



FDA Human Factors Draft Guidance Document: Agency Expectations for Human Factors Data in Premarket Submissions

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FDA /CDRH / ODE

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Medical Device Standards and Regulation**

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FDA HF Guidance

Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management

[http://www.fda.gov/
MedicalDevices/
DeviceRegulationand
Guidance/
GuidanceDocuments/
ucm094460.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094460.htm)

– *NOTE: issued in 2000*

Guidance for Industry and FDA Premarket
and Design Control Reviewers

Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management

Document issued on July 18, 2000

This document replaces the draft guidance document of August 3, 1999, entitled
Device Use Safety: Incorporating Human Factors in Risk Management.



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Division of Device User Programs and Systems Analysis
Office of Health and Industry Programs



Draft Guidance

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm259748.htm>

- NOTE: issued in 2011 – This guidance is **not yet in effect** but it reflects FDA-CDRH's current thinking and approach to human factors.

*Contains Nonbinding Recommendations
Draft - Not for Implementation*

**Draft Guidance for Industry and
Food and Drug Administration
Staff**

**Applying Human Factors and
Usability Engineering to Optimize
Medical Device Design**

DRAFT GUIDANCE


**This guidance document is being distributed for comment purposes only.
Document issued on: June 22, 2011**

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Ron Kaye at ron.kaye@fda.hhs.gov or (301) 796-6289, or Molly Story at molly.story@fda.hhs.gov or (301) 796-1456.

When final, this document will supersede Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management (Issued July 18, 2000).

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation




2011 *Draft* Human Factors Guidance

- Regulations, Guidance, Standards
- Considerations: Device Users, Use Environments and User Interfaces
- Preliminary Analyses and Exploratory HF/U Studies
- Risk Control and Design Iteration
- Human Factors/Usability Validation Studies



Regulatory Basis for HF at FDA

Quality System regulation:

21 CFR 820.30, Design Controls

– *The need for human factors is implied:*

c) **Design input** – includes “needs of the user and patient”

f) **Design verification** – performance criteria met

g) **Design validation** – “... devices conform to **defined user needs and intended uses** and shall include **testing of production units under actual or simulated use conditions**. Design validation shall include **software validation** and **risk analysis**....” [incl. use-related risks]



820.30(c) Design Input

- **User and Patient Needs**
 - **Relative to device *effectiveness***
 - Users can operate the device successfully for the intended uses
 - **Relative to device *safety***
 - Users can operate the device without injury or negative clinical consequences to either the user or the patient
 - **Potential use errors and failures have been eliminated or limited to the extent possible through appropriate application of human factors methods**

