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How ProPharma Helped SMi Build Their Company and QMS in Harmony

In late 2021, a group of dedicated professionals embarked on the journey of establishing SMi Systems, a new MedTech company targeting the medical device market. SMi worked with ProPharma to make it happen.

How it all began

Starting a new business from scratch is no easy task, but when that business is targeting the medical device market "difficult" takes on a whole new meaning. That's where a small group of us found ourselves towards the end of 2021. The world was just coming to terms with post pandemic life, with most people seeking some new form of "normal" and here we were quitting our old jobs, rolling up our sleeves and embarking upon the quite daunting task of creating SMi Systems, a new MedTech company.

We'd been working on the idea for years. The original two founders, both extremely clever scientists, were joined by an experienced finance guy whose remit was to bring in some investment, and then I became the fourth musketeer with the task of turning the idea into a saleable product. Throughout the pandemic, we spent late nights and weekends on caffeine fuelled zoom calls, shaping ideas, and confirming our theories.

Shortly after we secured a significant round of seed investment and a large UK government grant in 2021, we had a working prototype but that's still a world away from a saleable product. It wasn't just a product we needed to create, we also needed to build all the technical and business processes necessary to ensure quality and reliability. In short, we needed a quality management system and as we were targeting the medical device market, it made sense to comply with ISO 13485, the international quality management systems standard for medical devices.

I should probably tell you a bit about me, I'm Steve and I'm the Chief Operating Officer at SMi Systems. I started work life as a research engineer nearly 40 years ago, working for British Telecom on next generation telephony systems.

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It was there I got my first introduction to "Quality Management Systems", and it wasn't a joyous experience – it felt like I spent more time doing things because the QMS said I had to, rather than doing the development work that attracted me to the job in the first place. Quality was embodied in rows of filing cabinets and mantras like "say what you do and do what you say", but the implementation was more like "do what WE say and say what WE want to hear". I hate waste, be that wasted resources or wasted opportunities, it makes my blood boil – I couldn't shake the feeling that "quality" or at least this implementation of quality was a waste.

Fortunately, my scepticism didn't end my career before it started. BT sponsored me to do an MBA at the London Business School where I gained the skills and tools to help identify, articulate, and develop corporate value. I moved from the research division into BT's mainstream business taking on a series of roles with increased opportunities to build value and exposing me to many different departmental QMS implementations which led me to question the idea that "the way it's always been done" is proof of the "best way". After a couple of roles in other large corporates, I then moved into startups and experienced first-hand what "little/no process" and an "informal approach to quality" actually felt like; a bit like free climbing – really exciting unless it all goes wrong.

Back to SMi, our new company... four people, all with a lot of experience in our chosen fields, keen to succeed and build a company that behaved like a functional "family" – no one gets ignored, but no prima-donnas either. We set out to create something really valuable and worthwhile.

Of the original four I was the only one with prior QMS experience (albeit not medical). Whilst having a QMS is a basic requirement dictated by IVD legislation, here was an opportunity to implement something that helped rather than being a burden – we were a new company where there were no existing processes, so here was a chance to build the company and the QMS at the same time, making quality part of our foundation.

From a pragmatic standpoint, I can see the value potential of quality, I'm just very wary of past experience where poor implementation and management of a QMS hampered productivity. I fundamentally believe that done right, quality management presents no additional overhead and significantly reduces the risk of costly downstream errors.

Getting down to work

With ambitious targets ahead of us, we hired high quality experienced engineers in software and hardware to help turn our prototypes into product. To meet our goals, each team member had to deliver, and so it was important that our developing QMS was an "enabler".

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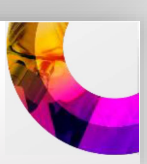

In an effort to ensure my development team stayed focused, I volunteered to take on the mantel of quality and build our company's QMS foundation ready to hire someone to take on its maintenance and improvement downstream. I believe "creators" and "improver/maintainers" are two different types of people – often great creators get restless when their initial job is done, and great improver/maintainers can feel overwhelmed when faced with a blank page so it made sense for the QMS to be built by me rather than hiring a head of quality at the outset.

To be effective, I knew I needed to develop my understanding of EN ISO 13485:2016, so I read the standard several times, then completed some introductory online training, and undertook an internal auditor course which made things a lot clearer. We also licensed one of the popular eQMS software systems to avoid the need for migration from a paper-based system later on.

