



Meet the Human Factors Pre-market Review Team at FDA's Office of Device Evaluation

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FDA / CDRH / ODE

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Overview

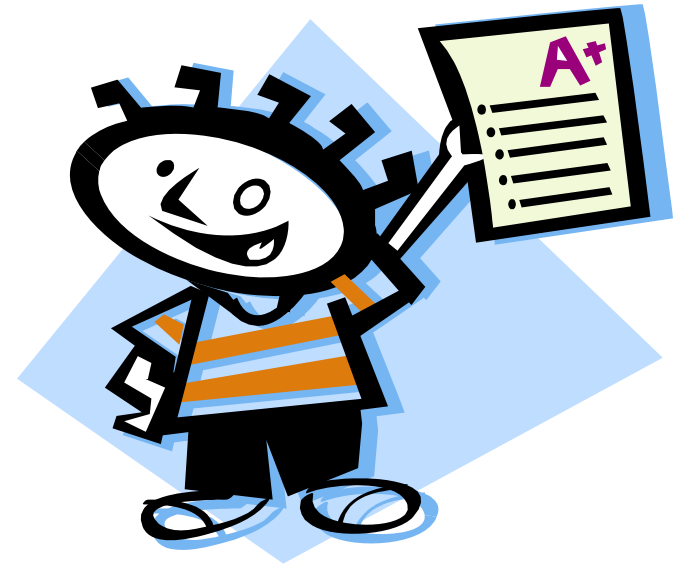
- **Introduction to FDA/CDRH/ODE premarket application review process**
- **Overview of new draft human factors guidance and comments received**
- **Special considerations for user groups and combination products**

HF Guidance from FDA



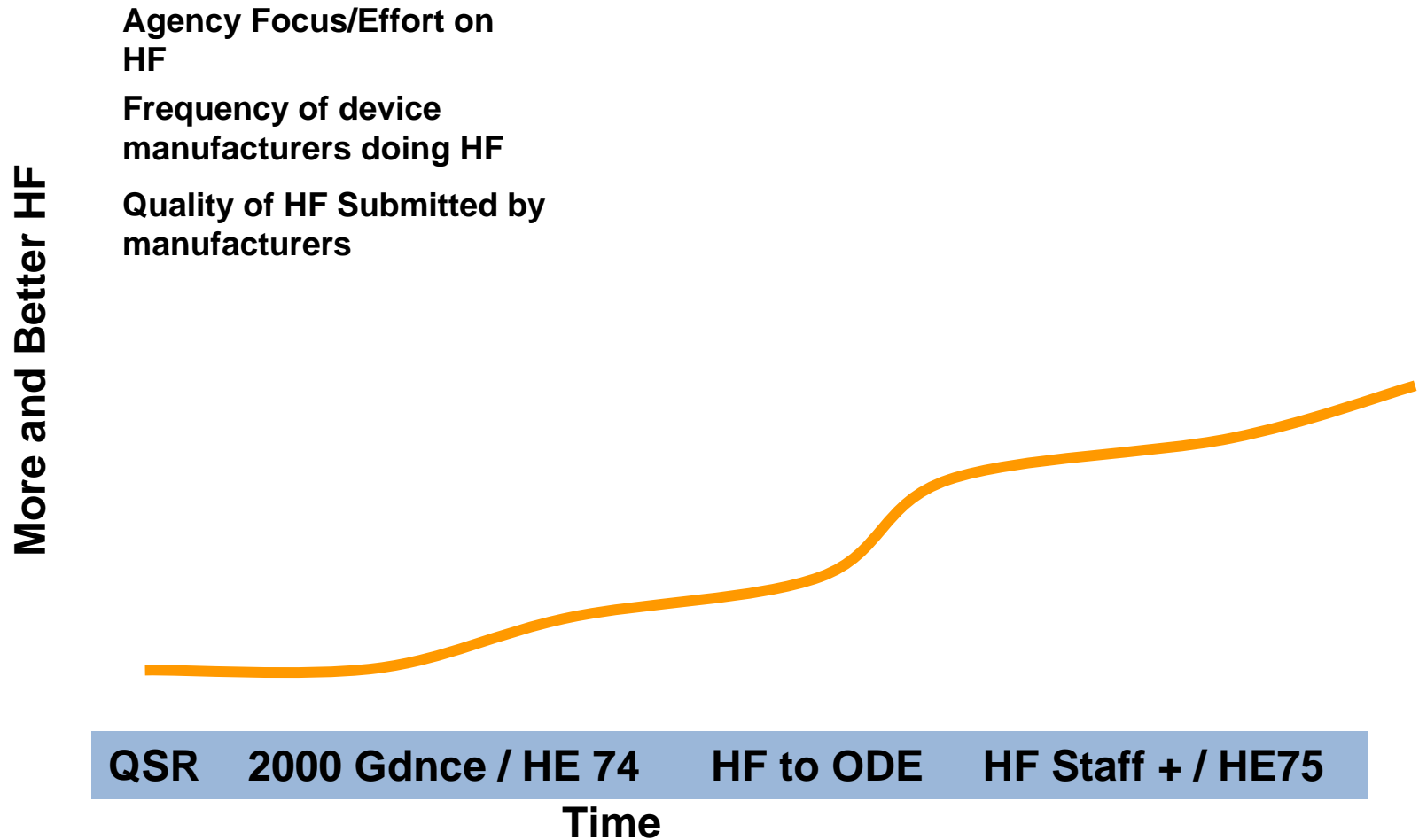
How to build a device user interface: **No**

