fully developed

Emphasizing Human Factors / Usability Engineering in the Systems Engineering Process for Medical Device Design

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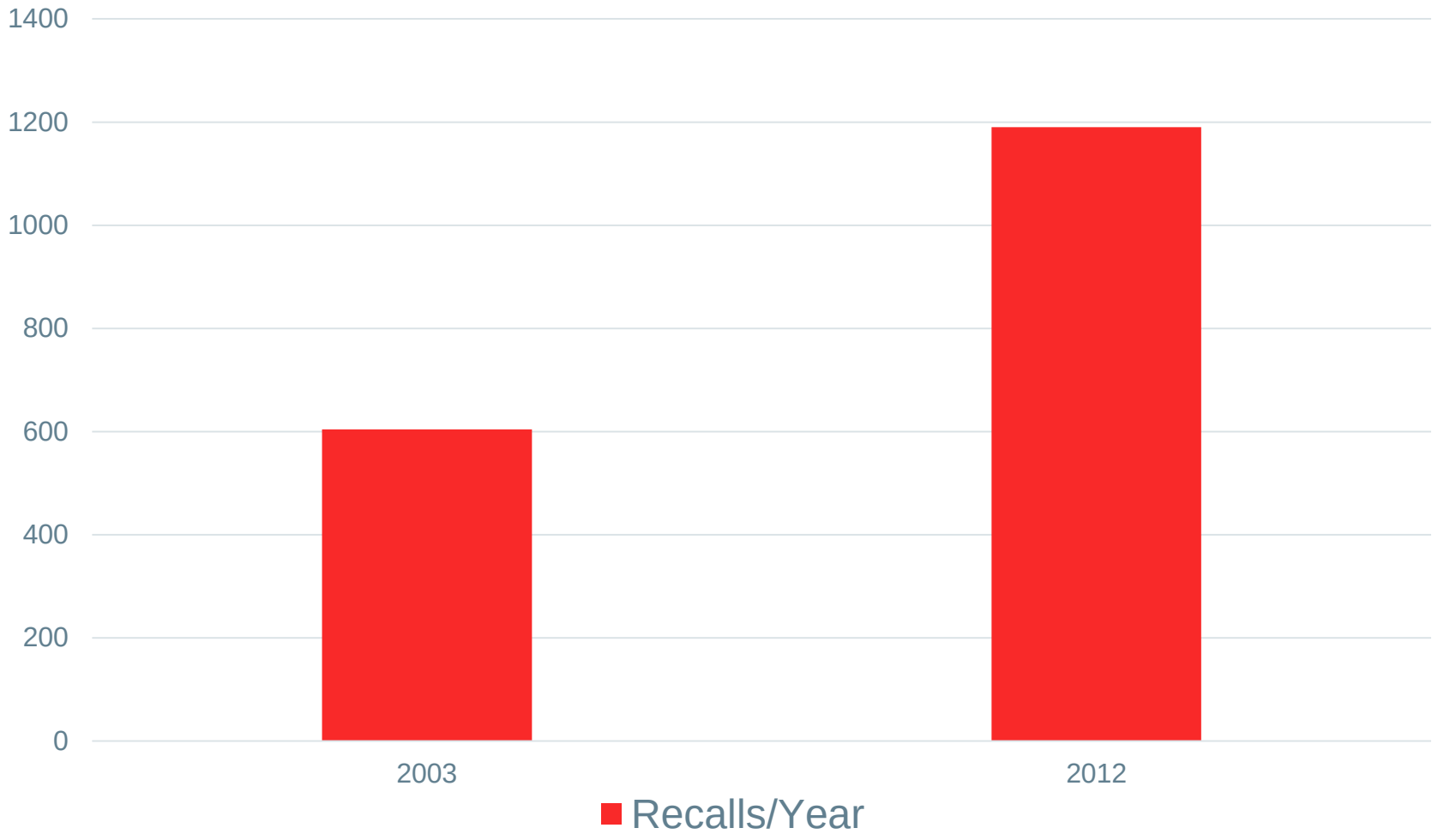
04.20.2018

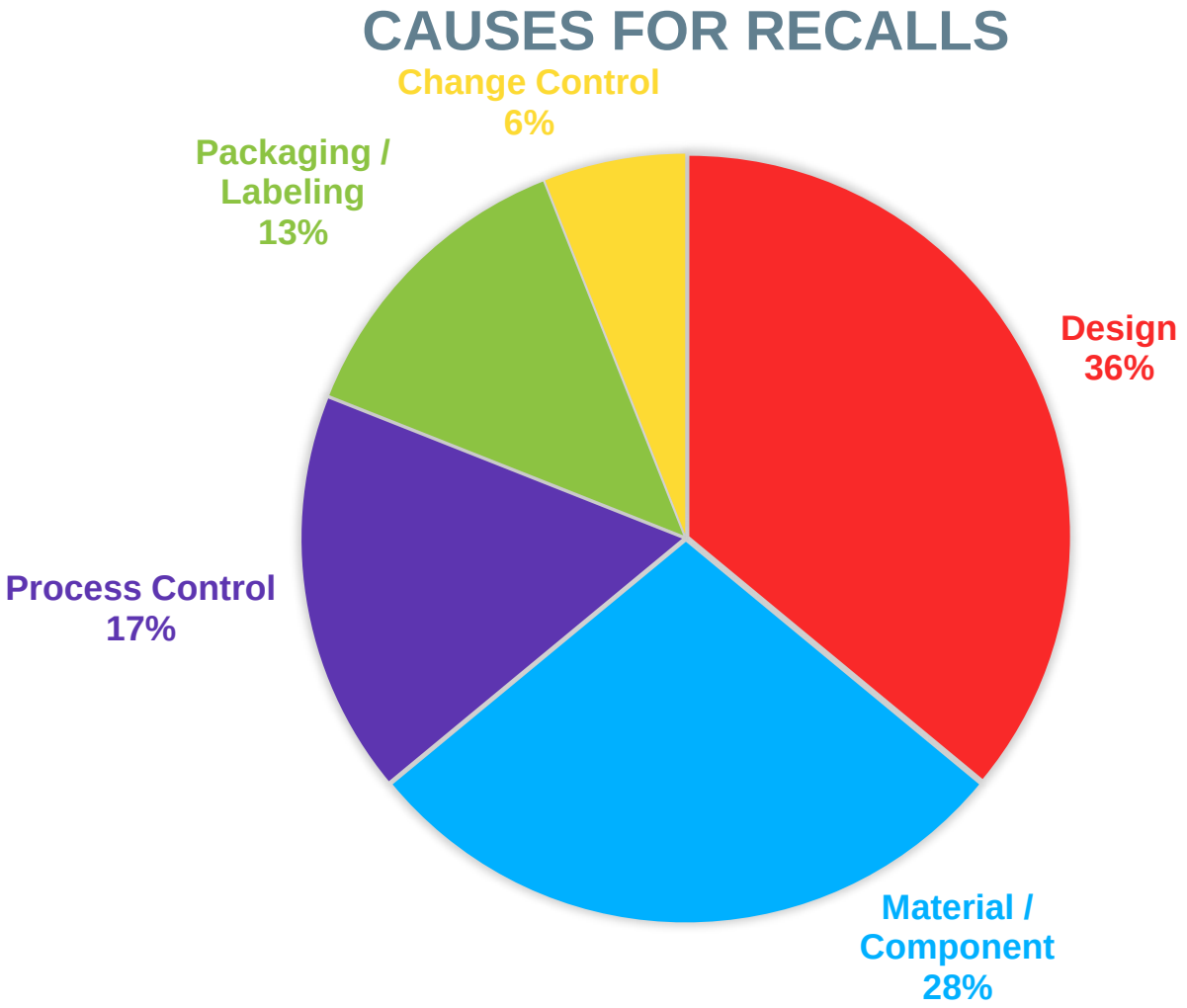
Why is Human Factors Engineering (HFE) / Usability Engineering (UE) so important?

