

ENP 110 - HUMAN FACTORS IN MEDICAL TECHNOLOGY



The comprehensive application of human factors engineering in medical technology development is central to ensuring the safe and effective use of medical technology.

Course background

The acute, regulation-driven need for medical devices to be demonstrably safe, effective, and usable has produced a high demand for the skills of human factors engineering (HFE) specialists. Today, regulatory bodies, such as the U.S. Food and Drug Administration (FDA), are upholding high expectations for the human factors engineering of medical devices, including those used in clinical environment to diagnose illness, deliver treatment, and monitor patients. The same, high expectations apply to medical devices used in home healthcare. In principle, the application of HFE in medical technology development should reduce the incidence of use errors that could lead to patient injury and death. It should help manufacturers ensure that users are able to perform key tasks effectively and efficiently. Also, it should help manufacturers keep a pace with marketplace demand for products that reflect the same level of usability and appeal as today's best consumer electronic products.

ENP 110 will prepare students to address the burgeoning need to apply HFE effectively in the medical technology industry. Not only does the industry need skilled practitioners to conduct the hands-on HFE work, but also it needs other, affiliated specialists to deeply understand how HFE fits into the medical technology development process, thereby enabling effective product planning and project budgeting, scheduling, and execution.

Target audience

The course is designed to meet the needs of students in undergraduate and graduate programs as well as individuals who either presently work in the medical technology industry or might in the future. Such individuals might serve in one of the following roles:

Human factors engineering specialist roles

- User/usability researcher
- User interface designer
- Usability testing specialist

Affiliated roles

- Medical device inventor
- Software user interface programmer
- Mechanical engineer (designing user interface elements)
- Electrical engineer (designing user interface elements)
- Risk manager
- Patient safety specialist
- Regulatory affairs specialist
- Verification and validation test specialist
- Product manager
- Project manager
- Investment analyst

Topics

The course will cover the following topics:

- The regulatory requirement to apply HFE in medical product development
- HFE standards pertaining to medical technology
- The medical device approval (i.e., clearance) process
- Planning a comprehensive HFE program
- Medical device classifications and associated HFE requirements
- Conducting research to identify user needs
- Converting user needs into user interface requirements
- Writing user profiles
- Writing use environment descriptions
- Principles of risk management
- Identifying use-related risks
- Analyzing adverse event reports
- Mitigating use-related risks through design
- Performing function and task analyses
- Designing a usable, error-resistant user interface
- Designing effective alarms systems
- Design effective warnings and labels
- Designing effective user documentation (e.g., user manuals, quick reference cards)
- Designing effective packaging
- Design verification and validation
- Conducting formative usability tests to evaluate a medical product
- Conducting summative usability tests to validate a medical product
- Root cause analysis of use errors
- Writing an HFE Report for FDA

Classroom experience

The course calls upon the student to adopt the mindset of an HFE consultant who works in an HFE consulting firm that specializes in medical technology. The instructor introduces real and hypothetical client-sponsored projects that require the student (a.k.a. consultant) to perform the HFE activities necessary to generate “deliverables” on the “client” mandated schedule.

Some of the “consulting projects” will require research skills while others will require design skills. There will be multiple “client projects,” one requiring teamwork.

Guest speakers

There will be multiple guest speakers who will share their professional experience and views regarding the application of HFE in medical technology development. Speakers are likely to include individuals who work in manufacturing companies and healthcare delivery.

Readings

Students will be asked to read various standards and guideline documents (many published by FDA and other regulatory bodies), various chapters from pertinent textbooks (including those written by the instructor), and articles in medical technology-related magazines and websites. The reading materials will be either available online, distributed by the instructor, or purchased. Students who are interested in building a library of applicable HFE literature may, at their option, purchase and/or download these documents:

Books

- M. Wiklund, J. Kendler, A. Strohlic. *Usability Testing of Medical Devices*
- M. Wiklund, A. Dwyer, E. Davis. *Medical Device Use Error – Root Cause Analysis*
- M. Wiklund, S. Wilcox. *Designing Usability into Medical Products*
- M. Weinger, Wiklund, M., D. Gardner-Bonneau. *Handbook of Human Factors in Medical Device Design*

Visit www.crcpress.com, discount code LHP03

- Institute of Medicine. *To Err is Human: Building A Safer Health System*

Standards

- ANSI/AAMI HE75, 2009 Edition. Human factors engineering – Design of medical devices
- ANSI/AAMI/IEC 62366:2007. Medical devices – Application of usability engineering to medical devices.
- ISO 14971:2007. Medical devices – Application of risk management to medical devices
- Draft Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Optimize Medical Device Design (available on the Web at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm259748.htm>)

Applications of course knowledge

ENP 110 students may apply the knowledge they gain from the course in diverse ways. That said, many are likely to apply it in the development of medical technologies such as:

- Critical care devices, such as an anesthesia workstation, ventilator, heart-lung machine, dialysis machine, defibrillator, and hemodynamic monitor
- Hospital equipment, such as a bed, stretcher, mobile cardiograph, and nurse call system
- Surgical devices, such as a surgical robot, endoscope, tissue ablation catheter, tissue stapler, and bone saw
- Diagnostic devices, such as an ultrasound scanner, blood gas analyzer, X-ray machine, and
- Home healthcare devices such as a glucose meter, nebulizer, pen-injector, inhaler, and drug patch
- Medical software (including mobile apps) used by clinicians and patients to diagnose medical conditions, create treatment plans, and track treatment progress
- Electronic health records used by clinicians and medical facility clerical staff

Time

The course is offered on Tuesday evening, 6:00 pm – 8:30 pm.

Place

Nelson Auditorium, Anderson Hall, Tufts University (Medford Campus).

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Michael Wiklund serves as general manager of the human factors engineering (HFE) practice at UL (Underwriters Laboratories). Previously, he ran his own HFE consulting firm – Wiklund Research & Design – that UL acquired in late 2012. He has a total of over 30 years of experience in human factors engineering, much of which has focused on medical technology development; optimizing hardware and software users interfaces as well as accompanying learning tools. He is a certified human factors specialist and licensed professional engineer. He is author, co-author, or editor of several books on human factors, including one titled *Usability Testing of Medical*



Devices and another titled *Handbook of Human Factors in Medical Device Design*. He is one of the primary authors of today's most pertinent standards and guidelines on human factors engineering of medical devices: AAMI HE75 and IEC 62366. He holds multiple user interface design patents. For 30 years, Michael has taught software user interface design at Tufts University.

Read more about Michael Wiklund's work at: <http://www.wiklundrd.com/>

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