Identifying Use Errors and Human Factors Approaches to Controlling Risks

Molly Follette Story, PhD
QuynhNhu Nguyen, BS
Human Factors Premarket Evaluation Team
FDA / CDRH / ODE

Public Workshop: Quarantine Release Errors
September 13, 2011

Overview

- Introduction to Human Factors (HF)
- Human factors methods for studying the problems and testing potential solutions
- Summary of use-related errors related to blood product handling
- Examples from Quarantine Release Error (QRE) reports
- Discussion/Review

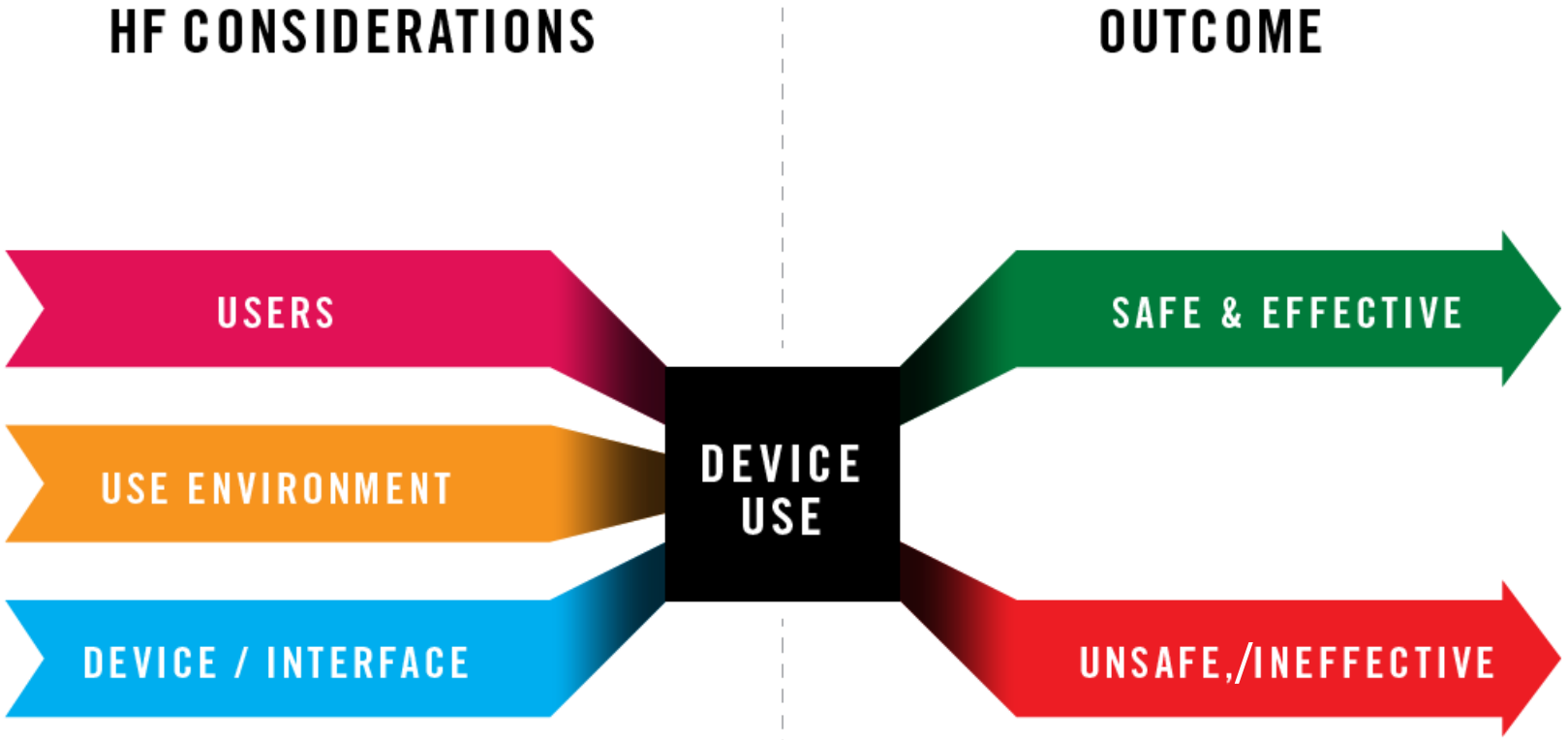
Brief History of HF at FDA

- **The FDA Human Factors program developed over the past 30 years within CDRH and is currently located in the Office of Device Evaluation**
- **The FDA-CDRH HF program focuses on "use safety" of medical devices for their intended users, uses, and use environments**
- **FDA-CDRH HF staff:**
  - Reviews HF content in premarket device submissions
  - Participates in selected postmarket and compliance activities
- **FDA encouraged AAMI to publish its first HF standard in 1988, followed by others, notably AAMI/ANSI HE75:2009, *Human Factors Engineering – Design of Medical Devices***

