Lab Systems Software Implementation & Val

MEDVACON's Pharmaceutical client planned on deploying Waters Empower 3 Chromatography software in their facilities for use with approximately 30-35 HPLCs. To ensure compliance with current Good Manufacturing Procedures Pharmaceutical Company engaged MEDVACON to perform Computer System Validation activities for the implementation. MEDVACON's activities included the following scope of work: Prepare the User and Functional Requirements (URS/FRS) and the Traceability Matrix (TM); Review Waters vendor software testing documentation per Detailed Design Specifications (DDS) including software modules, graphics, HMI components and batch reports; Review Configuration Specification/DDS documents against requirements; Author IOQ leveraging the vendor IOQs for the Waters Empower 3 Chromatography Data Software; Execute IOQ and prepare the IOQ summary report; Author PQ for the live environment; Execute PQ for the live environment; prepare PQ for summary report; Author data transfer and integrity testing protocol for transfer of data from Empower 2 to Empower 3; Execute data transfer and integrity testing protocol, prepare Summary Report; Prepare Validation Summary Report and final Traceability Matrix; Support deviation closure; Support developing SOP's; Generation of VSR; documentation; Provide Project Oversight and Management (PM)

21 CFR Part 11 & CSV Methodology Assessment

MEDVACON was engaged in a multifaceted compliance consulting initiative. MEDVACON provided professional consulting services in the area of 21 CFR Part 11 compliance as well as requisite requirements such as System Development Life Cycle (SDLC) and Validation. MEDVACON specifically provided: written 21 CFR Part 11 compliance assessment reports for the five types of computer controlled test equipment at cliet; written assessment report of the client site IT Policies & Procedures to ensure 21 CFR Part 11 compliance controls; written assessment report of site IT Policies & Procedures governing their System Development Life Cycle (SDLC) methodology required for developing software used in a GxP environment; Validation and 21 CFR Part 11 compliance consulting services specific to client's in-house developed MS Access based test-data collection and reporting system.

21 CFR Part 11 & CSV Methodology Assessment

MEDVACON was engaged by our partner to assist FDA lab staff by identifying where in their SOPs updates for LIMS need to be made far in advance of the lab implementation. MEDVACON ensured that the LIMS-relevant SOPs from the labs and QMS staff were available. This included instrument qualification, operational qualification, and performance qualification (IQ/OQ/PQ).

QMS Software Quality Assurance & Validation

An industry leader in Quality Management Software has engaged MEDVACON in a multitude of ongoing CSV, SQA and PM activities. MEDVACON has a dedicated team that prepares and executes PQ's for QMS providers' client implementations. MEDVACON has another dedicated team that conducts full SQA and validation of QMS providers' quarterly software releases.

PDMA Sample System Validation

MEDVACON's client that provides Prescription Drug Marketing Act (PDMA) sample compliance services engaged MEDVACON to validate their acknowledgement of delivery tracking system. MEDVACON developed the project plan, Validation Plan, reviewed the URS and FRS, developed the IQ/OQ and PQ. MEDVACON executed the protocols and developed the validation final report.

Pharmaceutical IT Policies & Procedures Development

A Pharmaceutical company focused on developing small-molecule anti-cancer therapeutics engaged MEDVACON to evaluate their existing IT Policies and Procedures and develop an overarching IT Quality System, along with development of requisite documents. MEDVACON developed sixty-four IT Polices, Procedures and Work Instructions which form the basis of their IT Quality System.