How to evaluate and test device use-safety and effectiveness: **Yes**





Center Effort and Industry Response



2000



PreMarket Review

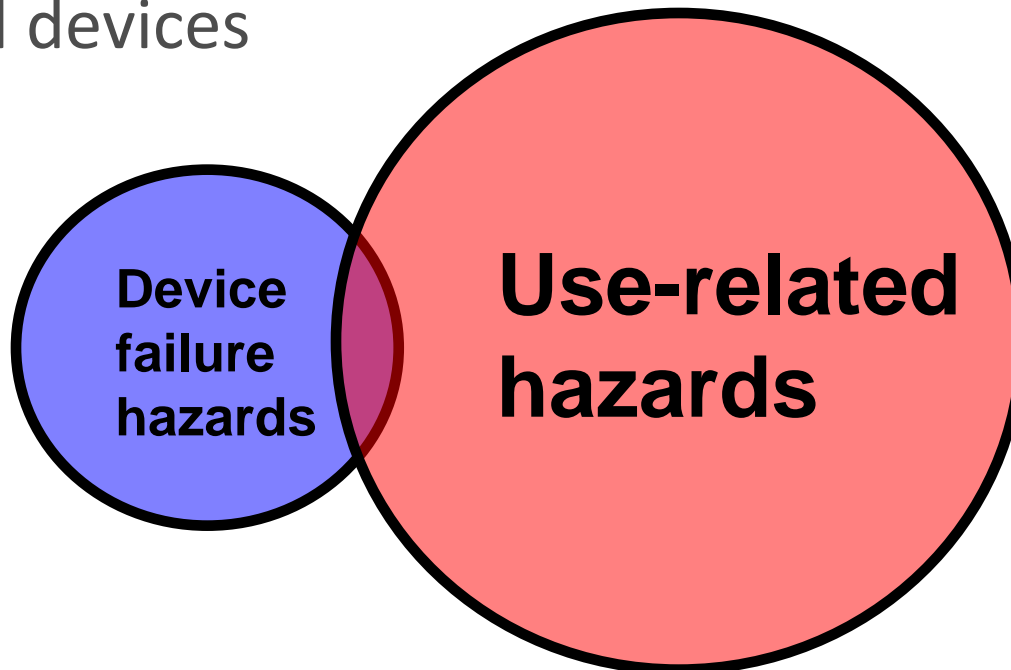
Draft Guidance

User Groups

Combo Products

2000 Guidance

- **Use error** is another kind of hazard to consider and control through application of HF to the design of medical devices



Human Factors Review Team



- Three full-time Human Factors reviewers
- HF Review staff is located in the Office of Device Evaluation (ODE), General Hospital Division (DAGID)
- Act primarily as “internal consultants”
- HF review is done for devices and device types
 - As requested by review staff
 - Priority on HF/Usability influenced by post-market reports, and Compliance actions
 - Work through Office of Combination Products (OCP) for submissions that are drugs or biologics intended to be used in conjunction with a medical device

Office of Device Evaluation

- **Premarket Notifications (510(k))**
- **Premarket Approval Applications (PMAs) and Supplements**
- **Humanitarian Device Exemptions (HDEs)**
- **Investigational Device Exemptions (IDEs), Amendments and Supplements**
- **Product Development Protocols (PDPs)**

“Pre-IDE” Meetings



- See: Guidance on IDE Policies and Procedures
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080202.htm>
 - *Pre-IDE Meetings*
 - *"Informal Guidance" Meetings*
- **Initially intended for IDE's; can be used for review even if there will be no formal IDE**
- **Good way to get review of a HF/Usability validation protocol prior to official premarket submission for a medical device**
- **Official review, though “informal”**
- **Quicker turnaround: Agency must respond within 60 days of receipt.**
 - We try to get these back within two weeks for HF protocols

Most Common HF/Usability Review Concerns (1 of 2)



- HF/Usability work is needed but not provided in submission
- No HF/Usability work prior to summative/HF Validation testing, discovering new use-related problems at this point and “explaining them away”
- Lack of effective followup on residual risk and performance failures; blame users in test or “review and modify IFU,” etc.
- Tasks involving use-related hazards not identified, no task prioritization provided, testing and evaluation not clearly related to tasks, unclear or nonexistent connection of HF evaluation and testing to risk analysis
- Inadequate or absent description or characterization of errors

Most Common HF/Usability Review Concerns (2 of 2)



- No systematic collection of subjective description of difficulties for critical tasks, task failures, or “near misses” by test participants
- Not testing with representative users of the intended population of users (e.g., not U.S. residents or using manufacturer’s own employees)
- Checklist or rating scale approach (only) for validation rather than systematic collection of user performance and subjective assessment
- Use of “usability objective” approach for HF/Usability validation where task selection and performance expectations are assigned arbitrarily rather than based on comprehensive focus on use-related risks

