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| **Contract Service Provider Questionnaire** | |
| **Service Provider Name** |  |
| **Service Provider Address** |  |
| **Service Provider Contact Name and Title** |  |
| **Service Provider Contact Telephone Number** |  |
| **Service Provider Contact E-mail** |  |
| **Service Provider Contact Signature/Date** |  |

| **Quality Assessment Inquiry** | **Response** | **Comments** |
| --- | --- | --- |
| **General Company Information** | | |
| Describe your company’s general service offerings. | Yes No  N/A  See Attached |  |
| What products or services are or would you be providing to LEXEO? | Yes No  N/A  See Attached |  |
| How many years has your company been in business? | Yes No  N/A  See Attached |  |
| Describe any changes in corporate structure in the last five years (e.g., mergers, acquisitions, Initial Public Offering (IPO)) | Yes No  N/A  See Attached |  |
| Describe any planned/announced changes in corporate structure. | Yes No  N/A  See Attached |  |
| Please provide the worldwide number of personnel, including contractors/consultants. | Yes No  N/A  See Attached |  |
| Please provide the number of employees, contractors, and consultants in the United States. | Yes No  N/A  See Attached |  |
| Please provide the number of employees, contractors, and consultants in the European Union. | Yes No  N/A  See Attached |  |
| What percentage of your workforce is temporary, contract or consultant? | Yes No  N/A  See Attached |  |
| Please provide a company organization chart that includes the reporting structure for your Quality Department. | Yes No  N/A  See Attached |  |
| What is the rate of employee turnover within the last five years? Which functional area has the highest turnover rate? | Yes No  N/A  See Attached |  |
| Is your company part of a larger group of companies? | Yes No  N/A  See Attached |  |
| Is your company, parent company(ies), or subsidiaries headquartered outside of the United States? If so, please specify. | Yes No  N/A  See Attached |  |
| Does your company maintain any licensures or accreditations (e.g., ISO, CAP, CLIA)? If so, please specify, along with expiration date. | Yes No  N/A  See Attached |  |
| Have any regulatory agencies inspected your company in the past 5 years? If yes, please attach relevant documentation. | Yes No  N/A  See Attached |  |
| **Quality Assurance** | | |
| Describe the structure, staffing and responsibilities of your Quality Department. | Yes No  N/A  See Attached |  |
| Name, Title, and contact information of Quality Department Head | Yes No  N/A  See Attached |  |
| What is the lead time for an onsite or remote audit? | Yes No  N/A  See Attached |  |
| Are written and signed job descriptions available for all roles with GXP responsibilities? | Yes No  N/A  See Attached |  |
| Are documented training and qualification requirements available for all GXP roles? | Yes No  N/A  See Attached |  |
| Please provide the procedure for new employee onboarding. | Yes No  N/A  See Attached |  |
| Are background and debarment checks performed for new employees? | Yes No  N/A  See Attached |  |
| What GXP and regulatory requirements (e.g., 21 CFR 312) are employees required to be trained on? At what frequency is refresher training required? | Yes No  N/A  See Attached |  |
| Are company personnel specifically trained to ALCOA++ principles for GXP data? | Yes No  N/A  See Attached |  |
| Please provide the Quality Policy, Quality Manual, and a list of Standard Operating Procedures (SOPs). | Yes No  N/A  See Attached |  |
| Please describe your company’s Risk Management program. | Yes No  N/A  See Attached |  |
| If the Quality Management System (QMS) is electronic, please provide the system name, version, and evidence of the most recent validation. | Yes No  N/A  See Attached |  |
| Please provide the procedure for managing QMS documents such as SOPs and Work Instructions (WIs). | Yes No  N/A  See Attached |  |
| Please provide the procedure(s) for conducting internal and external audits and provide the annual audit plans for the last two years. | Yes No  N/A  See Attached |  |
| At what frequency does your company conduct Quality Management Review? Please provide evidence of the last three Quality Management Reviews. | Yes No  N/A  See Attached |  |
