Formative Studies for Designing Better Healthcare Experiences

October 11, 2019
Boston Children's Hospital Simulation Center

The AM Session Only:
8:00am – 12:00pm

A user-centered design approach starts with Contextual Inquiry to help identify User Needs – but that shouldn't be the only touchpoint with users. The FDA expects medical device manufacturers to have representative users evaluate the emergent designs throughout the conceptualization and engineering phases, as part of an integrated Human Factors and Usability Engineering process. Learn how you can best collaborate with Human Factors Engineers to create studies that will test your design assumptions, provide timely feedback, and arm you with a user-centered basis for making informed design decisions, trade-offs, and compromises.

After more than two decades in the making, the FDA issued a finalized version of ***Applying Human Factors and Usability Engineering to Medical Devices*** in 2016. This guidance document "was developed to assist industry in following appropriate human factors and usability engineering processes to maximize the likelihood that new medical devices will be safe and effective for the intended users, uses, and use environments."

The FDA considers Formative usability studies to be a vital and essential means of assessing user interactions to identify the strengths and weaknesses of design alternatives, and to help identify potential use errors that could result in harm to the patient or clinician. Conducting these

studies in a Simulation Lab provides a rich environmental context and realism, even when they occur early in the design process with mockups or low-fidelity models.

Unlike other forms of user research that might focus on merely assessing market acceptance, Formative studies are designed to help detect usability issues and even reveal previously unrecognized use-related hazards, so they can be eliminated through an iterative design process. Although Formatives are best designed and conducted by a trained Human Factors practitioner, Industrial Designers play an important support role before, during, and after the study.

This half-day workshop will focus on building empathy for the FDA's expectations, understanding the perspective of the Human Factors Engineer, and the role of the Industrial Designer in Formative studies. After a presentation and discussion of theory, process, and best practices in a classroom setting, participants will have an opportunity to practice their newly-learned skills by participating in two types of Formatives – one conducted in the Sim Lab and one conducted in a lower-fidelity environment.

What are the expected take-aways?

- An understanding of what Formative studies are and why are they used
- Differentiation between Formative studies and other forms of user research
- An overview process of designing and conducting a Formative, from stimuli development and planning, through recruiting and execution, to analysis and documentation
- Key roles for the Industrial Designer
- A primer on data collection, note-taking, and debriefing
- Hands-on experience and the opportunity to learn through both observing studies and actively participating

Instructors:

Amrish Chourasia, PhD, Human Factors Engineer, Design Concepts, Inc.
Michael Hammond, Director of Industrial Design, Design Concepts, Inc.

Target Audience:

Although this course is primarily intended for Industrial Designers who want to have more *skin in the game* when it comes to evaluative research, it could also benefit interaction designers, user researchers, marketers, engineers, and academics interested in making better user-centered product design decisions.