CMC DEVELOPMENT PLAN UPDATED (DRUGS)

GLOBAL DRUG DEVELOPMENT

Goals/ Definitions

A detailed plan to address post-launch support – including technical issues during manufacturing and ongoing interactions with regulatory authorities.

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 the "Full-Scale Post-Launch Manufacturing Strategy In Place" milestone at DTF 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 DTF 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