| Please provide your company’s Quality Issue/Deviation/Corrective and Preventive Action (CAPA)/Customer Complaint/Data Integrity/Serious Breach procedure(s). | Yes No  N/A  See Attached |  |
| Does your company’s standard contractual language include reference to Serious Breach and General Data Protection Regulation (GDPR)? | Yes No  N/A  See Attached |  |
| Does your company’s standard contractual language include regulatory compliance language (e.g., GCP, 21 CFR 11)? | Yes No  N/A  See Attached |  |
| Describe your process for selecting, qualifying, and managing vendors. | Yes No  N/A  See Attached |  |
| Please attach audit certificates for any vendors that will be used for LEXEO activities. | Yes No  N/A  See Attached |  |
| Does your company maintain an approved vendors list for vendors with GXP impact? | Yes No  N/A  See Attached |  |
| **Records Management and Archive** | | |
| How does your company archive GXP records and information? | Yes No  N/A  See Attached |  |
| Please describe the retention period for all GXP records and describe the process and required approvals for record destruction. | Yes No  N/A  See Attached |  |
| Does your company have a written procedure for certified copies? | Yes No  N/A  See Attached |  |
| Does your company retain paper copies of GXP records? If yes, please provide details/specifications/floor plans of the archive space, including physical security, fire suppression, protection from water damage and natural disasters. | Yes No  N/A  See Attached |  |
| Who will be responsible for maintenance of LEXEO project documents? | Yes No  N/A  See Attached |  |
| How will LEXEO project documents be transferred to LEXEO at the conclusion of the project? Please describe all Quality Control (QC) steps that are required prior to transfer. | Yes No  N/A  See Attached |  |
| Per SOP, who will approve data and reports provided to LEXEO? | Yes No  N/A  See Attached |  |
| **Trial Master File (TMF)** | | |
| Does your organization provide or host a Trial Master File (TMF) for clinical studies? What system and what version is in use? | Yes No  N/A  See Attached |  |
| Is the TMF validated? Please provide evidence. | Yes No  N/A  See Attached |  |
| Does the system follow the structure of the [TMF reference](https://tmfrefmodel.com/) model? | Yes No  N/A  See Attached |  |
| Are sponsor personnel permitted to access the TMF? Please describe the process. | Yes No  N/A  See Attached |  |
| Is the TMF metadata included in the transfer of the TMF to LEXEO at the end of the study? Please describe the transfer process. | Yes No  N/A  See Attached |  |
| Does the LEXEO TMF undergo ongoing Quality Control? Please describe. | Yes No  N/A  See Attached |  |
| Does the TMF uses validated signatures? | Yes No  N/A  See Attached |  |
| Does your organization incorporate third party vendor documents into the TMF? Please describe the process and QC measures. | Yes No  N/A  See Attached |  |
| Are there any documents that your organization considers to be “Non-TMF” documents? If yes, please describe what they are and how they are managed. | Yes No  N/A  See Attached |  |
| Are regulatory inspectors permitted access to the TMF? If so, please describe the process. | Yes No  N/A  See Attached |  |
| **Business Continuity/Disaster Recovery** | | |
| Does your organization maintain business continuity/disaster recovery plans? | Yes No  N/A  See Attached |  |
| At what frequency are these plans tested? Are tests performed desktop only? Please attach the last three tests. | Yes No  N/A  See Attached |  |
| Describe physical security for your facility, including frequency of user access review. | Yes No  N/A  See Attached |  |
| Do you have a pest control vendor? What is the frequency of checks? | Yes No  N/A  See Attached |  |
| Does your facility have access to backup power in the event of a power outage? For how many days? | Yes No  N/A  See Attached |  |
| What percentage of employees are in office versus remote? | Yes No  N/A  See Attached |  |
| **Information Technology** | | |
| Are logical security controls in place for electronic systems? Please describe. | Yes No  N/A  See Attached |  |
| How often are user access reviews conducted for company electronic systems? | Yes No  N/A  See Attached |  |
| Please provide the Recovery Time Objective (RTO) and Recovery Point Objective (RPO) for any electronic systems that will apply to the LEXEO project. | Yes No  N/A  See Attached |  |