2011



PreMarket Review

Draft Guidance

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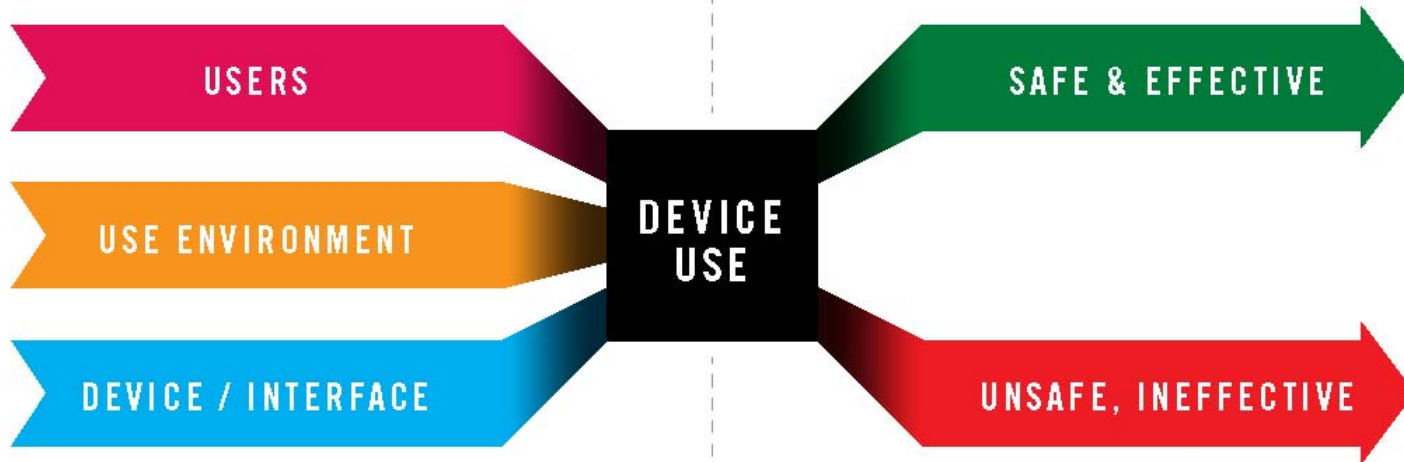
Draft Guidance: Major Sections

- **Device Users, Use Environments and User Interfaces**
- **Preliminary Analysis Methods**
- **Formative Evaluations and Hazard Mitigation and Control**
- **Human Factors/Usability Validation Testing**
- **Validation Test Report**

H

HF CONSIDERATIONS

OUTCOME



Device 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**



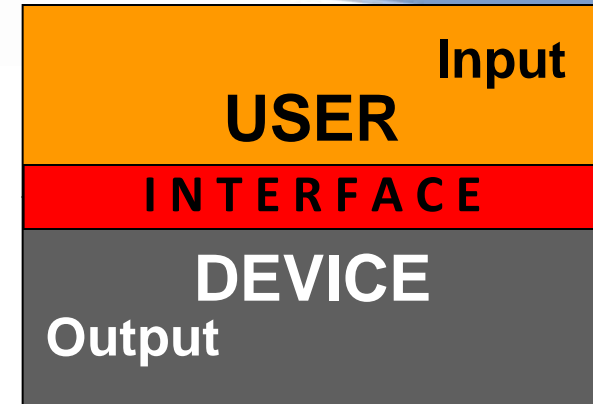
Device Use Environment

- **Clinical environment(s)**
- **Rehabilitation, assisted living, long-term care**
- **Home environment**
- **Community setting**
 - Office, school, retail, outdoors, etc.
- **Mobile environment**
 - Car, plane, train, bus, ambulance, medevac, etc.

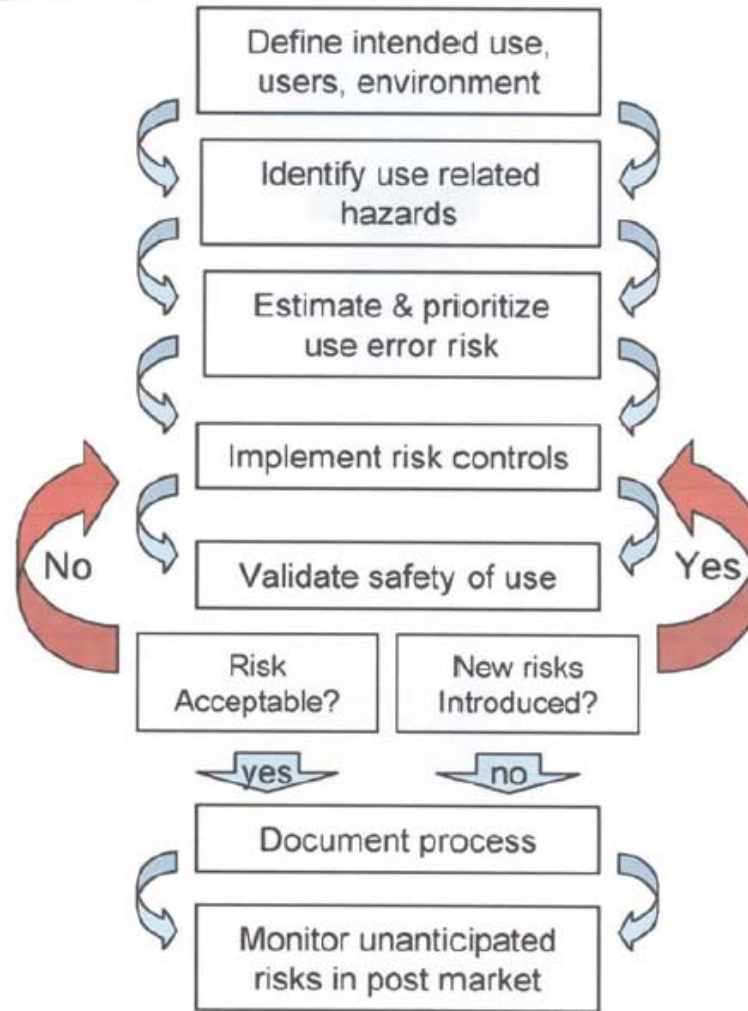


Device User Interface

- **Tasks**
 - Unpacking, assembly/set up
 - Use
 - Supply replenishment, maintenance, repair
- **Interactions**
 - **Input**
 - Knobs/dials, switches, buttons; connections
 - **Output**
 - Visual: displays, lights
 - Auditory: beeps, alerts/alarms, voice
 - Tactile: vibration, heat



