Human Factors / Usability Engineering Activity Plan

A globally aligned process for safer, market-ready medical devices

Purpose: This activity plan provides a structured Human Factors (HF) and Usability Engineering (UE) process that aligns with international regulatory frameworks and integrates seamlessly with your existing risk management and quality systems. It applies throughout product development — from early concepts to market-ready devices — and can be scaled for retrospective documentation, minor modifications, or low-risk products.

IEC 62366-1:2015 AMD 1:2020 (worldwide)	FDA (USA) HFE Guidance 2016	NMPA (China) UE Guidance 2024	MHRA (UK) HFE Guidance Update 2025	ISO 14971:2019 Risk Management Medical Devices	ISO 13485:2016 QMS Design Control

1 Preliminary Analysis & Planning

- **User Research (optional):** Understand the context of use to identify user characteristics, use environments and tasks
- **Use Specification:** Define intended user profiles and use environments in the context of the medical indication
- **HF/UE Plan:** Define scope, methods, timelines and integration with R&D, risk management and design control

Deliverables: Use Specification, HF/UE Plan, User Research Report

ISO 14971 Risk Management
Identifies user profiles and use environments for initial hazard identification

ISO 13485 / Design Control
Feeds into Design Input (user needs, user requirements) and Design Planning

2 Use-Related Risk Analysis

- **Hazard-Related Use Scenarios:** Define the potential use errors in the interaction steps of user with user interface
- **Use-Related Hazards:** Run the identified use errors through Risk Analysis to identify associated potential harm
- **Critical Tasks:** Define all tasks from the use scenarios as critical, which are associated with use errors and serious harm
- **User Interface Specification:** Define and document all risk control measures in the User Interface

Deliverables: Hazard-Related Use Scenarios, Critical Task List, Use-Related Risk Analysis (URRA), User Interface Specification

ISO 14971 Risk Management
Risk Analysis of us errors from the use scenarios to define the associated level of harm.

ISO 13485 / Design Control
Informs Design Input requirements and risk control measures to be verified and validated

3 Formative Evaluation & Risk Control Design

- **Iterative Testing:** Test early prototypes, wireframes and UI concepts with representative users or usability experts
- **Identify Use Problems:** Observe interactions, discover usability issues and potential use errors
- **Design Risk Controls:** Implement UI design improvements in product, training, labelling and instructions for use
- **Refine & Retest:** Iterate design based on user feedback until use-related risks are acceptable

Deliverables: Formative Evaluation Plans and Reports, Design Change Rationale, Updated URRA

ISO 14971 Risk Management
Implement and test risk control measures; evaluate use-related risks also for design changes

ISO 13485 / Design Control
Design Output verification and review; demonstrates design changes are controlled and traceable

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4 Summative Evaluation (Human Factors Validation Testing)

- **Planning UE:** Test tasks and protocols for all selected hazard-related use scenarios and all critical tasks
- **Planning Design Validation:** Acceptance criteria for all user needs to be validated
- **Recruiting and Usability Lab:** Recruit correct number of participants and test in a simulated but realistic setting
- **Reporting:** Demonstrate that all residual use-related risks are acceptable and all user needs are fulfilled

Deliverables: Summative Evaluation Report (Human Factors Validation Report), Design Validation Report

ISO 14971 Risk Management

Validate effectiveness of risk controls; confirm overall residual risk is acceptable

ISO 13485 / Design Control

Design Validation evidence; confirm device meets user needs in intended use environment

5 Documentation & Submission Preparation

- **Usability Engineering File (IEC 62366-1):** Compile all HF/UE records, analyses, test reports and traceability
- **Human Factors/Usability Engineering Report:** Summary document addressing all requirements of intended markets
- **Traceability:** Link user needs → risks → design requirements → risk controls → verification → validation
- **Post-Market Surveillance Plan:** Define ongoing monitoring for use errors and usability complaints

Deliverables: Usability Engineering File, Human Factors/Usability Engineering Report(s), Traceability Matrix

ISO 14971 Risk Management

Use-related risk documentation integrated into overall Risk Management File

ISO 13485 / Design Control

Part of Design History File (DHF) and Technical Documentation for regulatory submission

Scalability → Efficiency for your projects and product developments

- **Retrospective Documentation:** For existing products, focus on Phases 1, 2 and 5 to close documentation gaps
- **Minor Modifications:** Perform impact assessment of the modifications on hazard-related use scenarios and critical tasks and conduct focused activities if necessary - reference existing documentation
- **Low-Risk Products:** Apply a proportionate approach with simplified formative evaluation and reduced sample sizes; summative testing may still be required but can be streamlined
- **High-Risk or Novel Devices:** Full process with extensive formative evaluation cycles, pre-submission consultation with regulators, and robust validation testing

Benkana Interfaces supports you in tailoring this process to your device, risk level and target markets. From compact gap analysis and documentation review to complete HF/UE support with user research, testing and submission-ready reports. Contact us to discuss how we can support your Human Factors and Usability Engineering activities.

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