

BURDENED BY VALIDATION?

ACCELERATED VALIDATION

If you find it costly and time consuming to validate your systems, automated validation may be the solution you are looking for. CA Validator software, available from Compliance Associates, will enable you to accelerate your “entire” validation lifecycle process, while giving you confidence that your validation will stand up to even the most rigorous regulatory scrutiny. The structured and disciplined project management approach in CA Validator ensures control and compliance in validation.

Current validation procedures used in the healthcare industry are manual in nature and extremely time consuming and laborious. It is not uncommon for a healthcare industry to spend up to a year validating one system. Automation has greatly improved industrial and office productivity. So why not validation? An automated solution to validation can greatly improve productivity and compliance in your organization.



CA Validator is the only automated validation product available that automates the entire validation lifecycle and includes:

- ✓ Planning
- ✓ User requirements
- ✓ Risk assessment
- ✓ Generation of the validation plan
- ✓ Testing
- ✓ Deviation tracking
- ✓ Verification audits
- ✓ Gap analysis
- ✓ Remediation plans
- ✓ Generation of the validation summary report

CA Validator will make it easy for personnel in your organization to conduct validation. CA Validator provides a framework and strategy for computer system validation and 21 CFR Part 11 assessment and remediation, as well as a walkthrough approach for planning, test case design, and test case development/execution.

Validation documentation is generated automatically and is based on answers to a number of questions provided to the user through an intuitive user interface. Although CA Validator comes packaged with over 30 reports, client specific reports may be configured since the data is present in the CA Validator database. CA Validator uses a thorough methodology which captures all pertinent information required for validation deliverables.

The software has a built in workflow to ensure that the required steps are followed and completed prior to moving to the next step. In addition, CA Validator has a computer-based training module to verse the users in validation and 21 CFR Part 11. This reduces the validation training costs while meeting regulatory training requirements.

CA Validator was developed by health care professionals who specialize in validation and 21 CFR Part 11 and have been involved in the implementation and qualification of major pharmaceutical systems. CA Validator makes use of existing internationally recognized standards, guidelines, and industry best practices. It can be used to accelerate the qualification of all software applications whether large/small, complex/simple. CA Validator accommodates prospective, retrospective or revalidation of software.

SOFTWARE OBJECTIVES

The objective of introducing an automated validation method is:

- ✓ Automatic documentation generation such as validation plan, user requirements, detailed test plans, verification audits, test procedures, testing summaries, traceability matrices, incident reports, validation summary reports, remediation plans etc.
- ✓ Introduce a standardized structured and disciplined project management approach to validation
- ✓ A walkthrough approach to validation and 21 CFR Part 11 assessment and remediation
- ✓ Allow Risk assessment
- ✓ Built in sequence of validation events, ensuring control and compliance
- ✓ Allow electronic document workflow
- ✓ Decrease redundant effort spent on validation
- ✓ Capture and centralize all validation documentation
- ✓ Providing accessibility of information which can be used for multiple rollouts of identical systems within different entities of an organization
- ✓ Enable validation of processes, interfaces and integration
- ✓ An incident tracking mechanism which aids in building a remediation database
- ✓ Alerts on defined and documented dates, such as remediation target date, periodic review etc.
- ✓ Provide cost effective and practical approach to training personnel in validation and 21 CFR Part 11
- ✓ Based on existing internationally recognized standards, guidelines, and industry best practices.
- ✓ Meet requirements of global electronic records and electronic signatures
- ✓ Reduce the risk of failure
- ✓ Reduce operating costs



SOFTWARE MODULES

CA Validator software is a web-based application, which is comprised of the three modules - Enterprise System Automated Validation Module, Workflow Module, and Computer Based Certification Module. Each module can be accessed independently using a pre-defined login and password.

Enterprise System Automated Validation Module provides a framework and strategy for computer system validation, 21 CFR Part 11 assessment, remediation plan as well as the walkthrough approach for planning, test case design, and test case development/execution.

CA Validator Workflow Module allows electronic document workflow for the Enterprise System Automated Validation Module. Workflow refers to the ability to route electronic documents to individuals in accordance with a predefined order so that the document can obtain appropriate approvals as necessary.

Computer Based Certification Module is a compliant method of restricting access to the Enterprise System Automated Validation Module until the user has been trained and certified to perform their assigned tasks in validation. Upon completion of computer-based training, the user is provided with a unique certificate ID. This unique certificate ID grants the user access to the Enterprise system.



VALIDATION METHODOLOGY



SUMMARY

The answer is clear: *automate or face the burden of validation*. If you are feeling heightened to do more with less, while ensuring confidence that your validation will stand up to even the most rigorous regulatory scrutiny, the automated solution by Compliance Associates may be the answer for you. CA Validator software will enable you to accelerate your entire validation lifecycle; from Project Initiation through to Maintenance. The structured and disciplined project management approach in CA Validator ensures control and compliance in validation. Automatic documentation generation is expected to improve the quality of information, increase compliance, while dramatically decreasing the validation timeline, allowing organizations access to their business critical GMP systems sooner.

Automation is here! Failure to automate your validation leaves your organization at a competitive disadvantage.