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Medtech Tips: How To Design With Safety In Mind

by

Guest author Paul Kostek of software engineering services firm Base2 Solutions offers device-makers pointers on how to mitigate certain risks and make sure that safety is always a top concern when products are designed.

The medical device industry faces a unique set of challenges when it comes to complying with federal regulations and safety. The tracing and tracking of specifications necessary to move a product through the US Food and Drug Administration screening process is unavoidably strict. Companies must be cognizant of these requirements in each stage of the design process if they hope to release a successful product without lengthy and/or costly revisions.

For devices, risk management standard *ISO 14971* from the International Organization for Standardization is used worldwide for designing with safety in mind. It provides direction for developers on how to assess risk while offering a framework for the most important features and functions of the device. Companies that fail to comply with ISO 14971 are setting themselves up for a negative outcome from an FDA facility inspection, and a product shipping delay that often culminates in an expensive and extensive reworking of processes, documentation and testing.

About The Author

Paul Kostek is an advisory systems engineer at software engineering services firm *Base2 Solutions*, working with companies in defining system architecture, system requirements and risk assessment.

So, how can device-makers mitigate these risks and design with safety in mind? Below are four focus areas that firms may find effective.

Appoint A Safety Engineer

Designate someone on the design team who is well versed in ISO 14971 to have primary oversight responsibility for safety. Is there a systems engineer who has a passion for safety-based decision-making?

Once the safety engineer is selected, it's important to create a cross-functional team with a series of checks and balances to ensure compliance with FDA regulations. Have the team create a flowchart to be followed for each device that is designed. The details can change based on the specific device, but the process should remain consistent.

Hire A Usability Specialist

A usability specialist will provide the outside expertise needed to assess how the product will be used (and potentially misused) in the clinical or home environment. The specialist should work with the systems engineers and the greater team to come up with a task analysis detailing the intended purpose of the device, along with all potential secondary uses. Demonstrating potential errors and mitigating the ones that are most safety critical should be a key focus of the team.

As part of this process, the usability specialist should oversee the development of a usable, easily understandable set of instruction for operating the device. He or she should detail every function of the product in language that mitigates the likelihood of misuse. The usability specialist should have enough external insight and knowledge to address any common errors or potential operational confusion.

The final step includes a validation process. The usability specialist should go out into the clinical environment to validate how the device works and observe any potential issues. This process also provides crucial insights into the potential user errors that can occur when using the product.

Conduct A DFMEA

A Design Failure Mode and Effect Analysis (DFMEA) is a systematic group of activities used to recognize and evaluate potential system, product or process failures. It's important to determine how even the smallest system failure can lead to the potential for the entire device to break down.

Part of this analysis should include outlining the device's essential performance functions. What must the device do in order to meet its intended purpose? What needs to be considered to ensure that basic safety isn't compromised? What are the secondary uses of the device? Developers need to ensure they're developing every simple subsystem to the best of their ability because one small, poorly designed secondary system could lead to the malfunction of the entire device.

Outline Essential Performance

All medical devices need to identify essential performance. Essential performance functions could lead to an unacceptable risk. Medical electrical equipment standard *IEC 60601-1* from the International Electrotechnical Commission points out that "essential performance exists when the feature or function in question is either absent or its characteristics are degraded to a point that the ME equipment is no longer suitable for its intended use."

A Device-Maker's Burden

Manufacturers have the burden of ensuring devices work properly and performs the functions promised, while also managing the liability of a defect or design flaw resulting in an injury or death. To ensure that firms are able to design, build and bring to market a safe device, processes must be defined for the entire product life cycle.

Identifying and mitigating risk is essential to completing the device requirements. In addition to risk management, device developers must ensure clean and understandable Instructions for Use by trained medical professionals or the general public, depending on the device.

Finally, the documentation for the design and manufacturing of the device must be complete and maintained in a formal release system. This allows traceability of the device throughout the entire design process and beyond. By employing a comprehensive system and always designing with safety in mind, manufacturers can help ensure a smooth and efficient approval and go-to-market process for their products.