

MedStar Health and FDA to lead a post-conference workshop at Pre-Filled Syringes West Coast 2019

Developing a Human Factors Validation Plan with Consideration for the Digital Health Marketplace

SAN DIEGO, CA, USA, April 11, 2019 /EINPresswire.com/ -- This workshop will provide an overview of human factors validation strategies that companies should consider as the [pre-filled](#) syringe market increasingly takes on digital health components. A case study of a pre-filled syringe with connection to a mobile app will be utilized throughout the course to demonstrate the concepts under discussion and help participants work through a study plan.

The workshop aims to generate discussion around challenges, lessons learned, and future directions for human factors considerations regarding similar products.

- Hear regulatory and industry perspectives on study design for pre-filled [syringes](#)
- Understand current FDA thinking on human factors submissions
- Discuss considerations for products incorporating digital health

Rita Lin, Human Factors Reviewer, Center for Radiological Health and Devices, FDA will discuss and cover:

- FDA human factors guidance Applying Human Factors and Usability Engineering to Medical Devices
- Review Xcertia mHealth App Guidelines and discuss relevance to pre-filled syringe industry
- Discuss current directions and challenges with pre-filled syringes from regulatory and industry perspectives

About the workshop leader

Natalie Abts, Senior Program Manager, Usability Services

As the Senior Program Manager for the Usability Services team at the National Center for Human Factors in Healthcare, Natalie Abts consults with national and international clients in the medical device industry and leads a team that conducts human factors evaluations for a wide range of medical products. Natalie has specialized experience in planning and executing both formative stage usability evaluations and validation studies for medical devices and combination



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products on the FDA approval pathway. Natalie holds a master's degree in industrial engineering with a focus on human factors and ergonomics from the University of Wisconsin, where she was mentored by Dr. Ben-Tzion Karsh.

For more information on the workshop visit the event website at <http://www.prefilled-syringes-westcoast.com/einpr5>

Take advantage of the \$100 Early Bird discount on bookings expiring on April 30th, 2019.

Register for the conference and/or workshop at www.prefilled-syringes-westcoast.com/einpr5

Pre-filled Syringes [West Coast](#)

Conference: June 3rd – 4th 2019

Venue: Hyatt Regency Mission Bay, San Diego, USA

Half-day post-conference workshop: June 5th 2019

Pre-Filled Syringes West Coast 2019 Conference is proudly sponsored by:

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About SMi Group:

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