FDA RECALLS



US FDA Recalls by Category (2003-2012).

FDA RECALLS



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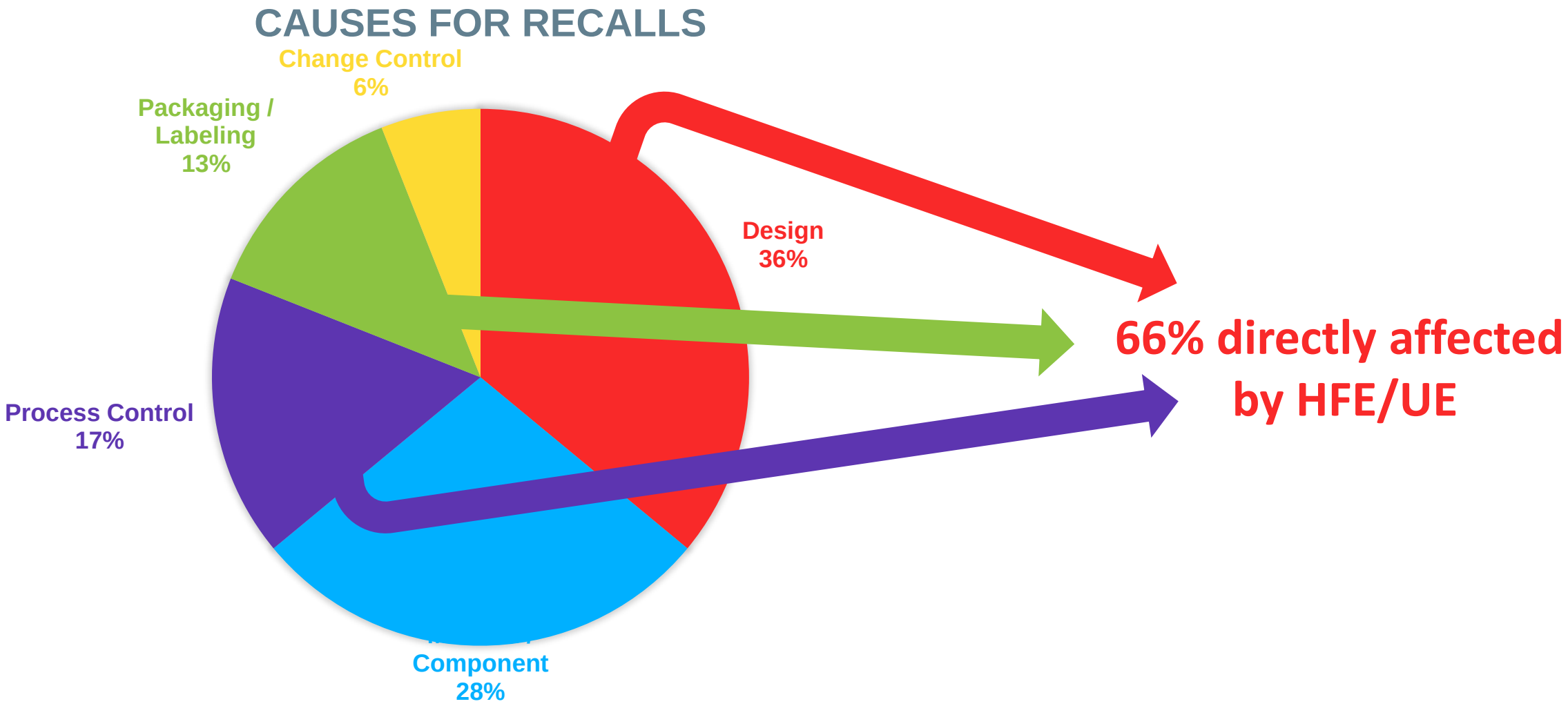

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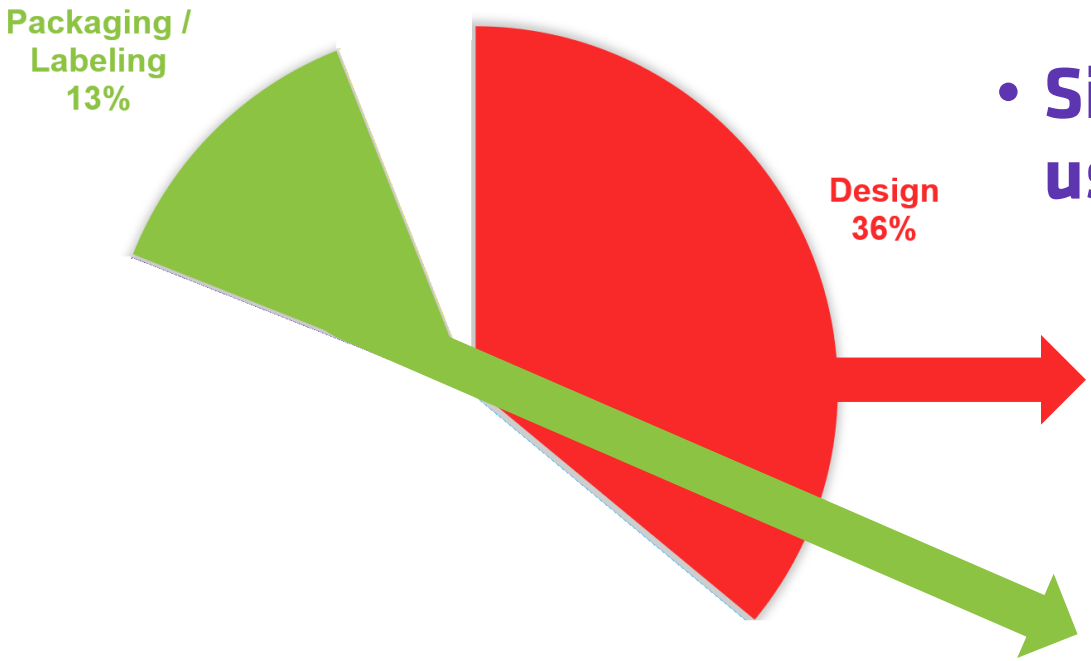
FDA RECALL EXAMPLES

