**LAB QUALITY QUESTIONNAIRE**

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| **ORGANISATION/LABORATORY DETAILS** |
| |  |  | | --- | --- | | Name: |  | | Address: |  | | Web Address:  *(if applicable)* |  | | Contact Person: *(Job Title)* |  | | Telephone No: |  | | Email: |  | |

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| **LABORATORY WORK/SERVICES COVERED** |
| *[Please state nature and purpose of laboratory work conducted as part of the trial, including production of data that is used to assess primary/secondary objectives]* |

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| There is a requirement for all laboratories that perform work in support of clinical trials to implement appropriate measures to assure the quality and integrity of the data they produce, and to exercise due diligence to ensure that the trial subjects rights are not compromised.  This audit questionnaire is based on the [European Medicines Agency Reflection Paper for laboratories that perform the analysis or evaluation of clinical trial samples](https://www.ema.europa.eu/documents/regulatory-procedural-guideline/reflection-paper-laboratories-perform-analysis-evaluation-clinical-trial-samples_en.pdf). The audit questionnaire is used by ACCORD as part of the vendor assessment programme and is designed to complement existing quality systems where they exist.  Please complete the questions as comprehensively as possible and include any other relevant information as attachments.  Upon completion, please return the questionnaire to the ACCORD QA Manager ([QA@accord.scot](mailto:QA@accord.scot)). |

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| **A** | | **PERSONNEL** | | | |
| () | | | Yes | No | Details: |
| 1. | Is there a documented training procedure for laboratory staff? | |  |  |  |
| 2. | Does your organisation have an organogram? *If so please attach a copy.* | |  |  |  |
| 3. | Does your organisation provide induction training to new employees? | |  |  |  |
| 4. | Are personnel training records maintained? | |  |  |  |
| 5. | How often is GCP for labs training given to employees? | |  | | |

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| **B** | | **QUALITY MANAGEMENT** | | | |
| () | | | Yes | No | Details: |
| 1. | Who is the head of quality/lab manager for your organisation? | | *State name & position:* | | |
| 2. | Does your organisation have a quality management system? | |  |  |  |
| 3. | Does your organisation possess an accreditation issued by a governing body? | |  |  |  |
| 4. | Does your organisation have a list / index of SOPs? *If so* p*lease attach a copy* | |  |  |  |
| 5. | Does your organisation have a self-inspection / internal audit programme? | |  |  |  |

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| **C** | | **EQUIPMENT & COMPUTERISED SYSTEMS** | | | |
| () | | | Yes | No | Details: |
| 1. | Do analytical equipment undergo user acceptance testing prior to use? Are tests documented and retained? | |  |  |  |
| 2. | Is apparatus periodically inspected, cleaned, maintained and calibrated? | |  |  |  |
| 3. | What computer systems (including software) are used for trial sample analysis and reporting of trial data? | |  |  |  |
| 4. | Are computer systems that capture, process, report and store data validated? | |  |  |  |
| 5. | Is there a documented procedure for disaster recovery? | |  |  |  |
| 6. | Are source documents (including electronic primary source data and lab results) archived, according to trial specific archiving requirements? | |  |  |  |
| 7. | Is access to computerised systems in the lab controlled? | |  |  |  |

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| **D** | | **TRIAL CONDUCT** | | | |
| () | | | Yes | No | Details: |
| 1. | Do you have a copy of the clinical trial protocol? | |  |  |  |
| 2. | Are there trial specific or process-specific work instructions? *If so, please provide a copy.* | |  |  |  |
| 3. | Do you have a documented deviation management procedure for reporting significant deviations to the Sponsor? | |  |  |  |

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| **E** | | **SAMPLE RECEIPT/STORAGE** | | | |
| () | | | Yes | No | Details: |
| 1. | Is there a documented sample receipt procedure?  *Please provide copy of sample tracking/receipt log(s)* | |  |  |  |
| 2. | How are samples transported to your site? | |  | | |
| 3. | Are sample storage areas monitored, controlled & alarmed? | |  |  |  |
| 4. | Is there a contingency plan/procedure in place should a fridge/freezer break down? | |  |  |  |
| 5. | Do you have a procedure should samples be received with identifiable data? | |  |  |  |
| 6. | Are there documented cleaning procedures? | |  |  |  |

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| **F** | | **PROCESSING & ANALYSIS** | | | |
| () | | | Yes | No | Details: |
| 1. | Are sample processing and analysis carried out in classified areas? | |  |  |  |
| 2. | Are analysis performed using appropriately validated methods with defined acceptance criteria?  *Note the validation of methods should be documented and on completion archived.* | |  |  |  |
| 3. | How are test results documented and reported back to the research team? | |  | | |
| 4. | Are quality control checks completed prior to the acceptance and release of results? | |  | | |

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| **ATTACHMENTS**  ***(Please reference any documents as attachments to the completed questionnaire)*** | | |
| Attachment Number | Document reference | Document Title |
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| **AUTHORISATION**  *(To be completed by representative from organisation/lab)* | |
| Name: | Job Title: |
| Signature: | Date: |

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| **OUTCOME**  (*To be completed by ACCORD QA Manager, or designee*) | | |
| Are the roles and responsibilities allocated to the vendor described in an agreement? | | ***Yes/No***  ***(delete as appropriate)*** |
| Does the agreement contain a GCP clause? | | ***Yes/No***  ***(delete as appropriate)*** |
| Computer systems (including software) have passed Computer System Validation checks? | | ***Yes/No/N.A***  ***(delete as appropriate)*** |
| Vendor approved? | | ***Yes/No***  ***(delete as appropriate)*** |
| ***Comments:*** | | |
| ***If not approved, actions to be taken (pre-qualification audit etc):*** | | |
| Name: | Job Title: | |
| Signature: | Date: | |