

IMPERIAL

MedTechONE Knowledge Base



How do you ensure safety and regulatory compliance during usability engineering?

- 1 What are the key regulatory requirements?
- 2 Integrating Usability into Risk Management
- 3 Define and Test Critical Tasks
- 4 Documentation and Regulatory Submissions
- 5 Post-Market Surveillance and Updates

1. What are the key regulatory requirements?

1. IEC 62366 (International Standard for Usability Engineering)

- What It Is:

IEC 62366 is the international standard that governs usability engineering for medical devices. It focuses on ensuring that medical devices are safe to use by minimizing use-related risks and errors.

- Key Components:

The standard outlines a usability engineering process that includes:

- Identifying intended users and their characteristics.
- Defining the use environment and conditions under which the device will be operated.
- Recognizing use-related hazards and mitigating these risks through improved device design.
- Conducting formative testing (during development) and summative testing (post-development) to ensure the device can be used safely and effectively.

- Pathway:

Compliance with IEC 62366 is required to meet regulatory approval in global markets. Manufacturers need to provide documentation of their usability engineering process, including risk management files, test reports, and design validation to regulatory bodies like the FDA and the European Union.

- Why It Matters:

The IEC 62366 standard is critical for ensuring that devices do not just work technically but are also easy and safe to use in practice. This standard also ensures compliance with other risk management standards like ISO 14971, which helps reduce potential harm caused by use errors

2. FDA Human Factors Guidance (U.S. Standard for Usability)

- What It Is:

The FDA's Human Factors Engineering and Usability Guidance is the core regulatory framework that governs the integration of usability into medical device design in the United States. This guidance focuses on how human factors engineering (HFE) should be used to minimize the risk of use-related hazards.

- Key Components:

- Identifying critical tasks where user errors can have the greatest impact on safety (e.g., setting the correct dose on an infusion pump).
- Implementing design features and mitigations to reduce risk and prevent user errors.
- Conducting both formative and summative usability testing to validate that the device can be used safely by intended users.

- Pathway:

For FDA approval, manufacturers must submit Human Factors Engineering Reports as part of the premarket submission (PMA or 510(k)). The report must demonstrate that the device design has undergone rigorous human factors validation and that it effectively minimizes the risk of use-related errors. Devices that do not meet these requirements may not gain FDA approval, delaying market entry.

- Why It Matters:

FDA's guidance ensures that human factors engineering is built into the design process from the beginning, addressing use-related risks. This process is essential for protecting patient safety and avoiding costly design changes later in the development process.

3. EU Medical Device Regulation (MDR 2017/745)

- What It Is:

The MDR 2017/745 is a regulatory framework that governs the design, testing, and post-market surveillance of medical devices in the European Union. It replaced the older Medical Device Directive (MDD) and introduced stricter requirements for proving the safety and usability of medical devices.

- Key Components:

- Emphasizes the importance of usability as part of the device's General Safety and Performance Requirements (GSPR).

- Requires manufacturers to conduct a clinical evaluation to demonstrate that the device meets performance requirements and is safe for its intended users.
- Mandates post-market surveillance to gather ongoing data on device usability in real-world conditions.

- Pathway:

For CE marking (EU market approval), manufacturers must provide documentation that usability engineering was part of the device's risk management and clinical evaluation process. This includes submitting a technical file that outlines the usability testing performed, risk management activities, and any design changes made to enhance usability.

- Why It Matters:

The MDR's stricter regulations ensure that devices entering the European market meet higher safety and usability standards. This focus on post-market surveillance also ensures that manufacturers continuously monitor device usability and adapt to any unforeseen usability challenges

4. ISO 14971 (Risk Management Standard)

- What It Is:

ISO 14971 is the international standard for risk management of medical devices. It provides a framework for identifying, assessing, and mitigating risks throughout the device's lifecycle, including usability-related risks.

- Key Components:

- Ensures that risk management is integrated into the device development process, from initial design through production and post-market monitoring.
- Requires identification of use-related risks and hazards, including those resulting from user interface design.
- Mandates a thorough risk-benefit analysis to justify any remaining risks.

