

GxP regulated companies have an ever increasing dependency on computerized systems when conducting their day-to-day business. The validated status of GxP applications that are dependent upon an underlying IT infrastructure is compromised if that IT infrastructure is not maintained in a demonstrable state of control and regulatory compliance. This is exactly why Computer Systems Validation comes into the picture.

On the enforcement side, if the FDA warning letters are observed, it will reveal that several of these are related to computer validation. Many observations are also related to the computer validation. Expectations have increased from various regulatory agencies for the documentation of software development, remote access and software modification.

For processes that are conducted at multiple sites, integration of multi site computer systems where clinical database or ERP systems are operating, the integration activities will increase the need for Computer System Validation, especially in situations where human judgment is received from processes.

A horizontal or platform based approach is normally used for CSV. Benefits of a horizontal approach include

- Higher level of standardization throughout the entire life cycle
- Minimal overlap in documentation & qualification
- Minimal overlap in audits, inspections & assessments

Risk Assessment should be performed at each major life cycle phase of any platform or data identified to be critical. Risk assessment comprises of 2 phases viz. risk analysis and risk evaluation.

### **Kevin's Offering**

Kevin has in-depth understanding & experience in providing CSV solutions meeting global regulatory requirements and can be customized to individual customer needs.

As part of CSV, we provide Validation services for the following

➤ Lab Equipments	➤ Computer Systems
➤ LIMS / DMS	➤ ERP / SAP Systems

For your requirements of the following, do contact us.

**VALIDATION - LAB EQUIPMENTS, PLC/SCADA/DCS/CMS  
ERP / SAP SYSTEMS / LIMS / DMS  
COMPUTER SYSTEMS  
CALIBRATION ORGANIZER SOFTWARE**