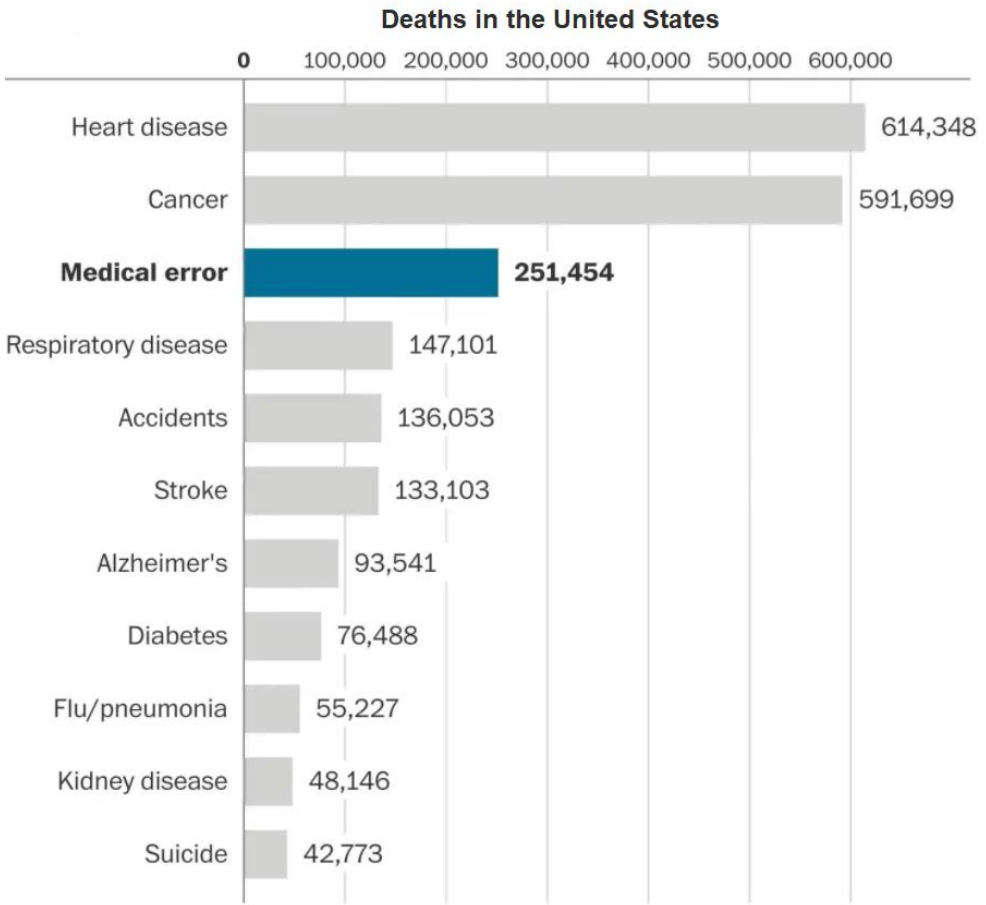


- **Significant recalls related to usability (Class I)**
  - A tracheal tube that kinks during patient use and blocks the patient airway
  - Unclear labeling and training material for life-supporting cardiac-assist (LVAD) medical device
    - Resulted in 4 patient deaths, 5 patient injuries

HFE/UE

Medical Device Recalls, FDA, www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/default.htm

USE ERROR



Adapted from the National Center for Health Statistics, BMJ, 2016 (353:i2139), *Medical error – the third leading cause of death in the US*.

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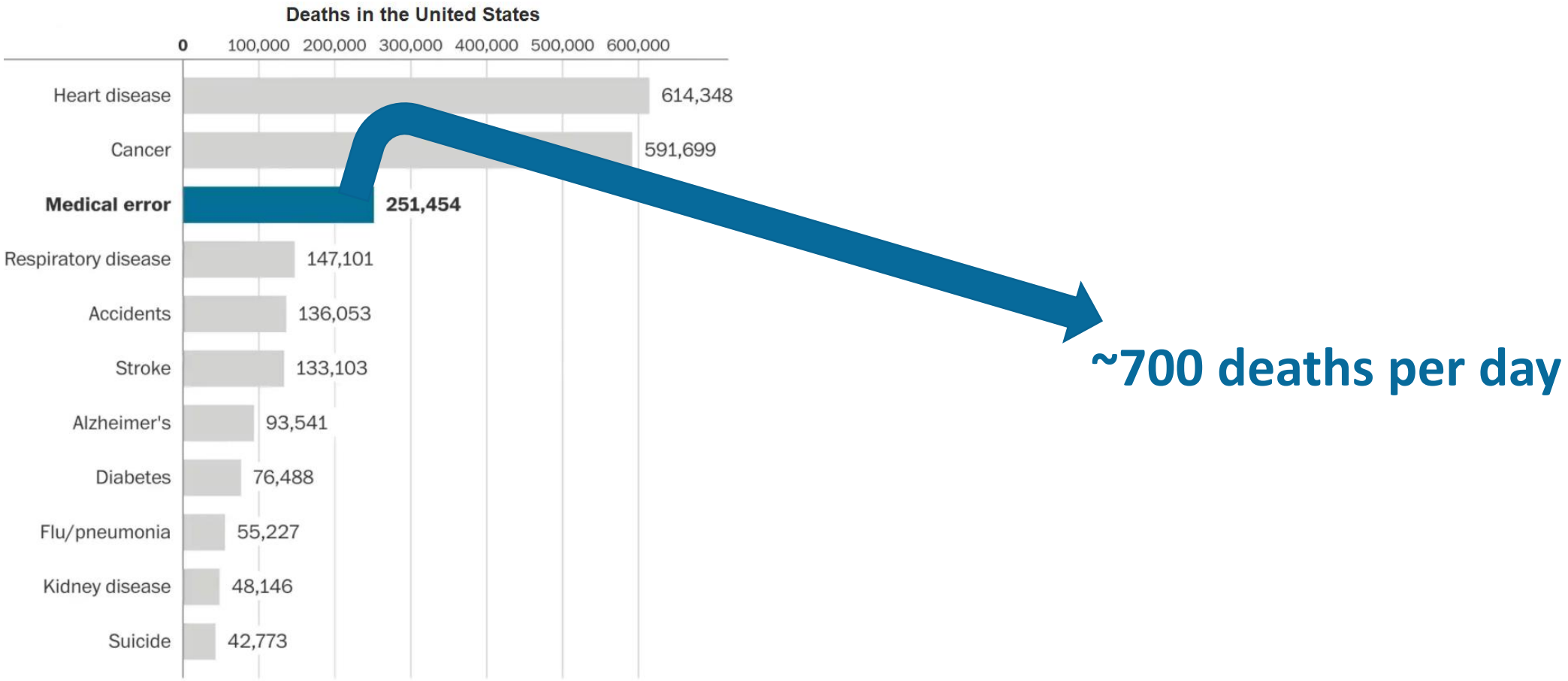
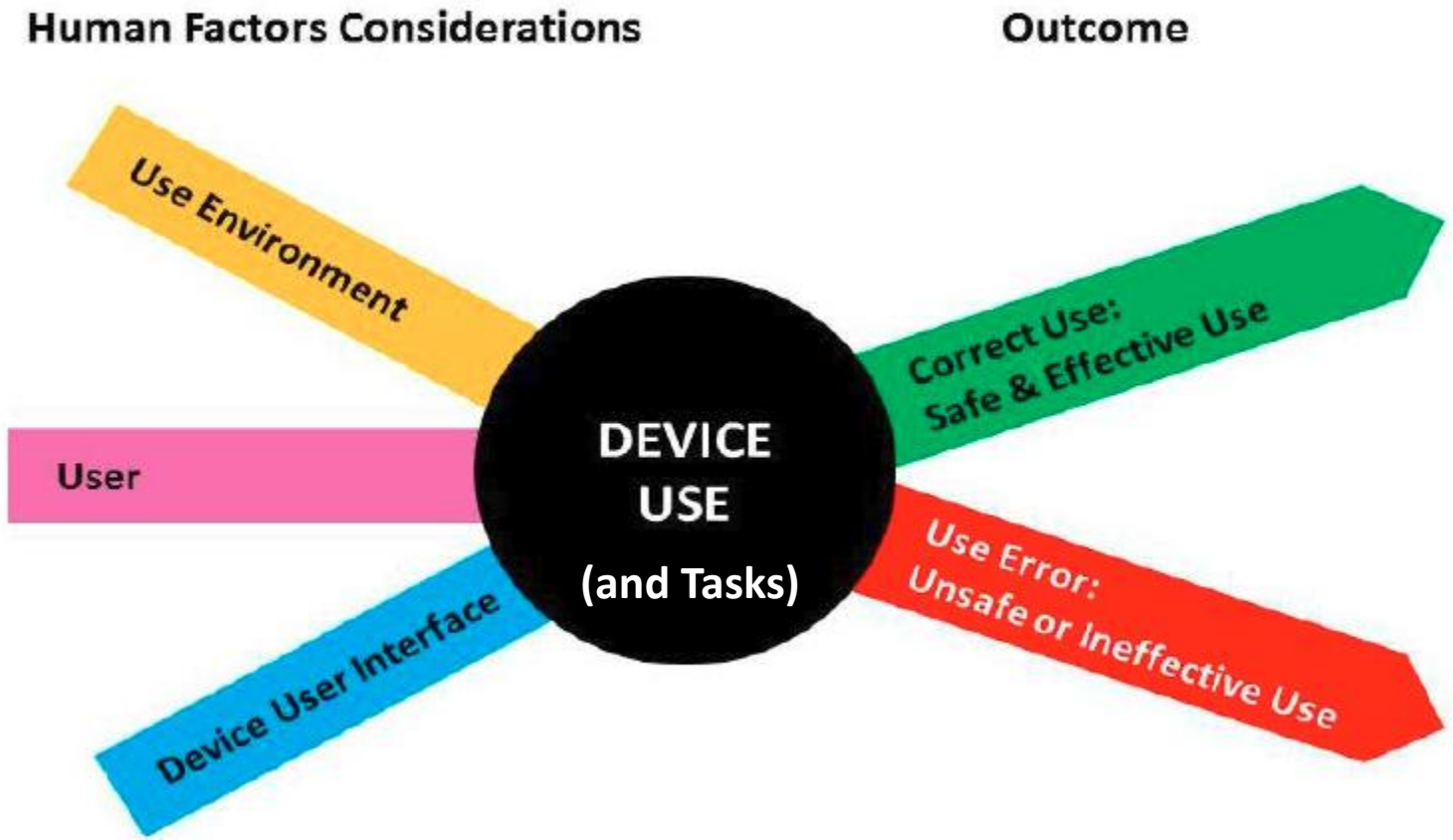


