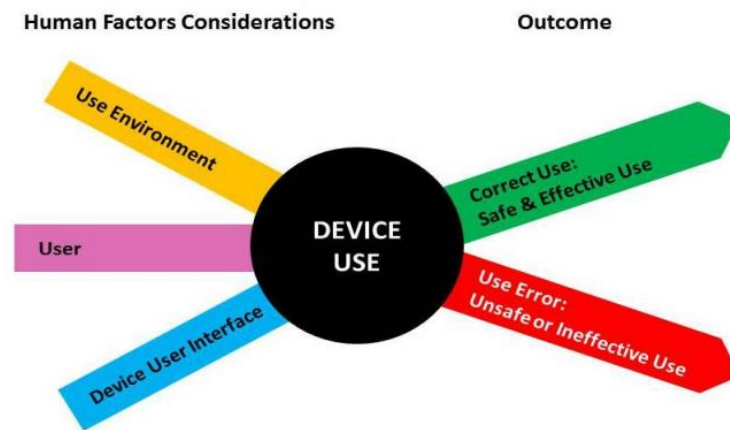


## Human Factors: Integrating the Human Condition into Medical Device Design

Human factors and usability engineering are synonymous terms which describe the application of knowledge about human behavior toward the design of a device. Understanding human behavior can easily result in adverse events with medical devices, the FDA recently issued the guidance document, [Applying Human Factors and Usability Engineering to Medical Devices](#), to provide recommendations on how to integrate usability engineering processes during medical device development.

The FDA's goal in incorporating human factors into medical device design is to "ensure that the device user interface has been designed such that use errors that occur during the use of the device that could cause harm or degrade medical treatment are either eliminated or reduced to the extent possible," as illustrated in the graphic below.<sup>1</sup>



Some of the FDA's key recommendations are as follows:

- Include human factors into risk management (i.e. use-related hazards)
- Consider device users, use environments, and user interfaces
- Develop a list of critical tasks that users should perform correctly for safe and effective use
- Modify the device user interface as the most effective way to reduce use-related hazards
- Demonstrate safe and effective device use by performing human factors validation testing

As part of human factors validation testing, medical device developers should always ensure:

- Test participants represent all intended (actual) users of the device
- A minimum of fifteen (15) participants be allotted per user group
- All critical tasks be performed during the testing
- Device user interface represents the final design
- Test conditions be realistic to represent actual use

If you need assistance incorporating human factors into your medical device design or performing human factors validation testing, please call 512-328-9404 or contact Kat McCarty at [info@qaconsultinginc.com](mailto:info@qaconsultinginc.com).

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<sup>1</sup> [Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff, February 3, 2016](#)