| Has your company certified to FDA per 21 CFR 11.100 that electronic signatures are in use? | Yes No  N/A  See Attached |  |
| What system(s) does your company use for electronic signatures? How was it validated? | Yes No  N/A  See Attached |  |
| Is multifactor authentication (MFA) required to access company systems? | Yes No  N/A  See Attached |  |
| How frequently are password changes forced? | Yes No  N/A  See Attached |  |
| Does your company maintain a list of electronic systems with GXP impact? How often are systems reviewed? | Yes No  N/A  See Attached |  |
| What systems would house LEXEO data and information? | Yes No  N/A  See Attached |  |
| In what geographies (e.g., EU, USA) will LEXEO data be stored? | Yes No  N/A  See Attached |  |
| Does your company develop and validate computerized systems? What SOPs support this activity? | Yes No  N/A  See Attached |  |
| Describe how your company assesses and implements commercial off-the-shelf (COTS) software. | Yes No  N/A  See Attached |  |
| Are audit trails available for all GXP systems? Does your firm have procedures for review of audit trails based on system and data risk? | Yes No  N/A  See Attached |  |
| Does your company use GAMP 5Ò classification for electronic systems? | Yes No  N/A  See Attached |  |
| How are software issues reported by clinical sites or sponsors like LEXEO handled? | Yes No  N/A  See Attached |  |
| How long are help desk tickets retained for? | Yes No  N/A  See Attached |  |
| Does your company use any open-source software? If so, how is this managed and what procedures are in place? | Yes No  N/A  See Attached |  |
| Describe the process used for major and minor software release planning, testing and implementation. | Yes No  N/A  See Attached |  |
| Describe your company’s process for managing system downtime during patches or upgrades. | Yes No  N/A  See Attached |  |
| Describe the process for user training on software. | Yes No  N/A  See Attached |  |
| Are sponsors and regulatory authority inspectors able to access software validation information? | Yes No  N/A  See Attached |  |
| **Privacy/Confidentiality** | | |
| Does your company have a Data Privacy Officer? | Yes No  N/A  See Attached |  |
| Does your company have a Privacy Policy or SOP? | Yes No  N/A  See Attached |  |
| Does your company have assessment and reporting procedures for privacy or confidentiality breaches? | Yes No  N/A  See Attached |  |
| Does your company have procedures in place to segregate and protect unblinded trial data for blinded trials? Please describe. | Yes No  N/A  See Attached |  |
| Does your company have procedures in the event a trial participant withdraws consent? | Yes No  N/A  See Attached |  |
| **Laboratory Services** | | |
| Does your company maintain, control, and periodically update laboratory reference ranges? | Yes No  N/A  See Attached |  |
| Does your company maintain medical oversight and prompt reporting of critical lab values? | Yes No  N/A  See Attached |  |
| Does your company use validated shippers for shipment of laboratory samples? | Yes No  N/A  See Attached |  |
| Are your personnel trained to laboratory safety, Environmental Health and Safety and IATA standards? | Yes No  N/A  See Attached |  |
| Please provide a facility map/floorplan. | Yes No  N/A  See Attached |  |
| Please describe temperature/environmental monitoring controls in your facility. | Yes No  N/A  See Attached |  |
| Please describe equipment calibration, validation, and preventive maintenance procedures. | Yes No  N/A  See Attached |  |
| Please describe reagent purchase, formulation, QC, and management. | Yes No  N/A  See Attached |  |
| Please describe calibration standard management. | Yes No  N/A  See Attached |  |
| Please describe procedures for sample management and archive, including ongoing reconciliation with the clinical database. | Yes No  N/A  See Attached |  |
| Please describe method validation procedures, including accuracy, linearity, precision, specificity, limit of quantitation, etc. | Yes No  N/A  See Attached |  |
| **Phase I Unit services** | |  |
| Describe procedures for trial participant recruitment, including verification of identity and washout from other trials. | Yes No  N/A  See Attached |  |
| Describe consent procedures. | Yes No  N/A  See Attached |  |
| Describe arrangement for emergency care. | Yes No  N/A  See Attached |  |
