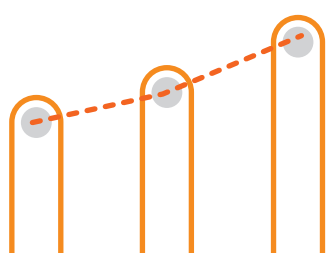


9 Human Factors Activities You Can Do Remotely

How to keep medical device development on track during COVID19



Competitive Landscape

It's important to develop robust user profiles to determine how existing devices on the market are being used, the effectiveness of those devices, and where the competition falls short.

Generative Research

Desk research, online surveys, phone interviews, video tours, and diary studies each provide us with answers to the ultimate generative question: What should our product be?

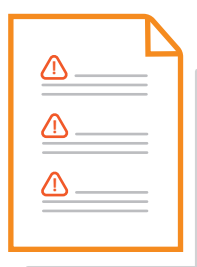


Formative Research

Remote usability testing enables participants to provide feedback from their own homes, while communicating with researchers via readily available technology, such as video conferencing software.

Expert + Heuristic Reviews

Experts can provide actionable insight by reviewing an interface and identifying potential usability issues. Recommendations may come from knowledge of the device domain, human behavior, understanding of cognition, and ergonomic principles.

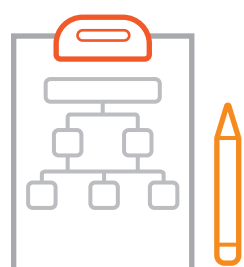
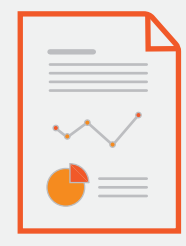


Risk Documentation

Any medical device that needs to claim compliance to IEC62366-1 requires considerate and deliberate use-related risk documentation, all of which can be created remotely.

Usability Engineering Documentation

As HF consultants, we often encounter the misconception that the Summary Report can only be started after a study is complete. On the contrary, we recommend writing most of the report prior to conducting your validation.



Threshold Analyses

The FDA defines three types of threshold analyses when comparing a new product: Labeling comparison, comparative task analysis, and physical comparison of the delivery device.

Gap Analyses

An excellent means of assessing the completeness of the Design History File, gap analyses clarify which research and documentation activities still need to be conducted before submitting to a regulatory body.



HF Team Training

Your company can leverage human factors consultants to develop a training program for internal staff who may be responsible for HF activities in the future.

Source:

<https://www.farmpd.com>

https://www.mpo-mag.com/contents/view_online-exclusives/2020-06-03/human-factors-activities-at-a-safe-distance/