Premarket Information - Device Design and Documentation Processes

Brief Description of Human Factors Pre-Market Review Process

The Human Factors Premarket Evaluation Team serves as consultants on the multi-disciplinary review team of various premarket submissions in CDRH and in other Centers within FDA. The team is responsible for evaluating use-related risk analyses, and human factors/usability information and validation study data included in the submission. The recommendations are reviewed and incorporated in FDA letters to the device manufacturers.

The team responds to device manufacturers' requests for advice on how best to conduct human factors evaluation and testing. The team works with manufacturers to resolve human factors deficiencies contained in premarket submissions via teleconference or face to face meeting.

Top

HFE/UE Validation Report Contained in a Premarket Application or Submission

A Human Factors Engineering or Usability Engineering (HFE/UE) report included in a premarket submission should provide information pertaining to device use safety and effectiveness in summary form. The report should discuss the safety-related HFE/UE considerations, issues, processes, resolutions, and conclusions. The level of detail of documentation submitted should be sufficient to describe your identification, evaluation, and final assessment of all serious use-related hazards for the device. To facilitate FDA review, materials used directly in the HF/UE process, including portions of risk analyses focusing on user interactions with the device and specific risk analysis processes, results and conclusions should be included in the HFE/UE report. A recommended structure for the HFE/UE report, which will support efficient FDA review of these materials, is listed and described in the table below.

Sec.	Contents
1	**Conclusion** The device has been found to be safe and effective for the intended users, uses and use environments. • Brief summary of HFE/UE processes and results that support this conclusion • Discussion of residual use-related risk
2	**Descriptions of intended device users, uses, use environments, and training** • Intended user population(s) and meaningful differences in capabilities between multiple user populations that could affect user interactions with the device • Intended use and operational contexts of use • Use environments and conditions that could affect user interactions with the device • Training intended for users
3	**Description of device user interface** • Graphical representation of device and its user interface • Description of device user interface • Device labeling • Overview of operational sequence of device and expected user interactions with user interface
4	**Summary of known use problems** • Known use problems with previous models of the subject device • Known use problems with similar devices, predicate devices or devices with similar user interface elements • Design modifications implemented in response to post-market use error problems
5	**Analysis of hazards and risks associated with use of the device** • Potential use errors • Potential harm and severity of harm that could result from each use error • Risk management measures implemented to eliminate or reduce the risk • Evidence of effectiveness of each risk management measure
6	**Summary of preliminary analyses and evaluations** • Evaluation methods used • Key results and design modifications implemented in response • Key findings that informed the human factors validation test protocol
7	**Description and categorization of critical tasks** • Process used to identify critical tasks • List and descriptions of critical tasks • Categorization of critical tasks by severity of potential harm • Descriptions of use scenarios that include critical tasks

Sec.	Contents
8	**Details of human factors validation testing** • Rationale for test type selected (i.e., simulated use, actual use or clinical study) • Test environment and conditions of use • Number and type of test participants • Training provided to test participants and how it corresponded to real-world training levels • Critical tasks and use scenarios included in testing • **Definition of successful performance of each test task** • **Description of data to be collected and methods for documenting observations and interview responses** • **Test results: Observations of task performance and occurrences of use errors, close calls, and use problems** • **Test results: Feedback from interviews with test participants regarding device use, critical tasks, use errors, and problems (as applicable)** • **Description and analysis of all use errors and difficulties that could cause harm, root causes of the problems, and implications for additional risk elimination or reduction**

Top

Support for Appropriate Application of Human Factors Methods to Medical Device Design

Quality System / Design Control Regulations

Medical device manufacturers are required to comply with the Quality System regulation, 21 CFR Part 820 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1). In particular, Section 30, Design Controls (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=820.30), includes requirements relevant to human factors.

- Quality System (QS) Regulation/Medical Device Good Manufacturing Practices (/quality-systems-regulation)
- Human Factors Implications of New GMP Rule; Overall Requirements of the New Quality System Regulation (/medical-devices/human-factors-medical-devices/human-factors-implications-new-gmp-rule-overall-requirements-new-quality-system-regulation)
- Design Control Guidance For Medical Device Manufacturers (/media/116573/download)
- Quality System Information for Certain Premarket Application Reviews; Guidance for Industry and FDA Staff (/media/71083/download)

FDA-Recognized Standards on Human Factors

FDA has officially recognized (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm) device-specific and general consensus standards published by national and international standards bodies. Standards recognized by FDA related to human factors and application of HFE/UE to medical devices are listed below:

Standard	Title	Main Purpose
AAMI/ANSI HE75:2009	*Human Factors Engineering – Design of Medical Devices*	Comprehensive reference that includes general principles, management of use error risk, design elements, integrated solutions
ANSI/AAMI/IEC 62366-1:2015	*Medical devices – Part 1: Application of usability engineering to medical devices*	HFE/UE process applied to all applying HF/usability to medical device design, with consideration of risk management
ANSI/AAMI/ISO 14971:2007/(R)2010	*Medical Devices – Application of risk management to medical devices*	Risk management process for medical devices
IEC 60601-1-6:2010	*Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*	Provides a bridge between IEC 60601-1 and ANSI/AAMI/IEC 62366
IEC 60601-1-8 Edition 2.1 2012-11	*Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*	Design standard for alarm systems in medical electrical equipment and systems
IEC 60601-1-11:2010	*Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*	Requirements for medical electrical equipment used in non-clinical environments, including issues involving medical device use by lay users

FDA - Guidance Documents Related to Human Factors

FDA has developed several guidance documents to support device manufacturers to apply appropriate human factors methods in the design of their products. These include:

- Applying Human Factors and Usability Engineering to Medical Devices (/media/80481/download)
- List of Highest Priorities Devices for Human Factor Review (draft guidance) (/media/95804/download)
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (/media/73065/download)
- Guidance for Industry and FDA Staff - Total Product Life Cycle: Infusion Pump - Premarket Notification [510(k)] Submissions (/media/78369/download)
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (/media/80265/download)

FDA - Guidance and Information on Medical Device Labeling

- Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers (/media/71030/download)
- Labeling requirements from Device Advice (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/default.htm)

Top