

Human Factors – Enjoy the Journey and the Destination!

Human Factors (HF) is not just a validation exercise or a check box at the end of your product development process. HF can help answer the question of whether you have designed the right product for your users by exploring new paths, so enjoy the journey!



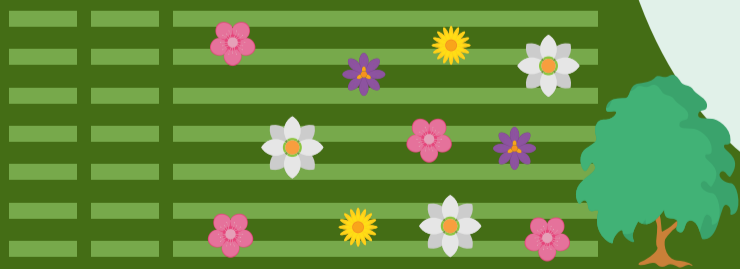
2. Make sure your passengers are comfortable

HF is about understanding how users interact with your product and optimizing the product user interface to help minimize risk in your product design that could result in harm or compromised medical care. Test your product with representative users!



4. Don't forget the GPS

Risk management informs the design of formative and validation testing as well as product expansion post-launch. Risk management requires a multi-disciplinary approach. Involve your engineers, clinicians, pharmacists, and designers!



1. Plan your trip wisely

Applying HF methodologies to product design and development early mitigates use risk and may generate competitive and commercial advantages such as new intellectual property, fewer product complaints, improved product differentiation, increased user preference and motivation.



3. Avoid obstacles

HF concerns can be reason for regulatory action as HF data focuses on demonstrating safe and effective use of the product and its user interface. Integrating HF will help you avoid common issues like these

- A failed or missing HF validation study or a deviated validation test method can lead to regulatory authorities requesting additional HF data by filing, midcycle, or a complete response (CR)
- Clinical trials can be halted if users are not using the products as intended and therefore clouding the safety and efficacy signal.



Ultimately, getting to your destination means conforming to key medical device regulations such as 21 CFR 820.30, Risk Management standards, and regulatory guidance. If you're planning your HF journey and need some help planning your trip, contact us!