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.

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>SAMPLE CONTENT REQUIREMENT</th>
<th>GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE</th>
</tr>
</thead>
</table>
| ▪ 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  
▪ 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  
▪ Complete manufacturing process optimization  
▪ Complete GMP manufacturing for Ph 3  
▪ Readiness for Tech Transfer  
▪ Complete technology transfer and validation of raw material, drug substance, and drug product analytical and functional release testing  
▪ Complete 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 PQ/LR CMC milestones is expected  
▪ Additionally, the Plan should identify potential development risks and risk mitigation strategies related to development timeline, costs and resource allocation  
▪ CMC Development Plan should be final at the DTF gate review |

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