Human factors engineering process for medical devices



Source: ANSI/AAMI
HE75:2009

Preliminary Analyses

Two ways of discovering use-related hazards:

1. Apply analytical techniques

- Identify anticipated hazards
 - Can be difficult to anticipate all hazards

2. Conduct user-based evaluations

- Identify unanticipated hazards
 - Sometimes called “Usability Testing” or “Use Testing” or “User Testing” or “Formative” Evaluations

Analytical HF Methods (1 of 3)



Identify known problems

- Customer complaint files
- Knowledge of training and sales staff
- Publications
 - Journal articles, proceedings, newsletters
 - Web sites, e.g.:
 - FDA/CDRH: MAUDE/MDR, MedSun, recalls, alerts and notices, public health notifications
 - ECRI: Medical Device Safety Rpts.

Search MAUDE Database Help | Download Files | More About MAUDE

Product Problem

Product Class

Brand Name 510K Number

Manufacturer PMA Number

Event Type Product Code

Date Report Received by FDA (mm/dd/yyyy) to

Enter one or a combination of the MAUDE Search Values and select Search
For full-text search, select Go To Simple Search button

Records per Report Page

Analytical HF Methods (2 of 3)



Analyze needs of current system users

- Who uses the system?
- Where do they work?
- What tasks do they perform?
- **Contextual inquiry**
 - User demonstration
 - Investigator observation and inquiry
- **Interviews and focus groups**
 - Targeted discussion

Analytical HF Methods (3 of 3)



Analyze critical risks

- **Risk analysis**
 - Identify critical use-related risks.
 - What hazardous scenarios could lead to these risks?
- **Function and task analysis**
 - Break down use tasks into discrete steps.
 - Are any use errors possible?
 - How might these use errors occur?
 - What are the possible consequences of each use error?
 - How might the use errors be prevented?
- **Apply risk mitigations; reassess hazards**



Formative Evaluations

- **While the device is still under development**
 - Include representative end users
 - Test simple mock-ups or early prototypes
- **Done early in the design process**
 - Therefore, use-related problems can be addressed more easily and less expensively
- **Best when performed iteratively**
 - Repeat until the device is optimized and ready for HF/usability validation testing

Formative Evaluations



- **Focus on issues that could have an impact on use safety and effectiveness**
 - E.g., Identify users' need for training; then design the content and format of the training:
 - Analyze the intended users, user tasks, and use of the device
 - Establish and prepare the training materials
 - Evaluate the training materials with a small group of users
 - Optimize the training materials based on user feedback or performance

Formative Evaluations: Cognitive Walk-Through



- **Small group of users is “walked through” the process of using a device**
 - **Observe user/device interaction**
 - **Collect information from participants on:**
 - Thought processes
 - Mental models
 - Perceived workload
 - **Solicit subjective feedback from users**
 - Use-related issues or difficulties

Formative Evaluations: Simulated Use Testing

- With representative system users
 - Test design ideas and prototypes *still under development*
 - Simulated use conditions
 - Identify major problems
 - Make choices between design options
 - Develop mitigations/solutions
 - Evaluate effectiveness of mitigations/solutions
 - Formative is not the same as summative!



Using Results from Formative Evaluations

- **Use-related hazards identified from formative evaluations should be designed out or controlled:**
 - **Modify the device design to remove a hazard, shield users from it, or reduce its consequences**
 - Make the user interface, including its operating logic, error tolerant
 - **Alert users to the hazard**
 - **Develop written procedures and training for safe operation**

=> Optimize the design of the device user interface prior to final validation testing



Benefits of Formative Evaluations (1 of 3)

- **Can be used to support decision making:**
 - User interface design and trade-off analyses
 - User training needs
 - Design of the instructions for use (IFU)
- **Clarify the dynamics of user-device interactions associated with known or suspected use errors**



Benefits of Formative Evaluations (2 of 3)

- **Support the design of and requirements for the subsequent validation study:**
 - Assist in the identification of use-related hazards and development of mitigation strategies
 - Inform of tasks selection and prioritization based on relative risks
 - Guide the development of use scenarios to be used in subsequent design validation testing
 - Support effectiveness of design mitigations

Benefits of Formative Evaluations (3 of 3)

- While FDA's premarket review focus is on the final validation study, we look for a discussion/rationale of how formative evaluations were used to:
 - Modify the design of the device user interface including IFU and training
 - Identify critical and essential user tasks
 - Inform the design of the validation study



HF/Usability Validation



- **“Validation” in the HF context pertains specifically to validation of use**
 - Implies HF/Usability testing approaches
- **Validation Test = “Summative Test”**
- **Includes “usability,” in this way:**
 - Use error = poor performance time when timely use is critical for effectiveness of device use (e.g., delay of treatment/failure to treat in time)
 - Inability to use at all

