Regulatory requirements
for connected medical devices

By Stephen Knowles, Managing Director of IDC

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Our Managing Director, Stephen Knowles, was interviewed about the regulatory requirements for connected medical devices.

Q: Currently there is a lot of interest in connected medical devices. Could you please explain the regulatory process for connected medical devices with data transmission?

A: The important thing is to always understand what you are measuring and how accurately you can measure it. So making sure the usability of the device is good, making sure the data is accurate, and the user is using it correctly, are the fundamental first points before you can really think about transmitting the data. There is no point in transmitting data to a doctor or healthcare company if the data isn't accurate.

So one of the big things you have to decide when you develop the medical device is what you are going to do with the data, what's the purpose of connecting it and how accurate does it need to be? So if you are monitoring somebody's heart rate remotely for example, if all of a sudden the device detects a dangerous situation, are you able to use the data to get help or an ambulance if it's an emergency? Or is the device just monitoring long term to see how the patient progresses and the data is purely for monitoring to see if the patient is improving? The key thing before the start of a project is to understand what you want the data for and how it will be used. If you just use it to do the statistics, that's different from doing a remote care\remote consultation. There are lots of different requirements.

In each situation, if you want to make a medical decision on the basis of the data, then you have to be sure the medical device is complying to standards and is accurate, and patients know how to use it properly so that they can get reliable results. These regulatory standards ensure that the medical device is just as good as any other medical device.

Data transmission itself doesn't actually demand a lot of regulation, as long as you can show that the data was in the device and has been accurately transmitted to the data centre remotely. If you have remote devices that work the other way around - with decisions made remotely and sent to the device to alter its operation and the patient's treatment - that obviously increases the level of regulatory requirements.

Basically there is a big difference between medical devices that you are going to base medical treatments on, and medical wellbeing and healthcare apps, which do not require the rigorous testing of medical devices. All proper medical devices require thorough medical device regulatory approvals.

Q: Regulatory research for medical devices is normally carried out in the first phase of a development, so what important work is included in this?

A: We start to think about regulatory requirements at the very first stage of the project. Key to the regulatory process is having a product requirement specification and a user requirement specification that defines what the user wants the product to do, what benefits

the product will provide to the user, how they are going to use it and how you can make it easy for them. So part of the initial work is trying to understand exactly what the user wants from the product.

The other key thing is to understand what classification of medical device it is. Medical devices are classified according to the risk level; in Europe they are separated into Class I, Class 2A, Class 2B, and Class 3. This determines what level of regulatory documentation you need, together with the testing and verification required. A Class I device can generally be self-certified, but you need to make sure that's a genuine Class I device. Class 2 devices typically involve a greater depth of testing and documentation and Class 3 devices involve more testing and are more likely to need clinical trials. Device classification is an important consideration for timescales, so if you are in a rush to get a product to market, you may need to consider dropping some features you'd planned for the product in order for it to be a lower risk category.

An integral part of the regulatory process is understanding which technical standards are required for your device. Understanding the requirements early on in the project and being able to plan for them throughout the project is essential for success.

Q: We all know that timing is important for business; people want their product to be launched in the quickest time possible, but sometimes the rigid regulation process takes a long time during the development. What do you think about the relationship between marketing timing and the long regulatory process when developing products?

A: The amount of regulation, testing and documentation to check the immediate standards and comply with the regulations can vary very much from a simple device, such as a clip used in surgery, to a much more complex device, so understanding what type and classification of device you have is important.

For simple products, the process can be very quick and doesn't need to slow the project down as long as you know what you are doing and think about it at the beginning. If you don't have a plan from the start, you can get to the end of the project and realise you haven't chosen the correct material, not assessed what the risk might be and the project can then have major delays.

If you are developing a complex machine or piece of equipment, then the process is more complicated. Every business wants to get their project launched as fast as possible but businesses must comply with the law and are legally responsible for making safe devices. If companies try to short cut the proper processes, then they may end up breaking the law. Following the correct regulatory route is essential. Sometimes it may seem inconvenient to

take an extra six months or a year going through all the tests and approvals but planning this out at the beginning can be a big help.

Q: For the regulatory process, IDC's design engineers also undertake the testing in addition to carrying out the design and development of the product itself. Could you explain how this helps to ensure that the design complies with regulatory requirements?

A: Understanding how to test and verify the product is again something that needs to be considered at an early stage of the project.

The product design specification is the document that tells you everything that you want that product to do. If, for example, you are developing a drug infusion pump, you would say it needs to not weigh more than 300 grams, it should be able to deliver between 5 ml and 20 ml per hour, etc, you go through all the requirements for the product design, all the things you want the product to do. Once you have all of the specifications, you think about how to prototype and manufacture the product, and how to verify the design and test that it does all it is supposed to.

Simple specifications such as dimensions and weight are quite easy to check, whereas more complex parameters such as accuracy need to be precisely tested and planned for. If we take the example of the infusion pump, there are often lots of tests defined in the standard for infusion pumps, which require additional regulatory tests to be done.

So the earlier the product design specifications can be defined, the sooner you can start to plan testing and take this into consideration with early models and prototypes to check that the design is headed in the right direction to meet regulatory standards.

When you get to the final production product, you need to do all these tests again with the device which is going to be sold to the customers to make sure the manufacturing process and materials meet the standards and all the requirements that were set out at the beginning. So from a development point of view, what you don't want to happen is to get to that end point and find you've got a problem, then you have to go back. The key is to make sure you test your design in the prototype stage to check the product will pass all the tests, so although it seems like the process is being repeated, it's important to take the risk out of the development before you commit to the big expense of tooling and scaling up for production.

Time for testing can vary a lot between different types of products. Generally, simple products with fewer functions are much quicker to take through the process. The more features a product has, particularly with complicated electronics, the more testing required to meet standards. Typically projects need to plan for a few months of testing and certification with medical regulatory authorities.