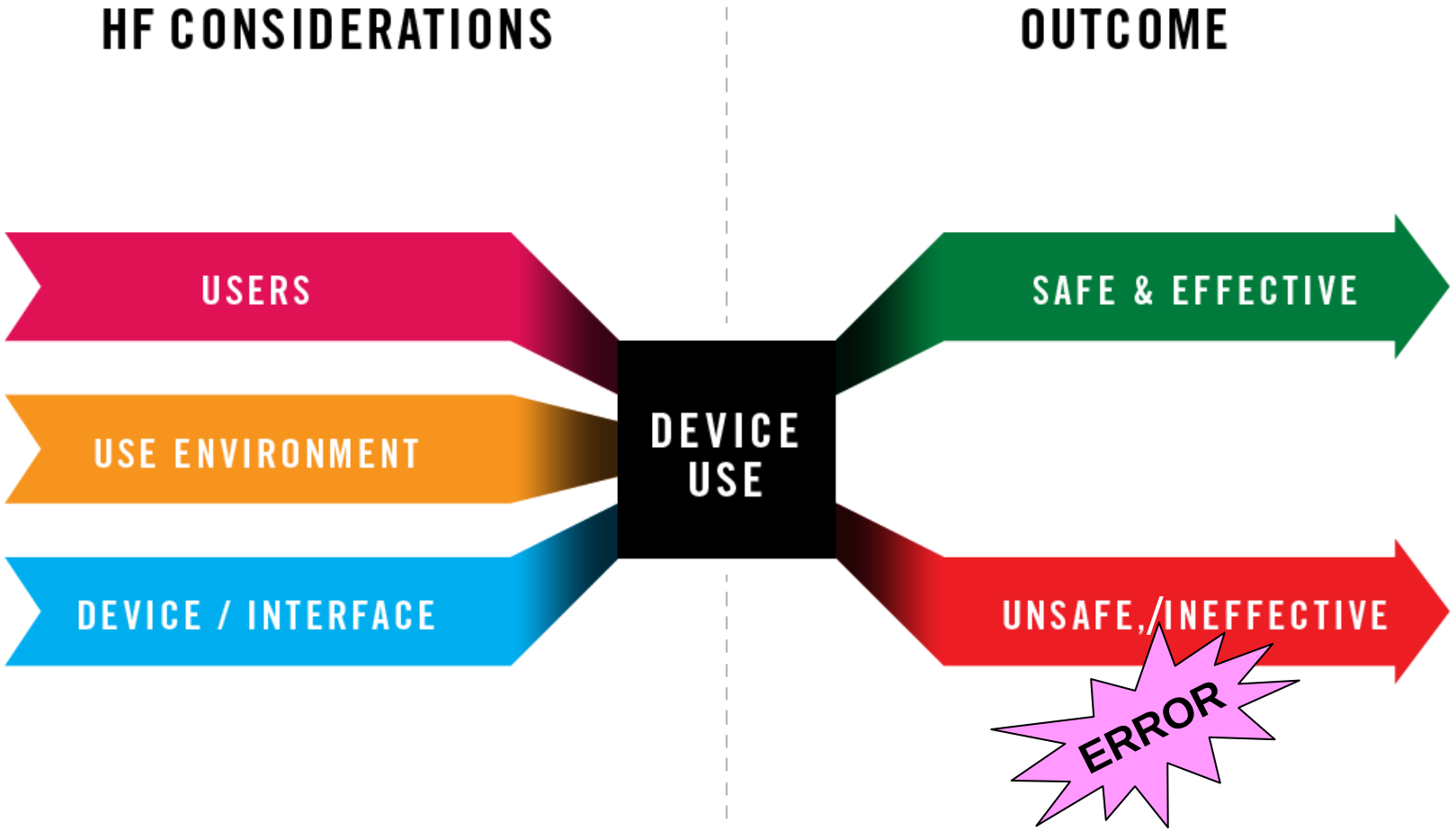
Regulatory Basis for HF at FDA

- **Quality System regulation, 21 CFR Part 820 Section 30, Design Controls - Implies human factors in design and evaluation**
  - 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**…."
- **Use errors and failures are specific types of risk**