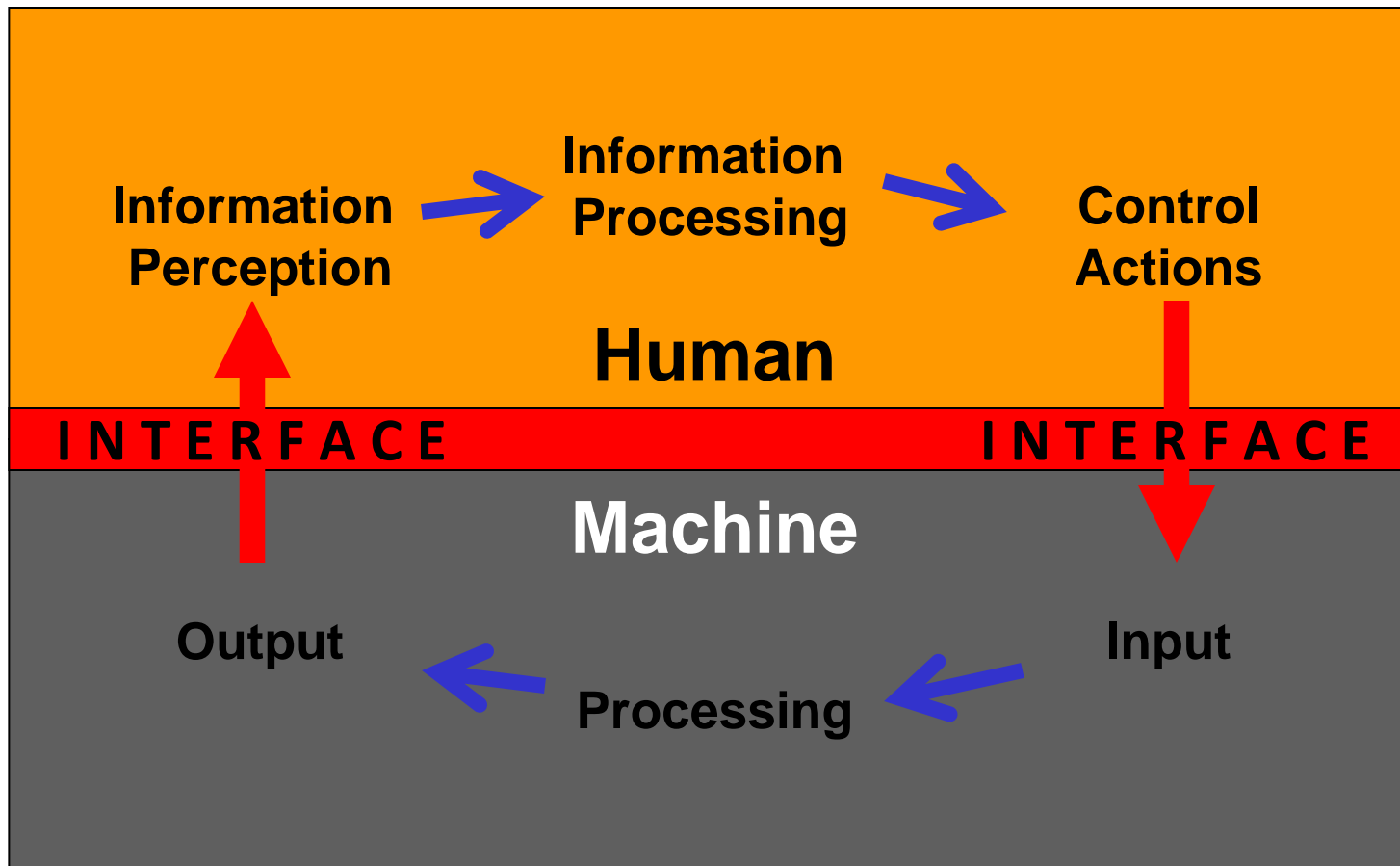


820.30(f) & (g) Design Verif. & Valid.

