HUMAN FACTORS STUDY PLAN COMPLETED

GLOBAL DRUG DEVELOPMENT

Goal / Definition

Development of a plan for the conduction of Human Factors studies (Formative and Summative) throughout the program

A study conducted with representative users to assess the adequacy of the combination product user interface design to eliminate or mitigate potential use-related hazards.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
• Human Factors Study Plan completed	a) Intended use statement with benefit of medical device reflected, including consideration on training, education, experience, physical condition, and frequency of use b) User Requirements Specification (URS)	▪ Summary report containing key data / information or information to substantiate conclusions ▪ Illustrative data tables or figures may be reported in an appendix