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 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