Quick Start Guide to Developing Documents
For a
Computerized System Validation (CSV)

Developing a Computerized System Validation process may seem onerous, however, performing a CSV is relatively easy. In its simplest form, a CSV is performing a series of tests to ensure that the processes run by a computer system achieve the intended result. For example, when testing multiple login attempts, does the system lock out appropriately? Consequently, a screen shot is captured to confirm the end result of this test. While Information Technology (IT) support may be required in the beginning, research staff will be able to perform a CSV once the process and documents have been developed. Please note that a Standard Operating Procedure (SOP) may be developed along side the process to meet institutional requirements. Please refer to our guidance and sample documents for more detailed information.

Developing the Documents:

1. **Risk Assessment**: A risk assessment determines the level of CSV you are required to perform (either full or reduced). We have provided a *completed sample* and *blank* Risk Assessment Tool for reference.
    - ☐ Complete Section 1. Under "Outline of System Attributes," attributes are defined as the fields that capture information in the system. (i.e. Patient name, DOB, etc.)
    - ☐ Complete Section 2. This section will determine the level of CSV you require, if any. If all answers are no, a CSV is not required.
    - ☐ Section 3 is a standard Good Automated Manufacturing Practice (GAMP) classification. Simply determine the category your system falls into. If you do not know this, you can consult your IT department.
    - ☐ Section 4 determines the outputs of the system. (i.e. Are you submitting clinical or non-clinical study reports to a regulatory authority? Does your system have the capability of electronic signature to sign off on data?) Answer yes or no to each item to determine your level of regulatory risk. Again, your IT team may need to help you to answer these questions.
    - ☐ Use Section 3 and 4 to determine your level of risk in Section 5. If a full validation is required, you will need to develop a Validation Master Plan (VMP). If a reduced validation is required, you may develop an Integrated Validation Document (IV).
    - ☐ Gather appropriate signatures upon completion.

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3. **Validation Master Plan (VMP) –** If upon completing the Risk Assessment, a *full* validation is required, you will need to develop a VMP. We have attached a *completed sample* Validation Master Plan. The headers and some of the language may be used as a template for developing a VMP for your system. This should be done in conjunction with your IT team.

- ☐ In Section 1, the Objectives and Scope are outlined. Terms/acronyms are defined that are specific to the site/document. List any SOPs, policy documents etc. that support the VMP, along with specific references.
- ☐ In Section 2, define who will be responsible for performing the CSV and who will oversee the process.
- ☐ Section 3 should be developed in conjunction with your IT Team as it will contain the technical qualifications.
- ☐ Section 4 is the description of the system and should be available from the system developer.
- ☐ Section 5 outlines how you will perform your CSV. This may also be outlined in an SOP. This can also be developed in conjunction with your IT team.
- ☐ Section 6 determines what is considered acceptable criteria when a CSV is performed.
- ☐ Section 7 outlines ongoing requirements (i.e. when major updates are implemented, either hardware or software, or a system is decommissioned).
- ☐ Gather appropriate signatures upon completion.

4. **Integrated Validation Document (IVD) –** If upon completing the Risk Assessment you determine you are required to conduct a *reduced* validation, you may develop an IVD. We have not developed a specific sample document for a reduced validation. However, the IVD is an abbreviated version of the VMP and typically contains the following sections:

- ☐ Introduction
- ☐ Reference Documents
- ☐ Installation Qualification
- ☐ System Description
- ☐ Signatures

5. **The Validation Document** – The validation is a series of test cases where screen shots are captured to show that the system is working as intended. The validation consists of four (4) sections: Requirements, Specifications, Traceability Matrix and Test Cases. To develop a validation document:

- ☐ Outline the purpose of the document.
- ☐ Develop a list of requirements. You may use the list of requirements we have developed as an example and/or add or modify for your own system requirements.
- ☐ Provide a list of the system specifications. These may be provided by the system developer or your IT team. Typically, it will be a combination of both.
- ☐ Develop a Traceability Matrix. This aligns the requirements with the specifications. (i.e. which specifications satisfy which requirements.)

- From you list of specifications and requirements, develop your test cases. Use the examples we have provided and add or modify to develop your own. Capture screen shots of all test cases once completed. This is your record of how the system performed during the test tasks.
- If any error messages occur during testing or there are problems in completing the tasks, your IT support or system administrator should be notified to rectify these errors. This should be documented, and the test case performed again.
- Gather appropriate signatures upon completion.

6. **The SOP** – Once all documents have been developed, an SOP according to your institutional guidelines may be developed outlining:
   - When a CSV should be conducted.
   - How it will be conducted.
   - Who is responsible for performing the CSV.

Congratulations! You have now developed the documents and performed a validation for the computer system you use to collect, analyze, transfer and report data that is in support of your clinical health research study/trial.