HF/Usability Validation



- If HF preliminary analyses, formative evaluations and design modifications were done well, the HF/Usability validation testing will show good performance and good assessment by users
- If Validation testing is the first HF effort, this often leads to discovery of use problems that must then be addressed

HF/Usability Validation: Purpose



- A demonstration and evidence that a medical device, as designed, can be used safely and effectively, and is perceived as such
 - By representative intended users
 - Under realistic use conditions
 - With high-risk and essential tasks are performed under conditions where
 - Failures are observed and recorded, and
 - Subjective data is collected from users

HF/Usability Validation: Test Conditions

- Should support results being “generalizable” to actual use
- Training level for test participants should be equivalent to that expected and intended for actual users
- Users should be “representative” of actual users
- Conditions of use (use environment) that could impact use should be incorporated

HF/Usability Validation: Essential Data

- Objective (performance) and Subjective (test participant's assessment)
- Failures are not simply counted but investigated and explained
- Subjective assessment by test participants is central for each observed failure
- Test method allows for unanticipated use-related problems to be detected and recorded
 - Not only use-related risks identified at the onset of the design process
 - E.g., Risk Priority Numbers (RPN)



HF/Usability Validation: Failures and Problems

1. **Performance failures on critical tasks, especially a pattern of similar failures**
 - All should be followed up on with specific subjective evaluation to get user's perspective
2. **Subjective responses indicating problems from the perspective of users on critical tasks**
 - Note: even if no performance failures
- **Explain how/why and failures occurred**
 - "Experimental artifact" may be a valid cause of user performance failure(s) if it is explained and reasonable



HF/Usability Validation: Mitigations, Reevaluations, and Residual Risks

- **Develop a mitigation strategy**
 - Modify interface design, user instructions, and/or training for the purpose of addressing problems observed in the testing
- **Not sufficient to simply state that device will be “reviewed” or that a mitigation exists**
 - Re-test and show effectiveness of mitigation
- **Residual risk is acceptable if discussed, reasonably limited, and not subject to elimination or further reduction (see Report section)**





HF/Usability Report

- The main source of information to support HF review for a new device submission
- As per the draft Guidance we expect discussion of major subject areas divided into sections with sub-sections:



HF/Usability Report

Sec.

Contents

- 1 **Intended device users, uses, use environments, and training**
 - 1.Intended user population(s) and critical differences in capabilities between multiple user populations
 - 2.Intended uses and operational contexts of use
 - 3.Use environments and key considerations
 - 4.Training intended for users and provided to test participants

- 2 **Device user interface**
 - 1.Graphical depiction (drawing or photograph) of device user interface
 - 2.Verbal description of device user interface

- 3 **Summary of known use problems**
 - 1.Known problems with previous models
 - 2.Known problems with similar devices
 - 3.Design modifications implemented in response to user difficulties

HF/Usability Report



Sec.	Contents
4	User task selection, characterization and prioritization <ul style="list-style-type: none">1.Risk analysis methods2.Use-related hazardous situation and risk summary3.Critical tasks identified and included in HFE/UE validation tests
5	Summary of formative evaluations <ul style="list-style-type: none">1.Evaluation methods2.Key results and design modifications implemented3.Key findings that informed the HFE/UE validation testing protocol
6	Validation testing <ul style="list-style-type: none">1.Rationale for test type selected (i.e., simulated use or clinical evaluation)2.Number and type of test participants and rationale for how they represent the intended user populations3.Test goals, critical tasks and use scenarios studied4.Technique for capturing unanticipated use errors5.Definition of performance failures6.Test results: Number of device uses, success and failure occurrences7.Subjective assessment by test participants of any critical task failures and difficulties8.Description and analysis of all task failures, implications for additional risk mitigation

HF/Usability Report



Sec.

Contents

7 Conclusion

The <Name Model> has been found to be reasonably safe and effective for the intended users, uses and use environments.

- 1.The methods and results described in the preceding sections support this conclusion.
- 2.Any residual risk that remains after the validation testing would not be further reduced by modifications of design of the user interface (including any accessories and the IFU), is not needed, and is outweighed by the benefits that may be derived from the device's use.

Public Comments on the New (Draft) HF Guidance Document



- **Comments are diverse, with few recurrent themes**
 - Some simply congratulatory or providing thanks for the guidance
 - Some say its easy to follow and a big help, some say its difficult
 - Some provide specific comment on the contents

Comments on Draft Guidance (1 of 5)

“Heuristic Evaluations and Expert Reviews should belong to Formative Evaluations, Sec 7, as they are generally pointed at reviews of designs of user interfaces and removing error potential after a preliminary design (or more mature design) has been established.”

Comments on Draft Guidance (2 of 5)

“The document does not discriminate between: (a) **use** errors (locus of control: developers & deployers) and (b) **user** errors (locus of control: individuals); this helps perpetuate the myth that use errors made by users are not the result of failures by developers and deployers.”

Comments on Draft Guidance (3 of 5)

“[The document] inadequately presents the universe of device users (e.g., assemblers, testers, installers, end-users, reproprocessors, disposers) - see list on page 11, even though some more is embedded in text of page 12; this helps perpetuate the flawed perception that the ‘customer’ is only the device operator.”

