IND Submission Process: Clinical Hold Risk

	Discovery & Planning	IND Submission	FDA	IND Lifecycle Management	R&D
Non-Clinical Consulting	■ Toxicology ■ Animal/ in-vitro pharmacology ■ Excipient, metabolite, impurity evaluations				■ Expanded non-clinical and clinical program integration
Regulatory Consulting	■ Gap analysis ■ Development strategy ■ Early phase clinical development plan ■ Regulatory risk assessment ■ Pre-IND FDA consultation ■ Strategic multi-discipline regulatory affairs ■ QMS assessment ■ Compliance ■ Qualification audits ■ Target product profile ■ Communication and publication strategies ■ Agency liaison ■ IND preparation ■ Medical writing	FDA Review 30 Days **Clinical Hold Risk**	Quality process changes and improvements based on FDA guidance	■ Regulatory operations	■ Orphan drug, breakthrough, and fast-track applications ■ NDA/BLA
CMC Consulting	■ Technical support ■ Process development ■ CDMO assessment ■ CMC assessment ■ GMP compliance ■ Strategic regulatory affairs ■ CMC vendor project management				■ QA/QC
Clinical Research and Development	■ Product development plan ■ Clinical development plan ■ Clinical pharmacology ■ Clinical trial medical monitoring ■ Clinical supply logistics				■ Study design ■ Process development ■ Clinical operations ■ Phase 1-4 clinical studies ■ Pilot and pivotal device studies