CMC DEVELOPMENT PLAN UPDATE (CP/ADDS) (1/2)

GLOBAL DRUG DEVELOPMENT

Goals/ Definition

A detailed plan for completing design verification and validation of the combination product at EP2 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 EP2 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 initiated • 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	▪ 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

CMC DEVELOPMENT PLAN UPDATE (CP/ADDS) (2/2)

GLOBAL DRUG DEVELOPMENT

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
• Process risk assessment initiated	a) Critical molding and assembly process parameters b) Identification of CMOs and assessment of impact on manufacturing costs and COGS c) Creation of manufacturing flow diagram and assess product demand to verify COGS based on projected demand forecast	a) Summary report containing key data / information to substantiate conclusions b) Illustrative data tables or figures may be reported in an appendix
• Critical component dimensions and specifications defined	a) Initiation of stability studies development b) Initiation of development packaging and labeling processes c) Transportation studies to determine if there are potential interactions between drug and device during transportation that would impact the performance/efficacy of the functioning of the device as well as the safety and efficacy of the drug action d) Verification and Validation Plans	
• Instructions for Use updated	a) Updated Instructions for Use as data/information becomes available at the appropriate points in the development stage	a) Summary report containing key data / information to substantiate conclusions b) Illustrative data tables or figures may be reported in an appendix
• Engineering testing of prototype and conduct simulated use or clinical testing	a) Completion of prototype for Summative Human Factors Studies	

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