Performing comparative UI and use-related risk analyses to justify
CDRH-regulated devices’ safety and effectiveness in lieu of HF validation

Introduction

In lieu of HF validation testing, it may be appropriate and acceptable to regulators to perform a detailed comparison of a new or modified device against an existing, marketed device to substantiate the new device’s usability and use-safety. Such comparisons could be leveraged to justify...

1. Why supplemental HF validation testing is not required to validate changes to a device’s user interface after HF validation testing, and
2. Why HF validation testing is not required when a device’s user interface is similar to that of a predicate device (e.g., for a 510k submission)

Comprehensive comparisons should reflect on the intended use, users, and use environment, and closely examine the (1) user interfaces, and (2) use-related risks and critical tasks of the two devices.

About the Tablo Hemodialysis System

Manufactured by Outset Medical, the Tablo® Hemodialysis System (“Tablo”) is an all-in-one, easy-to-learn system indicated for clinic, hospital, and home settings. Tablo includes an onboard water prefiltration system and a touchscreen Graphical User Interface (GUI) with step-by-step instructions to guide the user through system operation.

Tablo’s design resulted from a robust and compliant HFE process from early-stage preliminary analyses through product development and post-market surveillance, including iterative formative evaluations and UI refinements, HF validation testing, and regular monitoring of product and user feedback. Outset Medical has performed comparative analyses throughout Tablo’s development to identify the appropriate scope of HFE work for each round of system design changes.

Sample Comparative Analysis for Tablo

After changing Tablo’s UI, Outset Medical assessed whether any UI changes might impact users’ performance of critical tasks based on the Use-Related Risk Analysis (URRA). Outset Medical concluded that while the UI changes were associated with critical tasks, the updates did not change the system’s risk profile and the pre-existing mitigations remained acceptable (as per prior HF validation testing). Therefore, Outset Medical performed a comparative analysis of the changes, rather than additional HF validation testing. See below for a sample excerpt from the comparative analysis submitted to the FDA.

Tips for Comparative Analyses

- Only include user-facing (versus device-internal) changes
- Link each design modification to a specific issue tracking number
- Be concise, focusing on key changes and associated impacts
- Include illustrations and descriptive captions for each comparison point
- Provide supplemental information to describe complex changes (e.g., detailed screen flows, relevant User Manual excerpts)
- For the Use-Related Risk Analysis (URRA) comparison, focus on new or impacted critical tasks
- In the residual risk analysis commentary, focus on why the risk “remains acceptable” or “remains unchanged”
- Reference HFE data to support use-related risk assessments and final justifications (e.g., from formatives, HF validation, post-market surveillance)
- Integrate UI comparison and use-related risk information to streamline HFE submission content (see example below)

Relevant Regulatory Guidance References

Several HFE and risk management guidance documents reference comparative analyses as a means to assess and understand the impact of UI changes made to an existing medical device, as well as to compare a new device in development to existing, marketed devices.

Examples include:

- US FDA draft guidance from December 2022, Content of Human Factors Information in Medical Device Marketing Submissions, calls for comparing various aspects of a device’s users, use context, user interface, and use-related risks when determining HF data to submit for a new or modified device developed by the same manufacturer.
- ISO 14971:2019 and ISO/TR 24971:2020, Medical devices — Application of risk management to medical devices and the associated technical report, call for a “state of the art” analysis on similar, marketed products and suggest that manufacturers compare the intended use and risk level of a new product in development to that of similar, marketed products.
- China’s National Medical Products Administration (NMPA) draft guidance from 2020, Guidelines of Human Factors Design of Medical Devices (translated), recommends performing comparative analyses to assess design changes and focus HFE efforts on new features between an existing and proposed medical device.