~700 deaths per day

Adapted from the National Center for Health Statistics, BMJ, 2016 (353:i2139), *Medical error – the third leading cause of death in the US*.

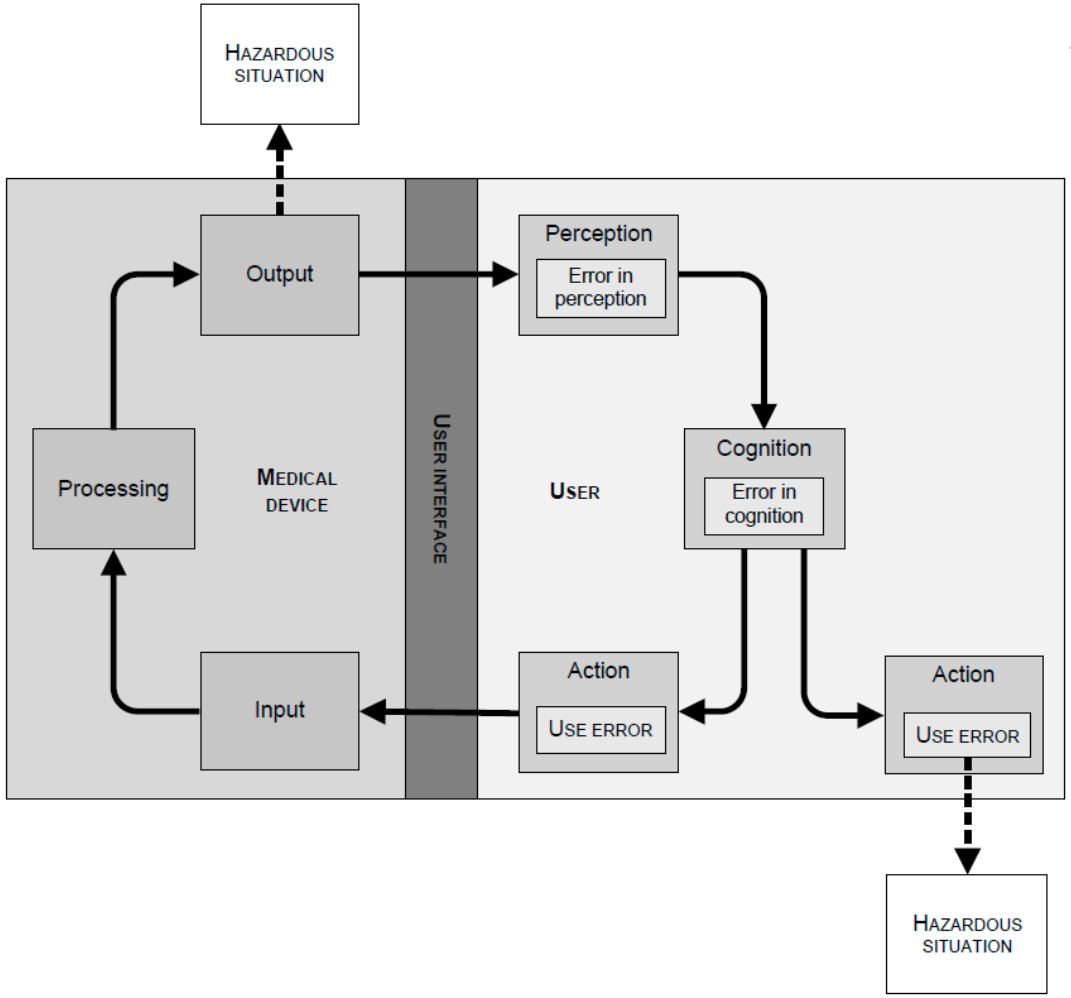
DEFINE THE PROCESS

CHARACTERISTICS TO DEFINE



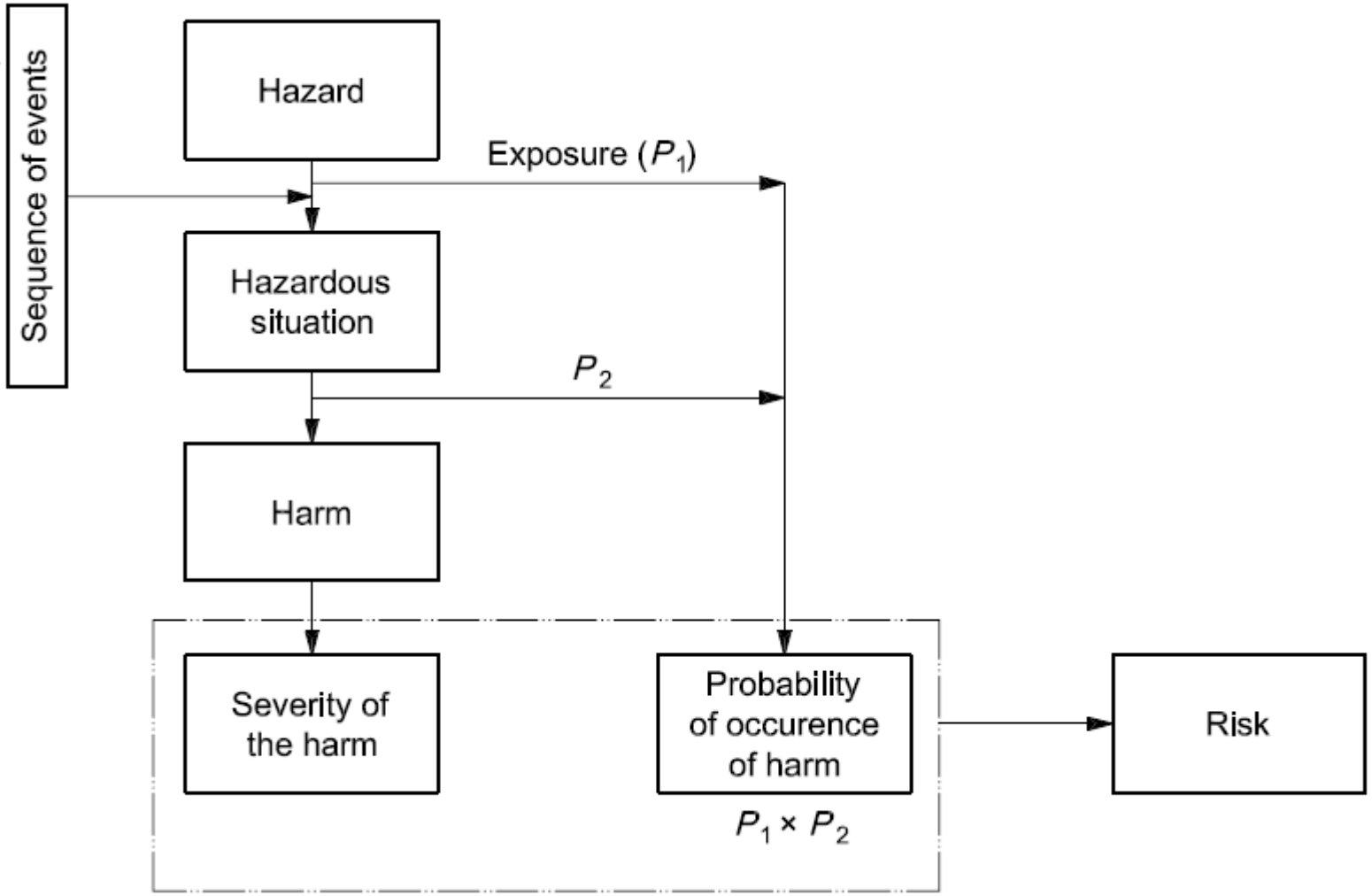
Adapted from *Applying Human Factors and Usability Engineering to Medical Devices*, FDA, 2016.

