Goals / Definition

To describe a detailed plan to complete process optimization considering feasibility for full-scale manufacturing, including a plan to assess tech transfer readiness to commercial scale manufacturing.

cGMP DS manufactured at kilo-scale and scale-up processes defined.

<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 DS/DP Manufacturing Process Optimized” and “Tech Transfer and Validation Plan In Place” milestones at EP2 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 CMC plan to achieve the EP2 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