**DIVISION OF RESEARCH AND INNOVATION**

**Computer Systems Validation Report**

**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: Validation Report**

This validation report is written to summarise the validation results of the [insert system name] system used for [insert description here].

***OR***

This validation report is written to summarise the validation results of the changes to the [insert system name] system. The purpose of the change was to [insert description here].

**System/Change** [*delete as appropriate*] **Requirements**

|  |  |  |
| --- | --- | --- |
| Requirement Number | Feature  *(For each of the requirements listed in the Validation Plan, describe how these requirements are met and/or any limitations and mitigations)* | Met?  Y/N |
| 1 | **IT requirements**  *Example text:*  *Computer meets minimum hardware specification as stated in the user manual* |  |
| **1.1** |  |  |
| **1.2** |  |  |
| **2** | **System scope** |  |
| **2.1** |  |  |
| **2.2** |  |  |
| **3** | **Security features and Access** (describe the security measures and any applicable information security policies. Describe the access arrangements for the system including system admins.)  *Example text:*  *Although initial access to the system has been tested, Software X does not require any form of authentication, nor does it use varying levels of system access.*  *Software X requires a login / code / valid license key as authentication. Separate logins / codes / licenses are required to activate different modules in the software.* |  |
| **3.1** |  |  |
| **3.2** |  |  |
| **4** | **Audit trail** |  |
| **4.1** |  |  |
| **4.2** |  |  |
| **5** | **Operational requirements**  *Example text:*  *Configuration*  *No changes to the configuration of Software X have been made since installation.*  *The default values set at the time Software X was installed can be reconfigured to suit the template requirements.*  *Custom calculations*  *No custom calculations / macros are used with Software X.*  *Reports*  *No reports are produced by Software X.*  *Software X generates reports based on input during measurements. Fields to be extrapolated from the data set can be customised and reports can be transferred into an Excel document.* |  |
| **5.1** |  |  |
| **5.2** |  |  |
| **6** | **Backup and restore** (describe type of backup and medium used. Describe the regularity and routine of the backup) |  |
| **6.1** |  |  |
| **6.2** |  |  |
| **7** | **Operation and maintenance** (what will happen when an update to the system is released and how often will the software be validated) |  |
| **7.1** |  |  |
| **7.2** |  |  |
| **8** | **Interface requirements** |  |
| **8.1** |  |  |
| **8.2** |  |  |
| **9** | **Data migration requirements** |  |
| **9.1** |  |  |
| **9.2** |  |  |
| **10** | **Staff Training** (Describe how and when training will be provided and who will provide, who will be trained and how this will be documented) |  |
| **10.1** |  |  |
| **10.2** |  |  |
| **11** | **Archiving and Retention** (archiving arrangements and archive access) |  |
| **11.1** |  |  |
| **11.2** |  |  |

**Functionality Testing**

Tests of major functions listed in the Validation Plan were carried out and are recorded in the CSV Test Sheet.

A summary of the tests conducted for each installation can be seen below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Function | Test | Frequency\* | Date testing completed | Pass/Fail |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

\* Include triggers for re-testing, for example, major updates or as part of disaster recovery.

**Validation Summary**

*[Describe key findings, and most importantly* ***confirm validation outcome*** *and* ***justify decisions****]*

|  |  |  |
| --- | --- | --- |
| **Validation Statement**  *Complete sections 1 - 2 of the Validation Report before you complete the statement below.* | | |
| Sections 1 - 2 of this Validation Report have been completed as required, and this system has been assessed as: | | |
| Full Pass |  | System meets all requirements and has passed all functional tests. |
| Pass |  | System has limitations but these have all been appropriately mitigated. |
| Fail |  | System has not met requirements and/or has not passed functional tests. There are limitations that could not be appropriately mitigated. |

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