Integrating Early User Insights in Complex Drug-Device Combination Product Development

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SUMMARY

This submission explores how applying Human Factors Engineering (HF) methodologies in the form of Early User Insights (EUI), before the well characterised usability engineering process, can improve usability, reduce risk, and support regulatory compliance. Drawing on recent case studies in drug-device combination product (DDCP) development, we will highlight strategies for adapting to increased product complexity by seeking patient insight, embedding early HF work and building internal capability.

KEYWORDS

Drug-device combination products, Usability Engineering process, Early User Insights

Introduction

The complexity of drug-device combination products (DDCPs) is increasing, driven by novel therapy areas, technological advancement and device connectivity. Standard approaches to Human Factors Engineering (HFE) can lead to challenges on critical path to submission activities and accelerated development timelines. This submission examines how adapting HFE processes, by integrating user insights early, characterising user groups and building internal capability, can enable teams to deliver safe, and effective devices without compromising.

Method

A reflective analysis of recent HFE activities for complex DDCP development within multiple global pharmaceutical device development programmes:

- Embedding exploratory studies for user and patient insights at the earliest stages of device kick off
- Early characterisation and identification of user groups, and the translation into active participants for formative HFE studies
- Developing a structured internal capability-building programme, focusing on must-win development areas to widen user access
- How the approach complements existing HFE regulatory frameworks

Results

Key findings from this approach include:

- Early exploratory studies enable rapid identification and mitigation of usability risks, especially in new and evolving therapy areas and technologies
- Internal capability-building reduced reliance on external vendors, improved knowledge retention, and fostered a culture of continuous improvement

- Cross-functional collaboration improved communication, accelerated problem-solving, and ensured that patient needs and voices remained central throughout development

Key Takeaways

- Integrating exploratory HFE methodologies early is essential for adapting to accelerated development timelines in drug-device combination products
- Building internal HFE capability enhances agility, reduces costs, and supports organisational resilience
- Inspiring project team device engineers, clinicians, and regulatory teams through early inclusion and collaboration to ensure HFE value is recognised and requested in future programmes