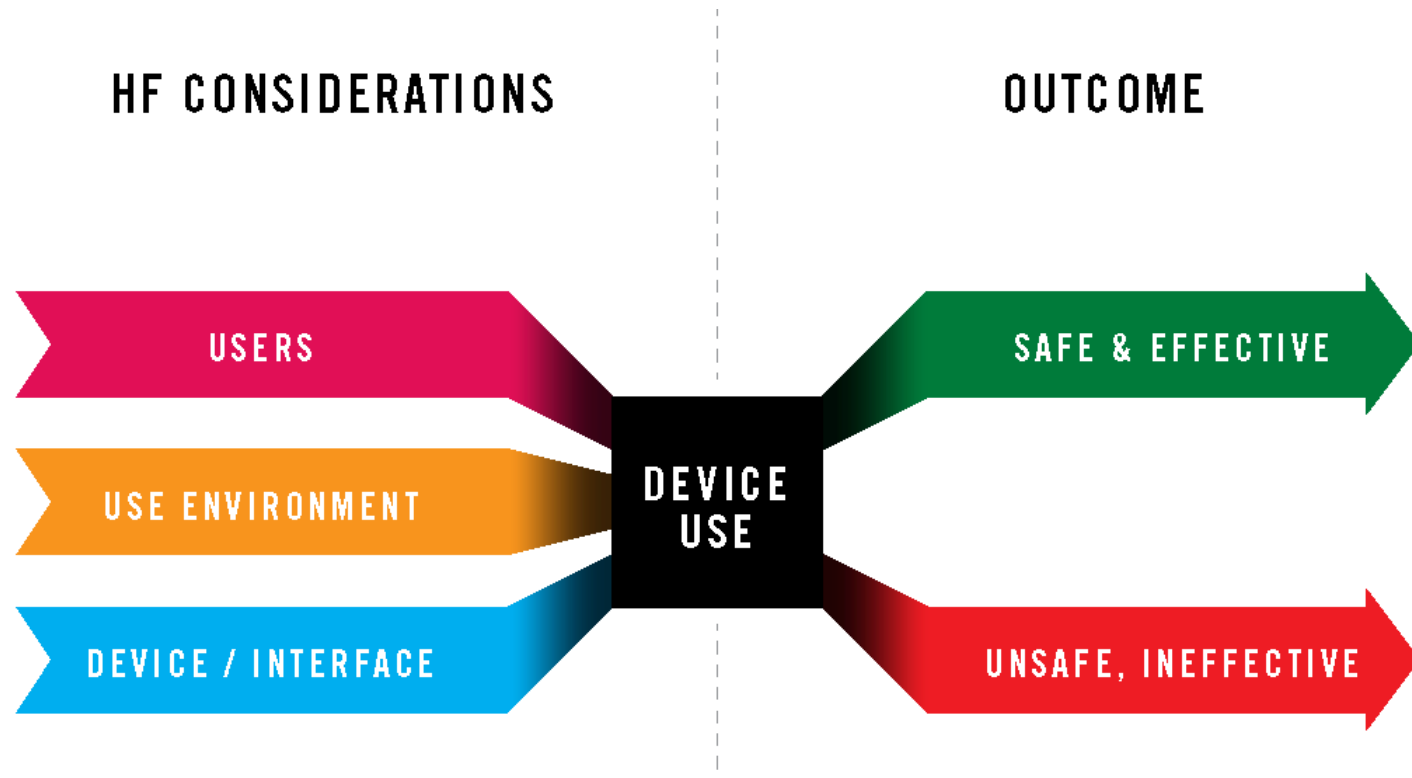
- **Design Verification:**
 - *Did I make the product right?*
- **Design Validation:**
 - *Did I make the right product?*



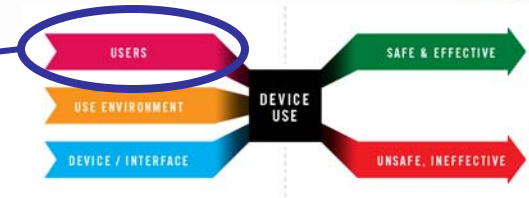
Device-User Interface



Human Factors of Device Use



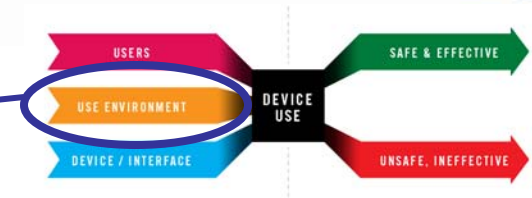
Users



- **Professional or non-professional**
 - Job title and responsibilities
- **Knowledge and experience levels**
- **Age and functional capabilities**
 - Physical, sensory/perceptual, cognitive/intellectual
- **Mental and emotional condition**



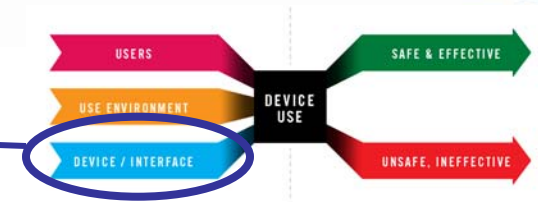
Use Environment



- **Clinical environment**
 - Hospital, clinic, etc.
- **Transitional care environment**
 - Rehabilitation, assisted living, long-term care, etc.
- **Home environment**
 - House, mobile home, townhouse, apartment, etc.
- **Community setting**
 - Office, school, retail, outdoors, etc.
- **Mobile environment**
 - Car, plane, train, bus, ambulance, medevac, etc.



