Human Factors Engineering of Combination Products and the FDA

Molly Follette Story, PhD
FDA /CDRH / ODE

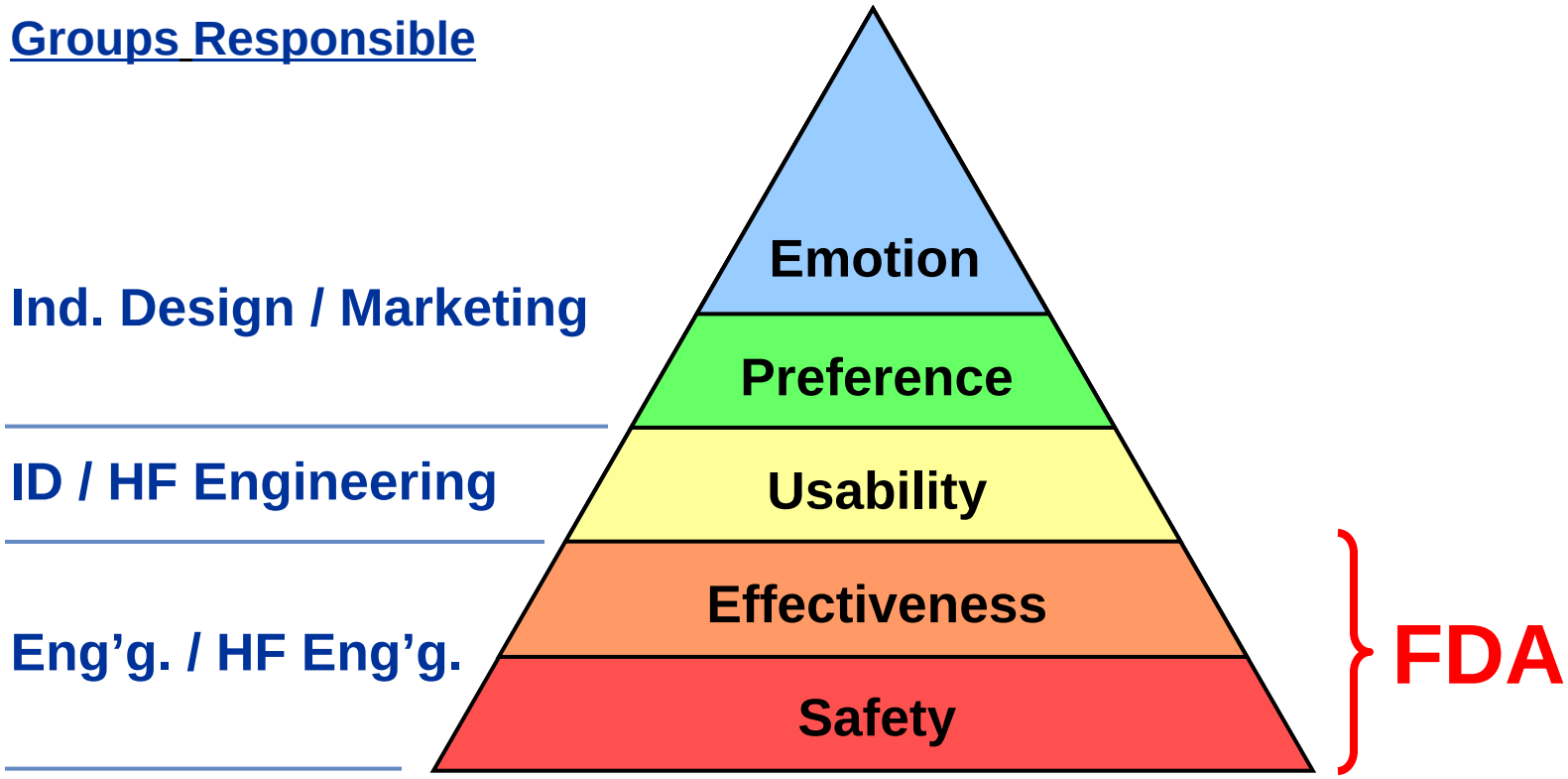
Drug Product for Biological Medicines: Novel Delivery Systems, Challenging Formulations and Combination Products

CaSSS CMC Strategy Forum – July 17, 2012

What are Human Factors? Usability?