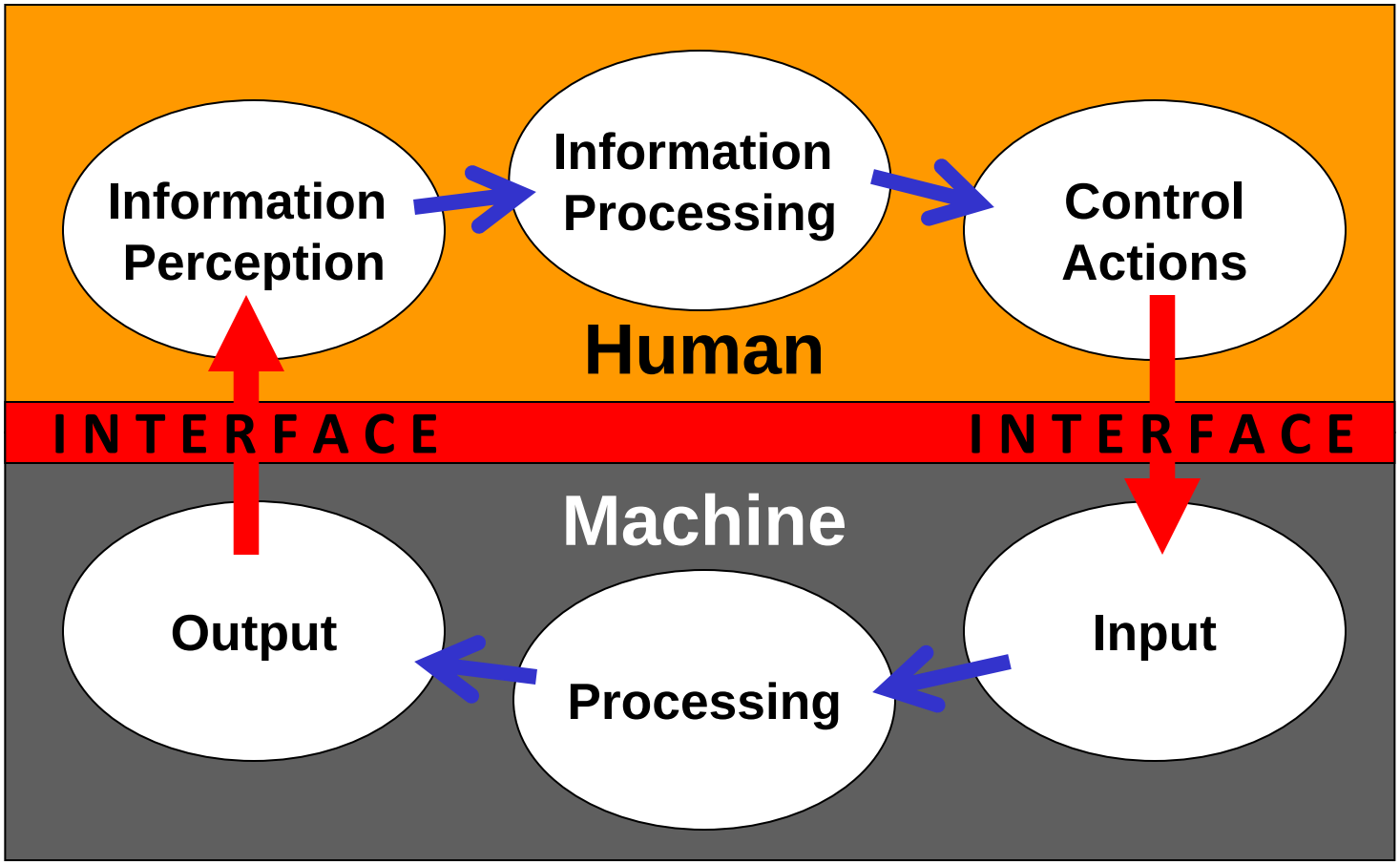
Human Factors of Device Use



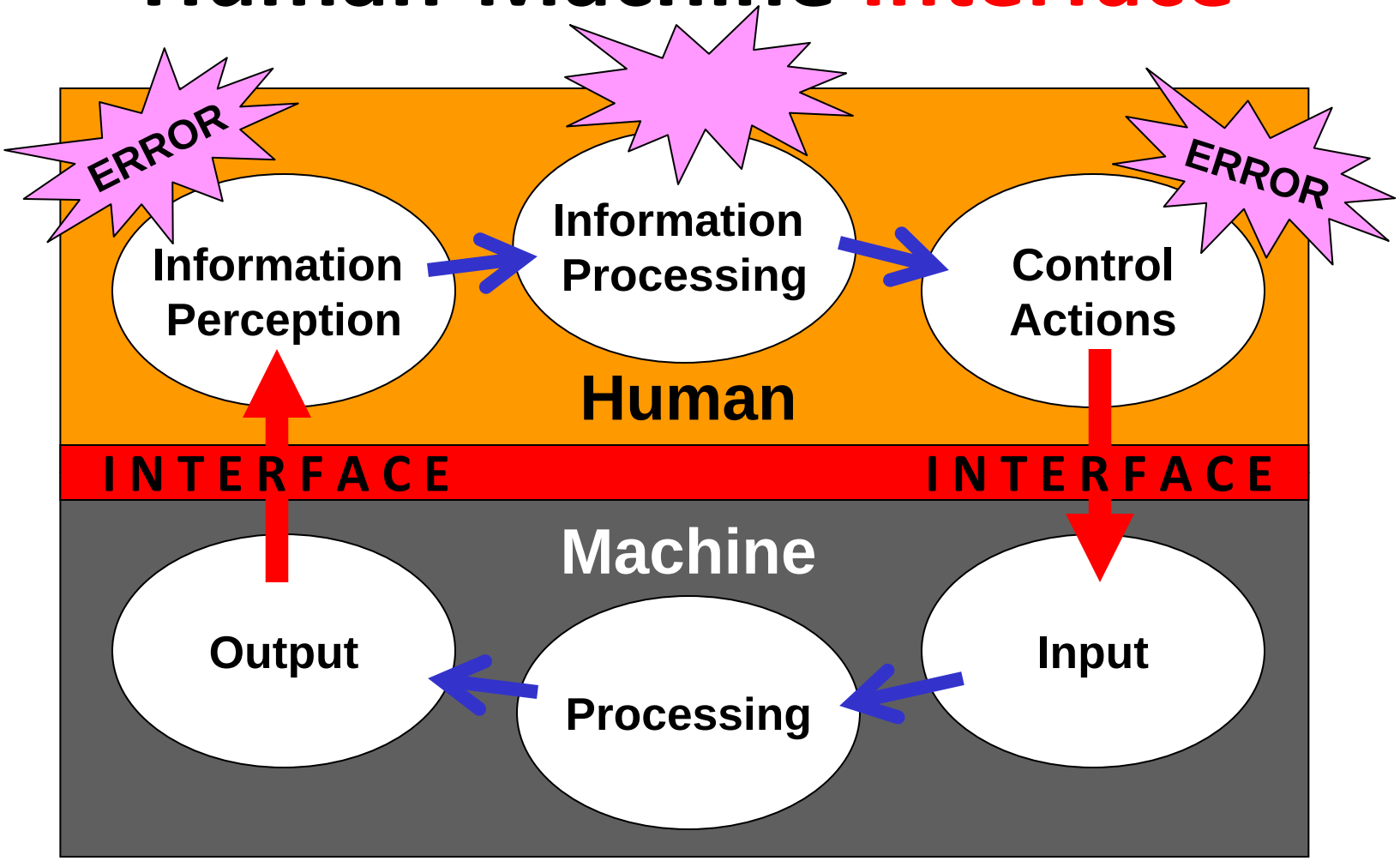
Human Factors of Device Use



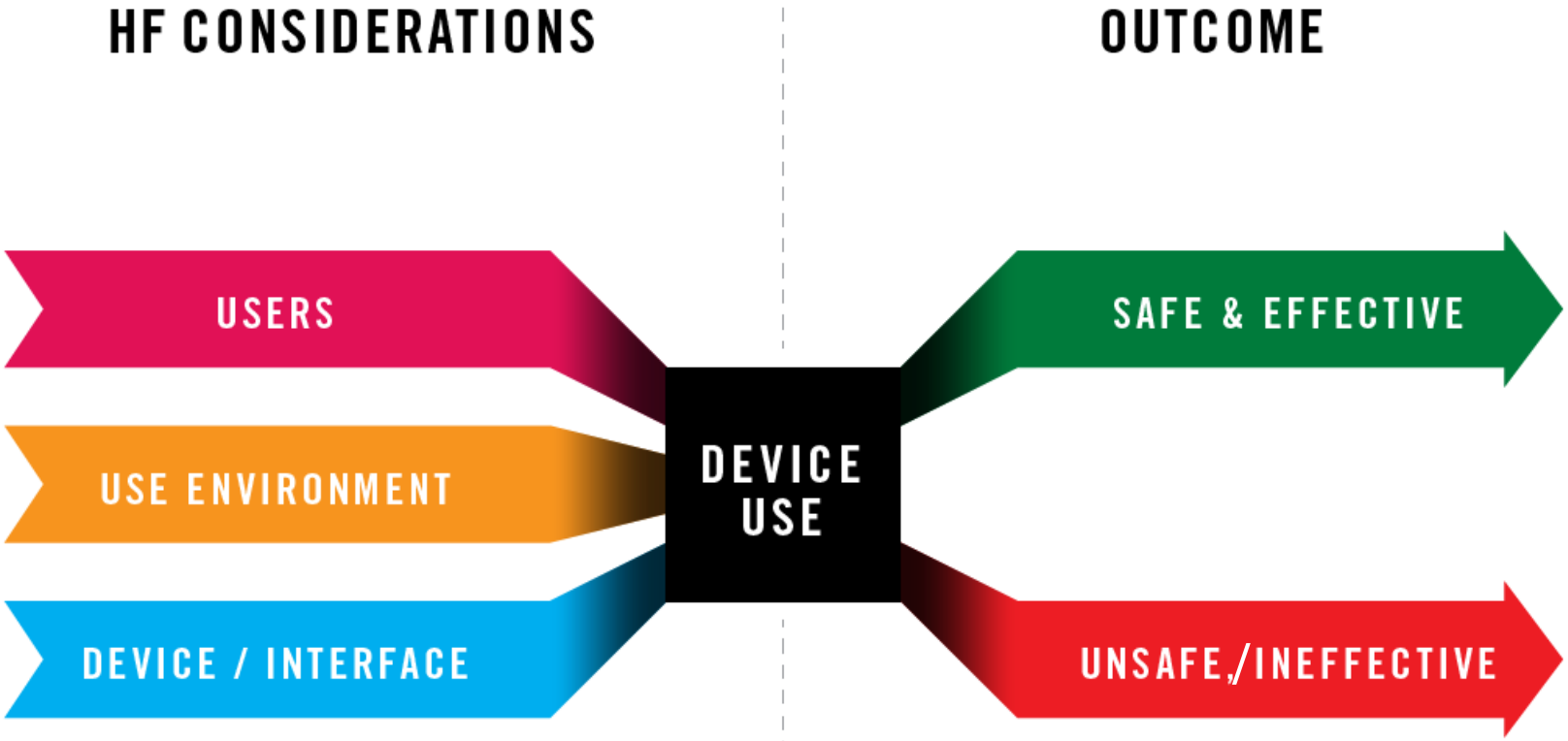
Human-Machine Interface



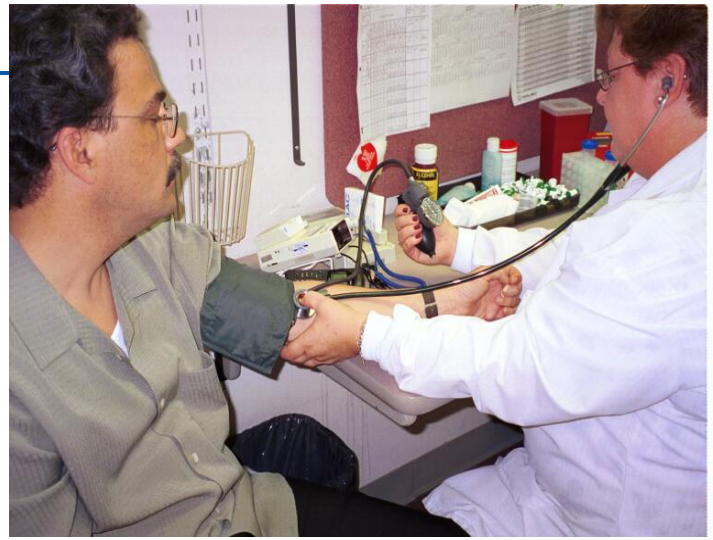
Human-Machine Interface



Human Factors of Device Use



System Users



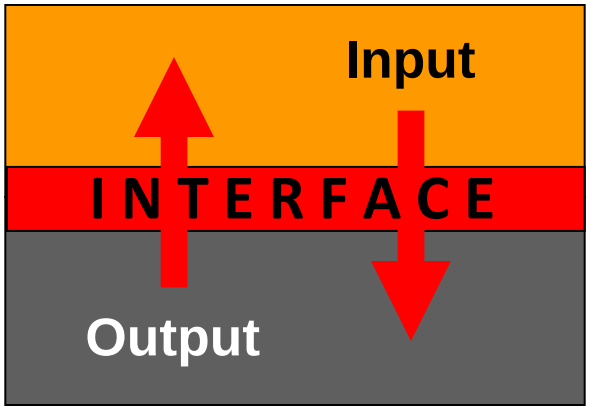
- **Professional specialties**
  - Job titles, responsibilities
- **Knowledge and experience levels**
- **Age and functional capabilities**
  - Physical, sensory/perceptual, cognitive/intellectual
- **Mental and emotional condition**