User Interface



- **Tasks**

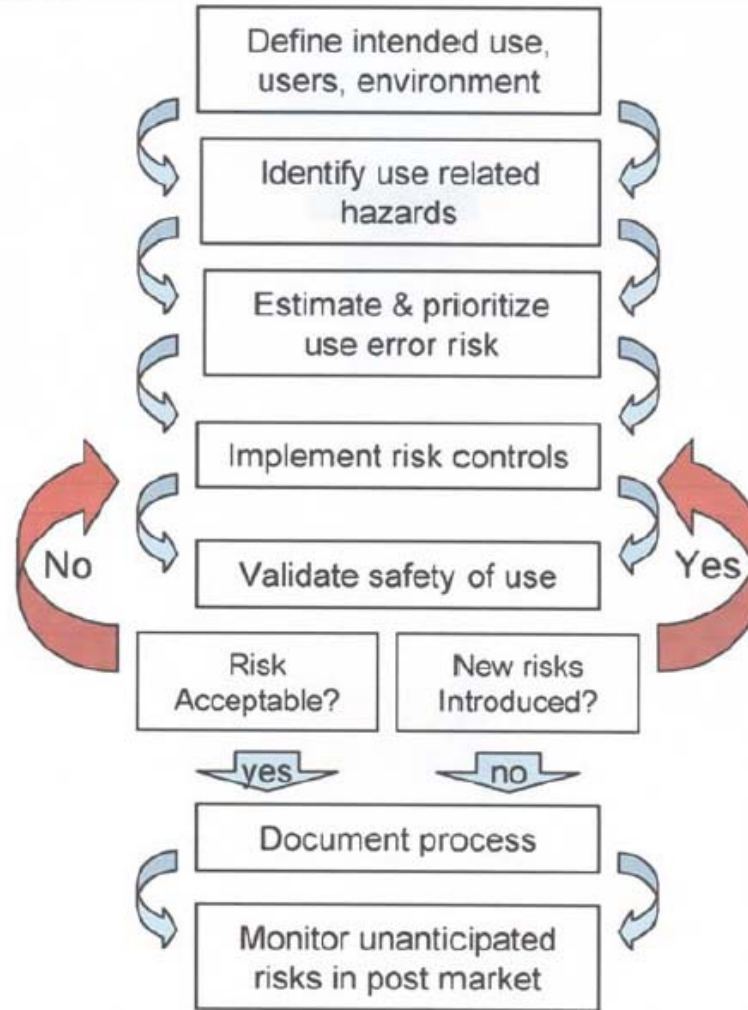
- Device set-up: installation, assembly, calibration, etc.
- Device use: various aspects
- Device cleaning, maintenance, disposal, etc.

- **Interactions**

- Input
 - Connections, knobs/dials, switches, buttons, touch screens, etc.
- Output
 - Visual: component status, displays, lights, etc.
 - Auditory: motors/fans, clicks, alerts/alarms, beeps, voice, etc.
 - Tactile: resistance, vibration, temperature, etc.