To get implementation underway, I asked each department head how they wanted to run their teams. My thinking was to build processes around the team which satisfied the requirements of EN ISO 13485:2016 but also (and equally importantly) made generating the evidence of compliance a natural consequence of the way they worked. Afterall, what's the point of hiring skilled people and then having them spend most of their time doing something that isn't part of their skillset? By involving them in the initial task, I hoped that my team weren't going to get something they objected to, being imposed upon them. I figured that, by involving them in the creation, they would also have a sense of ownership; and if I'm being cynical, no one else to blame.

In parallel, we looked at regulatory requirements and spoke to a number of potential consultants. After some consideration, we engaged ProPharma as our consultants to help us understand the EU-IVDR, UK-IVDR and FDA requirements. At the end of one of the calls with ProPharma, I got chatting about quality and EN ISO 13485:2016 with Jan Bart Hak, ProPharma's Director Medical Devices Europe. He asked questions about our goals and our vision of how to achieve them – to me these where the questions I was asking myself as well, so there was an instant connection. We talked about quality as a builder of corporate value, echoing my belief that, if done right, quality would be a significant increment to the growth of our company and value development.

Jan Bart and I discussed the vision of our QMS. We shared the understanding that a QMS shouldn't just be a collection of procedures that sit on the shelf making the lives of the team members more complicated. Jan Bart's position was that a good QMS is the description of the company, I'd not thought of it in those terms before, but it made perfect sense. Afterall, you don't build a QMS just to satisfy the authorities, rather you build a company to make the best possible product, maintain it and meet the customer and regulatory requirements. Jan Bart pointed out that quality can be defined as "a product meeting the requirements; both those of the customer and the regulator." For every company having products that meet requirements is a key part of being successful, so it follows that every company wants quality ~ whether they realise it or not.

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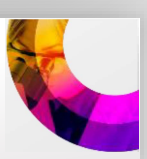

I'm a cynical soul, so was a bit concerned ProPharma would try and drop a one-size fits all consulting package on us that would make us dependent upon them forever and was waiting for that to happen; but it didn't. Instead, Jan Bart proposed an approach which would take what we'd done so far as a starting point, and assign a consultant to work directly with us to review and guide us with the end goal of ensuring we could manage things ourselves and be self-sufficient in the future.

Jan-Bart: When we first met, Steve came across as an open-minded person with a healthy amount of curiosity. Steve has a drive to make sure that he understands concepts, ideas and strategies with a focus on the goals ahead thereby protecting the young SMi company from too large or too risky (financial) activities. I believe this was very good combination for our discussions and figuring out how SMi could be best supported. Since having a QMS is regulatory requirement (EU-IVDR and UK-IVDR), it does not need long discussions if you will have one. But the way to implement and its design are crucial for the engagement of staff and protection of investment. Our open discussions were an absolute pleasure and created the necessary fundaments of trust to decide on the best QMS development strategy for SMi. And let's not forget, it is not about the QMS, the focus is on bringing an IVD to the market that meets the customer and regulatory requirements, continuously, and in order to do so, the company must have a QMS.

Our consultant, Arpita Desai, helped us take a practical approach working within our available resources, suggesting we first focused on the processes that were aligned to our product development stage. Jan Bart and Arpita both understood we didn't have limitless cash and we couldn't stop developing our product whilst we worked on the QMS. But equally they stressed the need to create a plan that maintained momentum and reduced the urge to succumb to the false belief that pausing QMS development to focus on product development could speed time to market.

With this mind, we started. Even though I was only partway through the development of our QMS, we agreed a first step of taking a few of our most important procedures (i.e. the ones that if we got them wrong would be the hardest to recover from). Arpita reviewed these and uncovered a couple of areas of minor misinterpretation of the EN ISO 13485:2016 standard and a small number of areas where what I'd proposed sounded great on paper and would indeed have worked well whilst SMi was small, but would quickly become difficult to manage as we grew. The best example of this was that in my enthusiasm, I'd proposed that every procedure should reviewed every year, but Arpita pointed out that a risk-based approach where internal audits reviewed procedures based upon the damage that would result from their not being followed correctly was a more practical approach.

Implementing the changes and incorporating the learning into the development of the remaining procedures was a big help. With support from the rest of the SMi management team, we continuously ensured that we kept focus on a QMS that enhanced the design of the company, not just implementing procedures because regulation or ISO told us to.

