**DIVISION OF RESEARCH AND INNOVATION**

**Computer System Risk Assessment**

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| --- | --- | --- | --- |
| **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.** | | |

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| --- | --- | --- |
| 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.

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| **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 | Date  DD-MMM-YY |
| System Owner |  |  |  |
| QA Representative/ Sponsor Representative |  |  |  |
| IT Representative (if applicable) |  |  |  |