

Our Process:

Any formal validation process begins with 1) a requirements specification followed by tests to verify that 2) the components were installed and configured correctly, 3) that they function properly, and 4) that they meet the applications specific needs. The available SmartScan validation template package contains a precise framework to allow each of these documents to be easily and accurately created.

Documentation/Validating:

SRS

An all-encompassing generic System Requirements Specification (SRS) is provided as a MS Word document that has been specifically structured to provide the foundation for the IQ, OQ, and PQ protocols. The prospective user simply fills in the blanks and makes various selections or adds to tables.

IQ

The Installation Qualification Protocol (IQ) is a template that is expanded based on the component tables contained in the SRS. Also included are sections where the user verifies the availability of pertinent Standard Operating Procedures. A major part of the IQ is devoted to verifying that the system is configured to match the requirements in the SRS. Again, there is a 1:1 mapping of the requirements to the IQ which eliminates the need for a traceability matrix.

OQ

The Operational Qualification Protocol (OQ) is supplied as a completely executed and fully documented package that covers the entire SmartScan server software product. The tests exhaustively verify every facet of the operation of the system. You can choose to use the OQ as is or an unexecuted version can be supplied for you or a third party validation contractor. Again, the OQ protocol matches the requirements stated in the SRS.

PQ

The Performance Qualification Protocol (PQ) is used to verify the critical operations for your specific application. These include sensor accuracy, data recording, data display, alarm detection, and alert delivery.

Timing:

It typically takes less than a week to prepare the validation documents for a medium sized lab or cleanroom monitoring application. Once the documents are available and have been approved, the installation can start. The IQ is normally executed during the installation process and should only take a half day to fill in. Once the system is operational, the PQ for a system with 30 points can be easily executed and documented in less than two days.