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FDA Highlights Human Factors In Three Recently Issued Guidance Documents

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The guidance documents relate to human factors testing, data, and clinical considerations.

The **US Food and Drug Administration** (FDA or the Agency) had a busy month in February with respect to human factors, issuing three new guidance documents:

- Final Guidance: Applying Human Factors and Usability Engineering to Medical Devices [1]
- Draft Guidance: List of Highest Priority Devices for Human Factors Review [2]
- Draft Guidance: Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development [3]

FDA also held a webinar on February 19, 2016 regarding the Applying Human Factors and Usability Engineering to Medical Devices final guidance.[4]

This focus on human factors guidance is indicative of FDA's current concerns about the potential impact that poor human factors engineering (HFE) and usability engineering (UE) practices can have on the safety and effectiveness of medical devices, as well as the public health risks associated with user error. Manufacturers of combination products and medical devices—particularly those devices identified in the List of High Priority Devices for Human Factors Review draft guidance—should be aware of the impact of these new guidances on FDA's expectations for human factors data in premarket submissions, HFE/UE-related processes and documentation, and human factors clinical study considerations.

Final Guidance: Applying Human Factors and Usability Engineering to Medical Devices

This final guidance supersedes the former draft guidance "Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management" that was issued on July 18, 2000.[5] The final guidance is intended to provide guidance to device manufacturers on the use of HFE/UE during device development to ensure that devices will be safe and effective for their intended users, uses,

and use environments.

The final guidance discusses the following:

- Key terminology
- HFE/UE as part of risk management
- Determining device users, device use environments, and device user interfaces
- Preliminary analyses and evaluations to identify user tasks, user interface components, and use-related issues/hazards early in the design process
- Elimination or reduction of use-related hazards
- Human factors validation testing
- Documentation of risk management, HFE/UE testing, and design optimization processes

Ultimately, FDA hopes that appropriate application of HFE/UE can optimize device design—improving safety while also reducing the risk of costly postmarket design modifications and updates.

Draft Guidance: List of Highest Priority Devices for Human Factor Review

This draft guidance document identifies those devices that FDA considers to have a clear potential for serious harm resulting from use error. The draft guidance recommends that manufacturers of such devices submit human factors data in their premarket submissions to demonstrate that the risks associated with use error have been appropriately addressed.

The devices listed by FDA include the following:

- Ablation generators (associated with ablation systems)
- Anesthesia machines
- Artificial pancreas systems
- Auto injectors (when Center for Devices and Radiological Health (CDRH) is lead center)
- Automated external defibrillators
- Duodenoscopes (on the reprocessing) with elevator channels
- Gastroenterology-urology endoscopic ultrasound systems (on the reprocessing) with elevator channels
- Hemodialysis and peritoneal dialysis systems
- Implanted infusion pumps

- Infusion pumps
- Insulin delivery systems
- Negative-pressure wound therapy intended for use in the home
- Robotic catheter manipulation systems
- Robotic surgery devices
- Ventilators
- Ventricular assist devices

Draft Guidance: Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development

This draft guidance document outlines certain types of human factors considerations for studies during the development of combination products. It addresses several topics, including recommendations for human factors information in combination product investigational or marketing submissions, clarification of the different types of human factors studies, the recommended timing and sequencing of such studies, and how human factors studies relate to other clinical studies.

Comment Period for Draft Guidance Documents

Interested parties have until May 3, 2016 to submit comments on the two draft guidance documents described above, which may be submitted electronically via www.regulations.gov or by mail/hand delivery/courier to FDA's Division of Dockets Management.

[1] U.S. Food & Drug Admin, Final Guidance: Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and FDA Staff (Feb. 3, 2016) http://1.usa.gov/1WLMzPO; 81 Fed. Reg. 5762 (Feb. 3, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-02-03/pdf/2016-01887.pdf.

[2] U.S. Food & Drug Admin., List of Highest Priority Devices for Human Factors Review: Draft Guidance for Industry and Food and Drug Administration Staff (Feb. 3, 2016); 81 Fed. Reg. 5756 (Feb. 3, 2016) .

[3] U.S. Food & Drug Admin, Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development: Draft Guidance for Industry and FDA Staff (Feb. 3, 2016).

[4] U.S. Food & Drug Admin., Applying Human Factors and Usability Engineering to Medical Devices - February 19, 2016, FDA.gov

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