# Human Factors/Usability for Medical Devices: An Historical Perspective

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#### Milestones

- 1974
   Bureau of Medical Devices
- 1976
   Medical device amendments to the Pure Food and Drug
   Act the most comprehensive legislation for medical
- devices ever passed by U.S. Congress1978
  - Anesthesia Gas Machine Standard
    - 80% of the standard addressed use error
    - Led to the establishment of a Human Engineering Committee within the Association for the Advancement of Medical Instrumentation (AAMI)

#### Milestones, cont.

1984

Congressional Hearings
Focus on anesthesia-related death rate
Record number of TV cameras
Al Gore presided
FDA praised and manufacturers castigated

- 1995
   AAMI/FDA HF Conference
- 1996
   Quality System Regulation: Design Controls

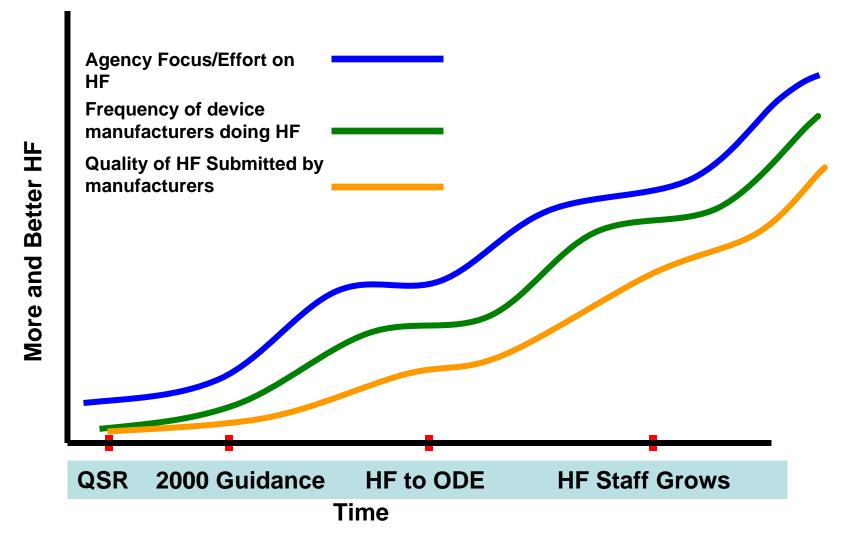
#### Milestones, cont.

- 1999
   IOM's "To Err is Human"
  - Up to 98,000 deaths in U.S. Hospitals resulting from medical error
  - 5<sup>th</sup> leading cause of death; exceeding auto accidents, breast cancer and AIDS
  - Cost to society: \$29 Billion
- 2000
   CDRH released Human Factors guidance where
  - "use error" was implicated as a necessary consideration within Risk Analysis
    - Human Factors techniques recommended to reduce use error risk

#### Milestones, cont.

- 2001
  - ANSIAAMI HE74 Human Factors Design Process for Medical Devices
- 2006
  - IEC 60601-1-6, Collateral Standards: Usability of Medical Electrical Devices
- 2007
  - HF Team relocates to Office of Device Evaluation
  - IEC 62366, Application of usability to medical devices
- 2010
  - HF pre-market review team increases in size
  - ANSI/AAMI HE75:2009 Human Factors Engineering –
     Design of Medical Devices

#### Center Effort on HF/Usability and Industry Response



# Key Factors that have influenced HF/Usability in industry

- Review of HF/Usability in pre-market submissions for new devices
- Outreach to industry

### Outreach to industry

- Presentations at conferences, workshops
  - Message: FDA believes that medical device use error impacts the health and well-being of the public and therefore looks closely at HF/Usability
  - Relevant guidance, national and international standards
  - Premarket review priorities and processes
  - Opportunity to receive anecdotal feedback on HF/Usability efforts in industry

#### Outreach Cont.

- AAMI sponsored course "Human Factors and Medical Devices"
  - Observation: Increasingly more medical device manufacturers with staff doing HF/Usability work for medical devices than in the past
- Participation on committees integrating HF content into national and international standards
- Informational "pre-submission" meetings with industry

## Anecdotal Feedback from Medical Device Industry Professionals

- "We have better, safer, medical devices now that we have HF/Usability input"
- Impact and progress is assisted by Agency efforts in outreach and premarket review
- Sales increase along with satisfaction of clientele for devices that receive HF/Usability attention

### HF/Usability pre-market review of medical device submissions

- HF/Usability evaluations, test methods and results
- Meetings with industry representatives
- Requests for additional information, disapproval can result from inadequate HF/Usability
- Priority on HF/Usability influenced by postmarket reports and analyses

### Most common HF/Usability review concerns

- HF/Usability work is needed and not provided in submission
- Lack of focus on priority of performance success for high priority tasks in validation testing
- Inadequate or absent descriptions or characterizations of errors
- Not obtaining test participant descriptions of difficulties or problems they experienced
- Not testing with representative users of the intended population of users (e.g., not U.S. residents or nonemployees)
- Checklist or rating scale approach to validation rather than systematic assessment of user performance and experience

### Summary

- Consideration of HF/Usability for medical devices at FDA has increased
  - From focusing only on anesthesia machines in the 80s and small beginnings in the 90s with a limited number of other devices
  - Several major milestones while addressing HF/Usability more directly are reflected in corresponding efforts in industry
  - Agency performs reviews of HF/Usability in new device submissions and conducts various outreach activities to industry

#### Results

- Increasingly manufacturers are doing good quality HF/Usability
- Better, safer, medical devices
- More medical device manufacturers with HF staff and doing HF/Usability work for medical devices than in the past
- Sales increase along with satisfaction of clientele for devices that receive HF/Usability attention