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CASE STUDY

From Concept to Certification: Building a QMS in the MedTech Space

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.

The founding team, composed of two scientists, an experienced finance professional, and Steve Reeder, the Chief Operating Officer, aimed to transform their innovative ideas into a saleable product while ensuring compliance with stringent industry standards.

With ambitious targets, they hired high-quality, experienced software and hardware engineers to help their vision come to life, so it was vital their Quality Management Systems (QMS) helped them to achieve this.

> “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.”

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challenge

Formation and Initial Challenges: Their prior experience with QMS made them cautious but aware of the value a well-implemented QMS could bring. With their first prototype developed and initial investments secured, SMi faced the task of not only perfecting their product but also building the necessary technical and business processes. **This included developing a QMS compliant with ISO 13485, the international standard for medical devices.**

Strategic Approach to QMS Implementation: Understanding the critical role of a QMS, Steve took on the task of developing it himself, with the intention of later hiring someone to maintain and improve it. SMi licensed an electronic QMS (eQMS) software to facilitate their implementation process.

Steve engaged each department head to ensure that processes were built around their workflows, ensuring compliance with ISO 13485 while making it a natural part of their daily activities. This approach aimed to integrate quality seamlessly into the company's foundation, preventing it from becoming a burdensome afterthought.

solution

Partnership with ProPharma: Recognizing the complexity of regulatory requirements, SMi sought external expertise and engaged ProPharma as consultants. Steve established a strong rapport with ProPharma's Director of Medical Devices in Europe who shared Steve's vision of QMS as a value builder rather than a mere compliance necessity. This understanding led to a collaborative approach where ProPharma guided SMi without imposing a one-size-fits-all solution.

Practical Implementation: A ProPharma consultant helped SMi focus on processes aligned with their product development stage. She emphasized maintaining momentum in QMS development alongside product development. Her practical suggestions, like adopting a risk-based approach to procedure reviews, were **tailored to SMi's specific needs and resources, ensuring the QMS was both effective and manageable.**

Internal and Supplier Audits: To validate their progress, ProPharma conducted a comprehensive internal audit. A senior ProPharma consultant performed a two-day onsite audit at SMi and a key supplier. This process involved executive management and department heads, fostering an environment of openness and continuous improvement. The internal audit highlighted areas for improvement, which were promptly addressed, **reinforcing SMi's commitment to quality.**

Engagement with a Notified Body: SMi decided to engage BSI as their notified body, conducting a gap analysis to prepare for their Stage 1 audit. The gap analysis was encouraging, with only minor non-conformities identified, which were quickly rectified. This preparation laid the groundwork for their successful Stage 1 audit in May 2024, bringing them closer to ISO 13485:2016 certification.

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results

Outcomes and Reflections: Partnering with ProPharma significantly accelerated SMi's learning curve and prevented delays that could have impacted their market readiness, with SMi sharing **"delays to market are really expensive, working with ProPharma has almost certainly saved us money"**[1]. The comprehensive QMS developed with ProPharma's guidance integrated quality into SMi's core operations, fostering a culture of continuous improvement and regulatory compliance.

Steve's vision of embedding quality into the foundation of SMi is being realized. The company's processes now add structure without being burdensome, and quality is ingrained in every activity. SMi has gained the confidence of suppliers, investors, and potential partners, who recognize the maturity and reliability of their operations.

Conclusion

The collaborative effort between SMi Systems and ProPharma has **successfully built a robust QMS that aligns with SMi's innovative culture and strategic goals**. This partnership has not only ensured compliance with regulatory standards but also positioned SMi for long-term success in the competitive MedTech market.

Future Plans

As SMi plans for growth, the QMS will continue to evolve. Leveraging ProPharma's expertise will help SMi maintain their innovative edge without falling into the trap of viewing quality as a siloed department. The partnership with ProPharma is expected to continue, with SMi describing the collaboration as being a **"highly valuable experience"** and they are **"confident that our partnership will stretch long into the future"**[1], ensuring that quality remains at the forefront of SMi's journey toward becoming a sustainably profitable company.

> "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."

References:

1. SMi case study
   SMi
   ProPharma

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