**Vendor Competency Form**

|  |  |
| --- | --- |
| **Research Project Title** | <<Please provide the full title or acronym of the research project >> |

| **Company Details** | | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Full Name:** | | | |  | | | | | | | | |
| **Full Address**  **(including postcode):** | | | |  | | | | | | | | |
| **Telephone:** |  | | | **Fax:** |  | | | | **Email:** |  | | |
| **Company Website (URL):** | | | |  | | | | | | | | |
| **Main Contact name:** | |  | | **Main Contact telephone number:** | | |  | | **Main Contact**  **e-mail:** | | |  |
| **Date Company was formed** | |  | | **Type of Company e.g. limited, sole trader, other** | | | **Please specify:** | | | | | |
| **Service(s) to be provided**  **(brief description):** | | |  | | | | | | | | | |
| **Number of people Company Employs:** | | | **Permanent Staff:** | | | | |  | | | | |
| **Contract Staff:** | | | | |  | | | | |
| **Please provide details of any change of ownership (last 2 years):** | | |  | | | **Last review date of disaster recovery / business continuity plan** | | | | |  | |
| **In relation to the services to be provided, please describe briefly the Company’s disaster recovery / business continuity plan**  **(in relation to the service(s) to be provided):** | | |  | | | | | | | | | |

|  |  |  |
| --- | --- | --- |
| **Regulatory Requirements** | | |
| **Please list any regulatory standards to which your company works:** | **Standard** | **Type of work** |
|  |  |
| **Please list any Licences/Accreditations (include dates) and provide the current certification:** | **Licences** | **Accreditations** |
|  |  |
| **Please provide a list of regulatory inspections for the last five years (where applicable):** | **Inspection type** | **Date of Inspection** |
|  |  |
| **Provide a summary of the Company’s audit universe/programme (both internal and external):** | **Type of Audit** | **Frequency** |
|  |  |
| **Provide a brief description of the key outcomes of the above inspections/audits, including any findings:** |  | |
| **Briefly describe the quality management system in place (include details of the SOP review system and a list of relevant SOPs):** |  | |
| **Briefly outline the staff training programme for the personnel to be involved:** |  | |

| **Equipment and Archiving** | | | |
| --- | --- | --- | --- |
| **Provide details of maintenance contracts for equipment relevant to service(s) provided:**  **(please provide a separate list if multiple items).** | **Item of equipment:** | **Maintenance provider:** | **Last maintenance date:** |
|  |  |  |
|  |  |  |
|  |  |  |
| **Briefly describe internal archiving system(s):** |  | | |
| **Name and address of off-site archiving facilities (if applicable):** |  | | |
| **Provide a statement of inspections/audit outcomes for the above off-site facility for the last five years (if applicable):** |  | | |
| **Describe the systems for the retrieval of data from off-site facilities (if applicable):** |  | | |

| **IT and Data Management (if applicable)** | |
| --- | --- |
| **Briefly describe IT security procedures (including back-up, computer system validation, password protection policies and ‘test-restore’ process):** |  |
| **Briefly describe Data Management systems (including details of Quality Control, GDPR compliance):** |  |

|  |  |  |
| --- | --- | --- |
| **Summary of Assessment (Swansea Trials Unit Use)** | | |
| **Areas of Concern and Mitigation :** | | |
| **STU Representative Name and Position:** | **Signature:** | **Date:** |
| **STU or Sponsor Authorisation (as required) Name :** | **Signature:** | **Date:** |