eurofins | Human Factors MD

Human Factors Testing

Medical Error, or "preventable adverse effects," is a leading cause of death in the United States. As a consequence, human factors testing is an expectation by the FDA and other regulatory agencies when designing medical devices and combination products.

Eurofins Human Factors MD helps bio/pharmaceutical and medical device companies create innovative products that are more usable, safe, and effective through robust evaluations and testing.

Why Choose Eurofins Human Factors MD?

Our team of dedicated human factors experts has worked exclusively with bio/pharmaceutical and medical device companies, providing human factors expertise at every phase of the development and regulatory approval process for over 20 years.

Our facility is a custom state-of-the-art medical usability research facility designed to meet the needs of human factors testing, with three test suites and the ability to simulate many types of use environments, from a simple home setting all the way to a fully-featured operating room or hospital pharmacy.

We offer video streaming and recording capabilities for remote observation as well as on-site meeting rooms for in-person collaboration.

Using our thought leadership in Human Factors Engineering, we develop strategies that satisfy regulators, are not overly burdensome, and give you confidence that your product is safe and effective.

Simulated Use Studies

One of the most important tools in our service portfolio is a simulated use study, which can be executed at any time during a product's development. For these studies, participants are recruited according to various physical and cognitive characteristics to match the intended users, such as age, gender, handedness, reading levels, medical conditions, and experience with similar products. Participants then utilize the product as they would in real life, without help or training. The goal is to identify what people understand, what they find confusing, and how effective instructions and labeling are in mitigating any potential use-related issues that may render the product ineffective or unsafe.

Human Factors Testing and Evaluation:

- Formative Usability Studies
- Human Factors Validation Testing
- Summative Testing
- Labeling Comprehension Studies
- Bridging Studies
- Threshold Analyses
- Heuristic Analyses
- Comparative Use Testing
- Competitive Benchmarking

Human Factors Strategy Support

- Human Factors Strategy
- Human Factors SOPs
- FDA Meeting Planning
- HF Integration Plans
- Use-Related Risk Analysis (URRA)
- Use Specifications
- Labeling Development
- HF Remediation Plans
- Gap Analyses
- Threshold Analyses
- Expert Reviews

We Test On:

- Combination Products
- Class I, II, and III Medical Devices & Software
- Kits and Container Closure Systems
- Laboratory Instrumentation and Diagnostics

Laboratory Features:

- Three Custom Designed Human Factors Testing Suites
- World-class A/V Recording and Streaming
- Simulation Flexibility (Home, Operating Room, Pharmacy, etc.)
- Hospital Beds, Surgical Tables, Pharmacy Hoods
- Client Meeting Rooms
- Consenting Rooms
- On-site Registered Nurse
- On-site Host
- In-House Recruiting

Comprehensive Testing & Analysis Services

Formative Usability Studies • Human Factors Validation Testing
Summative Testing • Comparative Use Testing • Threshold Analyses
Heuristic Analyses • Competitive Benchmarking • Ergonomic Testing
Use-Related Risk Analysis

What we work on

Combination Products
Class I, II, and III Medical Devices & Software
Kits and Container Closure Systems
Laboratory Instrumentation and Diagnostics

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