Get to Market Faster and Avoid Costly Mistakes:

New FDA Guidance for RF Wireless Medical Devices
To help companies ensure the proper functioning of wireless medical devices, the FDA recently released final guidelines on the topic. The following white paper explains their impact on product designs in the healthcare market.
Balancing the Benefits of Wireless with Safety and Functionality

With the rise of machine-to-machine communications, RF wireless technology can bring many functional and economic benefits to business and consumer applications. While wireless capabilities increase design complexity, they particularly pose unique challenges in the design of medical devices – including scrutiny from the U.S. Food & Drug Administration (FDA).

As with all new technologies, the improvements and benefits from wireless connectivity must be balanced with the proper functionality and safety of the very medical devices they enable and the patients they serve. The FDA is increasingly focused on ensuring that wireless medical devices meet existing safety criteria and do not interfere with other sensitive medical equipment in critical environments. Planning for proper product performance, validation testing and regulatory approvals helps minimize a company’s development costs, decreases time to market and improves the odds of successful product acceptance.

To help companies ensure the proper functioning of wireless medical devices, the FDA recently released final guidance on the topic – guidance that has been in development since 2007. Now more than ever, it is important to understand how the FDA is evolving its position on the design, testing and use of RF wireless medical devices. Successful product launches require excellent preparation and positive FDA audit results. Failing to align with the FDA’s new focus can result in costly delays.

To ensure that products will meet the existing wireless standards and new FDA guidelines, companies need to be forward thinking in their approach to safety and performance requirements.

To ensure that products meet existing wireless standards and new FDA guidelines, designers must be forward thinking. No one wants to launch a product that fails to meet performance or reliability requirements – or, worse, raises safety concerns – which are distinct possibilities for products that do not properly implement wireless technology or that have not completed rigorous testing. If this happens, the cost to a company’s reputation and brand can far outweigh the cost of proper design and testing.
Security

One of the most important emerging themes in the FDA guidance is its focus on security. Performance considerations for security are often overlooked. It is critical to design HIPAA-compliant safeguards against unauthorized access to hospital networks or the improper disclosure of sensitive patient data. Protecting the confidentiality of patient data in transit and ensuring the data is not tampered with or corrupted is vital to the success of a product and the security of a patient. In addition to protecting data in transit, it’s equally important to protect the device itself from unauthorized access and tampering.

Interoperability

One of the main drivers for adding wireless technology to medical devices is to enable them to share data with other wireless devices, peripherals and networks. For a device to succeed, it must interoperate reliably with multiple vendor solutions. Customers do not want to be cornered into using a single vendor’s products or having to replace existing infrastructure. It’s important to anticipate what other devices and networking equipment will be used in the system and properly test all of the components together.

Reliability

Wireless solutions must be robust and designed to work well, even in chaotic and noisy environments. This is especially important for medical devices, where poor wireless performance can impact health and safety. Dropped connections, timeouts and data re-tries caused by external factors are show-stoppers for many medical applications.

Future Proofing

Wireless technology is rapidly evolving and new standards are constantly being rolled out. Solutions must employ architectures that will continue to work or that can be upgraded as new wireless technology and standards are adopted and deployed. Companies must anticipate future changes to wireless infrastructure, like the cellular network or hospital/home Wi-Fi access points. Infrastructure planning demands flexibility for future capabilities.
Wireless Non-Interference

As wireless devices proliferate, it’s increasingly common for them to be used in the presence of other wireless devices and equipment. In many cases, nearby wireless devices even operate in the same frequency bands. To avoid potential interference and performance issues, it’s essential to understand the environment where the wireless device will be used, consider other wireless technologies that may be present, and evaluate their potential impact on the medical device. A variety of lab and field tests can detect and mitigate wireless interference issues.

Wireless Safety

When wireless devices are operated near the human body, some energy from the transmitted signal is absorbed by body tissues. For high-powered wireless devices, this poses several safety concerns. To prevent hazardous radiation, the FCC and other international regulatory bodies have defined radiation limits and procedures to measure the amount of energy absorbed by the human body from wireless devices. These limits must be considered in wireless product development and are especially important for implantable and body-worn devices.

International Considerations

Medical devices are frequently deployed globally. Just as local customs change from country to country, so do wireless infrastructure and regulatory requirements. Differences in wireless technology, spectrum allocation and power limitations imposed by foreign regulatory bodies may present unique design requirements on the radio and antenna. Be sure to thoroughly evaluate them early in the development cycle.
The Right Preparation and Planning

With the right preparation and planning, companies can effectively meet current FDA guidance, address emerging market trends and achieve superior product performance. This diligence will directly drive improved market launches, customer satisfaction and wireless medical device revenues. Too many people spend precious time and money attempting to navigate this landscape alone – you don’t have to. The best advice for organizations is to find an expert partner.

So many people spend time and money trying to navigate this landscape on their own before coming to us. You don’t have to.
Key Takeaways:

- Product designers are under greater pressure than ever to balance the benefits of wireless functionality with safety and functionality.

- The key design considerations include:
  - Security
  - Interoperability
  - Reliability
  - Wireless non-interference
  - Wireless safety
  - International considerations
  - Future-proofing

- Companies can take advantage of proven off-the-shelf components for faster time-to-market or design custom solutions for added differentiation.