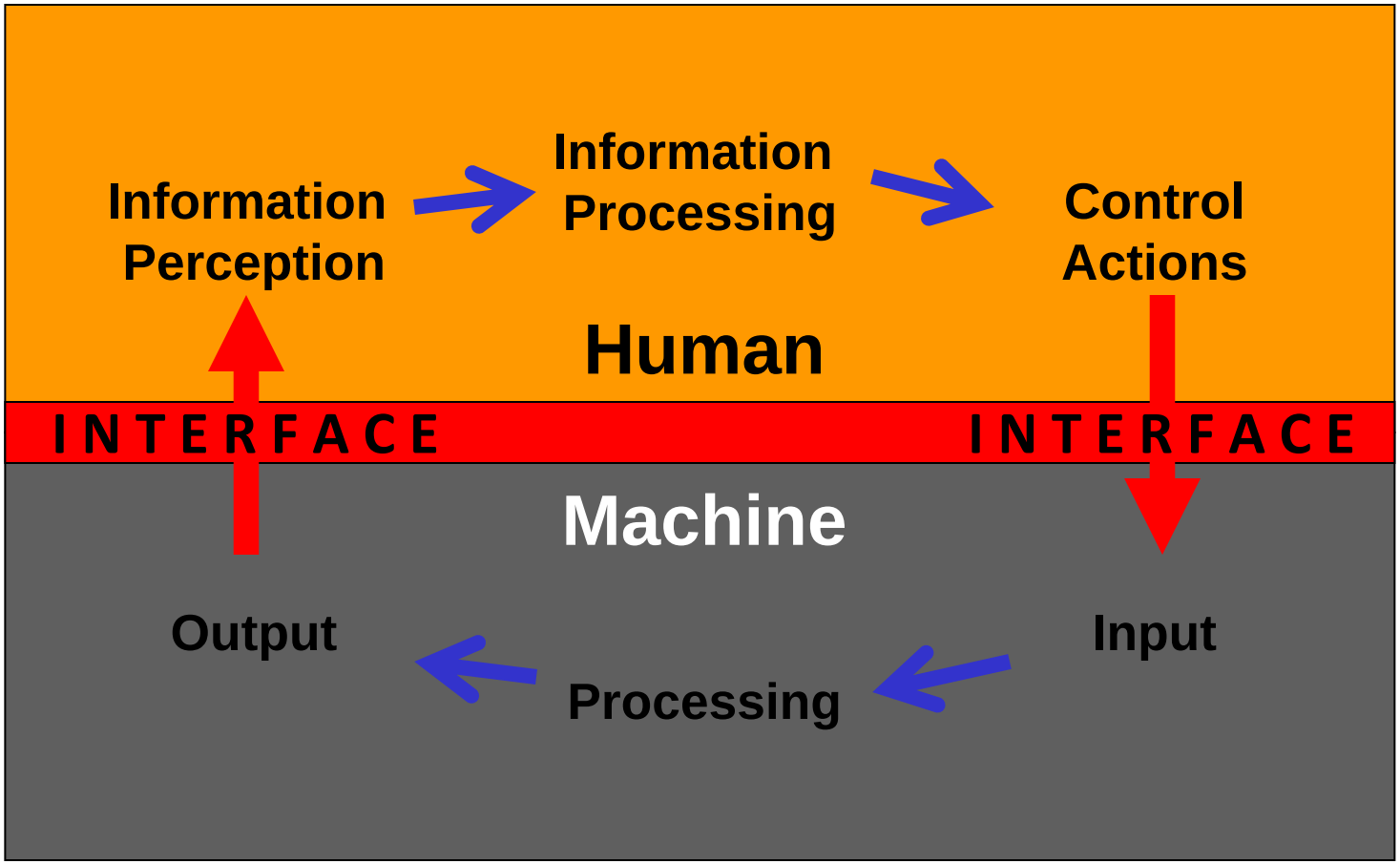
- **Human factors:** "…the application of knowledge about human capabilities (physical, sensory, emotional, and intellectual) and limitations to the design and development of tools, devices, systems, environments, and organizations…." (ANSI/AAMI HE75:2009, Introduction)
- **Usability:** "Characteristic of the user interface that establishes effectiveness, efficiency, ease of user learning and user satisfaction" (ISO/IEC 62366:2007, Definition 3.17)

