CMC DEVELOPMENT PLAN IN PLACE (DRUGS)

GLOBAL DRUG DEVELOPMENT

Goals/ Definition

A Detailed plan to complete initial substance (DS) and drug product (DP) characterization, and define the initial cGMP manufacturing process.

CMC development plan initiated.

(The CMC Development Plan is initiated during discovery and preclinical development and is expected to be in place by the PCD stage gate)

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
▪ List of activities that will be conducted, that lead to achieving the "Initial DS/DP Characterization" milestone at FIH stage gate	• **Complete initial drug product characterization** • **Define cGMP manufacturing process** • **Complete GMP manufacturing for Ph 1** • Finalize DS characterization & analytical method development • Manufacture DS at kilo-scale • Complete DP characterization • Complete DP package characterization • Manufacture DP to support the Phase 2 clinical trial • Manufacturing process optimization • GMP manufacturing for Ph 3 • Readiness for Tech Transfer • Technology transfer and validation of raw material, drug substance, and drug product analytical and functional release testing • Technology transfer and validation of drug substance & drug product manufacturing and packaging processes • Qualification of commercial-scale facilities • Commercial launch strategy • QA/compliance activities • Ongoing CMC Support to ensure uninterrupted supply of high quality DP in all markets	▪ A detailed plan to achieve the FIH CMC milestones is expected ▪ Additionally, the Plan should identify potential development risks to PQ, and risk mitigation strategies related to development timeline, costs and resource allocation

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