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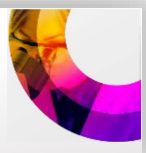

As the initial QMS buildout neared completion, Arpita scheduled a gap analysis where each requirement of EN ISO 13485:2016 was tested to ensure we had covered everything. In general, we were in pretty good shape, but there were a couple of gaps. Arpita and I worked together in deciding how best to address these, with SMi once again doing the implementation to ensure we continued to grow our inhouse skills. The GAP assessment helped to ensure that our QMS didn't miss essential processes which, in turn, gave confidence that we were in control of our product development and that the resulting products would satisfy the identified requirements.

Arpita: Performing this kind of Gap Assessment is extremely effective, since it is like a passive audit. I always believe that one size fits all is the exact opposite to what actually a QMS is about. It is in fact about having open mindset to let the new ideas flow on how one can implement the QMS in most practicable manner within their team. Precisely that is what I also suggested to SMi, very tailored approach to their existing QMS based on the identified gaps. Taking up the identified gaps as a true chance of improving the QMS, SMi was very proactive with my novel suggestions and Steve brought in his own ideas. It was a great cooperation and delight working with such an accepting and enthusiastic client.

These kind of Gap Assessments really open up the areas which actually need work, and many times, clients are not so actively interested in actually having a more practical QMS, but rather simply have documents to comply and get the certificate. While this approach may work for a while to get the certificate and keep it maybe for few years, but it won't really solve the real problem areas of day-to-day tasks of the medical device company. Think of QMS as a tool to make your processes run smoother and efficient, that way, everyone in the team has to be actively involved and then it will take your company to new heights. In my opinion, SMi did a great job to accept these gaps, having their team involved, although Steve being the leader (which is totally how it should be), but each one knowing their processes and involved in the documentation of the process.

This is what led to me actually being able to help them in the most efficient manner. It is very simple, 'you cannot help someone who doesn't want to be helped'. When you go to a consultant, you have to be accepting of any concerns they raise, along with a suggested solution – remember you hire us to HELP you, so you have to LET us help you. It is ok that you do not know somethings, that is why you come to us, but then having the willingness to actually accept what we suggest or recommend is key to having a successful consulting outcome. For example, with SMi, the procedure for monitoring and measurement of equipment was not very practical or captured the clauses of the standard entirely and having patience to actually listen to what I was training Steve on and implementing it step-by-step is what made that concept extremely clear to him.

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It is a unique approach to consulting we like to take, not only do things for you that you need/want us to do, but also train you in the process, so that you gain the knowledge for it and can perform that in future yourself. This is extremely advantageous for the client's future financial aspects too, besides developing their own in-house knowledge bank. I myself having a significant experience working in a small team/start-up, I have a good idea how things normally work in those kinds of set-ups. Additionally, being in Steve's shoes once in past, I could totally relate to the SMi's needs, having their company certified under EN ISO 13485:2016 would boost their funding chances to more than double and give the team great confidence in their own processes. I feel that is the beauty of our Medical Device team at ProPharma, diverse experience in multiple areas and that gives our core knowledge extremely strong foundation.

Verifying Progress

Obeying the fundamental principle of not marking your own homework, I couldn't audit our QMS and as we'd worked so closely on it, neither could Arpita. As I was SMi's only trained internal auditor at the time, we needed to bring in some additional impartial help. Part of the advantage of partnering with a global consultancy like ProPharma Group is their breadth and depth of consultants. ProPharma assigned Louis Habets, one of their senior consultants, to perform a 2-day onsite audit – we also added an onsite audit of one of our key suppliers, where Louis took the lead and I assisted, making it a 3-day visit for him.

Our internal audit was really enlightening, executive management was involved, as were the heads of each department. As Jan Bart had stressed, since top management is an essential team responsible for shaping and directing a medical device company, and as our QMS has been developed in harmony with the development of the rest of the company, their commitment and engagement in the audit was key. Having the executives demonstrating support through involvement really helped everyone see that through implementing the guidance of EN ISO13485:2016 into a functioning QMS, the company ensures that it is in control of every aspect of its products. Ahead of the audit, I stressed to everybody that this was a learning experience which was best served by being totally open ~ after all we'd learn nothing by telling Louis what we thought he wanted to hear rather than the 'warts and all' truth. All in all, it was very successful; a couple of issues were spotted in our regulatory strategy procedure (I'd forgotten that the UK was no longer covered by EU regulation) and a number of areas for improvement were highlighted; things were really coming together.

Louis: When visiting SMi Systems for performing an Internal Audit I met an enthusiastic team of people in this young organization. They were very proud to show their accomplishments in the development of a research and diagnostic system that revolutionizes molecular science with super-resolution imaging providing quantification of single molecules. They told me the system is targeted toward delivering fast, accurate and reliable results in protein-protein and protein-small molecule interactions enabling scientists and clinicians to make better informed decisions.