Comments on Draft Guidance (4 of 5)

“This document uses the ‘well understood’ term ‘**validation testing**’ in a novel way. This reviewer suspects this term was used intentionally to emphasize the fact that this type of usability testing is, and should be, part of the formal validation testing that manufacturers perform before bringing devices to market. **Unfortunately, use of this term may mislead readers into concluding that all validation testing is in fact usability testing.** That is most definitely not the case. Other literature, most notably ANSI/AAMI HE75, uses the term ‘**summative usability testing**’ to differentiate ‘formative usability testing’ (performed throughout design) from this type of “validation testing”.

Comments on Draft Guidance (5 of 5)

“The title suggest that one is optimizing design rather than optimizing devices. I suggest the alternative title: *Applying Human Factors and Usability Engineering to Optimize Medical Devices.*”

Special Considerations

- **User groups**
 - User group characteristics
 - Personal characteristics
 - Disability considerations
- **Combination products**
 - Examples
 - General Overview of Review Processes
 - Review Challenges Specific to HF

What is a “User Group”?

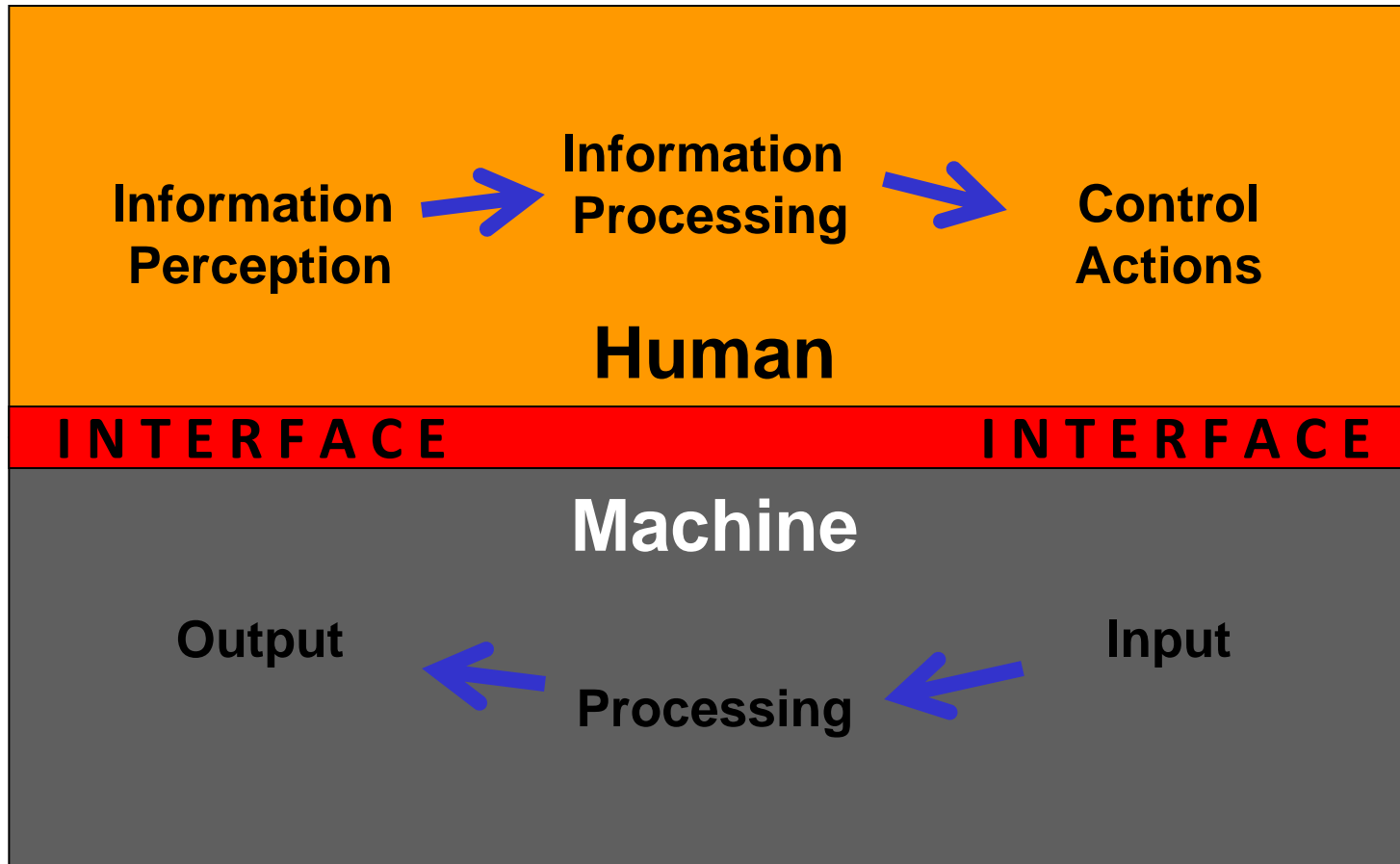


- Identify intended users of the device.
- Identify key attributes of each user group that would affect their use of the device:
 - **Tasks & responsibilities relative to device use**
 - Physician, nurse, technologist, biomedical engineer, home health aide, patient/lay caregiver, etc.
 - **Age ranges and functional capabilities**
 - Elder, adult, adolescent, child, infant, newborn
 - Independent, partially dependent, dependent
 - **Skill sets and experience levels with specific device type and similar products**

Personal Characteristics

- Health & comorbidities (i.e., multiple conditions/diseases)
- Physical size and capabilities
- Sensory capabilities
- Cognitive abilities
- Literacy and language skills
- Level of education and training on the medical condition
- Knowledge of the particular device and similar devices
- Mental and emotional state
- Ability to learn and adapt to a new device
- Willingness and motivation to use a new device

