Vortrag Biomedizinische Technik , 11 2023

Ladies and Gentlemen,

yesterday I received the great honor of being awarded the honor membership of the Austrian Society of Biomedical Engineering. I was invited to share some of my experiences at this conference, and it is a pleasure for me to do this here and now.

This will not be a presentation but a speech only, since time was short when I received the invitation. Your advantage is that you do not miss a slide when you have to be busy with your smartphone. And it will not be very scientific. I apologize in advance. My plan for this lecture is to bore you about the history, as you can expect from old men, and talk a little bit about lessons learned for the future. My viewpoint is positioned on the industry side.

40 years ago I started to be part of the biomedical engineering community and I am still an active and acting member. I have seen a lot of transitions, have learned a lot, had many successes and also a lot of failures and last but not least had a lot good moments and a lot of fun. Would I do it again? Absolutely yes! Would it be the same level of fun? Probably no. I will explain later.

In summer 1983 I finished my Masters education. I planned to find a job in the hydropower industry, because I was convinced that the carbon burning epoch will end soon and I wanted to contribute on the right side. When I returned a book to Professor Erich Leiter, who did run the department for Biofluid dynamics on the Institute of Fluid Dynamics at TU Wien he offered me a PHD research position. I spontaneously said yes. This is how I got started and things continued to be spontaneous.

The 1980's were the wild years of Biomedical engineering. There was no medical device directive, no quality management systems, but many creative researchers, who wanted to improve the life of persons with special needs. This was the time of Stefan Schuy in Graz and Herwig Thoma in Vienna. While Stefan Schuy was the scientist, Herwig Thoma was the entrepreneur , magician and general artist. Together with some other great personalities like Fritz Paschke they built the foundation for the scientific community in Biomedical Engineering. They were creative and brave, but they were not ruthless. They were aware of patient risks and necessary patient safety, and were willing to take personal responsibility, since there was no possibility to shift this to

institutional systems like ARGES with MDR and QM systems in the background. Working on a system for objective analysis of smelling I found myself on the ENT Clinics of Prof. Burian in AKH together with Inge and Erwin Hochmeier, who experimented there with Cochlea Implants. The labs were in the basement of the Josefinum and we were neighbors of the artificial heart labs there were Heinrich Schima was doing his epic work. Funding was poor but enthusiasm was great. I had to do absolutely everything for my projects like micromachining, hardware and software development. This was the perfect foundation for my start at Otto Bock in 1987, which happened spontaneous, since my PHD instructor died at a car crash and his department was immediately dismantled. I needed a job with or without PHD. Ottobock in Vienna was more or less a garage lab with 40 persons and miserable funding, but working on artificial limbs was fascinating. I was the first person there with an academic background. However since I started already in the age of 13 to mess around with motorcycles and cars I had experience about the survival probability of technical structures and therefore I was able to communicate on the shop floor. I had to learn a lot but at the same time I was able to start contribute by helping to implement new technologies like CAD, NC manufacturing or SMT technology. We were incredibly fast with our developments. It took us less than a year from the first line on the drawing board to the first patient trial for a completely new design of a pediatric artificial hand system. Off course documentation was simple, like putting a part on the copy machine and marking one or two control measures. And off course we developed Banana products: they ripened with the customer. But we always exposed the whole team to customers and patients during the whole development phase and so got the right feedback. Today these are very modern concepts in innovation and development: you can call it SIMULTANEOUS ENGINEERING if you go to the production guys and ask them if this is a good idea or impossible to produce. If you talk to customers and patients you can state that you work with FOCUS GROUPS. If you bring your prototypes to users and customers and see if it works or not and then adapt you can call it AGILE DEVELOPMENT WITH DESIGN LOOPS. I can confirm that these concepts work. But it is more important that the concepts are part of a company culture rather than processes, which are developed by consultants with only little real company experience and then popped on the R&D teams.

The nineties did bring a significant shift in the medical device industry. It started with first voluntary and later mandatory quality management systems and with the birth of the European Medical Device Directive. There was very little

understanding, some did fully ignore the challenge, other developed end of world scenarios. The consultants were the only ones who applauded and enjoyed the new business opportunities.