| Describe medical oversight. | Yes No  N/A  See Attached |  |
| Describe “house rules” for any in-house portion of a clinical study. | Yes No  N/A  See Attached |  |
| Describe onsite laboratory capabilities and sample management/shipping process. | Yes No  N/A  See Attached |  |
| Describe pharmacy capabilities, including radioactive substances and compounding capabilities. | Yes No  N/A  See Attached |  |
| Describe your company’s participation in protocol development and clinical study report writing for sponsors. | Yes No  N/A  See Attached |  |
| What electronic data collection tools are used? Are they validated? | Yes No  N/A  See Attached |  |
| **Safety Oversight** | | |
| Describe the qualifications of personnel reviewing, handling, and assessing adverse events (AEs) and Serious Adverse Events (SAEs). | Yes No  N/A  See Attached |  |
| How are SAEs tracked and reconciled? | Yes No  N/A  See Attached |  |
| What metrics are reported to LEXEO regarding compliance with SAE reporting? | Yes No  N/A  See Attached |  |
| Describe the process for safety signal detection. | Yes No  N/A  See Attached |  |
| Describe the responsibilities and process for medical monitoring. | Yes No  N/A  See Attached |  |
| Identify the system used for safety case management and provide evidence of validation. | Yes No  N/A  See Attached |  |
| **Project Management** | | |
| Describe meeting frequency and topics with LEXEO. | Yes No  N/A  See Attached |  |
| What time zone is the LEXEO Project Manager (PM) located in? | Yes No  N/A  See Attached |  |
| Describe the study plans that will be developed for the LEXEO project. | Yes No  N/A  See Attached |  |
| How are project decisions and communications archived? | Yes No  N/A  See Attached |  |
| How is project specific training identified, assigned, managed, and archived? | Yes No  N/A  See Attached |  |
| Describe the management of applicable external committees (e.g., safety review, dose escalation, Data Safety Monitoring Board, Blinded Independent Review Committee) | Yes No  N/A  See Attached |  |
| **Monitoring** | | |
| Describe your processes for onsite, remote, risk-based, and centralized monitoring. | Yes No  N/A  See Attached |  |
| Describe minimum monitor educational and training experience. | Yes No  N/A  See Attached |  |
| Describe monitoring onboarding and on the job training. | Yes No  N/A  See Attached |  |
| Describe escalation pathways and strategies for noncompliant sites and protocol deviations. | Yes No  N/A  See Attached |  |
| Describe how monitors confirm investigators have reviewed safety reports and submitted them to the applicable ethics committee. | Yes No  N/A  See Attached |  |
| **Data Management** | | |
| Describe the Electronic Data Capture (EDC) system and provide evidence of validation. | Yes No  N/A  See Attached |  |
| Describe the management of coding dictionaries. | Yes No  N/A  See Attached |  |
| Describe data transfer processes and controls (incoming and outgoing). | Yes No  N/A  See Attached |  |
| Describe procedures and controls for database lock/unlock. | Yes No  N/A  See Attached |  |
| **Statistical Analysis and Programming** | | |
| Describe version of statistical analysis programs used and describe validation. | Yes No  N/A  See Attached |  |
| Describe QC procedures for programs | Yes No  N/A  See Attached |  |
| Describe management and delivery of datasets. | Yes No  N/A  See Attached |  |
| Describe procedures for development, review and approval of the Statistical Analysis Plan and outputs. | Yes No  N/A  See Attached |  |
| **Medical Writing** | | |
| Describe templates used. | Yes No  N/A  See Attached |  |
| Describe version control. | Yes No  N/A  See Attached |  |
| Describe review and approval requirements. | Yes No  N/A  See Attached |  |
| **Regulatory** | | |
| Does your organization provide regulatory strategy or operations services? | Yes No  N/A  See Attached |  |
| What countries does your organization have expertise in? | Yes No  N/A  See Attached |  |
| Describe procedures used for CTIS and ClinicalTrials.gov | Yes No  N/A  See Attached |  |
| Does your organization provide regulatory publishing or is this outsourced? | Yes No  N/A  See Attached |  |

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| Completed By: |  |  |  |  |  |
| *Service Provider Representative* | Name |  | Title |  | Date |