Use Environments

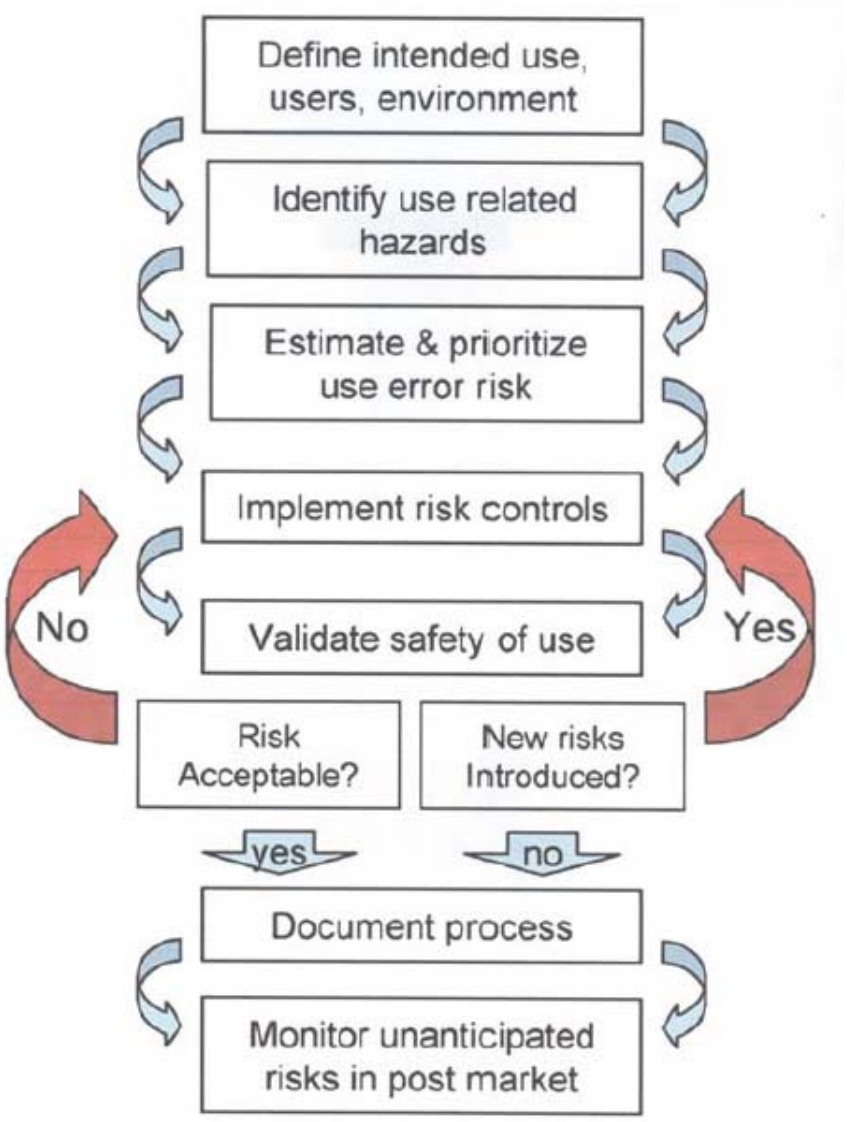
- Licensed Blood Establishments
- Unlicensed Blood Establishments
- Transfusion Services

User Interface

- **Tasks**
  - Donor screening
  - Donor deferral
  - Blood collection
  - Viral testing
  - Component preparation
  - QC and distribution
- **User input**
  - Product movement, labeling, data entry, documentation
- **System output**
  - Product location, labeling, time, temperature, SOP



Human factors engineering process for medical devices



Source: ANSI/AAMI HE75:2009

Risk Analysis

Two types of use-related hazards:

1. **Anticipated hazards**
   - Identified by using analytical techniques
     - Can be difficult to anticipate all hazards
2. **Unanticipated hazards**
   - Not identified by risk analysts
   - Most important goal of user-based evaluations
     - Sometimes called “Usability Testing” or “Use Testing” or “User Testing” or “Formative” Evaluations

Risk Analysis

Risk management process for use-related hazards:

- Identify anticipated use-related hazards (using analytical methods);
- Identify unanticipated use-related hazards (through formative studies);
- Develop and implement mitigation strategies;
- Demonstrate safe and effective use through human factors validation.

Analytical HF Methods (1 of 3)

Identify known problems

- **Internal adverse event and complaint files**
- **Knowledge of facility staff**
- **Publications**
  - Journal articles, proceedings, newsletters
  - Web sites – *for example:*
    - FDA/CBER: AERS/FAERS, CEARS
    - FDA/CDRH: MAUDE/MDR, MedSun, recalls, alerts and notices, public health notifications

Analytical HF Methods (2 of 3)

Analyze needs of current system users

- Who will use the system?
- Where will they be working?
- What tasks will 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** *(top-down)*
  - Identify critical use-related risks.
  - What hazardous scenarios could lead to these risks?
- **Function and task analysis** *(bottom-up)*
  - 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 Studies

With potential system users

- **Test design ideas and prototypes**
  - Fidelity can be low
- **Representative test participants**
  - Numbers can be low
- **Simulated use conditions**
- **Identify major problems; develop solutions**
- **Best when performed iteratively**

Human Factors Validation

- **Final design of device/system and labeling**
- **Critical tasks and use scenarios**
- **Realistic use environments and conditions**
- **Representative test participants**
  - Test the device, not the users
- **Realistic training levels and methods**
- **Data collection**
  - User performance and subjective data