Hierarchy of Human Factors Issues



Adapted from Hancock, Pepe & Murphy (2005), *Ergonomics in Design,* 13 (1), 8-14

Device-User Interface



Combination Product

- **Formal definition in 21 CFR 3.2(e):**
  - Comprises two or more regulated components:
    - Drugs, devices, biological products
  - Packaged together or intended for concurrent use:
    - Physically, chemically or otherwise combined or mixed,
    - Packaged in a single package or as a unit, or
    - Packaged separately but intended for use only with another approved product
- **Combination product examples:**
  - Device coated or impregnated with a drug or biologic
  - Prefilled syringes, pen injectors, autoinjectors
  - Metered dose inhalers, transdermal patches

FDA Review of Comb. Products

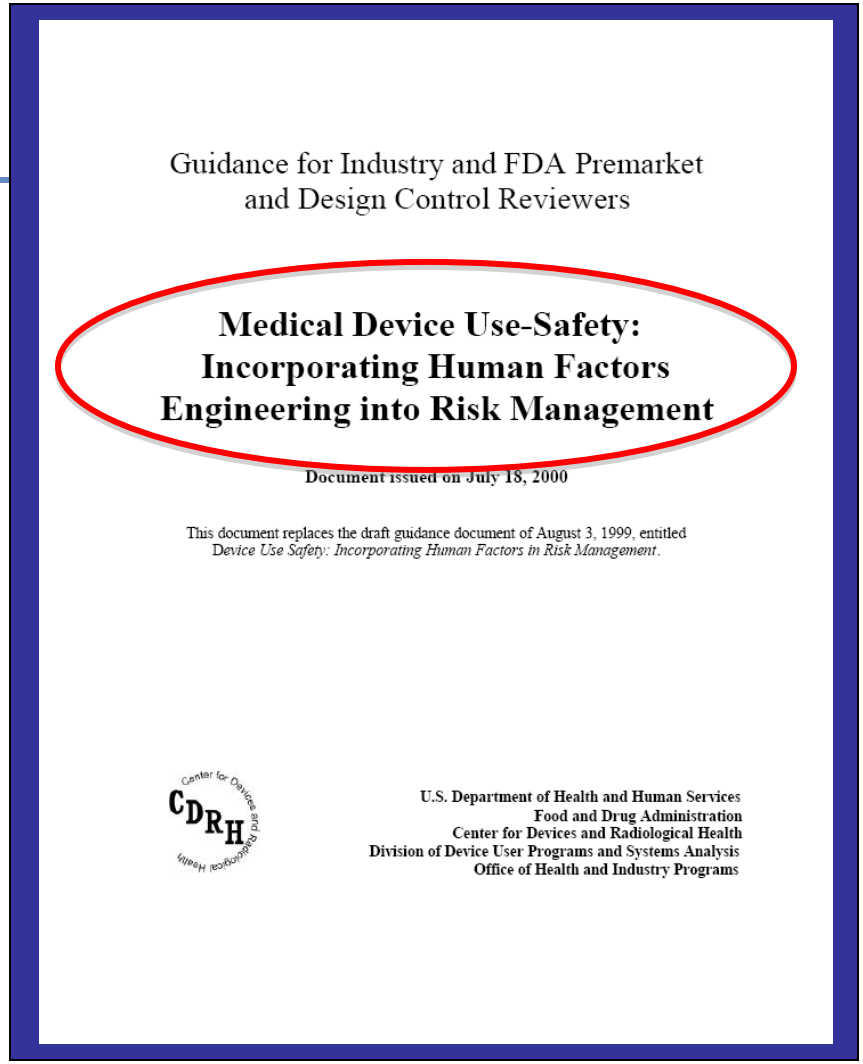
- **Involve multiple FDA Centers, e.g.:**
  - Center for Biologics Evaluation and Research (CBER)
  - Center for Drug Evaluation and Research (CDER)
  - Center for Devices and Radiological Health (CDRH)
- **Determination of lead Center for review:**
  - Generally based on primary mode of action of product
  - When product has 2 independent modes of action, based on questions of safety and effectiveness:
    - Consistent with products with similar questions, or
    - Center with most expertise to evaluate specific questions

