

Goals/ Definition

A detailed plan for completing Post-Launch Surveillance Plan for the combination product at PQ/LR gate.
CMC development plan updated.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
<ul style="list-style-type: none"> ▪ List of activities that will be conducted, that lead to achieving Product Definition and Planning milestone at PQ/LR stage gate 	<p>Plans to complete the following bolded items by the next stage gate:</p> <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> ▪ 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