Swedish Medtech for almost 15 years. Could you explain the role of the association?

This year we are celebrating our 50th anniversary, we have a long history that has been aided by Sweden's long history of medical device innovation. During my time here, we have been focusing on the value medtech brings to patients, healthcare and society at large. We also focus on the market and the long-term conditions of the industry. We have a fair amount of Swedish companies that are doing well, but very often they are talking about procurement and exhibitions, and they are not necessarily following what is happening with health economics or health technology assessment in the same way. We have been working to make sure that everyone knows about what the medical device industry is doing.

We are also trying to make sure that the industry knows the expectations that society, healthcare providers and patients have. Nowadays, there are more things required to sell, that includes a knowledge that goes beyond just the technology and engineering behind the products, the industry

needs to be closer to the patient.

How does Swedish Medtech help its members navigate the Swedish market?

In some ways, we are working as a traditional organization, in the sense that we have several groups where our members meet. The groups are organized both in a vertical and horizontal manner. We have groups that focus on regulatory issues, economic affairs, and innovation and growth; the idea is to cover as many relevant subjects as possible. We understand that these things affect the whole industry in one way or another, and the work has to be a reflection of that. We have a new group called Sustainable Affairs because our members are committed to the environment, society and corporate responsibility. That is also an area where most of our companies are performing well, but there is always room for improvement.

We also offer different networking opportunities through our two big yearly networking meetings, conferences, and education courses to train our members.

What are the main strengths of the Swedish medical device industry?

We have a very strong tradition of engineering and that has created a strong foundation for different areas in medical devices. We also have a non-hierarchical way of working, not only within an organization but also between them, which has made it easier for companies to approach healthcare together and work on common projects. That being said, we have seen that the need-driven innovation has been the core. The question is “who is deciding what is the need?”, because earlier on it was clear that it was a clinical medical need that drove the industry, but it is evident that patient needs are really driving what is happening in the medical device industry today; because it’s one thing to be cured of a disease, but it’s another to have a good life, one where you can continue with your activities not even noticing your medical condition.

Another asset is that the Swedish population has a positive approach to society, we generally believe in the state as a well-functioning body that is looking out for our interests, which is not always the case in other countries. As a result, an enormous amount of personal data is created and stored. One example is that we have the quality registries, which allows us to draw conclusion on various medical treatments. The question is how to use the information; if we do it in the right way, there is great potential for all of the life science sector.

There is a strong collaboration between industry, academia and the public sector in Sweden. How is the association contributing to that environment?

One thing about associations that is true in all countries, and of course in Sweden, is that it is much easier for stakeholders to interact with an association rather than directly with each individual company. What we can do is provide a platform where it is easier for the government to meet our members. Equally important is to create meeting opportunities for our members to meet and address patients and professionals working and living with their products. The trade associations are key in this mission, and, also, as a trade association, we represent a broad spectrum of companies. It would be difficult for the state, healthcare providers and universities to interact with the whole industry.

You recently spoke about an issue with certain cardiovascular devices that had to be removed from patients. What has the industry done to address the situation?

It’s important to emphasize that the industry has been working on safety for a very long time. It’s never acceptable that patients suffer. All successful medical device companies have to have the drive to do good, without it there is no future market. We have to be very open to the fact that we operate in a life or death area; when things go wrong, it can be catastrophic. When you work in this industry, you always have to have the mission of doing good present and not miss any steps. I honestly believe that a majority of companies have been addressing this issues for a long time, but it’s good that we have the spotlight to ensure that the industry brings good to society and that means we have to be very thorough when it comes to safety and security, we can never relax in this area.

Since the association collaborates with all levels of government, what are some policy changes you are advocating for at the moment?

For the medical device industry, it’s evident that we are going through changes with the new European regulations that will be implemented fully next year. We are in a transition period. We believe that the changes are good, but we worry that while the regulation is good, the infrastructure to make the regulation work is not yet in place; that’s a problem for the industry and the patients. First of all, all medical devices have to have a CE marking (European certification

mark), which means that the medical device is classified in terms of risk to the patient. We have four classes: number one has a lower risk and the fourth has the highest risk. The requirements on the products are basically the same as before, but if the product is in the higher risk categories, it needs a notified body to certify that the company and the product meet the requirements. Under the new regulation, there are currently only four European notified bodies that can certify products in all of Europe. In comparison, under the current directive we have 58 notified bodies. The process to receive the certification lasts around six months. The lack of notified bodies is a big worry because it creates a huge bottle neck and it's extremely hard for all companies to find one; smaller companies are essentially at a disadvantage.

Three Swedish companies were recently nominated for the Medtech Insight Awards, also known as the "Medtech Oscars". Why is Sweden able to produce constant innovation?

The Swedish population is to a very large extent tech-friendly, with the idea that technology can achieve positive outcomes. When I was a child, the government sponsored a program for people to have a computer at home and we were early to understand the capabilities of new technology. If you look at digital doctors, it requires a certain infrastructure to be in place and that patients agree to receive treatment through the internet. Also, we are not hierarchical in how we are thinking and acting, which makes it easier for different industries and ideas to create new innovations. The fact that you can bring people together from across different industries and professions creates a great climate for innovation, not only in medical devices. Looking at the success in digitalizing Sweden, we owe it both to the early adoption of new technology among our citizens but also a well-functioning infrastructure.

Swedish Medtech just had its 50th anniversary, what can we expect for the next 50 years?

Medical technology is an industry that provides solutions to big problems, it addresses the great needs of society. Most of them are very patient-related, but it's also about making it easier for nurses or doctors to work. We have an industry that is "future proof" because we address fundamental needs in society. I think the global medical device industry will keep on bringing good to the people, there is no other reason for it to exist.

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