BrightInsight

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10 questions to ask your potential SaMD platform partner

In biopharma, all the buzz is about Software as a Medical Device (SaMD) solutions. Between January 2019 and October 2021, the top five pharmaceutical companies invested a combined $270 million in SaMD initiatives. And they're not going it alone. They're seeking out partners to help them build, launch and maintain these regulated digital health solutions.

A whole industry of vendors has sprung up around this SaMD gold rush, but not every potential partner has the expertise and real-world product launch experience required to help guide biopharma companies through a successful regulated digital health solution product launch.

As you assemble your teams and build out your roadmaps for SaMD solutions, here are 10 specific questions you should ask every potential platform partner.

1. Tell me about the process you follow to build and launch a SaMD solution, including design, development, risk management, verification, validation, post-production preparation and submission.
2. Do you have a certified risk-based QMS to support global scalability?
3. Do you have the capability and experience to be our legal manufacturer of record?
4. What third-party software do you use? How is it vetted?
5. Do you have experience with premarket notification 510(k), premarket approval (PMA) and De Novo? Have you brought a Class III device to market?
6. How are you equipped to handle post-launch activities like complaints, trending, surveillance and reportable events?
7. How can you support us in producing clinically validated data? Do you have a dedicated team?
8. Tell me about your expertise in adhering to cybersecurity requirements. How can you help us avoid the financial and reputational risks of data breaches?
9. What is your approach to monitoring and acting on ever-changing global regulations?
10. How many SaMD's did you launch last year? What classes were they?

The right partner should provide specific, detailed answers, backed up by real-world experience bringing software-based Class II and Class III devices to market and a published ISO 13485 certification.

BrightInsight:
The trusted partner and proven platform you can count on

Founded in Silicon Valley with teams all over the globe, BrightInsight is backed by leading healthcare and technology VCs. Our leadership team brings over 100 years of combined digital health experience in the biopharma and medtech industries.

Our vision is to transform patient outcomes globally by bringing the power of digital technology to healthcare, and we work every day to achieve this by accelerating regulated digital health innovation for our customers through our scalable medical-grade platform.

We are the launch partner and underlying platform for the world's leading biopharma companies, completing seven SaMDs in 2021 alone. Our clients trust BrightInsight to accelerate time to market for their regulated digital health products, including apps, algorithms, medical devices, connected combination products, companion diagnostics and SaMD.

As the leading regulated platform for biopharma and medtech, BrightInsight has achieved the utmost privacy, security, regulatory and quality certifications to minimize customer risk and protect sensitive health information. See our Standards, Regulations and Certifications page for more.