TECH TRANSFER (DS, ANALYTICAL, DP & PACKAGING), VALIDATION COMPLETED (2/2)

GLOBAL DRUG DEVELOPMENT

Goals/ Definition

Completion of launch-related transition of manufacturing processes to full-scale/ commercial facilities to ensure uninterrupted supply of high quality product upon regulatory approval.

Drug manufacturing process technology transferred and validated.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
Qualification of commercial-scale facilities completed	a) Site master plan (e.g., facility design, maintenance, equipment, calibration schedule, staff training, etc.) b) cGMP certification c) Audits by FDA/NRAs and client d) Commercial-scale batch records e) Change control strategy f) Notice of Event/Deviation reporting mechanism g) Action plan for response to regulatory authority inspections, audits, questions/interactions	▪ Summary report
Documentation and Reports	a) On-going stability program b) Stability reports c) Process Qualification reports d) Master batch record for commercial manufacturing finalized e) Vendor qualification reports f) SOPs for commercial manufacturing, testing, storage and distribution g) Stability in DS and DP primary containers h) Labeling study report i) Shipping stability study report	▪ Summary report