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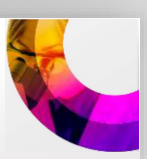

At that time, SMi focussed still on the development of the product. Guided and managed by a fully engaged top management team, that was available for providing input and answering questions during the audit, great spirit was detectable when looking around and having interviews with all people involved in the audit. Based on the drive of management, it was no surprise, that SMi was successful in selecting an experienced and well-qualified partner for supporting the development and the optimal manufacturing of the new product. The audit was really performed in a good, open, and cooperative, atmosphere.

The past year SMi developed a Quality Management System based on EN-ISO13485:2016. When setting up such a QMS three stages can be recognized, i.e., documentation, implementation and, finally, the implementation effectiveness. This first Internal Audit I focussed primarily on the first two stages. I am confident, that with this enthusiastic and passionate team, later Internal Audits will show effective implementation of the QMS which will have a positive impact on the quality of their products as well as assuring confidence at their future customers.

The supplier audit was another massive learning experience. We'd decided to audit our proposed outsourced assembler, Cogent Technology, who had themselves been subjected to many EN ISO 13485:2016 and FDA audits and inspections over the years. Observing the calm and confident way in which their quality people provided the evidence we were asking for, not only gave me great confidence that we'd made the right choice in selecting them to build our product, but it was a master class in how a well implemented QMS and well-trained people is a significant business benefit.

Engaging a notified body

Discussing our business needs and the markets in which SMi System's plans to sell with ProPharma led us to conclude that we should engage with the BSI as our notified body. SMi's top management agreed that scheduling a further gap analysis with the BSI would be a great opportunity to understand how they run remote audits which would better help us prepare for a Stage 1 audit.

The BSI gap analysis took place in August 2023 and the report was really encouraging, a couple of suggestions for further improvement and a strong indication that we were ready for Stage 1. In May 2024 the BSI conducted our Stage 1 audit, I was pretty confident we'd be ok, but as audits use sampling there's always a chance that something new will be uncovered so I was a little nervous.

Our Stage 1 audit was a success, we got two minor non-conformities for which I was able to provide a corrective action plan that the BSI approved by the end of the same week. We've since made the changes and are now working steadily towards our Stage 2 which is towards the end of this year.

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Looking back

Developing our company and product, supported by ProPharma, has been a highly valuable experience and I am confident that our partnership will stretch long into the future. We're quite self-sufficient now; we've trained up a second internal auditor and are building a body of evidence to support our Stage 2 EN ISO 13485:2016 certification audit. Working with an experienced partner ensured that our learning curve was much steeper and prevented delays which could have impacted our ability to reach the market in a timely fashion. As delays to market are really expensive, working with ProPharma has almost certainly saved us money.

My aspiration to build quality into the very foundation of SMi is being realised. Our processes add structure to what we do, but don't feel burdensome. Quality is ingrained and embedded in every activity we do. Everybody in the company has a very good understanding of the company processes and quality objectives, each has completed an EN ISO 13485:2016 overview training course, and most have been onboarded onto our eQMS. Each new starter receives EN ISO 13485:2016 overview training, eQMS familiarisation training, and relevant process training as part of their induction. Occasionally someone will moan about the time the training takes, but no one questions the value that quality brings to our company. Being quality driven, helps ensure that SMi's products will meet the requirements of the market, it increases our chances of success and of becoming sustainably profitable.

I feel we've invested a lot in quality, but we're already seeing the benefits. We have solid evidence that our products meet their stated requirements, and not just the requirements related to safety and performance; from our market research, we defined requirements for ease of use, maintainability and even manufacturing costs and the path to achieving each is managed through our QMS. We also have systems in place to solicit customer, supplier and market feedback to help us identify and manage the introduction of future product improvements.

We've had several visits from "startup wary" potential suppliers and they immediately recognise that we operate like a mature, but still highly innovative, company. Their confidence that we're worth working with has helped with lead times for sample orders and access to their technical support. Likewise, current and potential investors have expressed pleasant surprise at our advanced level of corporate maturity, which is telegraphed, in no small part, by our approach to quality.

We have big plans for growth at SMi and that will undoubtedly mean that our QMS will evolve. Leveraging ProPharma's experience of working with both large and small companies will help us ensure we don't accidently veer towards the silo "quality is a department" trap as we grow. Quality is our product – the QMS is our company.

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