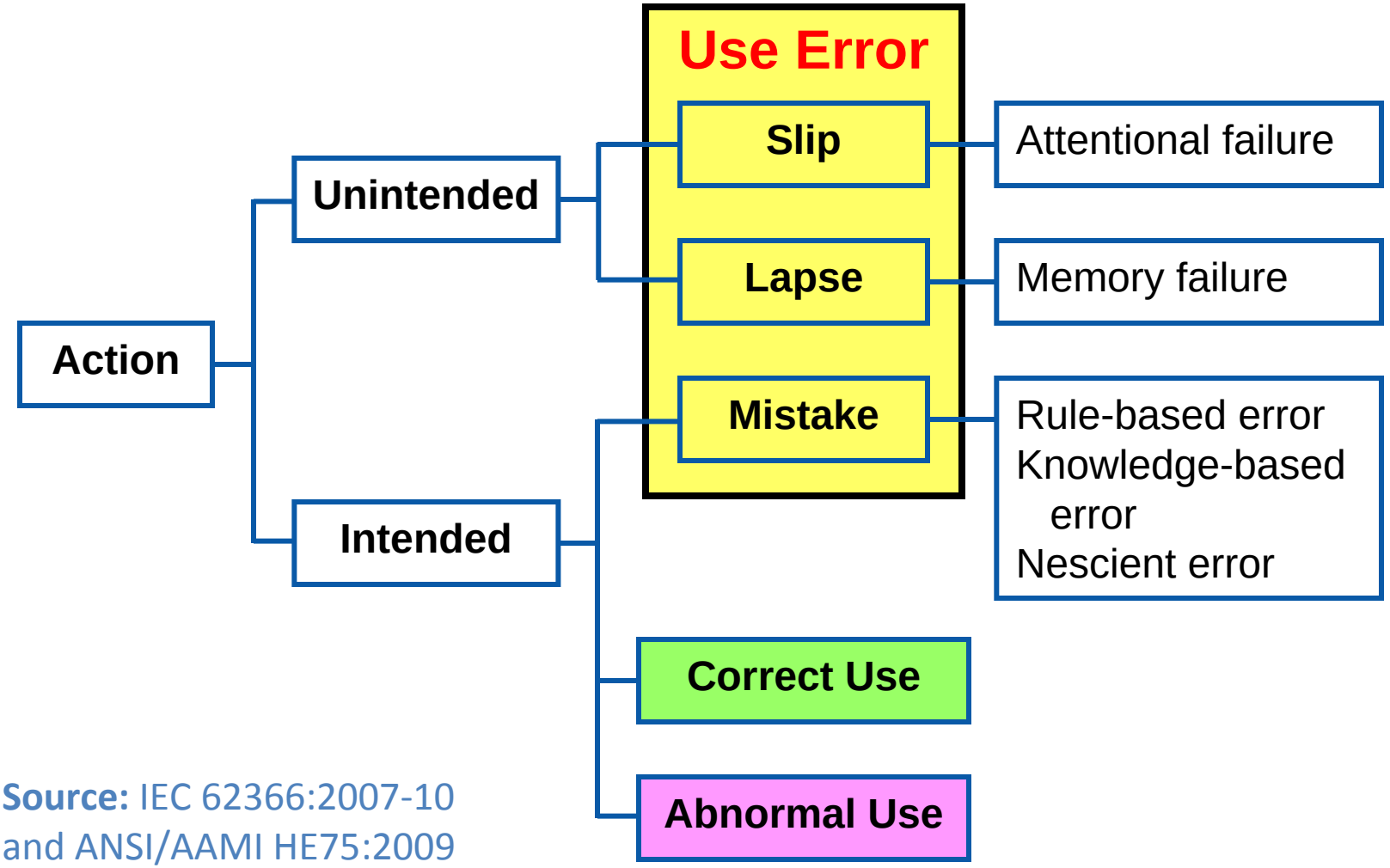
Validation: Post-Test Interview

- Open-ended and non-judgmental debrief
- Obtain general participant impressions of the system and the use experience
- Ascertain participant awareness of and reasons for making errors
- Solicit specific comments on design of the system, including labeling and training

Analysis of HF Validation Data

- **Identify use errors, "close calls," difficulties**
- **Identify potential negative clinical consequences and root causes**
- **Determine whether risk mitigation strategies are needed**
- **If so, design and implement strategies and revalidate:**
  - Were strategies successful at reducing risks?
  - Did strategies introduce new risks?