- Pathway:

ISO 14971 is often paired with IEC 62366 during regulatory submissions, as both focus on mitigating risks associated with user interaction. Risk management files must be submitted to regulatory bodies (FDA, EU MDR) to show how the manufacturer has addressed use-related hazards.

- Why It Matters:

Compliance with ISO 14971 is critical for identifying all potential risks, including those stemming from usability. Ensuring these risks are minimized or eliminated contributes to safer, more effective devices

5. Regulatory Pathways for Usability Testing

To meet regulatory standards, the following steps are typically required as part of the regulatory pathway for usability:

1. Identify Use-Related Risks:

- Assess how users will interact with the device and what potential hazards exist in that interaction.

2. Conduct Usability Testing (Formative and Summative):

- Perform formative testing early in development to identify usability issues and summative testing before submission to ensure the final design meets safety and usability standards.

3. Document the Usability Engineering Process:

- Keep detailed records of all usability activities, including identified risks, test results, and design adjustments. This documentation is critical for regulatory submissions.

4. Submit Reports and Files:

- For the FDA, submit a Human Factors Engineering Report as part of the premarket submission (PMA/510(k)).
- For the EU, submit a technical file and risk management documentation that proves usability was integrated into design and risk management processes

2. Integrating Usability into Risk Management

- **Why:** Usability-related risks, such as user errors, can lead to harm or device failure. Integrating usability into risk management helps identify, assess, and mitigate risks associated with user-device interaction
- **How: Hazard Identification:** During the design process, identify potential risks related to how users will interact with the device. This includes scenarios where users could make errors that lead to dangerous outcomes.
- **Risk Controls:** Apply usability-based design improvements that reduce the likelihood of these errors. For example, using clear, intuitive user interfaces or providing visual/auditory feedback to prevent misuse.
- **Validation:** Ensure that the controls effectively reduce risk by conducting usability testing, particularly during summative evaluations
- **Example:** If designing a medication infusion pump, risk management should address potential dosing errors by implementing interface designs that prevent input errors or by requiring user confirmation for critical tasks.

3. Define and Test Critical Tasks

- **Why:** Critical tasks are those that, if performed incorrectly, could lead to serious harm. Ensuring that these tasks are clearly defined and tested is a fundamental part of both safety and regulatory compliance.
- **How:**
 - Identify the most important tasks that users need to perform (e.g., setting up, administering treatment, or responding to alarms).
 - Evaluate these tasks during both formative and summative usability testing to confirm that users can complete them correctly and safely without errors.
 - Implement design features that guide users through these tasks (e.g., clear visual instructions, intuitive controls).

- Example: For a blood glucose monitor, the critical task would be ensuring users can correctly insert the test strip and interpret the glucose reading. Testing would focus on whether users can perform these tasks consistently and without confusion

4. Documentation and Regulatory Submissions

- Why: Regulatory bodies like the FDA and EU MDR require detailed documentation showing that usability engineering processes were followed to ensure the device's safety and effectiveness.
- How: Usability Engineering File: Maintain a comprehensive record of all usability-related activities, including user profiles, identified hazards, testing results, and risk mitigations.
- Human Factors Report: For the FDA, this report must outline how usability risks were mitigated and how testing validated the device's safe operation.
- Post-Market Surveillance: Continue gathering usability-related data after the device is released, including user feedback, and document any updates or design changes

5. Post-Market Surveillance and Updates

- Why: Even after a device is on the market, real-world use may reveal new usability challenges or risks. Monitoring and updating the device's usability ensures continued safety.
- How:
 - Collect User Feedback: Gather data from users in real-world settings to identify any issues that were not apparent during pre-market testing.
 - Address Issues: Use this feedback to implement design improvements, update instructions, or provide additional training where necessary.
- Example: After the release of a diagnostic tool, feedback may reveal that users struggle to interpret certain data displays. Post-market usability improvements could include a simplified data presentation or added tooltips to guide users.