Up to this time Prosthetics and Orthotics were not classified as medical devices at all. The manufacturer roles were pretty unclear for many more years. I was ignorant like many others and decided just to build a paper shell for the auditors. It worked a while but possibly was not the best idea. In 1997 the MPG was effective and this coincided with the launch of the C-Leg, which was at this time our most complex and revolutionary development. This did finally lead to a proper understanding of the beauty of quality management systems and the need of proper implementation. The launch of the C-Leg on the US market opened a completely new chapter in the field of regulatory affairs. The preparation of documents for regulatory clearance as well as necessary implementation and adaptation of processes changed a lot in the company. I must say it changed the character of many departments at Ottobock. Processes improved, but product development slowed down and customer orientation decreased. Optimization in the mid and later phase of a project got difficult, time consuming and expensive. Late requirements became the most hated items in R&D. At some point in development, if the customer says, this is shit, you only can tell we have to live with the shit but we can't make it better anymore. Since I define myself as an R&D personality and not so much as a process orientated manager I tried to reduce the bureaucratic workload from the engineers and did build a very effective regulatory department. Looking back I must say, this again did not have the expected effect since the very effective regulatory department created more demands in direction R&D engineers. We almost lost our ability to spontaneously picking up ideas and concepts from the market trying it out and making a product out of it.

Since I wanted to regain this ability I started an experiment in Berlin. We opened the Ottobock Open Innovation space: We created an environment, which was as free as possible from regulations and processes: It was a co working space for startups with the Fab Lab Berlin embedded with all necessary equipment for rapid prototyping in all disciplines. We were able to invite inventors to work with us and creative engineers of Ottobock could try our concepts there. This was one of the hottest places in Berlin, got a lot of press coverage and awards for this concept. But again it was not very effective for Ottobock, since the team leaders were nor really enthusiastic about sending engineers to Berlin.

Working with different small medical device companies as well as in my consulting work with startups I experienced similar patterns: once the company gets serious regarding Quality Management and regulatory affairs it is almost certain that innovation is slowed down or even paralyzed.

Do I have a solution for this problem? No. But I can make some recommendations:

- Select persons for QM/RA who have a strong binding to the products and systems you do. They should be in love with the outcome of R&D but not with their processes
- Spend as much time as possible with the QM/RA team to explain company goals and patient outcome. Tell them, that they are supporters and contributors of innovation, and this is what you expect from them.
- Stand behind your head of QM/RA. This person must know, that you take the responsibility and she or he is not left alone in the case of a liability or some other catastrophic event.
- Try to completely understand the intention of all regulations you have to comply with, try to find the value for patients, customer and your company and then implement with a win, win, win attitude. Optimize your QM system for the best benefit.
- Explain that there is always room for interpretation of regulations and very seldomly the most complex solution for an implementation is the best

When Ottobock did acquire some smaller companies especially in the USA I have seen very effective and very simple QM systems even for higher class products, which did survive FDA inspections and did absolutely not lead to warning letters. I can assure you, it is possible to have a slim QM System. You will not find it with Ottobock, but it is possible. If you are not satisfied with your current QM system I recommend to do an audit where you ask for every process or SOP: who benefits from this: the patient, the customer or the company?

Quite some medical device companies, which were smaller companies or startups in the 1990's developed great in the 2000's. Think about MedEl, but also Guger Technologies, Tyromotion and others. Ottobock left its garage company attitude behind and adopted to the rules of a medical device company like all the others. Also the educational field and the research environment at

the Universities developed nicely in these years and the variety of options for students and partners increased significantly.

There was not so much interaction between Ottobock and Universities. In 1998 we were awarded with the Austrian state price for innovation for the C Leg and this triggered a change. Drinking some glasses of wine after the ceremony, the head of the jury confessed, that we almost would not have been selected. In the scientific community nobody knew us. There was not a single Ottobock project, which was funded by research funds. Therefore they had doubts if the C Leg was really developed in Vienna. I decided to change strategy and we started to collaborate and work together with academic institutions mostly in funded projects. At the same time I started professional PR around our research activities, which was so successful, that I got problems with my boss, wo has some kind of Celebrity nature which should be considered and taken care. Once public started to be convinced that Vienna and not Duderstadt in Niedersachsen is the Headquarters of Ottobock I got banged on my head. He did not like this.

Off course there is never enough money, but in general the Austrian funding opportunities for applied research proved to be really effective, with little bureaucracy compared to other countries at these days. Especially the Forschungsprämie, as it was formerly administrated was not only for us but also for many other multinational companies a strong argument to invest in R&D in Austria. It made my life much easier to negotiate Vienna R&D budgets. Regrettably today this has changed significantly.