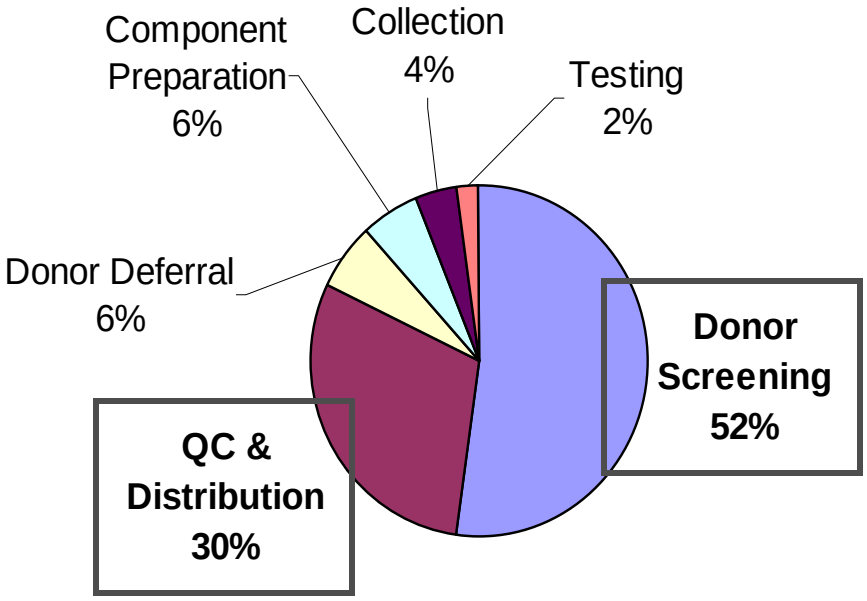
Use Errors



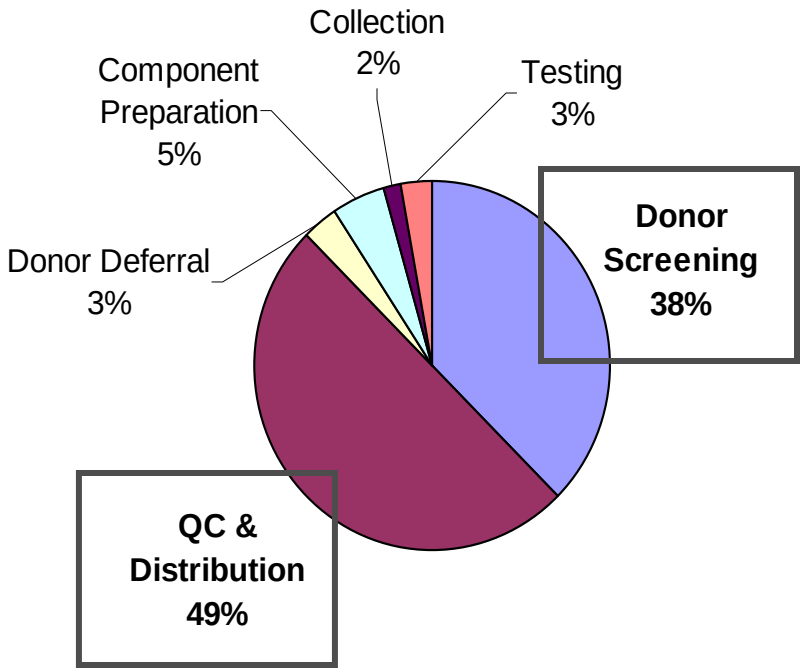
Source: IEC 62366:2007-10 and ANSI/AAMI HE75:2009