FDA HF Guidance

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

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

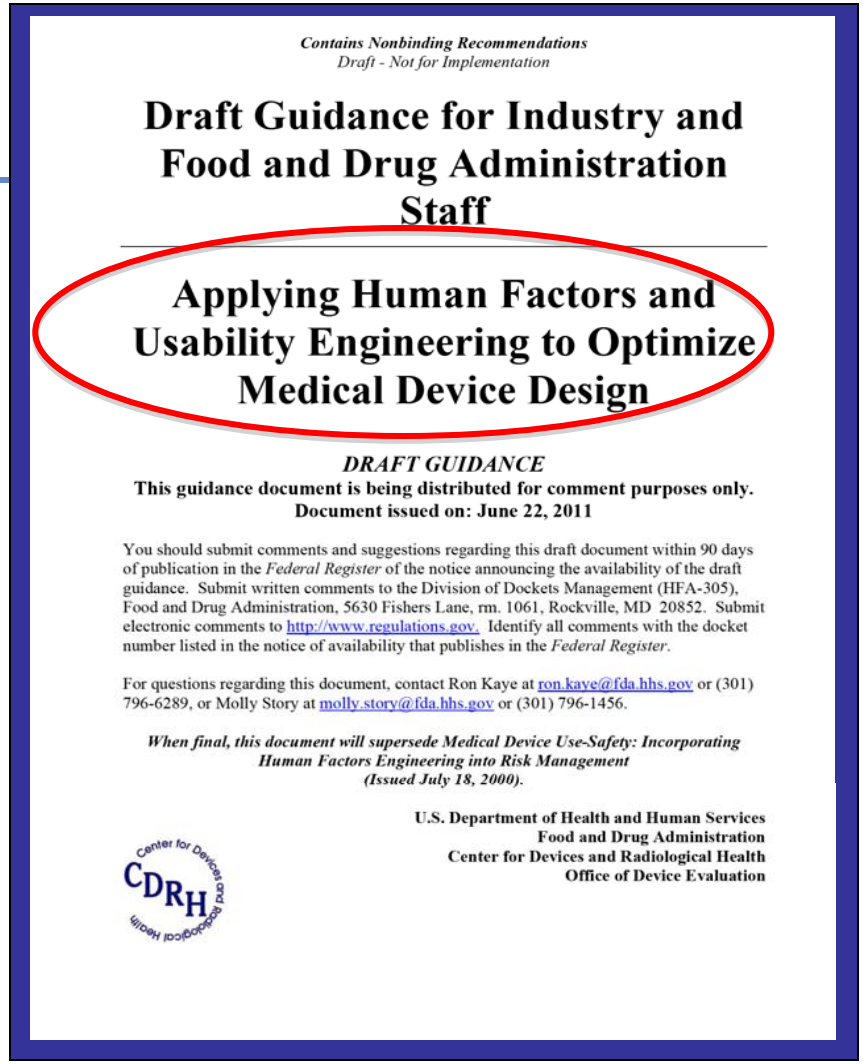
This document replaces the draft guidance document of August 3, 1999, entitled *Device Use Safety: Incorporating Human Factors in Risk Management*.

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 –* ***not yet in effect*** *but 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*.

