**DIVISION OF RESEARCH AND INNOVATION**

**Computer System Risk Assessment**

|  |  |  |  |
| --- | --- | --- | --- |
| **Version:** |  | **Date:** |  |

**Section 1: System Details**

|  |  |
| --- | --- |
| Hardware name (if applicable) |  |
| Software name |  |
| System version number |  |
| Manufacturer / vendor |  |
| Area of use  | *Specify the division, department, or study title and R&D number* |
| Outline of software use |  |
| Number of installations  |  |

**Section 2: Do I need to Validate?**

|  |  |
| --- | --- |
| Is the system used to support any of the following activities | Check Box |
| 1. Non-clinical laboratory studies intended for submission to or review by a regulatory authority?
 | [ ]  Y [ ]  N |
| 1. Clinical investigations or studies?
 | [ ]  Y [ ]  N |
| 1. Generation of, submissions to, or withdrawal of an application for marketing authorisation?
 | [ ]  Y [ ]  N |
| 1. Training records of personnel involved in the manufacture of drug product or API, or in the conduct of non-clinical, pre-clinical or clinical studies?
 | [ ]  Y [ ]  N |
| 1. Backup or storage of records supporting any of the above, in electronic format?
 | [ ]  Y [ ]  N |
| 1. Transfer of electronic records supporting any of the above from one GxP system to another?
 | [ ]  Y [ ]  N |
| Complete the appropriate box below according to the responses above:If any response is YES, validation is required - complete Section 3.If all responses are NO, validation is not required - complete and sign off Validation Statement. |
| Validation is NOT required: [ ]  | Validation **IS** required: [ ]  |

**Section 3: How Much Validation Should I Do?**

|  |  |
| --- | --- |
| Part A: Software Category | Check Box |
| 5 | Custom software application or custom extensions (e.g. macro, custom modules) to an existing commercial application | [ ]  |
| 4 | Commercially available software configurable using predefined software modules | [ ]  |
| 3 | Commercially available standard non-configurable software package providing an off the shelf solution to a business or regulatory process | [ ]  |

|  |  |  |
| --- | --- | --- |
| Part B: Regulatory Risk  | System Function / Regulatory impact | Check Box |
| High Impact Data | Data submitted directly to a regulatory authority | [ ]  Y [ ]  N |
| Support to pre- and/or non-clinical laboratory studies  | [ ]  Y [ ]  N |
| Clinical trial data from participant or supporting work | [ ]  Y [ ]  N |
| Medium & Low Impact Data | In-process monitoring of drug product and APIs | [ ]  Y [ ]  N |
| Supporting data not directly submitted to regulators | [ ]  Y [ ]  N |
| **Regulatory risk is high if ANY of the high impact options are YES.** |

|  |  |  |
| --- | --- | --- |
| Software Category 4/5 | Reduced Validation | **FULL VALIDATION** |
| Software Category 3 | Reduced Validation | Reduced Validation |
|  | Medium & Low Impact Data | High Impact Data |

**Level of Validation Required:** Full Validation is required where the software is Category 4/5 **AND** the data is High Impact. For all other combinations, reduced validation or testing of key functions only is required.

Note: Software categories 1 and 2 (operating system and instruments with read-only firmware) are excluded from this assessment. This assessment is only applicable to software in categories 3 - 5, i.e. commercially available, configurable or custom-built software applications.

|  |
| --- |
| **Validation Statement***Complete sections 1 - 3 of the Risk Assessment before you complete the statement below.* |
| Sections 1 - 3 of this Risk Assessment have been completed as required, and this system has been assessed as: |
| HIGH risk | [ ]  | Full validation of all functions is required.  |
| LOW risk | [ ]  | Validation of key functions is required.  |
| NO risk | [ ]  | No further action is required. |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Name | Signature | DateDD-MMM-YY |
| System Owner |  |  |  |
| QA Representative/ Sponsor Representative |  |  |  |
| IT Representative (if applicable) |  |  |  |