Types of QRE Reports Received

Licensed Blood Establishments



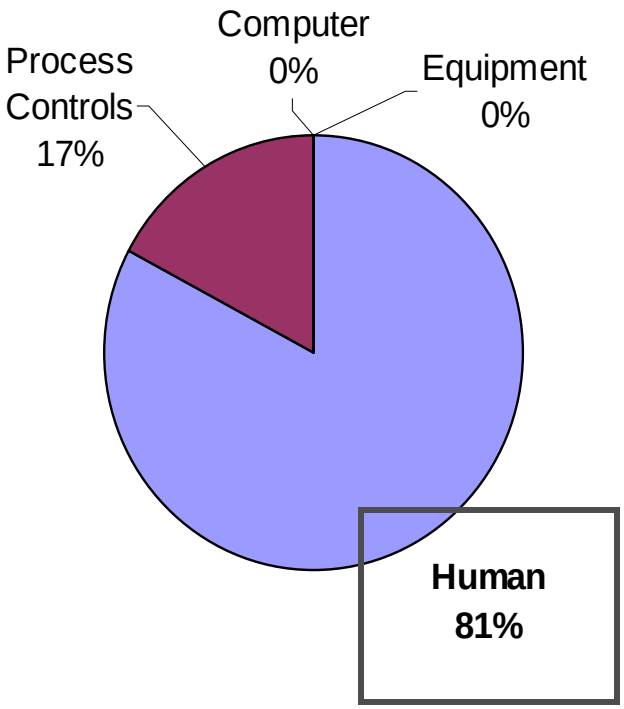
Unlicensed Blood Establishments



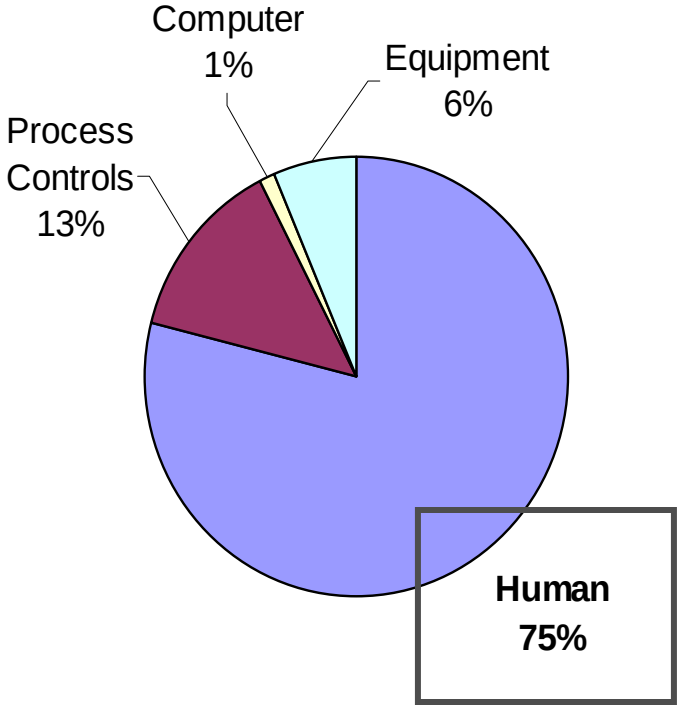
Factors Contributing to QREs

Licensed Blood Establishments

Donor Screening



QC and Distribution



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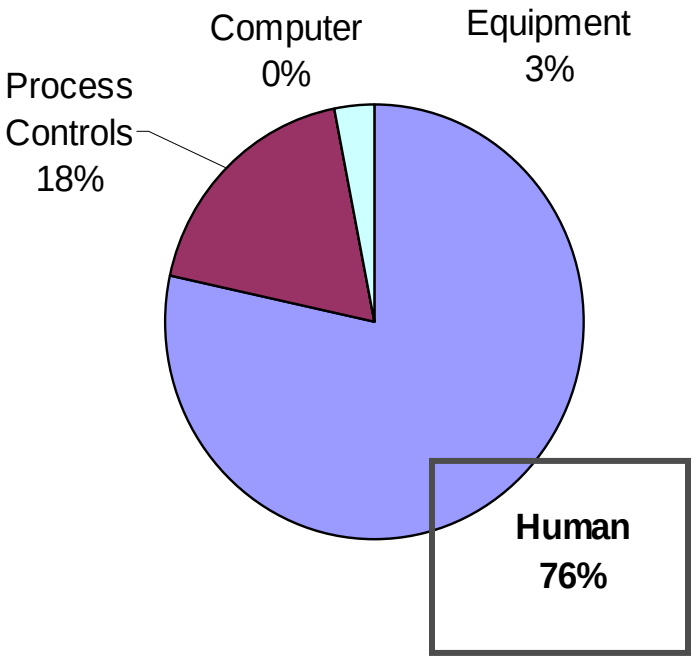

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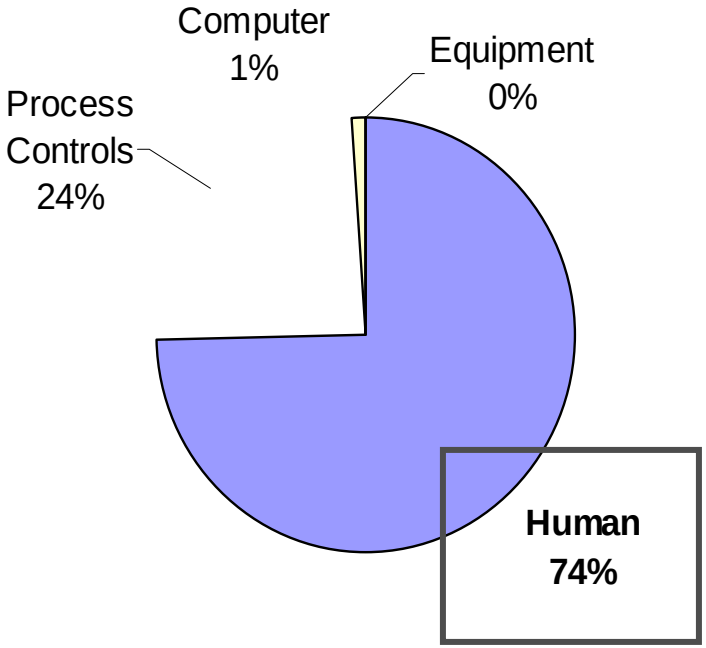

Interface Design and Use Errors

- **Errors often result from well-intended use**
- **Flaws in the design of a medical device user interface can allow and even induce use errors**
  - Errors are not created equal; some are more significant
- **Human factors methods can be applied to address hazardous user interface designs before (or after) products reach the market**
- **Warnings and instructions in user manuals can help but should not be depended on to compensate for flawed design**

Examples from QRE Reports

1. **"A unit was labeled and transfused before required viral markers and NAT testing were performed"**

HF Approaches:

- **Debrief the user to understand root causes of the error**
- **Interview co-workers to understand user expectations of typical task processes and workflow**
- **Observe workers performing critical tasks and identify sources of use error and difficulty**
- **Consider modifications to labeling and use of SOP:**
  - **E.g., add a set of check boxes to the unit label for users to mark tests that have been performed**
  - **E.g., create SOP quick-guides or checklists and place them strategically so that it is obvious to all of the users**

Examples from QRE Reports

2. **"…Units… were not used after being out of storage for 45 minutes…. Tech did not notice… and accepted the units back to inventory."**

HF Approaches:

- **Debrief the user/co-workers to understand root causes of error**
- **Identify sources of use error and difficulty**
- **Consider modifications to check-in/out procedures:**
  - **E.g., provide timers: one would accompany each bag and be started when the unit is checked out**
  - **E.g., create a computer-based system: scan the unit when it is taken out of the refrigerator; scan it again when it is returned and reject any that has been out for more than 30 minutes**

Examples from QRE Reports

3. **"…Unit on the return shelf in quarantine was not investigated and returned to inventory. This unit was subsequently issued and transfused."**

HF Approaches:

- **Debrief the user/co-workers to understand root causes of error**
- **Identify sources of use error and difficulty**
- **Consider modifications to quarantined unit handling process:**
  - **E.g., store quarantined units in a secured and separate location**
  - **E.g., require users to complete a status verification process before allowing any units to be returned to inventory**

Hazard Control Hierarchy

From most to least desirable:

1. **Attempt to reduce or eliminate the problem through design modifications;**
   - **E.g., Add a set of check boxes to the physical device label to mark tests performed (QRE example # 1)**
2. **Implement protective measures to reduce the probability that users will come into contact with the hazard;**
   - **E.g., Store quarantined units in a secured and separate location (QRE example # 3)**
3. **Provide users with information for safety, such as specific instructions, warnings, and other information necessary to avoid hazardous situations.**
   - **E.g., Create SOP quick-guides or checklists and post them in strategic locations (QRE example # 1)**

Review and Discussion

- Introduction to Human Factors (HF)
- Human factors methods for studying the problems and testing potential solutions
- Summary of use-related errors related to blood product handling
- Examples from QRE Reports

FDA Guidance on Human Factors

- 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 will be open until September 19, 2011.

Questions

Molly Follette Story
Molly.Story@FDA.HHS.gov

QuynhNhu Nguyen
Quynht.Nguyen@FDA.HHS.GOV

Web site: www.fda.gov/humanfactors