Medical Services

Comprehensive Regulatory and Compliance Solutions for Wireless and Traditional Medical Devices.

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The Industry

As the medical industry continues to innovate, more and more medical products are being used in homes for personal use. These devices have begun incorporating wireless technologies and are used for a variety of diagnostic, monitoring, wellness and clinical applications. This shift is dramatically improving the link between caregivers, clinicians, treatment centers and remote patient-monitoring devices. It provides unprecedented mobility for patients, easy access to patient data, and of course, less inhvasive monitoring and treatment methods for common diseases. But this expansion in medical device technology is not entirely without challenges and risks.

The Challenges

#1: Understanding Regulatory Requirements for Target Markets

Medical device manufacturers must be sure to understand and comply with product safety standards and regulatory requirements that differ from country to country. It can be quite difficult understanding theh various regulations that exist within different markets. Non-compliance often leads to delayed product launches and costly pitfalls.

#2: Data Privacy and Cybersecurity

One growing concern for manufacturers is securing and protecting medical devices from cybersecurity risks. Manufacturers must not only protect the vast amounts of sensitive data that is processed by these devices, but they must also secure the physical use of the device. In the event of a hack, a security breach could alter the physical properties of the medical device and cause harm to a patient.

#3: Performance

Medical equipment manufacturers must ensure their device can send and receive data throughout the connected network – interoperability. Device manufacturers must also be sure that the device meets the necessary levels of network performance, which relates to how weak the device's signal can be while remaining connected and still pass information.

#4: Ensuring Product Quality

With fierce competition in the emerging markets, device manufacturers must be vigilant in ensuring quality products and avoiding costly recalls. Recalls and poor quality products often lead to negative impacts on a company's brand and reputation.

Our Services

Cybersecurity
- Vulnerability Assessments
- Penetration Testing
- Software Source Code Analysis
- Required Controls Assessment (MDISS or HIMSS)
- 510(k) Report Preparation
- Threat Modeling

EMC/Radio/Wireless/FCC
- IEC 60601-1-2 4th Edition (EMC Testing) including CB Scheme, IVD and FDA Requirements
- Co-existence according to FDA's RF/Wireless guidelines
- WiFi, Zigbee, Bluetooth, SigFox, LORA and other

Market Access Services
- End-to-end radio/telecom approvals
- Conformity Assessment Body (CAB) and certificate issuer for many countries.
- Retain Memorandum of Understandings (MOU) and Mutual Recognition Agreements (MRA)
- USA/CAN testing for NRTL-mark (cTUVus-mark), FCC, TCB
- Reports applicable for many countries
- Governing body recognition and test labs: Brazil, India, Japan, Mexico, Taiwan, South Korea

Product Safety
- IEC/EN/AAMI & CSA 60601-1 safety testing for Medical Electrical Equipment, including most collateral and particular standards
- Product Safety certifications according to CB- scheme, OSHA/NRTL (USA) and SCC (Canada)

Green Ser vices
- Evaluation and Testing to comply with RoHS 2 Directive

International Directives, Regulations and Standards
- European Union (EU) Medical Devices Regulation (MDR) and In Vitro Medical Devices Regulation (IVDR) Certification
- Medical Device Single Audit Program (MDSAP), covering USA, Japan, Australia, Canada and Brazil
- EN ISO 13485: Quality Management certification for medical device manufacturers
- ISO 9001, ISO 14001 and ISO 27001: Quality Management certification for manufactures
- EN ISO 15378: Quality Management certification for manufacturers of primary packaging materials for medicinal products
- Radio Equipment Directive (RED) – 2014/53/EU
- General Data Protection Regulation (GDPR)
- Restriction of Hazardous Substances Directive (RoHS 2)
- Waste Electrical and Electronic Equipment Directive (WEEE)
- Other EU Directives and standards as applicable, e.g., for batteries and accumulators, packaging, physical agents, etc

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