

MedTech Frontiers

Human Factors -- What Does this Really Mean for Medical Devices?

Date: Thursday, March 3, 2016

Time: 6:00 – 9:00 pm, presentation begins at 6:45 pm

Location: Triple Ring Technologies
39655 Eureka Drive, Newark

Speaker: Shannon Clark

Cost: The seminar is free, but registration is required for planning purposes



About the Seminar:

February 3, 2016 was an important date in the history of medical device usability. On this day, the FDA issued the guidance, "Applying Human Factors and Usability Engineering to Medical Devices," which emphasized the importance of designing usable medical devices. The guidance outlines the FDA's recommended process for developing usable medical devices.

Shannon Clark's talk will describe what "Human Factors" means to the FDA, why Human Factors has become such a popular topic in the field of medical device development, and what usability engineering process needs to be followed when developing new medical devices. Shannon will share her experience conducting usability testing for medical devices, and she will discuss how to identify and assess use-related risks for medical devices.

About the Speaker:

Shannon Clark, is founder and CEO of UserWise, a consultancy that helps medical device manufacturers and start-ups to design safe and easy-to-use medical devices. The consultants at UserWise conduct usability testing for a variety of medical devices ranging from surgical robots to home-use injection platforms. UserWise consultants also perform safety assessments to comply with U.S. and international regulations related to Human Factors.

Before UserWise, Shannon was a Human Factors Engineer at Intuitive Surgical, where she worked on da Vinci surgical systems, instruments, and accessories including the da Vinci Xi System.

In 2012, Shannon completed Abbott Laboratories' Professional Development Program, working in various supervisory, R&D, Quality and Regulatory functions in divisions including Abbott Vascular, Abbott Diagnostics, Abbott Diabetes Care, and Abbott Medical Optics.

Shannon graduated in 2010 from UCLA with a B.S. in Mechanical Engineering and a technical breadth in Technology Management. In addition, Shannon is a Certified Professional Industrial Engineer, holds two patents, and has written and published three books.

Curiosity ...

We ask (and answer) hard questions. Complex and abstract technical challenges delight us. Whether on our own, with a start-up, or with large corporate partners, we investigate fundamentals, assumptions, and development plans. Brainstorming together across technology spaces galvanizes us, be it with our internal teams or clients. As a seasoned group of technologists, designers, and problem solvers, more discovery means clearer pathways, and better technical solutions.

Creativity ...

While our approach has evolved over the years, it remains, to its core, about communication, trust, and flexibility. This allows us to customize our approach around our client's needs. We've found that flexibility fosters an open mind and spurs creativity during the course of a discussion or project. We strive to listen closely, and to respond. Through this discourse, we can begin to self-organize around your problem set. We believe that we work particularly well in the early development phase – this is likely due to our experience as researchers and inventors. We aim to foster continued structured and unstructured learning while building upon our knowledge and experience.

Collaboration...

We are a diverse team of scientists and engineers. Of the 120 individuals on our technical team, 30 hold Ph.D.s, and 9 have been Vice Presidents of Engineering. Collectively, we've accumulated over two hundred patents, hundreds of publications, and 70 medical product registrations (including 510(k)s and PMAs). We cross-pollinate the regulated industries we're active in – medical device, homeland security, aerospace, and life sciences.

TRT seeks partners across technology spaces, and works collaboratively to create and refine concepts, strategies, and products. We strive to build upon our curiosity and creativity by opening doors, inviting dialogue, and building trusting relationships. Our services cover the entire breadth of needs analysis, technology creation, proof-of-concept, prototyping, productization, strategic support, and commercialization. Existing companies utilize our proven research, product development, and post-market analysis expertise. Virtual and growing companies engage Triple Ring to prove concepts, develop intellectual property strategies, analyze markets, secure financing, prototype, test, and accelerate their development efforts.

Completion ...

TRT is an on-demand core technology and product creation lab with headquarters based in the Silicon Valley (SV), along with an office in the Boston area. Our SV Newark, CA office is an 88,000 sq. ft. facility that includes dedicated laboratories for radiation source development, optics, mechanical prototyping, client office space, a machine shop, clean room, wet lab, and more. We host monthly gatherings to discuss the promising and exciting future of medical and applied technologies and are proud supporters of a number of our Silicon Valley neighbors.

Whether technology development, or strategic support, Triple Ring Technologies has been a trusted collaborator on over 400 projects with more than 180 partners. To start a conversation, please visit us here in the Bay Area or Boston, navigate to www.tripleringtech.com, follow us on Twitter @3ringtech, or join the discussion with #TRTech.

Thanks to tonight's culinary conversation starter: A Tasteful Affair
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