# Digitalisation of HFE in Medical Product Development: Challenges and Opportunities

**Diego Cortez & Erin Davis**

Emergo by UL Solutions

## SUMMARY

This paper presents current challenges of applying human factors engineering (HFE) throughout medical device development, and the opportunity digitalisation creates for innovation in the field. The paper focuses on describing current HFE challenges and examples of how digital tools and software applications can contribute to the work of HF specialists in the medical industry, noting that there is large, unmet need for more HF expertise. Finally, it briefly presents a case study of a software released by Emergo by UL Solutions which aims to address some of these challenges.

## KEYWORDS

Human factors, digitalisation, healthcare

### Content

Presently, there are approximately 600,000 medical devices available on the UK market (Department of Health & Social Care, 2021) with approximately 806 medical manufacturers (Bold Data, 2022). However, there is nowhere near that many HF specialists, even assuming one person per company was sufficient. The Chartered Institute of Ergonomics & Human Factors (CIEHF) lists 513 registered members and fellows, many of which work in multiple industries beyond just the medical industry. Considering the growing demand of rigorous HFE driven by regulators of the biggest medical device markets such as the US, the UK, the EU, and China, there are not enough HFE/medical specialists to meet the industry's needs. The insufficient supply of HFE specialists and the increasing demand for more HFE expertise encourages the development of digital solutions.

Digitalisation could address some of the challenges that medical device manufacturers face when integrating HFE into the development of their products. First, digitalisation can contribute to teaching specialists and non-specialists about basic and, in some cases, more advanced and nuanced aspects of applying HFE to medical technology. Second, digitalisation can provide practitioners with a framework for performing HFE work in a complete and effective manner that will address today's regulatory and commercial imperatives. Third, digitalisation can provide practitioners with productivity tools as well as tools that help them produce innovative and high-quality results, including essential analyses, user interface designs, and evaluations.

Oversimplifying the HFE process in medical devices into three steps (i.e., concept, design, evaluation) for didactic purposes, Table 1 illustrates current HFE challenges and digitalisation opportunities for each step.

Table 1: HFE Challenges and Digitalisation opportunities

| HFE Step | Today's Challenges | Future digital solutions |
|---|---|---|
| Concept | Uncertainty regarding regulatory requirements driving certain types of HFE projects | Digital checklists, tools, and workflows that guide users through key decisions and recommend HFE activities |
| Concept | Finding relevant results in a known problems analysis; reviewing unstructured and inconsistent data | Machine learning and/or artificial intelligence enabled data analysis |
| Design | Lack of special-purpose and convenience tools to assess whether design meets HFE design principles (e.g., text legibility) | Digital calculators that translate HFE principles into actionable design recommendations |
| Evaluation | Drawing upon supporting HFE principles during root cause analysis of use errors and appropriate root cause analysis descriptions | Digital libraries that present easy-to-leverage HFE principles that inform root causes |
| Evaluation | Writing clear and appropriate root cause analysis descriptions | Digital libraries of common root cause analysis descriptions |
| Evaluation | Analysing large, unwieldy data sets arising from large-sample usability tests | Automated data transfer from datasheet to HF validation report tables |
| All | Challenges performing nuanced, intensive HFE tasks (e.g., use-related risk analysis, residual risk analysis) | Digital tools that guide teams through key analyses and enable them to evaluate the quality of HFE deliverables |
| All | Due to lack of awareness of HFE, HFE experts must first convince management on the value of HFE before sufficient resources are allocated to get the work done | Help all stakeholders understand HFE by creating organisation-wide awareness of why and how to perform HFE using e-learning training packages. |

Recognising these challenges, Emergo by UL Solutions embarked in an intensive two-year research and development effort involving dozens of medical product manufacturers and HFE subject matter experts from the US, the UK, The Netherlands, and Japan. Emergo's HFE platform the Optimal Product Usability Suite (OPUS™), matches a trend toward the use of digital tools to facilitate the work of HFE specialists. OPUS addresses common HFE challenges by a) being targeted towards users working in the regulated medical industry to meet regulators' guidance and industry standards (e.g., IEC 62366-1:2015); b) providing self-paced, online training regarding the specifics of applying HFE for medical devices subject to regulatory approval; c) providing helpful tools to support common research and design analyses; and d) ensuring that practitioners have "checked all the boxes" when developing a medical device subject to regulatory approval.

For the most part, digital solutions will not replace human experts. Rather, the solutions will complement and augment the work of experts. As such, human factors experts should explore opportunities to create digital solutions that will enable them to work efficiently and focus their efforts on the most demanding HFE tasks that only a human can perform.

## References

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