HUMANFACTORSCPR

KATHY KUELZ SMITH

EXPERIENCE

- Over 20+ years of human factors/usability, user requirements gathering and user interface design/specification experience in the medical device industry
- Planned and executed multiple FDA compliant validation (summative) studies for software-intensive products, including IV & syringe infusion pumps, insulin pumps, and blood analyzers.
- Planned and executed numerous formative studies: including phone interviews, in-hospital contextual inquiries, focus groups, one-on-one interviews and usability studies.
- Performed and documented use-related hazard analyzes for software and non-software devices, including vital signs monitors, infusion pumps, and auto-injectors.
- Served 3+ years as Engineering Project Manager leading cross-functional teams in the design/development/ verification/validation of QMS-compliant projects. Managed hardware & software projects ranging in size, complexity & resources.
- Served 5+ years as Lead User Interface Designer for all patient-monitoring product initiatives. Responsible for user interface requirements gathering/ analysis/specification. Translated user requirements into simple & efficient designs by creating & iteratively testing alternative solutions.
- Created a patented next generation, global GUI for a multi-parameter patient monitor through iterative, formal usability testing. Maintained design's integrity through feature enhancements across multi-generational product platforms.

CREDENTIALS

- Member of AAMI and AAMI's Human Factors Engineering Committee
- Member of Human Factors and Ergonomics Society and HFES's Healthcare Technical Group and attended the 2012 and 2014 HFES Healthcare Symposia
- AAMI courses completed:
    - o Human Factors for Medical Devices, 2013
    - o Risk Management and Human Factors, 2014
- PMP certified (since 2009) and member of the Project Management Institute
- PMI certifications in progress include:
    - o Agile Certified Practitioner (PMI-ACP)
    - o Risk Management Professional (PMI-RMP)
- Certified Usability Analyst (since 2008) and member of Human Factors International
- Virginia Commonwealth University School of Medicine, Richmond, VA MS Biomedical Engineering, 1991
- Clemson University, Clemson, SC BS Computer Engineering, 1989