HAZARDS DURING USE



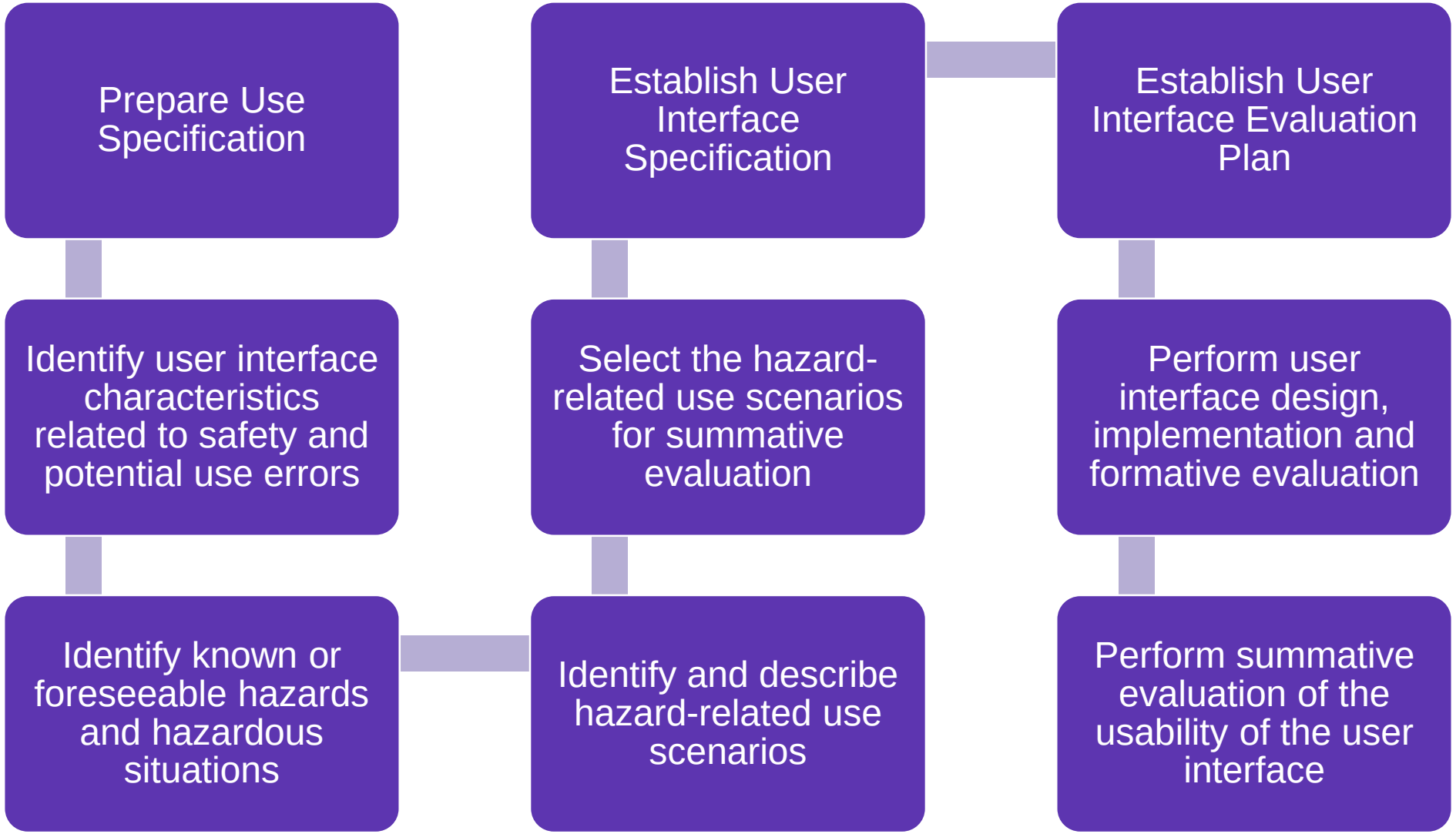
Adapted from IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*.

