CMC DEVELOPMENT PLAN IN PLACE (CP-ADDS)LG

GLOBAL DRUG DEVELOPMENT

Goals/ Definition

A detailed plan for completing the definition and planning of the combination product FIH stage gate.

CMC development plan updated.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF - DETAIL NEEDED AT EACH GATE
▪ List of activities that will be conducted, that lead to achieving Product Definition and Planning milestone at FIH stage gate	Plans to complete the following bolded items by the next stage gate: • User capabilities and preferences assessment • Ethnographic studies completion • Hazard identification initiation • Concept assessment completion • **Design and development plan initiation** • **Instructions for Use drafts** • **Human Factors Study Plan** • **Application risk assessment completion** • **Design History File initiation** • **Design Input Review completion** • **High-level Project Plan and definition of critical product attributes (if prototype available)** • **Preliminary device prototype generation** • Design Output Review completion • Formative human factors study completion • Design risk assessment completion • Process risk assessment completion • Critical component dimensions and specifications definition • Design and Development Plan updates • Instructions for Use updates • Design History File updates • Engineering testing of prototype and conduct simulated use or clinical testing • Summative human factors study initiated • Design verification execution • Design Verification Review completion • Design validation execution • Design Validation Review completion • Design transfer completion • Design Transfer Review completion • Supply chain / logistics plan completion • Complaint handling process definition • Pharmacovigilance plan completion Completed in PCD stage	▪ A detailed plan to achieve the FIH CMC milestones is expected ▪ Additionally, the plan should identify potential development risks to launch and risk mitigation strategies related to development timeline, costs, and resource allocation

* Items in **bold** font reflect suggested reporting guidelines for this stage gate