# The 5 Ws of a Human Factors Strategy

**Elizabeth Mauer, Senior Technical Director**

It's a common occurrence that biopharma and medical device companies address human factors engineering requirements too late in their design and development process. They might know certain human factors engineering activities are required (i.e., by law or by a standard), but they don't understand the time and resources required and how those things can impact regulatory submissions, commercialization, and product lifecycle. Oftentimes the root cause can be attributed to lack of a *human factors* strategy.

## What is it?

Sometimes companies believe a human factors *strategy* is the same as the human factors plan that is described in IEC 62366-1:2015. However, a strategy is much more comprehensive than a plan.

A successful human factors strategy includes the set of human factors engineering activities that ensures a medical product's user interface supports safe and effective use for the intended users in the intended use environments, by reducing use error. And although its focus is use-related safety (as that is the goal of regulatory bodies such as US FDA), it's an excellent way to also mitigate business risk because it ensures medical products are useful, usable, and desirable in the marketplace. The strategy also includes what activities should be performed at which milestones during the design and development process, what resources are required for those activities, and what obstacles could throw a wrench into things so alternative plans can be pursued, if needed. This ensures that human factors engineering activities are integrated at the correct design, development, and post-market milestones and have the necessary resources (i.e., time, money, personnel, product samples, etc.).

Importantly, human factors strategies are scalable based on the amount of use-related risk a product presents. They can and should look different for a new product with no known predicate versus a combination product that will be commercialized in an off-the-shelf drug-delivery device, for example. There is no "one size fits all" approach.

## Why do you need it?

A human factors strategy is an effective planning tool to ensure your product's use-related risks and business-related risks are as low as possible (thereby satisfying regulatory agencies and stakeholders), all while optimizing time, money, and resources in the process. Human factors strategies can help with ensuring compliance with 21 CFR 820.30, IEC 62366-1, and FDA human factors expectations.

## When do you need it?

A human factors strategy should be developed during the initial stages of product design and development, just as other key planning documents such as a design and development plan, risk management plan, etc. It's critical to include it early for sustaining engineering activities (e.g., updating an existing product with new features). And as previously mentioned, strategies can continue after commercial launch with post-market surveillance, bridging studies, etc.

## What's involved?

Human factors strategies vary from product to product. There are many considerations when developing the appropriate strategy and the strategy may change as the product develops. They include:

- Product Type (e.g., medical device, combination product, etc.)
- Intended use (e.g., lay use, medical professionals only, training required, etc.)
- Intended users (e.g., HCPs, patients, caregivers, children, people with specific conditions, etc.)
- Is it used on its own or in the presence of or in combination with other devices?
- Type of environment where it will be sold and/or used (e.g., hospitals, clinics, homes, etc.)
- Frequency of use (e.g., emergency use, infrequently, daily, etc.)
- Predicate / similar products (e.g., reference products)
- Types of use-related hazards that can be reasonably foreseen
- Type of regulatory submission (e.g., NDA, BLA, OTC, PMA, 510(k), etc.)

The outputs from your strategy will include use specifications, use-related risk analyses, labeling development, formative studies, human factors validation tests, post-market obligations for monitoring and responding to unanticipated use-related hazards once a product is commercialized, and visions for upgrades and future iterations of a product.

## Who should develop a human factors strategy?

Choosing an experienced organization is critical to success and meeting product development milestones. Partner with organizations with trained human factors specialists who are experienced  with medical devices and combination products and know the expectations of the regulatory authorities in your chosen market. Your partner will develop a tailored human factors strategy and navigate potential challenges (e.g., if FDA does not provide feedback on a human factors validation test protocol within their stated timeline, if product samples are not available for testing) that can de-risk your regulatory submission and subsequent commercialization . Your human factors engineering partner will also collaborate with your company's engineering, design, clinical, quality, and regulatory teams to ensure the human factors strategy is in alignment with all stakeholders.

## Conclusion

A comprehensive and appropriately-scaled human factors strategy implemented early during the planning phase is key for manufacturers of medical products to bring their products to market with as little risk as possible and to navigate the regulatory environment required to do so.

Contact us to share your challenges and partner with our seasoned experts, all of whom have 20+ years of experience in this specialty, to develop robust human factors strategy that fits the needs of your company.