Human Factors Engineering/Usability Engineering (HFE/UE) Capabilities

After investing time and money into the design and development of your combination product, few things are as frustrating as having your work rejected by the Food and Drug Administration (FDA) asking for more data, or more testing.

Navigating the complex and often ambiguous FDA approval process can be a trying journey. When the regulatory path isn’t clear, companies are left trying to guess what to include in an FDA report submission—only to receive a rejection.

Rejections cause delays—and resubmissions cost time, money, and effort.

One key reason behind rejections is that companies do not fully understand FDA expectations. Your expertise is your product—ours is the FDA process for Human Factors Engineering and Usability Engineering.

Whatever stage you are at in development of your combination device, we can help—from performing HFE/UE analyses to supporting product design, to supporting product verification and validation testing, our expertise can demystify the FDA approval process.

**Analytical & Requirements Generation:**
- Requirements Definition: Quantitative, Qualitative, Functional, Operational, and Behavioral
- Market Research: Focus Groups, Site Visits, Surveys, Contextual Inquiries, and more
- Day-in-the-Life Analyses/Use Case Scenarios
- Function Definition and Allocation
- Risk-based Task Analysis/Use Failure Modes and Effects Analyses
- Competitive Analysis, Technology Trade Offs, Data Mining, and more

**Design Support:**
- UI and Product Specifications
- Exploratory Testing: Usability Tests, Trade-off Evaluations, Rapid Iterations
- Functional Flows and Wireframes
- User Interface (UI) Design (HW, SW and labeling)
- Product Design Specifications: SRS, IFU, Training Materials, and more

**Test & Evaluation:**
- Formative Testing
- Summative Validation Testing

“We recognize the value that Suttons Creek has brought to our team. I frankly do not know how we could have achieved our goal without their help.”

—Executive Director of Device Quality, Global 200 Pharma Client