# CMC DEVELOPMENT PLAN UPDATED (DRUGS)

GLOBAL DRUG DEVELOPMENT

**Goals/ Definition**

**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 Updated" milestone at PQ/LR stage gate | • Complete initial drug product characterization<br>• Define cGMP manufacturing process<br>• Complete GMP manufacturing for Ph 1<br>• Finalize DS characterization & analytical method development<br>• Manufacture DS at kilo-scale<br>• Complete DP characterization<br>• Complete DP package characterization<br>• Manufacture DP to support the Phase 2 clinical trial<br>• Complete manufacturing process optimization<br>• Complete GMP manufacturing for Ph 3<br>• Readiness for Tech Transfer<br>• Complete technology transfer and validation of raw material, drug substance, and drug product analytical and functional release testing<br>• Complete technology transfer and validation of drug substance & drug product manufacturing and packaging processes<br>• Qualification of commercial-scale facilities<br>• **Commercial launch strategy**<br>• **QA/compliance activities**<br>• **Ongoing CMC Support to ensure uninterrupted supply of high quality DP in all markets** | ▪ A detailed plan to achieve the PQ/LR CMC milestones is expected<br>▪ Additionally, the Plan should identify potential development risks and risk mitigation strategies related to development timeline, costs and resource allocation<br>▪ CMC Development Plan should be final at the DTF gate review |

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