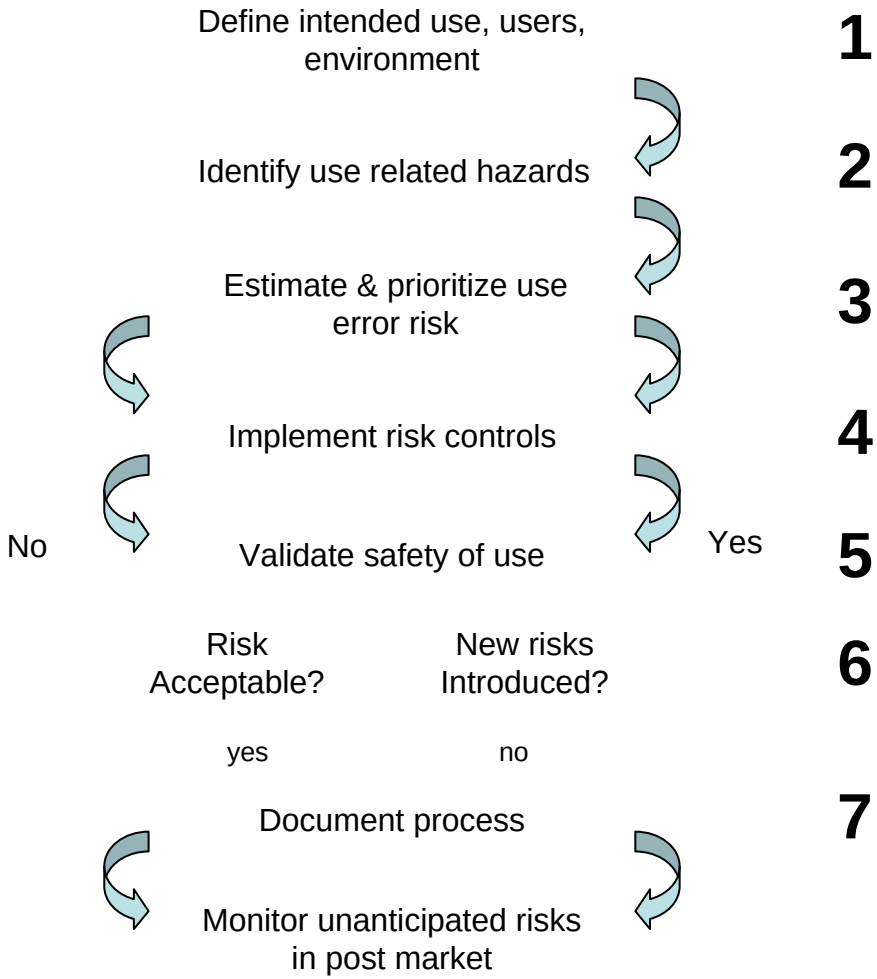
For questions regarding this document, contact Ron Kaye at ron.kaye@fda.hhs.gov or (301) 796-6289, or Molly Story at molly.story@fda.hhs.gov or (301) 796-1456.

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 Hands-On Studies
- Risk Control and Design Iteration
- Human Factors Validation Studies