RISK ASSESSMENT



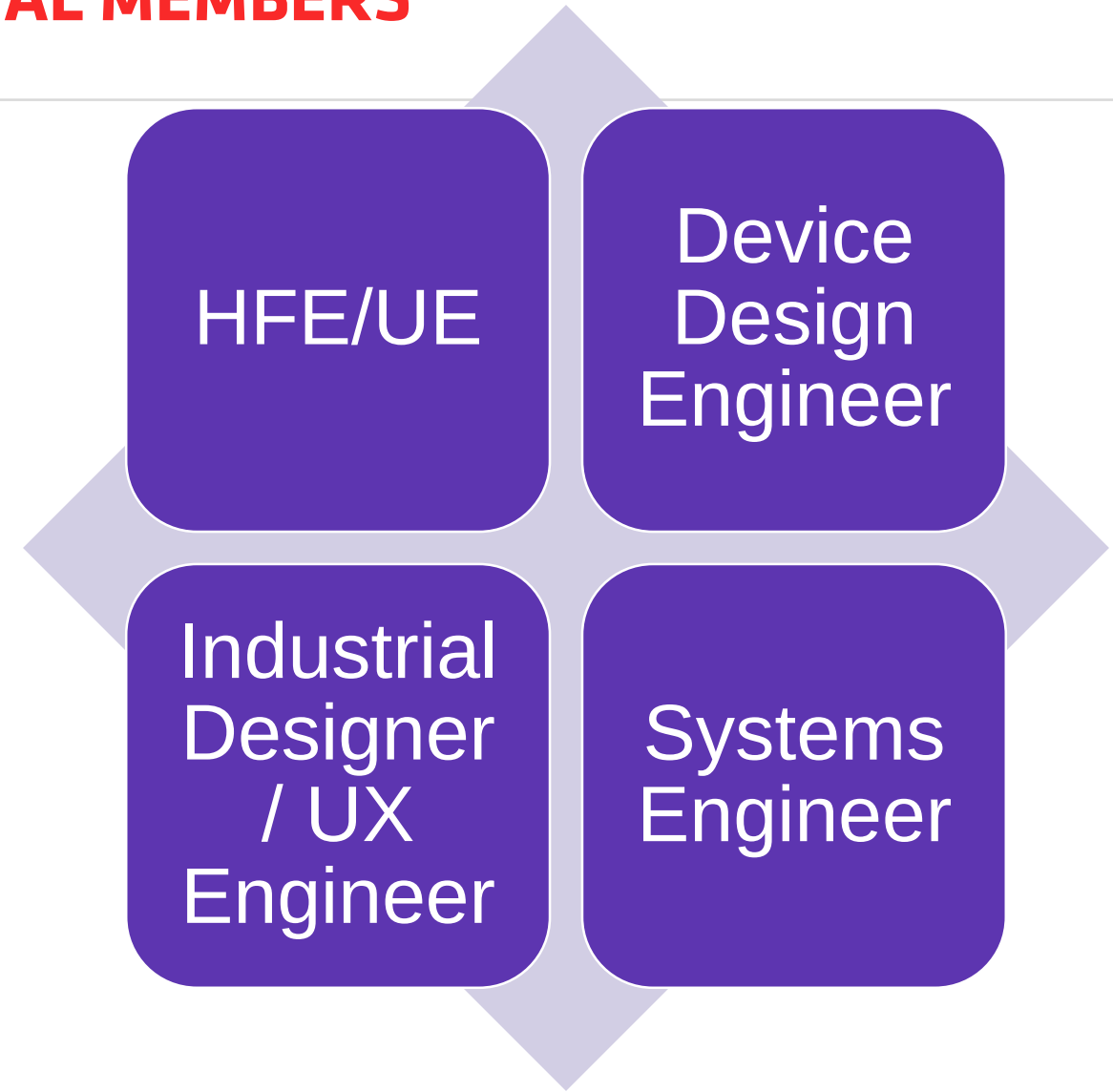
Adapted from ISO 14971:2012, *Medical devices – Application of risk management to medical devices*.

HFE/UE PROCESS

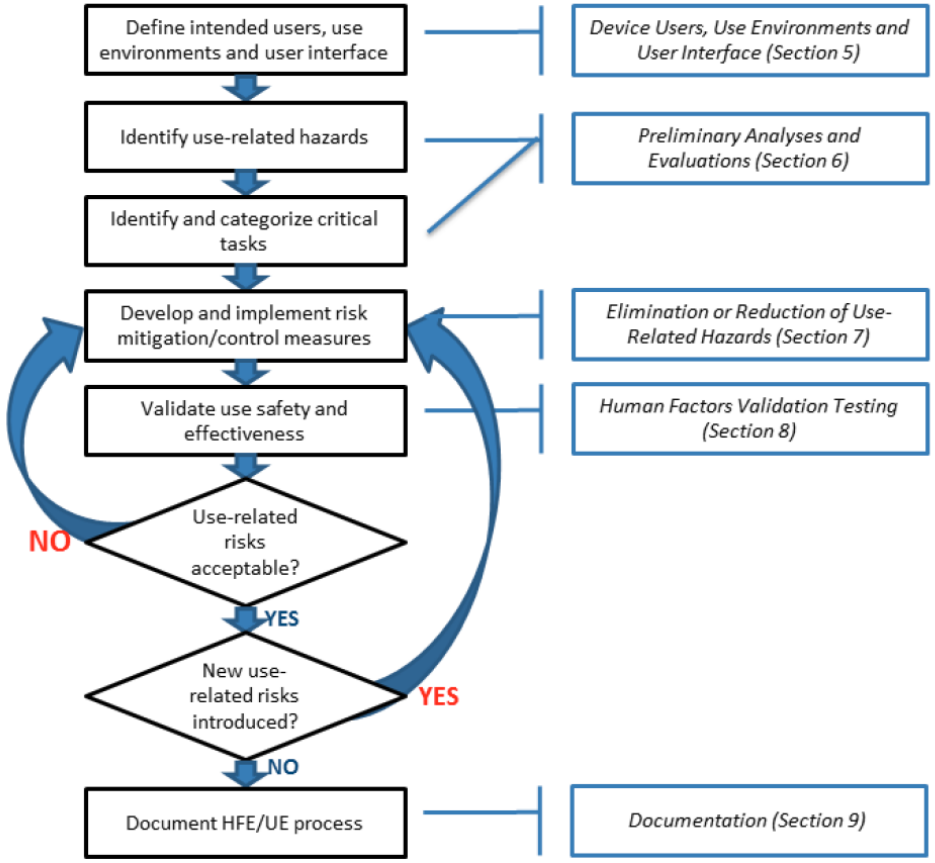


MAKE IT A CROSS-FUNCTIONAL TEAM EFFORT

CROSS-FUNCTIONAL MEMBERS



HFE/UE VS. HAZARD ANALYSIS



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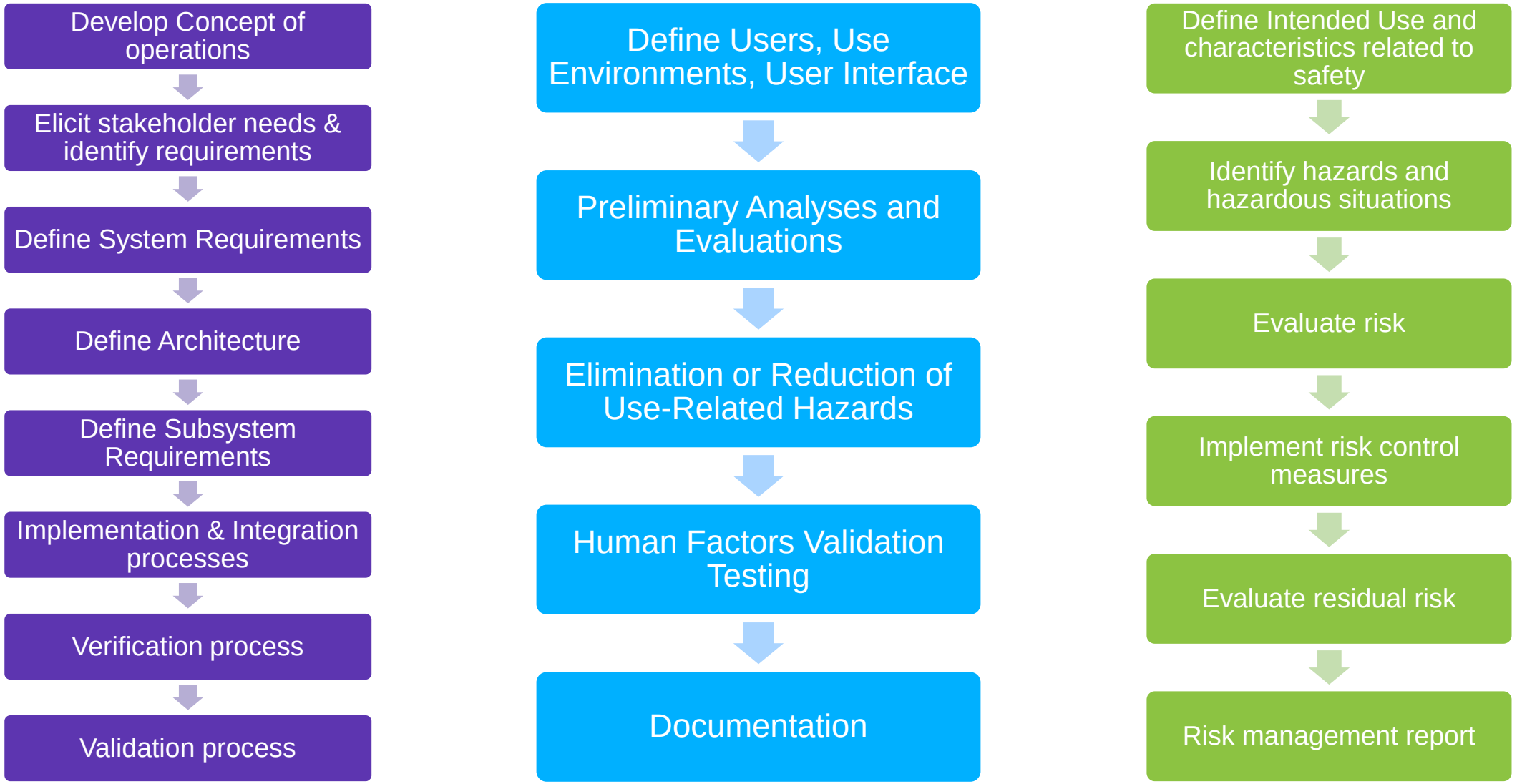
LINK TO SYSTEMS ENGINEERING PROCESS



