Q&A eBOOK WITH AVERNA

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1. How is the Internet of Things (IoT) transforming the medical world and what specific trends are making waves in the industry?

Traditional "wired" patient monitors are evolving into wireless devices, providing patients with increased post-operative comfort and mobility, which can accelerate healing and shorten hospital stays. For example, a monitor using WiFi, Bluetooth or another wireless protocol that transmits patient vitals to a central nursing station can allow the patient to more easily get in and out of their hospital bed, move around the hospital and even be monitored remotely via a secure connection on their home wireless network. All of these developments can be very good for patient morale and rehabilitation, and simplify nurses' routines.

In terms of improving care for people with chronic diseases, the new generation of RF-enabled devices (such as insulin pumps for diabetes) is transforming how sufferers are treated and monitored, also giving them more autonomy and generating important actionable data about their conditions.

Increased RF connectivity among traditional medical devices in healthcare facilities means that there is far more data being transmitted and available on networks (such as patient records, machine performance, equipment locations), all of which requires additional testing, monitoring, security, storage and backups.

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Averna's Test & Quality expertise for the Life Sciences industry draws from close collaboration with dozens of companies around the world.

The connectedness and accessibility of RF-enabled devices means faster patient-record sharing among healthcare stakeholders (e.g., general practitioners, specialists, health maintenance organizations/HMOs) and quicker remote device maintenance and updates, as well as other benefits.

Healthcare apps on personal "non-medical" devices such as smartphones, smartwatches and fitness bands are capable of recording, tracking and sharing data on heart rates, sleep patterns, stress levels and other personal indicators, which creates implications for healthcare monitoring beyond typical doctor-patient relationships.

2. How can OEMs keep up with the accelerated need for innovation?

Traditionally, medical device OEMs have had all the expertise they needed to develop, validate, manufacture and support medical devices. Currently, the IoT revolution brings many challenges for them. In the past, for example, they did not have to worry about device interoperability or processing data except on proprietary devices and closed networks. Since many device and data providers are now taking advantage of the benefits of, for example, cloud computing and real-time data access, many OEMs must rethink their device designs in terms of connectivity and data handling/exchanges.

Class II and Class III medtech product lifecycles (from design and development through regulatory approval, market launch and on to sustaining) are typically very long (10-15 years is not unusual). In fact, they are considerably longer than in the automotive and consumer electronics industries. And unlike the rapid innovation seen in those industries, innovation in medtech happens much more slowly due

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to a) the life-prolonging or life-saving nature of the products and b) the paramount importance of preparing for and ensuring regulatory compliance. A poorly tested or prematurely launched product could cripple a company by harming healthcare providers or patients. For these reasons, few OEMs would sacrifice the integrity of their device development and quality strategies just to meet the latest trend. Innovation does happen, just more slowly than in other industries.

An effective strategy for many life sciences companies in the face of accelerated technological evolution is to partner with companies from other sectors that have proven IP and technology that they do not have and that would require significant resources to acquire. For example, a company producing traditional vital-sign or respiratory monitors could partner with a company that excels in wireless connectivity and another company that specializes in electronic health record (EHR) processing and analytics.

3. How can manufacturers ensure the highest level of quality when it comes to wireless medical devices while complying with the FDA, Health Canada, etc.?

OEMs need to focus on the inherent quality of their devices to perform as designed. While a wireless capability is a strong selling point, the device must above all else function as designed on a medical level by saving, prolonging, monitoring or improving human life.

The quality of a device's wireless connectivity/functionality is typically assessed by organizations like the U.S. Federal Communications Commission (FCC), which "oversees the use of the public radio (RF) spectrum within which RF wireless technologies operate."[1]

OEMs will need to integrate FCC-type compliance verification into their test strategies and systems to ensure their products feature seamless connectivity, while continuing to provide the very best in patient care.

4. How are robotics and automation changing medical device testing and production?

Automation and robotics essentially take the human out of the loop in production environments, which improves repeatability and reduces variability. For example, automation ensures every test procedure, sequence and step is followed precisely for every unit under test (UUT). No two human operators, no matter how well trained, will test exactly the same way at all times. As well, robots can be programmed, for example, for tedious lifecycle tasks such as repeated button-pushing, knob-turning, screen-reading or other kinds of UUT verification that even the most patient operator will tire of quickly.

[1] https://www.fda.gov/MedicalDevices/DigitalHealth/WirelessMedicalDevices/default.htm

Given the enormous amount of R&D and technological innovation occurring in medtech, it's unlikely that there will be enough skilled engineers, technicians and managers to handle all the opportunities in the coming years. That means that more robotics will need to be integrated into every aspect of medical device production: from automated assembly and handling to automated testing.

And as robotics-driven production becomes more economical, some business activities that were previously done offshore (typically in Asia) will be brought back to North America (called "reshoring" or "nearshoring"). For many companies, having production and R&D in closer proximity will also reduce communication errors and help solve the challenge of shorter product lifecycles and faster access to their quality data.

5. What are a few tips you have for OEMs in the medical world that are trying to stay ahead of their competition?

Work with a company that excels at Design for Test (DFT) and Design for Manufacturing (DFM). The earlier in the product lifecycle that you can identify and eliminate product design flaws the better. These processes will help you save time and money while avoiding many frustrations and setbacks.

Automate testing. Wherever possible, automate product validation and verification (V&V) routines. No matter how disciplined or professional your employees are, people introduce variability and subjectivity into test procedures and results. Automated testing provides objectivity and repeatability, essential for proper decision-making, fast troubleshooting and regulatory compliance.

Use industry-standard hardware and software. While proprietary systems might serve you well initially, they do not scale or replicate well and expose many companies to the risk of too much tacit knowledge in an inflexible system. A robust, industry-standard test environment is simpler to manage and update and, if a key team member leaves the company, easier for a new hire to learn.

Capture and analyze up-to-date test data. The best way to identify and correct problems, simplify processes and monitor progress is to have access to clean and consolidated data. As well, it gives all stakeholders an important common frame of reference and shared analysis tools.

Focus on what you excel at and outsource everything else. In today's fast-paced high-tech world there are few things financially riskier than trying to develop a non-core capability from scratch. Better to partner with a company that has crucial skills or products in an area where you are weak.

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