Developing sustainable research collaborations proved to be far more difficult. Although we had developed visibility in the global research community in rehabilitation we failed three times in the COMET program to found a Competence center. Finally we gave up and did successfully start a Chistian Doppler Lab, headed by Oskar Aszmann at MU Wien. This proved to be very successful and benefited a lot from multiple other research collaborations, which we had developed in the meantime. I am proud, that we were able to introduce researchers like Dario Farina from Imperial College London, Rikard Branemark from University Goteborg, Todd Kuiken from RIC Chicago or Hugh Herr from MIT in Boston. Oskar was able to pick up and build strong ties and collaborations. As a result he developed a globally unique Lab for Bionic Reconstruction with an excellent reputation in the global research community.

As a consequence of the Irak and Afghanistan wars there was a strong research interest in prosthetics in the USA in the mid 2000's. We were able to be part of

some large research programs. Looking back I can see mixed outcomes. All programs did lead to significantly improve technological skills at Ottobock. In lower extremities a DOD program pushed our high end program for transfemoral prosthesis. A lot of benefits for patients evolved from this funding initiative and I doubt if, without it prosthetics today would be on the same technological level. The program involved only few handpicked partners, who were pretty complementary. In upper extremities DARPA developed the 600 Million Dollar Revolutionizing Prosthetics program. Huge consortiums were formed to win the calls. We were invited to some of them and decided to join the team of Johns Hopkins University, which won the major call. Yes, we learned a lot, but the participation was a chaotic nightmare. I refused to participate on the continuation. The program is still ongoing to some extend but I do not see any relevant patient outcome. The best outcome for us was a nice picture of our prototype on the cover of the Time Magazine… We have made similar, maybe not so drastic experiences in bigger European community programs, also in big German research programs like the Bernstein Neuroscience program. All these multiparter programs suffer from conflicting interests of the partners and from different priority levels at the partners. I believe it is important that government institutions start such programs. However a professional management would be needed plus some measures which guarantee, that promised tasks are executed in time. Off course we are reaching to the stars and many attempts will fail, but everybody in a program should reach out with the same passion and intensity. Possibly some scoring system, which measures the reliability of research partners would be beneficial. Today if I would be invited to a big consortium I would be very critical regarding the other contributors.

The 2010's at least on our side had a strong focus on clinical evidence. Prosthetics and Orthotics was finally a mature member of the medical device universe and had to comply with the rules defined by authorities and reimbursement. In addition the MDR was Ante Portas and did set new levels for verification and validation of results. Now the developed research partnerships proved to be excellent. Long term scientific work with researchers like Andreas Kranzl in Speising or Richard Crevenna at MU Wien allowed to work out new methods for proving clinical evidence in rehabilitation. This was complemented by the foundation of the Max Näder lab at the Ability Lab in Chicago, which developed to the leading lab for technical rehabilitation outcomes in the USA. We have invested a lot in this field. As industry leaders I believe we have to do so, even though most of our results are hijacked by

competition. If I would work for a small company, which is follower and not leader, I would do the minimum necessary and try to hijack the results of the industry leaders.

In 2017 Prof. Näder, the owner of Ottobock decided to bring private equity on board. I was raised in a company, where I could argue with the owner agree or disagree and do my thing. I knew that the company will change in a way, which does not fit to my habits and temper and therefore resigned from all management positions. I am sure it was the right decision for me. Since then I focused on digitalization of fitting processes in O&P including generative production technologies. Today I am still with Ottobock and take care of the remaining patients who have been implanted with the Actigait drop foot stimulator.

Was it fun? Yes! So many epic moments: patients with tears in their eyes, when they regained quality of life, big moments when things worked as hoped and expected, and the great times with all the gifted colleges and partners! Many became friends.

What would I do today if I had to run a startup in the medical device industry?

- First I would not start a startup but a company. I would only start with the perspective of long term financing by strategic investments, not by institutional investors, who want to cash out in 5 years. This is a far too short perspective for medical devices. Every financing round is a painful procedure, which disrupts the whole entity.
- Check every day if the problems you try to solve with your technology do really exist. Most startups solve non existing problems and therefore have a short life expectancy
- Try to find a mentor who has experience in this field, especially in the field of QM/RA, but make sure this person has experience with small medical device companies
- Build a fully trustful and honest company culture and relationships based on trust in your team and invest a lot of time for this
- Start as early as possible to build solid clinical partnerships
- Develop a perfect understanding of the reimbursement possibilities of your technology

I believe it is still possible to have a lot of fun in this field and I love it but I miss the wild days of biomechanical engineering

Thank you