Human factor process for medical devices



Source: ANSI/AAMI
HE75:2009



Preliminary Analyses: Rationale

- Identify and analyze intended users and expected use scenarios and use environments
- Develop initial product concepts and prototypes
- Identify and explore potential device use-related hazards and risks and their potential clinical consequences
- Explore different design alternatives and identify the trade-offs between them



Preliminary Analyses: Methods

Two ways to discover use-related hazards:

1. Analytical techniques

- To identify use-related hazards and risks
 - *Use-related hazards and user behavior can be difficult to predict*
- To focus the process and prioritize resources

2. Exploratory human factors/usability studies

- Conduct exploratory, hands-on, simulated-use testing to discover and explore unanticipated hazards
 - *Sometimes called “Usability Testing” or “Use Testing” or “User Testing” or “Formative” Evaluations*



Preliminary Analyses: Methods (1 of 2)

- **Contextual inquiry**
 - User demonstrates; researcher observes, inquires
- **Interviews and focus groups**
 - Discussions are targeted; researcher is neutral
- **Function and task analyses**
 - Break down device use into discrete steps
 - Identify use-related hazards associated with each step of use
 - Identify potential causes and consequences of user encountering each hazard
 - Develop risk mitigation strategies, if needed



Preliminary Analyses: Methods (2 of 2)

- **Heuristic analysis**
 - Formally evaluate user interface against well-established design rules or heuristic guidelines
- **Expert review**
 - Use clinical and human factors experts
 - Experts provide personal opinions of usability and safety of user interface, based on professional knowledge and experience



Exploratory HF/U Studies: Rationale

- **Identify issues not findable through application of analytical techniques - e.g.:**
 - The use environment has negative effects
 - The demands associated with use of the device exceed the user's capabilities
 - Aspects of device use are inconsistent with the user's expectations or intuition
 - The device is used in unexpected ways
 - The device is used in inappropriate but foreseeable ways, for which adequate controls were not applied



Exploratory HF/U Studies (1 of 2)

- **Done while the device is under development**
 - Conduct studies iteratively to optimize the device design and ensure the human factors/usability validation testing results will be successful
 - Testing can involve simple product mock-ups or early prototypes, or even partial designs (e.g., components) operating in simulated-use modes
 - Test participants should be representative of the intended user population(s)
 - At early stages, use-related problems can be addressed more easily and less expensively



Exploratory HF/U Studies (2 of 2)

- **Conduct separate studies on labeling and training (recommended):**
 - Assess the clarity and effectiveness of all labeling (e.g., instructions for use, other documentation, packaging)
 - Determine the level and nature of training that will be necessary (if any)



Risk Control and Design Iteration

- **Develop risk mitigation strategies as needed:**
 - Modify the interface design, user instructions, and/or training to address the problems found
- **Re-test to assess whether mitigation strategies:**
 - Effectively reduced the known risks and
 - Did not introduce any new risks
- **Residual risk can be acceptable if it is:**
 - Reasonably limited, difficult to eliminate or further reduce, and outweighed by the device's benefits



Human Factors/Usability Validation

- **Demonstrates and provides evidence that a medical device, as designed, can be used safely and effectively:**
 - By people who are representative of the intended users
 - Under expected use conditions
 - For essential and critical (high-risk) tasks



Test Populations

- **All intended user populations – e.g.:**
 - Healthcare professionals, engineers/technicians, home health care aides, family caregivers, patients
 - Pediatric and geriatric populations need careful consideration
- **Not company employees**
- **U.S. residents**



Device Testing Conditions

- **Use finalized device design and labeling**
- **Present within typical context of use**
- **Incorporate expected use conditions**
 - E.g., lighting, sound, and activity (distraction) levels
- **Allow realistic device-user interactions**
 - Provide participants with device as they would receive it (e.g., in its original packaging, with all documentation)
 - Allow participants to use the device as they normally would (e.g., without interference from test facilitator)



Selection of Tasks Tested (1 of 2)

- **Include in the HF/U validation study protocol and report a rationale for the tasks you choose to include in your testing**
 - Base task selection on results of preliminary analyses
 - E.g., task analyses and identification of use-related risks
 - Incorporate findings of exploratory HF/U studies
 - E.g., tasks found to be error-prone or difficult for users
 - Define criteria for task success prior to the test



Selection of Tasks Tested (2 of 2)

