How does a Quality Engineering approach ensure a compliant Medical Device?

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The healthcare industry is undergoing a transformation with new medical devices and treatments being developed and applied. Medical devices have become important cogs in the wheels of this transformation that would enable greater connectivity to perform data analytics and remote patient monitoring with ease. The changing dynamics of the market warrants medical devices to stay on the innovative curve and leverage technologies such as analytics, mobility, wireless, and cloud. The need of the hour for the medical devices is to better monitor the healthcare parameters of patients, conduct accurate diagnosis of ailments, and optimize costs, among others. Thus, to ensure optimized performance, software testing for medical devices should be the norm in the SDLC. Also, enterprises should customize the design of such devices for convenient usage and quality compliance.

The criticality of medical devices cannot be underscored enough given their impact on human lives. To ensure the safety, accuracy, and effectiveness of healthcare services, medical devices should be tested rigorously. They should undergo proper verification and validation process to deliver outcomes like reliability and quality. However, given the competitive dynamics of the industry, manufacturers should insist on using quality engineering for medical devices. This is because quality engineering services can ensure integration of the Voice of

Customer into the product design. If implemented properly, quality engineering tools and processes can greatly influence the quality and cost of medical devices.

Why quality engineering for medical devices?

Quality engineering is a step higher than quality assurance, for it ensures medical devices are designed and manufactured to not only meet but exceed customers' expectations. Here, quality is built into the design and development phases wherein glitches are identified in the early stages of development and cost is minimized. Quality engineering for medical devices comprises a comprehensive range of methodologies and tools and a cross-functional approach.

Since medical devices are subject to the strictest of regulatory compliances and are expected to deliver exceptional performance, safety, and effectiveness by the end-users, quality engineering should drive [medical devices testing](). The process should begin from the design phase and extend up to the production phase. The quality assurance for medical devices strategy should ensure compliance with regulations, namely, FDA, PCI DSS, and HIPAA, among others.

Medical device software validation: targeted areas

Software testing for medical devices needs to target certain areas for better outcomes in terms of compliance, performance, accuracy, and safety. The areas are as follows:

Safety compliance for radiation emitting devices: By incorporating proper checks in the design phase, quality engineers can ensure the product is built in the right way. This is of utmost importance as certain medical devices, say digital X-ray equipment, CT scan systems, or linear accelerators can emit radiation. If dosage is not regulated up to the prescribed safety limits, the patients and healthcare professionals handling the equipment can suffer fatal consequences.

Integration with multiple systems: Medical devices are mostly connected to the healthcare facility's IT infrastructure (WAN) comprising multiple systems. So, the test approach should include validating the integration of medical devices to the overall WAN system. Through such process of integration testing, quality engineers can ensure the medical devices function to their optimum while being connected to the workflow. They ensure the response systems of medical devices are up and running with proper access to information. For example, if a doctor wants to view the results of radiotherapy for a patient, he or she can simply visit the respective menu on the healthcare WAN system and get the findings. [Quality engineering services]() can

ensure these medical devices are integrated into the overall healthcare system and deliver accurate outcomes.

Security: Hackers can manipulate the built-in software within medical devices to give false readings thereby endangering the lives of patients. Through medical device software validation, the functioning of built-in firewalls can be checked and issues like intrusions, data breaches, and manipulation of data can be addressed.

Privacy: Any information related to the health parameters of patients is sacrosanct and should be accessed by authorized stakeholders in the value chain only. With quality engineering, proper checks and balances can be incorporated into the overall system and medical devices to ensure the privacy of patient-related information.

Conclusion

Medical devices play a critical role in the diagnosis and treatment processes followed within the healthcare ecosystem. However, they are prone to malfunction, generating erroneous readings, and intruded into by hackers. A proper quality engineering approach can ensure the optimal and accurate performance of medical devices while strictly complying with the safety requirements.

Resource

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