CMOs-CROs SELECTED (1/2)

GLOBAL DRUG DEVELOPMENT

Goals/ Definition

Rationale and justification for selection of drug development partners.

Drug development service providers engaged and qualified
(*Partner Selection may be completed prior to either the PCD or FIH gate reviews, depending on specific product requirements)

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
▪ Contract research partners (to facilitate / enable preclinical process development) engaged and qualified	a) Scope of work required (e.g., functional activities, process & method development, etc.) b) Partner engagement strategy (e.g., outsourced activity, insourced activity, consultation, etc.) c) cGLP certification d) Audits by FDA / NRAs and client e) Confirmation of capabilities, equipment, equipment qualification & process/method validation packages, staff training, SOPs, etc. f) Previous experience with partner (e.g., successes & failures) g) Preliminary cost information h) Lead times / time in the queue i) Contract terms and long-term contingencies	▪ Summary of key data and rationale to support partner selection ▪ Additional detail may be reported in an appendix

CMOs-CROs SELECTED (2/2)

GLOBAL DRUG DEVELOPMENT

Goals/ Definition

Rationale and justification for selection of drug development partners.

Drug development service providers engaged and qualified
(*Partner Selection may be completed prior to either the PCD or FIH gate reviews, depending on specific product requirements)

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
▪ Contract manufacturing partners (to facilitate / enable clinical supply) engaged and qualified *** CMC experts should be engaged to assess partners for drug substance, drug product manufacturing and analytical services**	a) Scope of work required (e.g., functional activities, process & method development, etc.) b) Partner engagement strategy (e.g., outsourced activity, insourced activity, consultation, etc.) c) cGMP certification d) Audits by FDA / NRAs and client e) Confirmation of capabilities, capacity, quality control systems, equipment, equipment qualification & process/method validation packages, staff training, SOPs, etc. f) Previous experience with partner (e.g., successes & failures) g) Preliminary cost information h) Lead times / time in the queue i) Contract terms and long-term contingencies	▪ Summary of key data and rationale to support partner selection ▪ Additional detail may be reported in an appendix
▪ Support service partners (e.g., to enable initial regulatory requirements, file patents, provide legal counsel, etc.) engaged and qualified	a) Scope of work required (e.g., IND preparation, patent creation, legal counsel, etc.) b) Partner engagement strategy (e.g., outsourced activity, insourced activity, consultation, etc.) c) Confirmation of capabilities & services d) Previous experience with partner (e.g., successes & failures) e) Preliminary cost information f) Lead times / time in the queue	▪ Summary of key data and rationale to support partner selection ▪ Additional detail may be reported in an appendix