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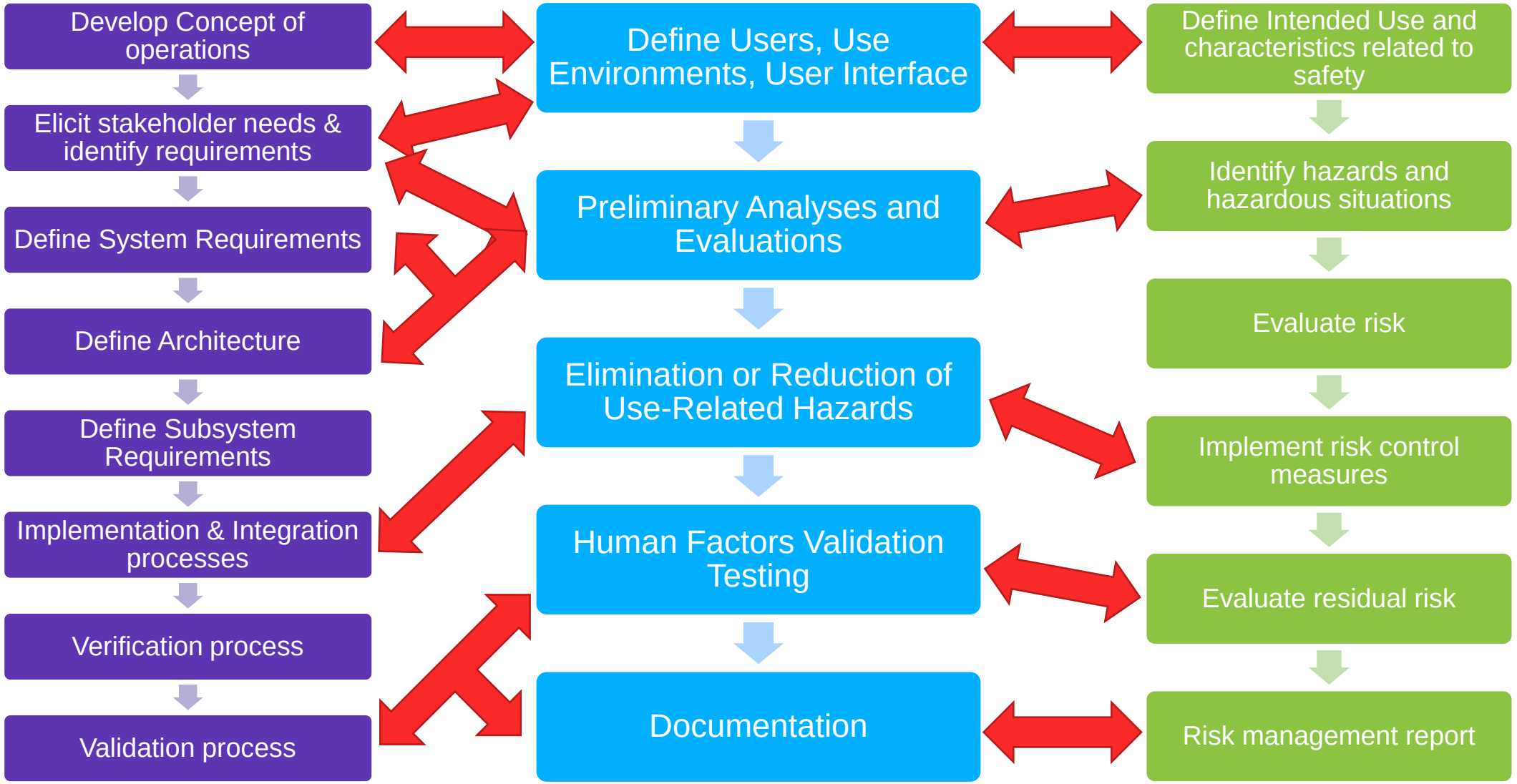


EXAMPLE: HOME USE MEDICAL DEVICES

Adapted from Bellerophon Therapeutics – INOpulse, http://www.bellerophon.com/pipeline/inopulse-technology

SWEAT THE DETAILS

USE ERROR ROOT CAUSES

- **Assumptions**
  - Focus placed on user and user interface
  - Incomplete definition of tasks/use cases and the use environment
  - HFE/UE disconnected from Systems Engineering Process

