DILIGENT® QUALIFICATION PLATFORM

RFI QUESTIONNAIRE FOR VENDOR QUALIFICATION

Diligent's top 20 question categories with sample questions to evaluate service or technology providers for clinical trials

The categories and example questions below are taken from the Diligent Core RFI questionnaire. The full questionnaire contains over 400 questions.
Every service and technology vendor on the Diligent Qualification Platform provides answers to these questions so they are ready for use by clinical trial sponsors that subscribe to the Platform.

CATEGORY	SAMPLE QUESTION
Regulatory Knowledge	Does the business ensure compliance with all established local, state, regional, national and international regulations and guidelines, and maintain awareness of the impacts of regulatory differences across regions?
Document Management	Does the business have processes for reviewing and maintaining all SOPs and processes on a regular basis to ensure that they are kept up to date and reflect corporate changes, lessons learned, and changes in regulations and industry standards?
Document Archival	Does the business have a documented process for document retrieval management from archives?
Safety Event Reporting	Does the business have a SOP to promptly communicate any potential safety event (e.g. AE, SAE, SUSAR) to the Sponsor or Sponsor-designated recipient (e.g., CRO)?
Financial Accounting & Stability	How does your organization segregate client cash advance funds to protect those funds from being consumed for unrelated activities?
Insurance	Does the business have a cyber insurance policy, also referred to as cyber risk insurance or cyber liability insurance coverage (CLIC), which is designed to help an organization mitigate risk exposure by offsetting costs involved with recovery after a cyber-related security breach or similar event?
Ethics, Anti-Corruption, Anti-Bribery	Does the business have a policy and documented practices to ensure compliance with ABAC laws, and does it monitor and audit the activities of its employees and disbursement and expense records to ensure compliance?
The Patient Protection and Affordable Care Act	Does the business have a program that ensures compliance with global regulatory requirements to track and report all transfers of payment or value to Healthcare Providers (HCPs) and government officials?

CATEGORY	SAMPLE QUESTION
Privacy	Does the business have a documented process for conducting Privacy Impact Assessments or documentation explaining why they are not applicable to their organization?
Personal Data Protection	Does the business train all individuals who have access to personal data on the policy and/or practices that ensure confidentiality, protection, and security of personal data?
Facility Requirements	Does the business have temperature controls and an appropriate industry-standard ventilation system?
Business Continuity/Recovery	Does the business have a Business Continuity/Recovery Plan that is reviewed and tested annually, with the results documented?
Human Resources	Is the business compliant with all global, regional, national, and local labor/worker rights laws based on core principles such as dignity, fairness, equality, respect, and autonomy?
Training	Does the business ensure that all staff have a role-based, clearly defined, and periodically reviewed training curriculum, including GxP and all currently applicable regulations and data integrity principles and responsibilities that apply to the work performed, including ICH GCP E6 (R2) Section 5.0, where applicable?
Quality Management System	Does the business have a Quality Management System (QMS) that operationalizes quality policies into well-structured activities that facilitate common understanding and consistent application?
Risk Management	Does the business have a SOP describing the process, standards, documentation requirements, and responsibilities for continual/ periodic review of the risk assessments/ evaluations (e.g., when new information, protocol amendments, new data are available, or serious breaches occur)?
Vendor Oversight	Does the business maintain a list of approved third-party Providers of external services and materials, including qualification/ requalification history and status?
Computer System Validation & Maintenance	For all GxP systems, does documentation describe system ownership and responsibilities, validation, maintenance, security, and administration?
Data Management	When the business manages or transfers data, does it prepare a Data Management Plan specific to each project?
Data Integrity	Does the business define data integrity requirements in the database system and validation specifications, including requirements for data and audit trail review processes, data retention, and technical controls to prevent unauthorized changes to the system configuration settings?