GET TO MARKET FASTER AND AVOID COSTLY MISTAKES: FDA GUIDANCE AND KEY CONSIDERATIONS FOR WIRELESS MEDICAL DEVICES

To ensure the proper functioning of wireless medical devices, the FDA regularly issues requirements and guidelines. This white paper describes their impact on product designs in the healthcare market, and how to ensure you meet your go-to-market goals.

Balancing the Benefits of Wireless with Safety and Security

With the rise of wireless IoT technology, connected devices can bring many functional and economic benefits to enterprise, industrial and medical applications. On the flip side, wireless capabilities increase design complexity and security risks by virtue of being connected over networks. And wireless medical product designs, in particular, pose unique challenges with regard to the security of patient data and potential interference with other medical equipment. To get to market, these products must meet specific requirements from the U.S. Food & Drug Administration (FDA).

The FDA regularly issues guidance that evolves along with advances in technology and medical science. Medical Device Manufacturers (MDMs) must understand and meet the FDA requirements and guidelines for wireless product designs to ensure the end device will meet regulatory requirements. Failing to align with the FDA's guidelines can result in costly delays.

The Changing Environment for MDMs

The development paradigm is changing for those developing products in the medical space.

For example, in the past, a product that had passed certifications had to be fully recertified, at great expense, if the product was updated. Today, with the shift to connected wireless products, it is acknowledged that MDMs need functional updates and security fixes over the life of the product.

Additionally, for the most stringent security management, it is increasingly critical for security updates to be proactive and instantaneous. Just as our mobile phone manufacturers send firmware and security updates to our phones, MDMs must be able to rapidly update devices to address new security threats or critical functionality enhancements.

Today, MDMs are allowed to do security updates as part of the normal process. When you ship a product, it must be connected so that you can manage new security vulnerabilities with remotely installed security updates.

Most importantly, MDMs can reduce cost and risk throughout the prototyping, development, testing and distribution of wireless medical products by working with the right partner. Digi offers the Digi ConnectCore 8 development platform of highly integrated, highly secure system-on-modules (SOMs) for modular, connected product designs that meet FDA requirements and can be managed over time to remain in compliance — reducing cost, risk and ongoing management challenges.

Designing Medical Products to Meet FDA and Market Requirements

In this section we cover the key focus areas for MDMs to achieve their go-to-market goals while ensuring their products can meet certification requirements and remain in compliance over time.

1. Security

One of the most important themes in FDA guidance is a focus on security. Cybercriminals regularly attempt to breach connected devices in order to penetrate medical facilities. It is therefore critical to design secure, connected products with multi-layer defenses to thwart hackers. Data must be encrypted at every point along the way — from patient to records management — across all connected devices. In addition to protecting data in transit to prevent the disclosure of sensitive patient data, it's equally important to protect the device itself from unauthorized access and tampering.

2. 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 in this environment, it must interoperate reliably with multiple vendor solutions. Medical facilities need their products to interoperate seamlessly and securely with the hospital infrastructure. It's important to anticipate what other devices and networking equipment may be used in the system and properly test all of the components together.

3. Mobility

In a hospital environment, patients and equipment are often on the move, and must remain connected and powered. For that reason, design considerations involving optimal power management are important when, for example, a patient is moved and a device such as an infusion pump may not have an external power source for an extended period of time.

4. Reliability

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

5. Future Proofing

Wireless technology is rapidly evolving. New standards are constantly being rolled out, especially with the introduction of 5G in many regions. Solutions must employ architectures that will continue to work or can be upgraded as new wireless technology and standards are adopted and deployed. Healthcare organizations must anticipate future changes to wireless infrastructure, like the cellular network or hospital/home Wi-Fi access points. Prudent infrastructure planning demands flexibility for future needs and capabilities.

6. 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.

7. 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. MDMs must integrate related safety measures in wireless product development, especially for implantable and body-worn devices.

8. International Considerations

Medical devices are frequently deployed globally. Just as local customs and medical practices 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 for 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. Diligence in investigating all of the potential regulatory issues ahead of time will directly drive improved market launches, customer satisfaction and wireless medical device revenues.

Work with a partner that helps to ensure your success from day one. Digi supports your development journey with a highly secure, modular development platform and can provide the design services to help you get to market on time. Digi experts have deep knowledge of FDA and FCC requirements as well as successful testing procedures and certifications. Digi Wireless Design Services can support your time-to market goals. With a team of experienced engineers and a full development and testing lab, they can help you at any point along the way from proof-of-concept through design, testing and manufacturing readiness.

Summary of Key Considerations:

- ✔ Security
- ✔ Interoperability
- ✔ Mobility
- ✔ Reliability
- ✔ Future-proofing
- ✔ Wireless non-interference
- ✔ Wireless safety
- ✔ International considerations

Companies can take advantage of proven, secure, off-the-shelf system-on-modules for faster time-to-market or design custom solutions for added differentiation. To reduce risk, work with a partner that integrates security and interoperability at every level, with wireless certification and rapid time-to-market in mind.

Contact us to start a conversation, and learn how designing your next medical product with Digi ConnectCore modules can accelerate the development process and help you meet the strict requirements of FDA certification.

Why Digi?

Digi is a complete IoT solutions provider, supporting every aspect of your project, from mission-critical communications equipment to wireless design services to get your application designed, installed, tested and functioning securely, reliably and at peak performance.

Digi builds its products for high reliability, high performance, and versatility so customers can expect extended service life, quickly adapt to evolving system requirements and adopt future technologies as they emerge. Digi cellular routers, servers, adapters and gateways support the latest applications in traffic, transit, energy and smart cities.

Our solutions enable connectivity to standards-based and proprietary equipment, devices and sensors, and ensure reliable communications over virtually every form of wireless or wired systems. An integrated remote management platform helps accelerate deployment and provide optimal security using highly efficient network operations for mission critical functions such as mass configuration and firmware updates, including system-wide monitoring with dashboards, alarms and performance metrics.

Company Background

- Digi is publicly traded on the NASDAQ stock exchange, symbol DGII
- Founded in 1985, Digi has 35+ years of experience connecting the “things” in the “Internet of Things” — devices, vehicles, equipment and assets
- Headquartered in the Twin Cities of Minnesota, Digi employs over 700 people worldwide
- The business has been profitable for 18 consecutive years
- Digi’s annual revenue is around $300 million
- The company has 285 patents issued and pending (150 issued)
- In our three decades in business, we have connected over 100 million devices

As an IoT solutions provider, Digi puts proven technology to work for our customers so they can light up networks and launch new products. Machine connectivity that’s relentlessly reliable, secure, scalable, managed — and always comes through when you need it most. That’s Digi.

Contact a Digi expert and get started today

PH: 877-912-3444
www.digi.com

Digi International Worldwide Headquarters
9350 Excelsior Blvd. Suite 700
Hopkins, MN 55343

/digi.international @DigiDotCom /digi-international