TECH TRANSFER (DS, ANALYTICAL, DP & PACKAGING), VALIDATION COMPLETED (1/2)

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
▪ Technology transfer and validation of raw material, drug substance, and drug product analytical and functional release testing completed	a) SOP-driven tech transfer and validation protocols b) Validation package including, at a minimum, the following data for each method used for analytical and functional release testing (in line/at line/off line): • Specificity • Sensitivity • Variability/reproducibility	▪ Summary report
▪ Technology transfer and validation of drug substance & drug product manufacturing and packaging processes completed	a) SOP-driven tech transfer and validation protocols b) Overview of manufacturing process, siting, equipment, quality control tools, etc. c) Safety and ecological assessment of drug substance and drug product manufacturing processes d) Validation package including, at a minimum: • Batch campaign summary • Final operating conditions • Control strategy for on-going production e) Three validation batches on stability	▪ Summary report

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

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

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