Introduction to Human Factors Engineering – The Key to Developing Safe, Effective, and Usable Medical Devices

Presenter: Allison Strochlic | Co-founder and Senior Research Director of Emergo

Allison Strochlic, co-founder and Senior Research Director of Emergo by UL's HFR&D team conducted a webinar exploring the crucial role of Human Factors Engineering (HFE) in medical device development. The 60-minute presentation delved into the fundamental concepts of HFE, highlighting the specific "human factors" that influence user interactions with products. Allison also discussed the regulatory landscape, outlining the key standards and guidance documents that mandate the application of HFE throughout the medical device development process. The webinar further emphasized the commercial advantages of implementing HFE, including improved end-user satisfaction and positive business outcomes. Finally, Allison provided a comprehensive overview of the activities involved in creating a robust and compliant HFE plan, outlining the essential deliverables to ensure successful implementation.

Full On-demand Recording

On-demand Chapters:

00:00 - Intro of webinar & Bio of Allison Strochlic
02:57 - Emergo by UL - Our Focus on Medical Technology, Our Services
04:00 - Emergo by UL - Our Digital Platform, OPUS
04:55 - Introduction to HFE
09:15 - HFE Applies to a Wide Range of Medical Devices
11:23 - Specific Human Factors
16:53 - The Regulatory Imperative
27:58 - Overview of HFE Activities and Key End-Products
52:36 - Tips for Good HFE Process
54:25 - Questions

Presenter: Allison Strochlic | Co-founder and Senior Research Director of Emergo

Allison was one of the Emergo by UL, Human Factors Research & Design team's co-founders in 2005. She has spent her entire career applying human factors engineering principles to medical and pharmaceutical product development. She advises clients on how to apply human factors engineering (HFE) in a manner that meets FDA's and other regulators' expectations, including developing program plans and leading key meetings on various HFE topics with regulators. Allison contributes to and oversees a wide range of research and evaluation activities and helps manage the team's Quality Management System. Allison is a co-author of a book titled Usability Testing of Medical Devices, an author of several technical articles, and is an editor for the Human Factors in Healthcare journal. She frequently delivers conference presentations, leads panels, and presents webinars on various HFE topics. Allison is a Certified Human Factors Professional and holds undergraduate and graduate degrees in human factors from Tufts University and Bentley University, respectively.