Navigating Post-Market Human Factors in High-Stakes Medical Device Decisions

GODDARD PRODUCT DEVELOPMENT

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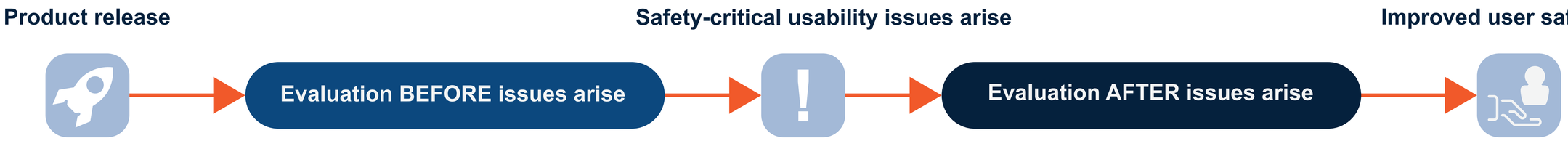
What is post-market human factors engineering?

Post-market human factors engineering is the implementation of human factors processes for devices that have already been released to market.

Human factors input at this stage can range from gathering usability data on recently released products to supporting large-scale design changes.

The scope of post-market human factors involvement is largely shaped by when human factors input is brought in and the complexity of the device.

What does human factors work look like in the post-market environment?



Usability evaluation BEFORE

Case Study:
A proactive human factors evaluation was undertaken following mechanical failures in a fluid administration device.

User studies and participant interviews revealed a mismatch between expected device use and actual device use.

Packaging and Instructions for Use (IFU) were redesigned to more accurately mirror users' actual step-by-step workflow, reducing the likelihood of usability issues in the field.

Be proactive

Proactively evaluating usability before issues arise reduces the likelihood of Corrective and Preventative Action (CAPA) and remediation efforts.

Usability evaluation AFTER

Case Study:
Alarm design was required for a cardiovascular device that patients have used for years.

An existing alarm tone had to be applied to a new alarm state. Users' mental model of the urgency of the alarm tone had to match the urgency of the device issue to elicit the appropriate behavior.

Through extensive user studies, an alarm was selected that balanced urgency with clarity.

Know your user

Redesigning in-use devices requires deep consideration of users' mental models, which might be at odds with standard usability guidance.

Usability evaluation AFTER

Case Study:
User interface redesign was required as part of remediation of a life-threatening device failure.

User studies highlighted user interface limitations, including limited detectability of safety relevant features.

Using thorough risk management processes, the residual usability risks were determined to be outweighed by the benefits of device release, resulting in successful and timely regulatory submission.

Assess benefit-risk

Identifying what is required versus "nice to have" from a usability standpoint can facilitate accelerated time to market for life-saving device changes.

Conclusion

Post-market human factors engineering poses unique challenges compared to pre-market development. These challenges include advocating for proactive evaluation and navigating trade-offs between usability and time to market. A risk-driven approach based in a strong understanding of actual device use ensures effective post-market support.

What challenges have you faced in post-market human factors?
Scan to contribute to the word cloud and see how others in the community responded.

SCAN ME