IQ/OQ/PQ and Validation Guideline Documents

DataTrace® for Windows (DTW) and DataTrace® Radio Frequency (DTRF) software programs allow the user to program, read and analyze data collection from DataTrace loggers. The IQ/OQ/PQ and validation documents provide the means to document the DataTrace system in the user’s process for all regulatory requirements, including an FDA “closed system” (21 CFR Part 11).

The DataTrace IQ/OQ/PQ Guidelines Manual provides guidance and objective documentation that the DataTrace system operates as specified, and includes the appropriate instructions for all equipment qualifications and the reports, maintenance records, and supporting documentation which are directly related to these qualifications.

The DTW and DTRF Software Validation Manuals are designed to assist customers in validating their DataTrace software. The software validation procedure can be used in conjunction with the DataTrace IQ/OQ/PQ Guidelines Manual for a complete system validation for both hardware and software.

The DataTrace IQ/OQ/PQ Guidelines Manual and the Software Validation Manual are provided in two separate documents because not all customers need to perform both operations. Having two separate documents allows users to obtain only those parts they actually need.

Combined, these two documents provide:

- A description of the DataTrace® system.
- Verification that all DataTrace system equipment, software and accessories are received in good condition.
- A step by step instruction to provide a signoff for the individual(s) performing the IQ/OQ/PQ procedures verifying that each step has been completed.
- Procedures to verify that DTW or DTRF software is installed properly on the target workstation(s), including instructions on establishing security (if required).
- Verification that the installation of DataTrace equipment is completed properly and proper communication between the Logger(s) and the workstation(s) is occurring.
- Procedures for functional verification of all DataTrace Loggers.
- Training logs for each individual to document their level of training with the DataTrace equipment.
- Logger log forms as permanent records of factory and field calibrations and service.
- Instructions for handling and maintenance information for DataTrace equipment.
- A CD with the IQ/OQ/PQ manual, includes electronic images of the entire IQ/OQ/PQ document, all forms and logs, and the SOP document; two CDs in the DTW or DTRF Software Validation Manual which includes the software and a second CD with test files.
- A guideline SOP for the DataTrace System which the owner is free to use for in-house SOP documentation.
Included logs and documents:
- Setup Verification Record
- Equipment Location Record
- DataTrace Logger Log
- DataTrace Field Calibration Log
- Employee workstation Training Record
- Generic SOP describing DataTrace use

IQ/OQ/PQ:
The IQ/OQ/PQ manual is intended as a customer aid in completing the validation requirements associated with the installation and proper use of the DataTrace System in a regulated environment. It is also designed to help develop the customer’s validation plan as defined in the FDA current Good Manufacturing Practice (see 21 CFR 820), with the completed original forms, reports, and supporting documentation.

The IQ/OQ/PQ manual provides guidance and objective documentation that the DataTrace System operates as specified, and includes appropriate instructions for all equipment qualifications and reports, maintenance records, and supporting documentation which are directly related to these qualifications.

Validation:
The DTW or DTRF Software Validation Manual workbook assists customers in validating their software. The validation procedure provides evidence that the DataTrace software functions as intended. The software validation procedure can be used in conjunction with the DataTrace IQ/OQ/PQ Guidelines Manual to complete the required documentation of the DataTrace system for your particular regulatory environment. The combined procedures provide documentation that software of a known quality is operated by trained people in accordance with written procedures in the environment and conditions the system was designed and intended for.

Contact your DataTrace representative to obtain further information regarding the DTW or DTRF Software Validation Manual and the appropriate DataTrace IQ/OQ/PQ Guidelines Manual.