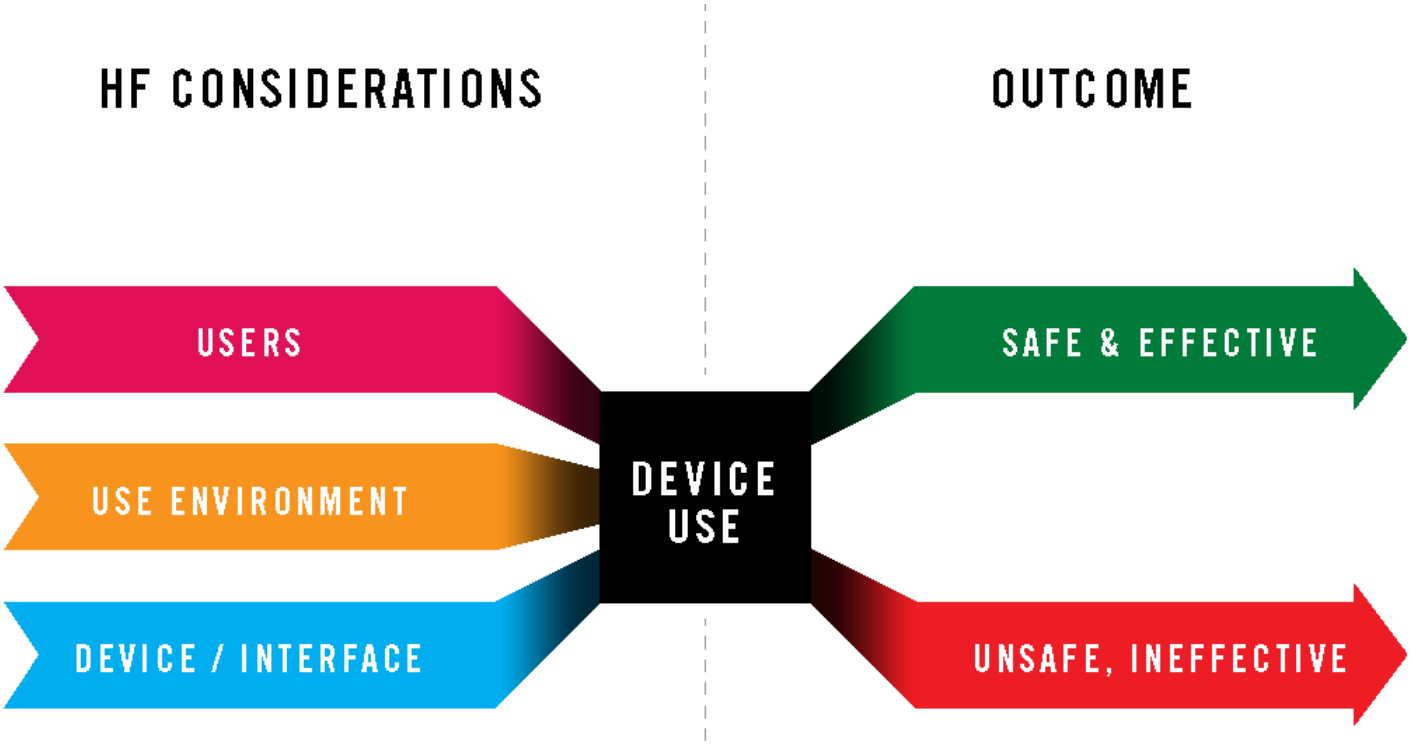


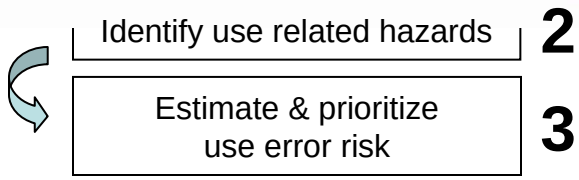
Source: ANSI/AAMI HE75:2009

Human Factors of Device Use

Define intended use, users, environment

1





Preliminary Analyses

Two ways to discover use-related hazards:

1. **Apply analytical techniques**
   - Apply variety of techniques to identify use-related hazards and risks
     - *Can be difficult to anticipate all hazards*
2. **Conduct user-based evaluations**
   - Conduct hands-on testing to identify unanticipated hazards
     - *Sometimes called "Usability Testing" or "Use Testing" or "User Testing" or "Formative" Evaluations*

Preliminary Hands-On Evaluations

- **Identify use problems 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
  - Users use the device in unexpected ways
  - Users use the device in inappropriate but foreseeable ways, for which adequate controls were not applied

Risk Control

Implement risk controls **4**

- **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 Validation

Validate safety of use 5

- **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

Human Factors Validation Testing

- **Test populations**
  - Represent all major intended user groups – e.g.:
    - Healthcare professionals, pharmacists, patients, etc.
    - Pediatric & geriatric populations need careful consideration
- **Device testing conditions**
  - Use finalized design of device, packaging, and labeling
  - Present device within the typical context of use
    - Incorporate expected use conditions that might affect user interactions with the device
  - Allow realistic device-user interactions

Human Factors Validation Testing

- **Selection of tasks tested**
  - Not necessarily everything in the instructions for use
    - Include *essential tasks* – i.e., tasks necessary for successful use of the device for its intended purpose
    - Include *safety-critical tasks* – i.e., tasks on which users could make errors or tasks that users could fail to complete and which could have negative clinical impact on user or patient
- **Participant interaction with instructions should approximate reality**
- **Provision of training should approximate reality**

Human Factors Validation Data

- **Objective (performance) data:**
  - Facilitator observes and notes all use errors, failures and difficulties, including details about performance, e.g.:
    - Task success or failure, use error, close call, reference to instructions for use, need for assistance, evidence of difficulty or confusion, unsolicited comments
- **Subjective (narrative comment) data:**
  - Discuss user performance after use, particularly regarding reasons for any essential and critical task errors, failures and difficulties
  - Solicit participant feedback on design of device, packaging, labeling and training

Validation Data Analysis

Risk Acceptable? | New risks Introduced? | 6

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

Human Factors Report

Document process 7

1. Intended device users, uses, environments
2. Description and images of device user interface
3. Summary of known use problems
4. Use tasks: descriptions, risk priorities, success criteria
5. Summary of preliminary evaluations
6. Validation study protocol, results and analysis
7. Conclusion

FDA Expectations for HF Data

- Conduct a comprehensive risk assessment
- Identify and mitigate risks, including all use-related risks
- Conduct human factors/usability validation testing on any strategies implemented to mitigate *significant* use-related risks
- Document everything in the Design History File

Contact Information

Molly Follette Story:

molly.story@fda.hhs.gov

FDA/HF web site:

www/fda.gov/humanfactors