

Human Factors Engineering / Usability Engineering Deliverables

Deliverable	Description	Output
Human Factors Plan	The Human Factors Plan specifies the planned HF activities and deliverables that will be considered during the project. This plan shall be updated as deliverables are completed.	This Document
Usability Specification/ User Needs	The Usability Specification/User Needs documents the intended medical indication, intended patient population, intended part of the body or type of tissue applied to or interacted with, intended user profile, use environment, and operating principle.	User Needs
Hazard Analysis	The hazard analysis is the system level risk assessment that serves to analyze, estimate, evaluate, control, and evaluate the residual risk acceptability throughout the lifecycle of the product (use, design, manufacture, transport, and disposal).	Hazard Analysis
Risk Analyses	The risk analysis serves to identify and estimate the user interface characteristics that are related to safety, potential use errors, and the hazard related use scenarios. Critical and Non-Critical Use Tasks are defined in the risk analyses (uFMEA).	Use Task Analysis Use FMEA
Usability Requirements	The user interface specification comprises use-related requirements that describe the user interface of the product.	Product Requirements Specification (Usability Requirements)
Formative Evaluation Protocol(s)	This deliverable specifies the methodology to be followed for formative evaluations. It also identifies the acceptance criteria in the form of usability requirements.	Formative Evaluation Protocols
Formative Evaluation Report(s)	This deliverable provides a summary of the evaluations performed. The findings may result in the creation or refinement of requirements, or updates to the risk documents as appropriate.	Formative Evaluation Report
Summative Evaluation Protocol(s)	This deliverable specifies the methodology to be followed for summative usability evaluations, including Human Factors User Interface Design Validation activities. It also identifies the acceptance criteria in the form of usability requirements.	Summative Evaluation Protocol
Summative Evaluation Report(s)	This deliverable provides a summary of the evaluations performed, including Human Factors User Interface Design Validation activities. The findings may result in the creation or refinement of requirements, or updates to the risk documents as appropriate.	Summative Evaluation Report
Human Factors Engineering / Usability Engineering Report	This deliverable provides an overall summary of the human factors program in accordance with FDA Guidance. The report will also serve as final evidence of overall Human Factors validation.	HFE/UE Report