Human-Machine **Interface**



Disability Considerations (1 of 2)

- **Vision**

- Visual acuity, near/far vision, field of vision, perception of color, depth perception, sensitivity to light
- Low vision varies and is not the same as blindness



- **Hearing**

- Frequency range, speech comprehension, directional cues

- **Sensation**

- Tactile sensitivity (texture), temperature

- **Balance**

- Visual stimuli + mechanism in the ear + limb movement

Disability Considerations (2 of 2)

- **Dexterity**

- Grasping, manipulating, releasing of objects
- Strength, stamina, coordination, control

- **Mobility**

- Moving body to different location, changing body position
- Walking, crawling, scooting, rolling
- Weight bearing ability, stride length, walking speed
- Strength, stamina, coordination, control

- **Cognition**

- Understanding, integrating, processing of information
- Learning, reasoning, memory, concentration, expression



Implications for Design & Testing

- **Intended users = design = testing = labeling**
 - **Design for your users and their limitations**
 - Some devices are designed for people with specific medical conditions that are associated with disabilities or impairments – e.g., diabetes, arthritis, allergies
 - **Test a representative sample of these users**
 - Low vision is not the same as blindness
 - **Include information in your labeling about the populations for which the device is appropriate**
 - **Provide a rationale in your FDA submission**

Home Health Care + OTC Devices

Special considerations:



- **Environmental conditions**
 - Location, layout, utilities, cleanliness, clutter, temperature, air flow, dampness/humidity, contaminants, children, pets, EMI, etc.
- **Labeling**
 - Instructions for use, quick-start or quick-reference guides, package inserts, packaging and labels, etc.

Section 4203 of Affordable Care Act

“Removing Barriers and Improving Access to Wellness for Individuals with Disabilities”

- **Amends Title V of Rehabilitation Act of 1973**
 - **Section 510 – Establishment of Standards for Accessible Medical Diagnostic Equipment**
 - Allow independent entry to, use of, and exit from the equipment by individuals with accessibility needs
 - Examination tables, examination chairs, weight scales, and imaging equipment used for diagnostics
 - **Access Board is writing standards with FDA input**



User Diversity is Increasing

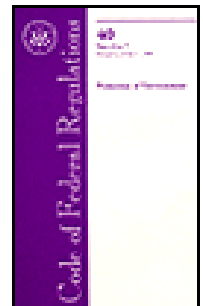
- **People are living longer and surviving more serious injuries and illnesses than ever before**
 - Increasing number of older adults
 - Increasing prevalence of chronic conditions
 - Large veteran population with multiple conditions
- **More health care is moving into the home**
 - Patients are released from hospitals sooner
- **The healthcare workforce is growing and becoming more diverse**

HF Reviews of Combination Products

- **Definition**
- **Examples**
- **Overview of Review Processes**
- **Review Challenges Specific to HF**

Definition of Combination Products

- **Formal Definition can be found in 21 CFR 3.2(e)**
 - Combination products are therapeutic and diagnostic products that combine drugs, devices, and/or biological products.
- **Requires interaction between various FDA Centers:**
 - Center for Biologics Evaluation and Research (CBER)
 - Center for Drug Evaluation and Research (CDER)
 - Center for Devices and Radiological Health (CDRH).
- **May be regulated under one or more marketing applications**
- **Raise many regulatory, policy, and review management challenges.**