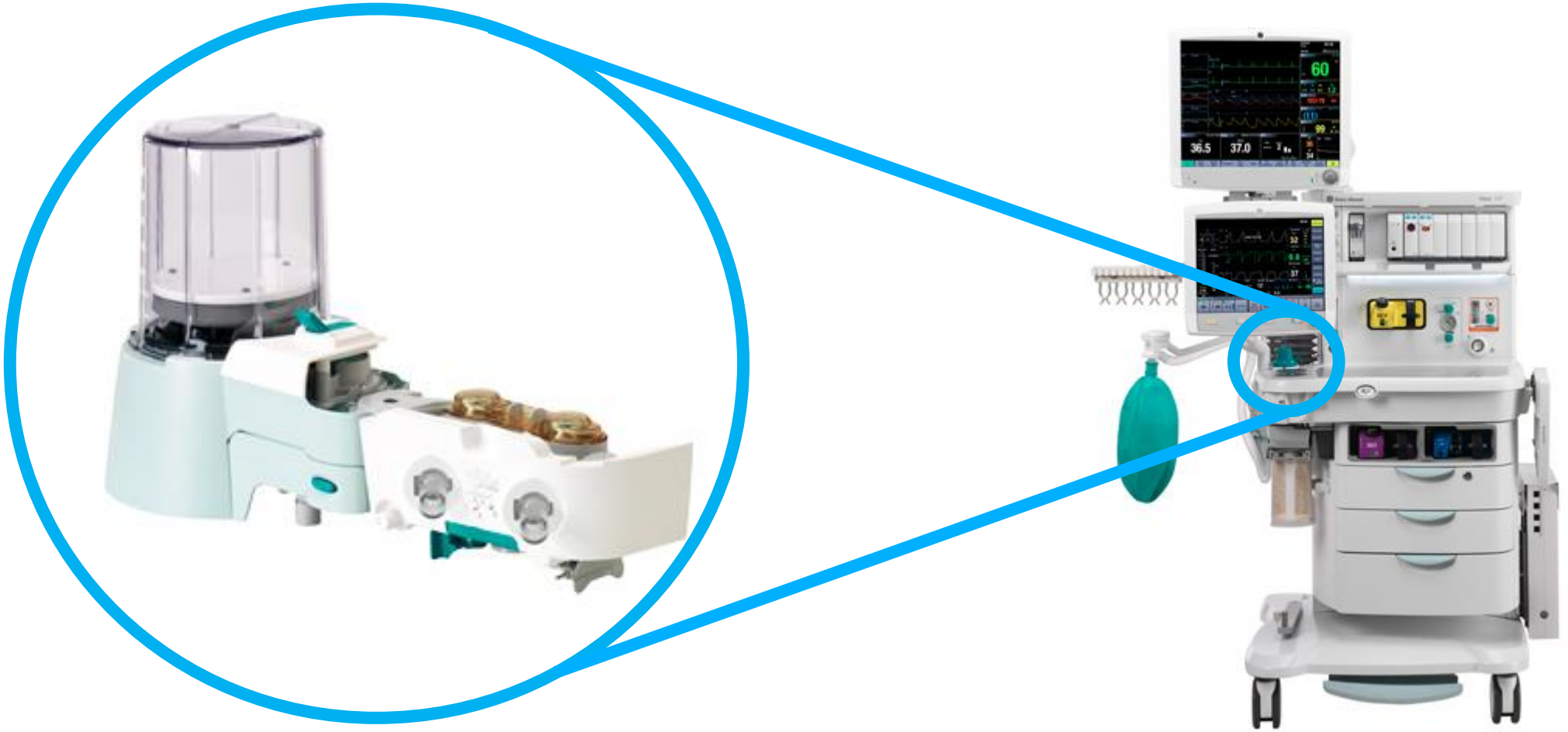
USE ERROR ROOT CAUSES

- **Be Exhaustive**
  - Consider all possible combinations
  - Consider potential error steps at each interaction
    - Tailor based on risk

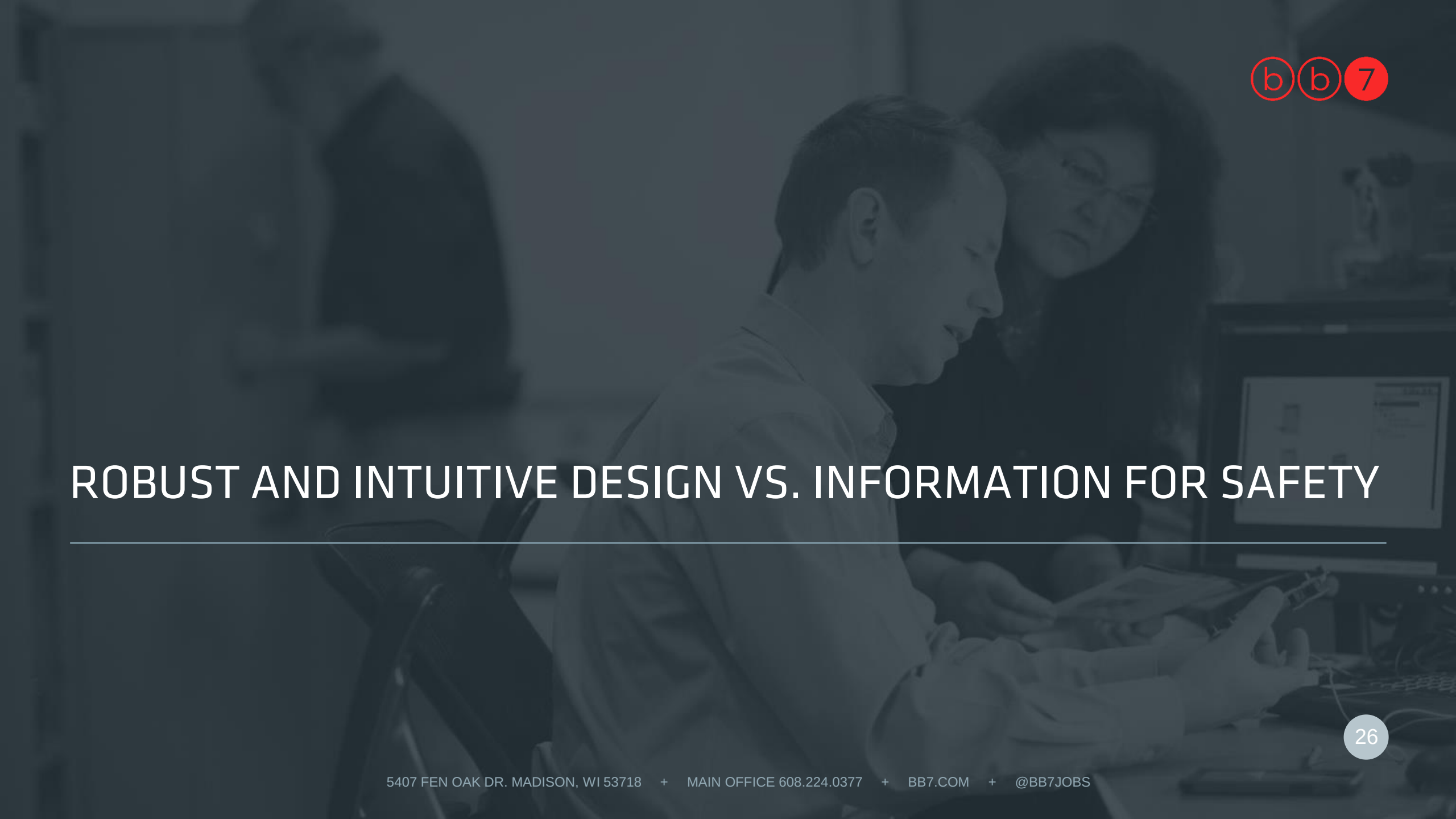
USE ERROR ROOT CAUSES

- **Be Exhaustive**
  - Consider all possible combinations
  - Consider potential error steps at each interaction
    - Tailor based on risk
  - Build HFE/UE into System Requirements & System Design Description
    - Ensure full traceability

EXAMPLE: ANESTHESIA BREATHING SYSTEM



Adapted from GE Healthcare – Aisys CS^2,
http://www3.gehealthcare.com/en/products/categories/anesthesia_delivery/aisys_cs2



ROBUST AND INTUITIVE DESIGN VS. INFORMATION FOR SAFETY

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INFORMATION FOR SAFETY

- **Traditional Approach**
  - Training for the user
  - Training for the trainer
  - User Guides / Instructions for Use

A lot of people wore their oxygen masks wrong during the Southwest emergency landing

By **Thom Patterson**, CNN

Updated 6:43 PM ET, Thu April 19, 2018

Adapted from CNN, https://www.cnn.com/2018/04/19/health/oxygen-masks-southwest-emergency-landing/index.html

INTUITIVE DESIGN VS. INFORMATION FOR SAFETY

- **Modern Approach**
  - Mitigate by design (no need for instructions or alarms)
  - Intelligent user alarms
    - Initiated by multiple conditions
  - Integrated Start-Up Guide
  - Tailored user information
    - Based on user preferences, use trends, early indicators


Recap
GET
REAL
RALLY
CONTACT
END
2016

HFE/UE OBJECTIVES

Primary

- Improve the safety of medical device usage
- Minimize potential for use error

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Secondary Benefits

- User satisfaction – ease of use, wider/faster adoption
- Reductions to project schedule and/or cost

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Requires proactive cross-functional involvement and engaged systems engineering

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REFERENCES

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- *Applying Human Factors and Usability Engineering to Medical Devices*, FDA, 2016
- ISO 14971:2012, *Medical devices – Application of risk management to medical devices*
- AAMI HE75:2013, *Human Factors Engineering – Design of Medical Devices*
- *Medical Device Directive (MDD), 2007/47/EC*
- *Medical error – the third leading cause of death in the US*, National Center for Health Statistics, BMJ, 2016 (353:i2139)
- Medical Device Recalls, FDA, www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/default.htm