

Goals/ Definition

Development of a strategy to assess operational readiness for full-scale manufacturing launch, including a plan to engage internal CMC experts that have long-term experience with specifics of product and process development with commercial partners.

Operational readiness for full-scale manufacturing.

(*Full-Scale Post-Launch Manufacturing Strategy is initiated prior to the DTF gate review and is updated & reviewed again at PQ/LR gate review.)

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
Commercial launch strategy	<ul style="list-style-type: none"> a) Product expiry date proposal/strategy for regulatory submission b) Commercial launch strategy for each country market c) Finished product Warehouse qualified and operational d) Shipping validation complete 	<ul style="list-style-type: none"> ▪ Summary report
Quality Assurance/Compliance activities	<ul style="list-style-type: none"> a) Product registration b) Facility audit reports c) Audit observation compliance (CAPA, if required) d) Pre-approval inspection strategy, clear roles and responsibilities of partner and CRO/CMO 	<ul style="list-style-type: none"> ▪ Summary report
Plan for ongoing CMC Support to ensure uninterrupted supply of high quality DP in all markets	<ul style="list-style-type: none"> a) Establishment of bio-equivalence as appropriate (if the clinical development form and commercial form are not the same) b) Regular meetings with CMOs to monitor supply chain, review of quality incidents c) Ensure corrective actions such as improvements in systems/procedures, staff training d) Ensure timely support of technical support for manufacturing problems e) Evaluate process deviations/excursions during manufacturing that might affect quality f) Scientific evaluation of commercial product stability reports/problems g) Monitor and address changes in raw materials that affect manufacturing/product quality h) Timely submissions of periodic regulatory reports and regulatory agency interactions i) Assess impact of changes in Strategic Demand Forecast, determine whether alternate/additional manufacturing site or additional raw materials suppliers needed 	<ul style="list-style-type: none"> ▪ Summary report