Examples of Combination Products

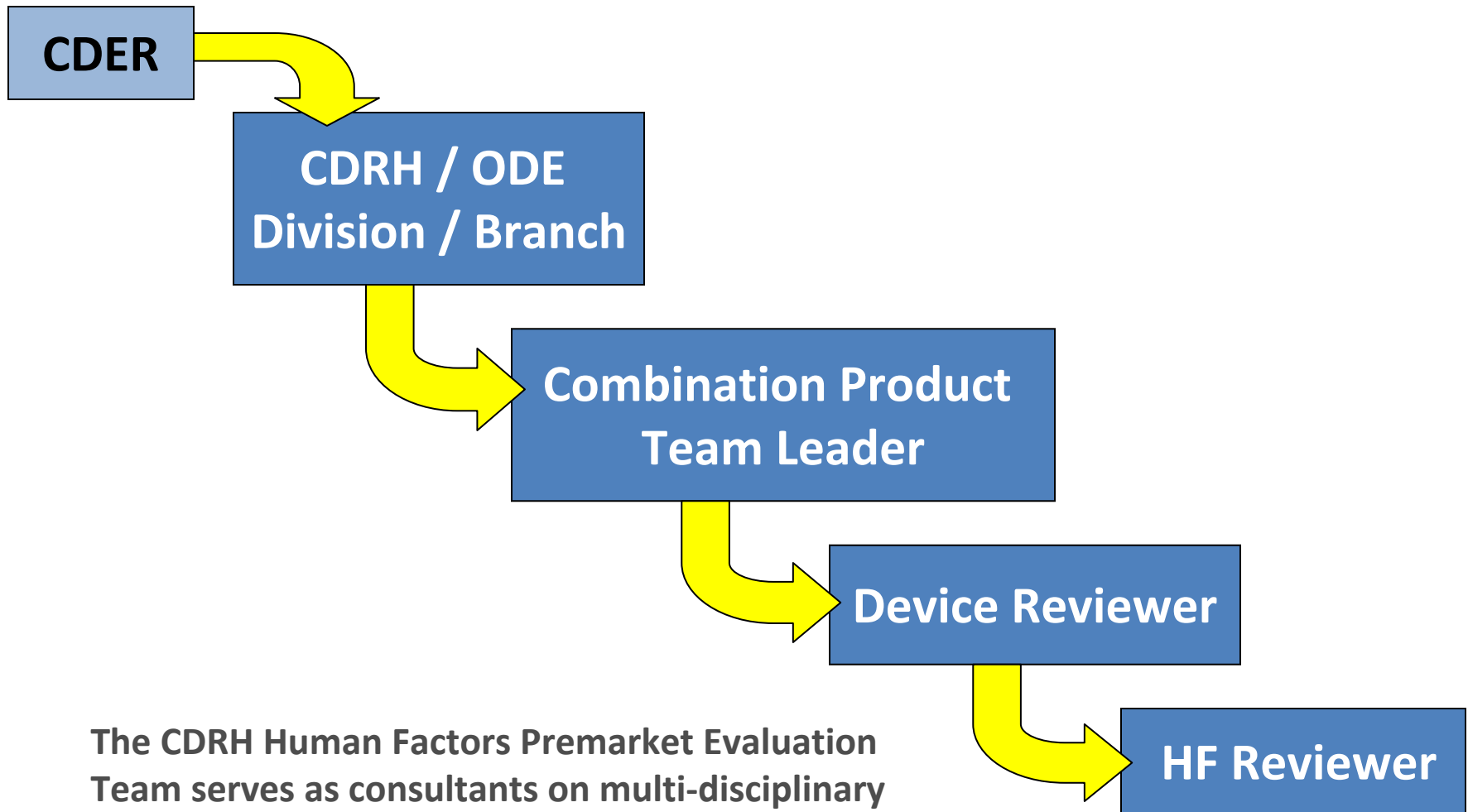
- **Prefilled Syringes, Pen Injectors, or Autoinjectors**
- **Pharmaceutical Aerosol Delivery Devices/Inhalation Products**
- **Transdermal Medication Patches**



Overview of Review Processes

1. **OCP determines lead FDA center (jurisdiction)**
2. **Lead FDA Center requests consultative reviews from other FDA Center**
 - Complete InterCenter Consult Form through Office of Combination Products
 - Specify nature of consultative reviews needed
3. **Other FDA Center responds to consult requests by:**
 - Providing specialized reviews in memo forms
 - Participating in internal and external meetings

Example: CDER - CDRH Product (with a CDER lead)



The CDRH Human Factors Premarket Evaluation Team serves as consultants on multi-disciplinary premarket review teams for combination products

HF Review Process for Combination Products

- **The Human Factors consultant reviewer:**
 - Evaluates use-related risk analyses and HF/usability information and validation study data
 - Collaborates with CDER's Division of Medication Errors Prevention and Analysis in providing consistent reviews
 - Provides recommendations based on evaluation of manufacturers' design validation documents as required by the Quality System Regulation
- **The HF recommendations are reviewed with the intercenter team and incorporated in FDA letters to the IND, NDA or Master file holder, as appropriate**

HF Review Challenges (1 of 4)



- **Study Participants**

- **Caregivers – Lay people versus professionals**

- Tasks analyses and risk profiles

- **Individuals with disabilities**

- Need to be well-characterized and well-defined and be included in the validation study
 - Information about the types and levels of disabilities accommodated will need to be communicated to prescribing physicians via labeling

- **Pediatric populations (<21 years of age)**

- FDA Guidance on characterizing pediatric patients

HF Review Challenges (2 of 4)



• Selection of Tasks

- Should be derived from results of a use-related hazard and risk assessment
- Should represent the tasks that could lead to use errors/failures and have negative clinical impact
- A rationale for your task selection should be included in the study protocol and report
 - Not all tasks included in the IFU have to be tested
- **Include both safety-critical tasks and essential tasks**
 - E.g., preparatory tasks before performing an injection

HF Review Challenges (3 of 4)

- **Realistic Testing Conditions**

- **Use of finalized device design/IFU/labeling**
 - Drug delivery devices – use of placebo is ok
- **Conditions should be derived through analyses of use hazards**
 - E.g., use with gloves or wet hands, in dim lighting, noisy situations
- **Simulated realistic environmental conditions**
 - Provide device and IFU, allow patients to use the device as they normally would, and observe user-device interactions
 - Limit facilitator's coach or providing assistance while participants are performing tasks
 - If stress and other environmental factors might affect safe and effective use, simulate to the extent needed and reasonable





HF Review Challenges (4 of 4)

- **Include realistic levels of training & exposure to instructions**
 - **User interaction with IFU and training should represent the “expected case” in actual use**
 - Decide: instructions or no instructions
 - Decide: users trained or untrained
 - Worst-case situation = no instructions and no training
 - **Conduct separate studies prior to validation to:**
 - Assess the clarity and effectiveness of IFU
 - Determine the level and nature of training necessary

FDA Guidance on HF



- Guidance document (2000): ***Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management*** – available online at:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094460.htm>.
- Draft guidance document (2011): ***Applying Human Factors and Usability Engineering to Optimize Medical Device Design*** – available online at:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm259748.htm>.
 - *NOTE: This guidance is not yet in effect but it reflects FDA-CDRH's current thinking and approach to human factors.*
 - The public comment period was open until September 19, 2011.

New HFES-AAMI Web Site



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.



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



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