3 Digital Health Considerations for Connected Device & Software as a Medical Device Leaders

There were a number of challenges—and successes—that came out of the "Wild West" era of the late 1990s and early 2000s as biopharma companies began launching their first combination products. Next came the connected versions of those products. Today, digital health biopharma and medtech innovators are experiencing their own new frontier as they drive forward digital health algorithms and Software as a Medical Device (SaMD).

Ready to navigate this new era of smart devices? Here are some key considerations.

1 Design the system, not the device.

Successful leaders focus on more than just the device—they prioritize the entire system. Step back from the solution itself and make improved patient outcomes your goal. Your product will be deployed within an ecosystem that may include third parties and Health IT systems, such as Electronic Health Records. Utilize that knowledge by defining the core platform and staying focused. As much as possible, leverage a few platforms rather than trying to leverage every platform a little bit. This will speed your time to market.

2 Do not underestimate the maintenance, support, and management of Software as a Medical Device solutions.

Maintaining a compliant SaMD solution is very different from the approach required for traditional drugs and devices. You must prepare for the ongoing post-launch iteration, maintenance, support, and lifecycle of your digital tools. Focus on launching the Minimum Viable Product (MVP) as early as possible so you can start capturing data and learning from it. Forget the traditional two-year patient research window before launch—software is a whole new ballgame. You'll also need to make product changes much more often. Aim for monthly or weekly, rather than yearly. Round out your efforts by creating a plan for supporting Regulatory and Quality compliance, such as complaint handling, pharmacovigilance, and post-market monitoring.

3 Regulatory, privacy, and security requirements are just as vigorous for SaMD. There are no shortcuts.

The good news is, there's no need to find your own ways to comply with the regulations. You can learn from the regulatory and quality systems biopharma already has in place. Software development is an ongoing process, so you need to commit to investing long-term in updating lifecycle management, complaint management, and other requirements. This is especially important when you launch your product in new regions. The EU, for instance, is raising the regulatory bar for SaMD.

BrightInsight provides the leading global platform for biopharma and medtech regulated digital health solutions. When speed matters, we help companies accelerate time to market for regulated digital health offerings including apps, algorithms, medical devices, combination products, or Software as a Medical Device (SaMD). BrightInsight replaces the need for lengthy and complicated 'build from scratch' implementations and instead offers pre-built software modules and a proven platform built under a Quality Management System to support global security, privacy, and regulatory requirements.

When you build your digital health products on the BrightInsight Platform, you're future-proofing your highest-value offerings from a compliance standpoint and unlocking opportunities to scale, both in terms of geography and product portfolio.

contact@brightinsight.com brightinsight.com

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