- **Tasks tested in validation do not necessarily include everything in the instructions for use**
 - Include *essential tasks* – i.e., tasks necessary for successful use of the device
 - Include *safety-critical tasks* – i.e., tasks on which users could make errors or could fail to complete, which would have negative clinical impact
 - All warnings and most caution statements in the device labeling imply safety-critical tasks
 - All tasks requiring responses to alarms are safety-critical



Instructions and Training

- **Participant interaction with instructions should approximate reality**
 - Labeling used in device validation should be final versions
 - Availability of labeling should represent realistic situation
- **Provision of training should approximate reality**
 - Training used in device validation study should be comparable to the training that actual users will receive
 - Consider integrating period of time for learning gained through training to “decay” before conducting device validation study, depending on actual conditions of use



Human Factors/Usability Data (1 of 2)

- **Objective (performance) data:**
 - Use errors, failures and difficulties are observed
 - Include details about performance – e.g.: success or failure, use error, reference to instructions for use, need for assistance, close calls, evidence of confusion
 - Measuring speed of task completion is only appropriate if it is clinically meaningful
 - Number of task attempts allowed varies by type of device and context of use
 - Facilitator should not interfere with independent and realistic use



Human Factors/Usability Data (2 of 2)

- **Subjective (narrative comment) data:**
 - Discuss user performance after use, particularly regarding perceived reasons for any essential and critical task errors, failures and difficulties
 - Solicit participant feedback on design of device, labeling and training
 - Forced-choice questionnaires or Likert rating scales collect limited information and can bias responses
 - Use of “think aloud” technique is inappropriate for validation because it does not reflect realistic use



Validation Data Analysis

- **Analyze all use errors and failures**
 - Determine root cause and consider potential consequences
 - Determine need to modify device, labeling, training
 - Identify true residual risks
- **Use errors/failures are not of equal importance**
 - Some might be frequent but inconsequential;
 - Some might be rare but reveal a hazardous design deficiency that was not previously recognized



Human Factors/Usability Eng'g. Rpt.

1. Intended device users, uses, environments
2. Device user interface
3. Summary of known use problems
4. Use task selection, characterization, priorities
5. Summary of preliminary evaluations
6. Validation studies
7. Conclusion



FDA Expectations for HF Data

- **Conduct a comprehensive risk assessment**
- **Identify and mitigate risks, including use-related**
- **Conduct human factors/usability validation testing on any strategies implemented to mitigate *significant* use-related risks**
 - Use representative users & realistic testing conditions
 - Fully describe testing protocols and results
 - Analyze and justify residual risks
- **Document everything in the Design History File**



Advice: Consult FDA Early

- **Discuss product development plans with FDA before your design is finalized (and changes would be difficult)**
 - Through a pre-submission mechanism
 - Interact with experts in CDRH (and CDER/CBER) who have advice to share based on experience
- **FDA will review human factors/usability validation study protocols on request**
 - *Before implementation is recommended!*



“Pre-IDE” Meetings

- **Can be used to interact with FDA regarding any future submission or application**
 - Can request a face-to-face meeting or teleconference or simple written response
 - Quicker turnaround: FDA often responds within 60 days
 - Can be used to request review of human factors validation study protocols
 - We try to turn these around within two weeks
- ***Guidance on IDE Policies and Procedures:***
 - [http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Guidance Documents/ucm080202.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Guidance%20Documents/ucm080202.htm)



Status of Draft Guidance Document

- **Document issued June 22, 2011**
- **Comment period closed Sept. 19, 2011**
 - More than 600 comments were submitted
- **We are reviewing the comments**
 - Some are minor and easy to address
 - Some are significant and require ODE to establish new policies
- **We hope to finalize the document soon...**



FDA/CDRH Human Factors Program

<http://www.fda.gov/humanfactors>

- Premarket Info
 - Design & Documentation
- Postmarket Info
 - Surveillance & Reporting
- Info for Consumers, Patients, Caregivers
- General Human Factors Info and Resources

The screenshot shows the FDA website page for Human Factors and Medical Devices. The page is titled "Human Factors and Medical Devices" and is part of the "Medical Devices" section. It includes a navigation menu, a search bar, and a sidebar with a "Spotlight" section. The main content area discusses the Human Factors Program at FDA, the Human Factors at Center for Devices and Radiological Health (CDRH), and the Office of Device Evaluation (ODE). The page also features a "Contact Us" section for the CDRH Human Factors Team.

