

### 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.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
<ul style="list-style-type: none"> <li>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</li> </ul>	<ul style="list-style-type: none"> <li>Complete initial drug product characterization</li> <li>Define cGMP manufacturing process</li> <li>Complete GMP manufacturing for Ph 1</li> <li>Finalize DS characterization &amp; analytical method development</li> <li>Manufacture DS at kilo-scale</li> <li>Complete DP characterization</li> <li>Complete DP package characterization</li> <li>Manufacture DP to support the Phase 2 clinical trial</li> <li><b>Manufacturing process optimization</b></li> <li><b>GMP manufacturing for Ph 3</b></li> <li><b>Readiness for Tech Transfer</b></li> <li><b>Technology transfer and validation of raw material, drug substance, and drug product analytical and functional release testing</b></li> <li><b>Technology transfer and validation of drug substance &amp; drug product manufacturing and packaging processes</b></li> <li><b>Qualification of commercial-scale facilities</b></li> <li>Commercial launch strategy</li> <li>QA/compliance activities</li> <li>Ongoing CMC Support to ensure uninterrupted supply of high quality DP in all markets</li> </ul>	<ul style="list-style-type: none"> <li>A detailed CMC plan to achieve the EP2 CMC milestones is expected</li> <li>Additionally, the Plan should identify potential development risks to PQ, and risk mitigation strategies related to development timeline, costs and resource allocation</li> </ul>

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