**Cloud computing & Medical devices**

How do standards, guidelines, best practices and regulation ensure the ongoing safety and effectiveness of medical devices and why is this important to medical device manufactures?

The last 3 decades has seen a growth in software-embedded medical devices, with and without user application. More recently, the advent of pure software-based medical devices (SaMD) has advanced medical device technology and their uses even further. These new developments have forced regulatory bodies to develop new standards and best practices to accommodate and meet the development of these higher-level methodologies and the accompanying threats to cybersecurity and data privacy, at the time of distribution as well as post market and during maintenance and upgrading.

These new standards and regulations have brought an onslaught of difficulty challenges to the healthcare industry. Often, meeting these challenges may seem insurmountable and this shift to the cloud for software-based medical devices and the burden placed on medical device manufacturers creates additional uncertainty and a lack of consensus.

**The importance of medical devices combined with medical devices**

Cloud computing is both cost effective and flexible, thereby allowing for the quick scaling of computing resources as well as the provision of new services on based on real-time demand. In other words, cloud computing has turned capital expenditures into operational expenditures, increasing availability.

The increasing demand for cloud-computing and the seemingly endless opportunities for cloud-based software-embedded devices has led to the rapid growth of cloud infrastructure, as well as a multitude of various services. In fact, the growth is so rapid -there are hundreds of new devices moving through various stages of development, even as you read these words.

Not yet convinced? In healthcare alone, over 35% of healthcare providers have already transitioned to cloud-based technology.

**The FDA regulation- Obstacles and other compliance-related issues for cloud-based medical devices**

FDA requirements

The FDA requires that verification and validation (V&V) should take place whenever maintenance changes are made to a product baseline. This is to validate that the design structure, system logic, is not negatively impacted anywhere in the device. V&V processes must be consistently documented.

When manufacturers/companies have full control over each and every element of the software and computational environment, these requirements, relatively straightforward.

With a cloud-based environment, the V&V process is much more challenging. The manufacturer does not have full control and the cloud provider can regularly make updates to the customer’s technology stack, *without prior notice – and without advanced customer approval.*

The medical device manufacturer’s challenge – how to validate the software and maintain FDA validation without knowing when and what updates are being done by the cloud service provider? Before we address this particular challenge, let’s take a closer look at the validated state as necessitated by the FDA.

As with many other aspects of cloud computing, companies using the cloud weigh the tradeoff of having less control over their computing environment with the incredible economies of scale of public cloud vendors

**What is "the validated state"?**

The [“validated state”](https://orthogonal.io/?p=105613) as dictated by the FDA, is proof that the medical software and quality systems are working as intended, and as affirmed by the previously accepted regulatory filings and the FDA’s quality management systems standards. This concept is the cornerstone of safe medical devices including Software as a Medical Device (SaMD), Digital Therapeutics (DTx) and connected medical device systems development. Without trust in the validation of the device software, there can be no trust in the ability of MedTech to improve health outcomes.

**How can your company maintain a validated state for your cloud-based medical device?**

The Association for the Advancement of Medical Instrumentation (AAMI) is an organization for advancing the development, and safe and effective use of [medical technology](https://en.wikipedia.org/wiki/Medical_technology). The AAMI was formed to introduce innovative medical devices into common medical practice and to set safety standards in both their design and usage. For cloud computing, the AAMI has a designated task group to focus on the issue of appropriate use of public cloud computing for quality systems and medical devices.

At this time, this task group has concluded that given the circumstances of cloud-based software, a continuously validated state cannot be achieved when using the cloud. In lieu of a continuously validated state, the task group holds that the best alternative is to achieve an intermittently validated state where the validation is periodically examined and confirmed.

**Risk management approach**

The types of validation that a medical device manufacturer needs to perform and the frequency with which these validations need to be conducted, depends on the level of risk associated with the use of the cloud service for a particular device. The risk-based approach requires manufactures to ask themselves several questions:

1. What changes can occur between validations?
2. How the change will impact safety and effectiveness?
3. How to detect the change?
4. How long will it take to correct the issue?
5. What harm could happen?

Following on the above 5 questions, there is one essential question that must be factored into risk management: How to increase the chance of detecting a change and reduce the fixing time?

Essential to meeting the challenge of V&V, the following actions will help lower risk:

* Implement a set of automated testing that can be run at the frequency that will ensure the services remain in a validated state
* Identify the intended function of the cloud computing resources within the product or service
* Perform appropriate risk analysis to address potential issues specific to each individual device that may arise from cloud service changes or any malfunctioning of cloud services
* Plan for the changes that may occur in real-time in the cloud, and respond thoughtfully and responsibly

**About AAMI**

The panel of industry experts formed a Task Group (and BioT is part of this group), sponsored by AAMI to create [*AAMI CR510:2021*](https://store.aami.org/s/store#/store/browse/detail/a152E000006X3mmQAC)*, Appropriate use of public cloud computing for quality systems and medical devices*, published in September of 2021

The report is an initial discussion and guidance in emerging areas – it sets the tone for a formal examination into the topic and continue to work and develop valuable guidance on cloud computing in the MedTech industry.

Randy Horton from Orthogonal and Pat Baird from Philips will reprise their CR roles as co-chairs for this Technical Information Report.