Device Advice: Comprehensive Regulatory Assistance

- ▶ **Human Factors (Medical Devices)**
 - Premarket Information - Device Design and Documentation Processes
 - Postmarket Information - Device Surveillance and Reporting Processes
 - Information for Consumers, Patients, and Caregivers
 - General Human Factors Information and Resources
 - Contact Us

Human Factors and Medical Devices

Human Factors Program at FDA

FDA works with manufacturers to help ensure the application of human factors engineering to the design of new products as well as to postmarket surveillance of currently marketed products.

Human Factors at Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

The Human Factors Premarket Evaluation Team is located in the Office of Device Evaluation (ODE). The purpose of the FDA's Human Factors Pre-Market Evaluation Team is to ensure that new medical devices have been designed to be reasonably safe and effective when used by the intended user populations. The effort primarily involves reviewing new device submissions, promoting effective and focused human factors evaluation and good design practices for medical devices.

The premarket team works with scientific reviewers across the Office to evaluate use-related risk analyses, and human factors/usability information and validation study data submitted as part of various types of premarket submissions (premarket notification [510(k)] submissions, premarket approval (PMA) applications, Investigational Device Exemption (IDE) applications, and Pre-IDE submissions). The team provides recommendations on human factors components of manufacturers' design validation documents as required by the FDA's Quality System Regulation. The team also collaborates with colleagues in other FDA Centers by providing human factors recommendations, such as for combination products (i.e. autoinjectors, pen injectors, inhalation products, pre-filled syringes, etc.) in their pre-approval

Spotlight

- Meet the Human Factors Premarket Review Team at FDA's Office of Device Evaluation, 2011 HFES Annual Meeting (September 2011) (PDF - 1.1MB)
- Identifying Use Errors and Human Factors Approaches to Controlling Risks, Public Workshop: Quarantine Release Errors (September 2011) (PDF - 539KB)
- Guidance Document: Applying Human Factors and Usability Engineering to Optimize Medical Device Design (2011)
- Presentation: Identifying and Mitigating Potential Use Errors (June 2011) (PDF - 215KB)
- Presentation: Human Factors/Usability for Medical Devices - An Historical Perspective (June 2011) (PDF - 62KB)

Contact Us

CDRH Human Factors Team
☎ (202) 205-6272



New HFES-AAMI Web Site

[http://
www.medicaldevice
humanfactors.org](http://www.medicaldevicehumanfactors.org)

- Resources
- Consultant Directory
- Organizations
- Events


MedicalDeviceHumanFactors.org

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Welcome to MedicalDeviceHumanFactors.org, your source for resources (standards, guidelines, science, best practices, books, journals, etc.), consultants, organizations and events related to medical device human factors and ergonomics (HF/E). Companies that manufacture FDA-approved devices are encouraged to use this site to become knowledgeable of HF/E requirements, resources, and consultants who can help you meet the requirements.

This site was jointly developed by the [Human Factors and Ergonomics Society](#) (HFES) and the [Association for the Advancement of Medical Instrumentation](#) (AAMI). We hope that you find it a useful resource for guiding your efforts towards developing a new or revised medical device with HF/E principles in mind.





Advancing Safety in Medical Technology

Inquiries about this site should be directed to the staff of the Human Factors and Ergonomics Society, who maintains the site.
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Questions



Molly Follette Story:

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FDA/HF web site:

[www/fda.gov/humanfactors](http://www.fda.gov/humanfactors)

