



## PROGRAM ANNOUNCEMENT

Wednesday, 28 February 2018

### Speed Networking AND Monthly Program:

### Demystifying the FDA's Human Factors Guidance

Program Speaker:  
Russell Branaghan, PhD  
President, Research Collective  
Tempe, AZ

#### Event Agenda:

Date: Wednesday, 28 February 2018

Time: 5:15 – 6:00 PM Registration & Snacks  
**5:30 – 5:55 pm Speed Networking**  
6:00 – 6:05 PM Welcome and Announcements  
6:05 – 7:05 PM Program Presentation  
7:05 – 7:30 PM Q & A

**LOCATION:** BD (former CareFusion) (directions on last page of this flyer)  
3770 Torrey View Court  
San Diego, CA 92130

Program Speaker: Russell Branaghan, PhD

#### Program Topic:

In 2016, the FDA finalized its human factors guidance for medical devices. This guidance document cleared up some of the uncertainty about how manufacturers should implement human factors into their product development process. However, due to the wide diversity of medical devices manufactured today (auto-injector vs. infusion pump vs. robotic surgical system etc.), manufacturers often struggle to understand how the regulatory guidelines apply to their own specific device(s).

#### Program Summary:

This presentation will break down FDA's human factors guidance into a list of actionable steps. It will describe proven strategies that will help manufacturers: (1) improve their time to market and overall design through early implementation of human factors and (2) pass their human factors validation test for FDA clearance.

Specifically, you will learn:

- An understanding of usability testing and its role within the field of human factors
- How to improve overall product design and speed to market by implementing human factors into design controls
- Strategies to pass a human factors validation test on the first attempt
- The importance of including in their human factors strategy all of the tasks impacted by the device use (device setup, instructions for use, cleaning, disposal, etc.)
- The first step a manufacturer should take after receiving a deficiency letter that mentions a lack of human factors
- The future of post-market usability surveillance

### **Speaker Biography:**

Dr. Russell (Russ) J. Branaghan is Associate Professor of Human Systems Engineering in the Ira A. Fulton Schools of Engineering at Arizona State University, where he directs the Human Factors Engineering Laboratory and teaches Human Factors, Human-Computer Interaction, Consumer Psychology and Cognitive Science. Russ also serves as Visiting Professor of Human Factors in the Master of Product Design and Development Program in the McCormick School of Engineering at Northwestern, and has been a Visiting Scientist at the Kern Center for the Science of Healthcare Delivery at Mayo Clinic in Rochester, MN.

Dr. Branaghan's academic research focuses on applying cognitive science to the endeavor of making products easy to learn, efficient to use, and desirable. This requires an understanding of the structure and functions underlying human learning, memory, decision-making and emotion. In addition, it requires mastery of the qualitative, quantitative and physiological research methods to investigate these topics. Branaghan's academic research has been sponsored by the National Science Foundation, IBM, Science Foundation of Arizona, US Air Force Research Laboratory, Federal Aviation Administration, Mayo Clinic, Motorola, JP Morgan Chase, and others. He has published numerous articles on human factors, human computer interaction, and consumer psychology (especially brand personality), and has directed over thirty MS and PhD theses. His former students have gained employment at Intel, Google, HP, Honeywell, Amazon, General Dynamics, Exponent, and other great companies.

Before joining ASU, Russ spent 15 years in industry as a Sr. Human Factors Engineer at Hewlett-Packard and as an Advisory Human Factors Engineer at IBM. In consulting, Russ served as the Senior Vice President of Research and Strategy for Fitch in Columbus, Ohio, directing the strategy and user research activities of three offices (Columbus, Boston, and San Francisco) and dozens of psychologists, anthropologists, industrial designers, brand planners, and business strategists. After leaving Fitch, Russ served as Sr. Vice President and Partner for Lextant Corporation, a User Experience Research and Strategy consultancy. To this day, Russ continues to collaborate with Lextant. Upon leaving Lextant, Russ reunited with the former CEO of Fitch to serve as Senior Vice President at Big Red Rooster, also in Columbus.

These days, Russ' consulting work is done through Research Collective in Tempe, AZ. Research Collective is a team of human factors engineers, usability specialists and consumer psychologists who conduct user research (qualitative and quantitative), usability testing, and consumer brand research. Research Collective is housed in a user research facility with two usability laboratories with observation mirrors, state of the art audio, pan-tilt-zoom cameras, live streaming, and participant recruiting. They conduct additional research through partnerships with the Arizona Heart Institute (for medical device usability testing requiring surgical suites and exam rooms) and through partner usability labs worldwide.

Over the years, Russ has been fortunate to partner with many medical clients, including:

- Abbott Labs, Aerosure, Actegy, Agilent, Alere, Bard, Becton Dickinson, Cardinal Health, Emergent Biosolutions, Exact Sciences, Flowonix, Guidant, Intuitive Surgical, Mayo Clinic, Medtronic, Midmark, Ohio Health, Ohio State University Hospital, Olympus, Owlet, Respironics, Sanofi, SynCardia

To register for the meeting, click on the link below to access the SDRAN registration system (123Signup) for this event:

<https://www.123signup.com/register?id=hszys>

Please make your reservation early. The online registration due date is Monday, 26 February 2018. Credit Cards are accepted online only. Cash and Check are accepted at the door.

**Online registration (through Monday 26 February 2018):**

\$15 SDRAN Member

\$25 Non-Member

**Onsite Registration:**

\$25 SDRAN Member

\$35 Non-Member

For Questions Email: [programs@sdran.org](mailto:programs@sdran.org)

**Directions to BD (former CareFusion):**

**From the North 5:**

I-5 South toward San Diego  
Exit toward Carmel Mountain Rd Left onto Carmel Mountain Rd Left onto Torrey View Court Facility is on the right

**From the South 5:**

I-5 North toward Del Mar  
Merge onto I-5 local Bypass  
Take Carmel Mountain Rd exit (32)  
Turn right onto Carmel Mountain Rd  
Turn left onto Torrey View Court  
Facility is on the right