

FULL-SCALE POST-LAUNCH MANUFACTURING STRATEGY UPDATED

Goals/ Definition

An updated strategy to address operational readiness for full-scale manufacturing launch, as more information around identification commercial partners, launch markets and manufacturing scale based on strategic demand forecasts becomes available

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) Regular meetings with CMOs to monitor supply chain, review of quality incidents b) Ensure corrective actions such as improvements in systems/procedures, staff training c) Ensure timely support of technical support for manufacturing problems d) Evaluate process deviations/excursions during manufacturing that might affect quality e) Scientific evaluation of commercial product stability reports/problems f) Monitor and address changes in raw materials that affect manufacturing/product quality g) Timely submissions of periodic regulatory reports and regulatory agency interactions h) 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"> ▪ High level plan

Prior to PQ/LR stage gate, in collaboration with Regulatory, Compliance and other project team members, commercialization partner CMC will prepare a strategy for interactions with regulatory authorities related to regulatory review of registration documents and commercial manufacturing sites. CMC will update, as required, post-launch CMC support strategy

*Candidate progression is discussed at standing grantee update meetings with the investment team