Visit our website to watch an 8-minute video that explains: What Computer System Validation is & Why you need it.

- Complete 21 CFR Part 11 and Annex 11 compliance related to SOPs, training, product features, and software validation.
- Services include gap analysis, remediation plans, vendor audits, and project management.
- Electronic signatures, biometric signatures
- VMust in regulated environments.

Cost-Reduction Without Increasing Regulatory or Business Risk

- The 10-step risk-based approach uses fill-in-the-blank templates to capture the essential validation documentation related to: requirements, specifications, installation, risk assessment, testing, SOPs, training, and system release.
- Increase corporate productivity, and individual workforce member productivity.
- Efficiently create validation documentation.
- Determine risk in a process. Write test cases that trace to elements of risk management.
- Significantly lower costs and reduce software implementation time.

Founder David Nettleton is a 21 CFR Part 11, Annex 11, HIPAA, software validation, and Computer System Validation consultant involved with the development, purchase, installation, operation and maintenance of computerized systems used in FDA compliant applications. He is considered one of the nation’s foremost experts in the field.