



Spectrasoft – Regulatory Compliance Services

Spectrasoft is a full service contract compliance and validation firm specializing for healthcare industry (Pharmaceuticals, Biotechnology, Medical Devices and Clinical Trials) that must comply with FDA Regulations, GxP, 21 CFR Part 11, and EMEA Regulations. We understand cGMP's, GLP's and GCP's and provide audits, validation and compliance support for some of the best companies in the business.

In the ever changing FDA regulated industries, you can count on Spectrasoft as your partner to ensure all necessary validation and compliance records are comprehensive, controlled, defensible and maintained as necessary.

Services:

Validation Services - Computer Systems

Spectrasoft, Inc provides total validation services to ensure that your computer systems are compliant with FDA, GxP, 21 CFR Part 11 and other industry standards.

Our Services include:

- Validation Strategy and Implementation.
- Validation Documentation and Deliverables.
- GAP Analysis and Risk Assessments.
- Revalidation.
- Retrospective Validation
- Change Control.
- Vendor Audits.
- Training.
- Validation Staffing
- Quality Review Services.
- Computer Systems Validation
 - Network and Infrastructure Qualification.
 - Document Management Systems.
 - Clinical Trials Systems.
 - Drug Safety Systems.
 - Quality Management Software (QMS).
 - EDC Systems.
 - CAPA Systems.
 - Prospective and Retrospective Validation.

Validation Services - Equipment and Lab Systems

Spectrasoft, Inc provides complete Laboratory and Equipment Validation Services to ensure that your lab systems and equipment meet GLP, GMP and GCP standards along with 21 CFR Part 11 and other industry standards and regulations.

Our services include:

- Development and Implementation of Master Validation Plans.
- Develop and Execute IQ/OQ/PQ for Laboratory Systems and Equipment.
- Develop Standard Operating Procedures (SOP's) for Administration and Maintenance.
- Conduct GAP Analysis and Risk Assessments and Develop Remediation Plans.
- Evaluation of Current Compliance States.
- Quality Review of Documentation, Protocols and SOP's
- Lab Sytems: HPLC's, UV Vis, Densitometer, Polarimeter, LIMS, Bioanalytical LIMS, Titrators. Projects: Waters Empower, Agilent Chemstation, Brinkmann Workcell / TiamoWorkstation, ImageQuant, Analyst and more.

Spectrasoft's Value Proposition:

- Core practice since inception.
- Free analysis of current validation practice and gap assessments.
- Elimination of 'middleman' to provide value to the clients.
- Inhouse training to keep upto date with changing standards and regulations.
- Customized Services - Overall validation practice or System Specific Validation practice.

