Like minds: what to consider when choosing a software partner

By the Engine Room
Friday 22 June 2018

CATEGORIES:

What are the qualities you should look out for when you're selecting the company that will implement the software side of your device? Vladimir Timashov, Delivery Manager, Healthcare & Life Sciences, at global technology consultants DataArt shares his thoughts

In the age of digitalisation, technological demand grows daily even in highly conservative areas. Smart medical devices and enhanced medical software products such as the AI-powered insulin pump or Embody's pre-operative planning software allow a seamless user experience, reduce risk and apply new approaches such as AI or VR to help reduce the cost of diagnosis.

A lot of medical device companies are now at the beginning of their digitalisation journey. Some of these manufacturers historically have no software technology capabilities in-house. At the same time, there are also niche start-ups in the industry, which are founded by doctors who are struggling with software development expertise and resources.

While the option of building an in-house technology department could still be considered, this approach requires significant upfront investment and can extend time-to-market. Therefore, involving a technology partner may be a solution that will offer the required expertise and resources for the long-term journey towards digitalisation.

According to ISO 13485 and ISO 9000-family standards, a manufacturer should control the outsourced processes and remain responsible for them. So, if you are a CIO of a medical device manufacturer and you're just starting out on the journey of selecting a software technology partner, you will need to perform due diligence on companies you consider working with. Alongside some of the obvious points like technology expertise and cost estimates, here are a couple of other things to consider as part of the selection criteria:

- **The supplier should be flexible and able to adapt to your product development life cycle**

A supplier's flexibility makes adaptation possible throughout the entire journey. Each individual medical device has specific risk factors and intended uses, alongside compliance with the company's standard procedures. Therefore, you may not necessarily need a black-box software solution, but rather a service to make it possible to implement a software component for your medical devices in close collaboration with your company's guidelines, as a step-by-step approach. A supplier should be capable of developing and adjusting their procedures and fit to the manufacturer's QMS needs.

- **The supplier should be experienced in medical device software development**

Flexibility doesn't mean the absence of control or avoiding necessary routines. Being a highly regulated industry, medical device development requires thorough approaches when it comes to design controls. Partnering with a technology provider that has all the required knowledge and experience in place makes it possible for the software development lifecycle to be built properly from the very start of the journey and ensures that no important steps are missed.

- **The supplier should be capable of helping to plan and set up quality controls**

You will walk hand-in-hand through planning, solution design, risk assessment, development and validation with the supplier you select. Therefore, it's important to make sure your future partner has the ability, knowledge and resources to support you throughout the journey. Bringing the technology experts in at the early stages of the planning will help identify and mitigate possible risks related to technology and outline your technology strategy.

- **The supplier should fit your culture**

Even though it's not specifically about medical devices themselves, the corporate culture of the parties plays a significant role in building a relationship. It's helpful to keep in mind that shared values, operational routines and management styles make it possible to avoid conflicts, help align priorities easily and significantly speed up the overall process.

Due diligence when selecting a supplier is a crucial step in the whole journey. In fact, it's actually the step that affects all the other processes taking place: the lack of a proper selection process can be detrimental to the entire project. At the same time, you should always remember that the initial selection of the supplier is still just the first step – it's important to regularly ask yourself whether your current supplier still mirrors your goals and adds value. That is not only required by the standard, but it also allows you to make sure the partnership remains meaningful in the long run.

Original article can be found here: https://medtechengine.com/article/like-minds-what-to-consider-when-choosing-a-software-partner/?highlight=vladimir