Clarmon
Compliance Management Solutions

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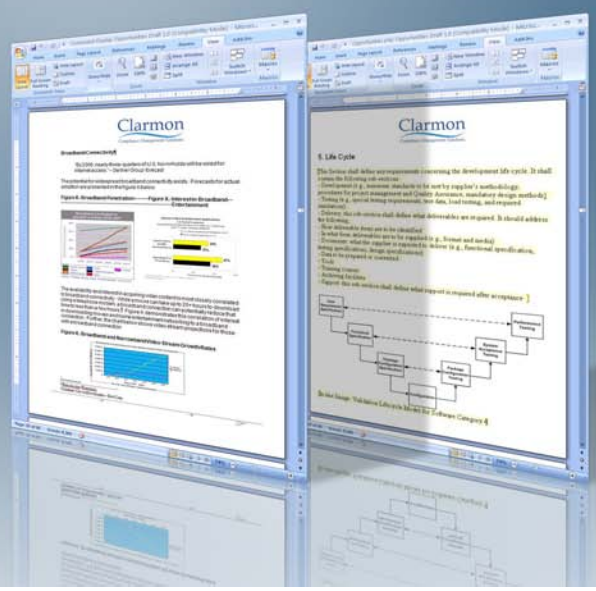
QAvalid CSV™
Computerized System Validation

All software used for regulatory activities within healthcare companies must be validated to comply with applicable regulations. Computerized system validation (CSV) involves documenting all processes from specifying the system requirements to training the users.

The current approach which relies on paper and manual systems is time consuming and inefficient as documents are needlessly recreated and tedious manual tasks are performed on a daily basis.

QAvalid CSV™ is a Web based system designed to manage efficiently the complete validation lifecycle for computerized systems. Life Science companies can replace tedious paper or manual systems with a fully electronic, automated validation environment that supports the risk based approach.

Users work in a controlled and compliant manner in Microsoft® Office and the system drastically improves validation efficiency by automating recurring tasks, supporting information reuse, improving visibility or generating up-to-date traceability matrices and displaying the impact of any change.



Why QAvalid CSV™?

- Electronic test script management and execution, requirements management and risk assessments
- Configurable electronic workflows supported by automatic audit trails
- Integrated system inventory and change management
- Up-to-date traceability matrices and change impact generated automatically for any set of documents
- Supports maximum visibility and control of validation activities across multiple sites
- Controlled document editing and testing in Microsoft® Office using the QAvalid Add-In

CSV Challenges

While the costs of paper are negligible, the costs of using paper to document validation can be tremendous in the Life Science industry. Tedious and inefficient manual processes that have to be routinely performed lead to a high cost of compliance.

The main problems associated with paper or manual validation are:

- **Lack of oversight and control**

Managers cannot promptly identify and fix problems due to the lack of visibility and control.

- **Lack of standardization**

The information that is captured is insufficient, incorrect or does not follow the required format. The risk of non-compliance and the validation costs increase as processes and documents are inconsistent.

- **Slow collaboration**

Making documents available when they are needed where they are needed is not possible. Approvals are delayed without visibility of responsibilities and current document status.

- **Validation status for systems is unknown or missing or out of date**

The system validation status is not updated when validation activities are completed - instead manual updates are performed after periodic documentation reviews.

- **Manual traceability matrices and high efforts to perform updates**

Creating and updating traceability matrices manually is highly time-consuming and can lead to errors; when changing one document, there is no information about the other impacted documents.

- **Information is recreated**

Instead of reusing information created in previous projects, documents are needlessly recreated.

- **Document versions are difficult to find and reference**

Problems and confusions appear as people can't find the right document and reference the wrong versions.

- **Poor requirements management**

Projects fail to deliver the expected results because of poor requirements management. The manual handling of requirements and lack of traceability increase the compliance risk due to missed requirements and expensive rework.

QAvalid CSV™

QAvalid CSV™ helps you reduce validation efforts and costs by up to 60% by eliminating the problems associated with paper and manual based validation.

The centralized system enables users to focus on the crucial tasks by managing the full validation lifecycle electronically and automating recurring processes.

Unique Linksense™ technology enables users to connect related content across separate documents and supports automatically generated traceability matrices and instant change impact.

Flexible and Simple Document Editing, Yet Always Compliant and Consistent Documents

Unlike other solutions, QAvalid CSV™ does not require users to re-enter information and allows you to work in a familiar and yet controlled and compliant manner. The QAvalid Add-In for Microsoft® Office supports controlled document editing and testing in Word. Documents can be written in Microsoft® Word while working offline and then uploaded to the centralized system.

QAvalid CSV™ benefits

Electronic Test Execution, Integrated Risk Assessments and Requirements Management

The application enables electronic testing, integrating risk assessments and requirements management capabilities and meets all FDA requirements for electronic signatures and electronic records. The solution includes GAMP 5 best practice document and project templates for off-the-shelf, configurable and custom applications which accelerate the initial phase of validation projects and sustain knowledge reuse.
Specific GxP workflows sustained by automatic audit trails improve collaboration and ensure compliance. Offline testing, writing, reviewing and approving can be performed in Microsoft Word and is fully controlled using the QAvalid Add-In for Microsoft® Office.

Automatically Updated Traceability Matrices Generated On Demand and Change Impact

The traceability matrix is automatically updated to reflect changes in the project and can be generated on demand to show how plans, specifications, risk assessments, tests, deviations and other project information is related. This allows users to check that requirements have been implemented and verified or to justify the extent of testing as the risk assessment for each requirement can be shown within the matrix.
When performing software upgrades or other changes to the system, documents such as specifications need to be updated as well together with all related information in order to maintain compliance. QAvalid CSV™ instantly displays the impact of any change drastically reducing the time to update documents.

Advanced Information Reuse

Reusing information is essential in order to reduce the time and costs associated with validation projects. QAvalid CSV™ features several methods to reuse information.
Configurable document and project templates allow users to capture information and make it easily available for reuse across the system to all users. After one part of a master document is selected to be reused (ex. a number of specifications) the system can automatically copy related sections from other master document (ex. test cases). Developing validation documents can also be accelerated by automatically generating new draft documents based on other selected documents. For example, tests can be generated based on selected requirements.

Integrated Change Management and Equipment Inventory

Change control and configuration management are integrated in QAvalid CSV™ to ensure that all changes are implemented consistently.
Change control workflows supported by automatic audit trails are integrated within the system. Change requests are linked to configuration and document baselines which remain stored in QAvalid. This ensures modifications are implemented in a controlled manner and that changes can be tracked to show what changed, why and who approved it.
QAvalid connects the inventory list with requirements, risk assessments or qualification documents. This ensures that the inventory is maintained up-to-date and that the compliance status of each equipment can be promptly justified.

Standardized Validation Approach

QAvalid CSV™ allows you to standardize validation activities across multiple sites by defining standard document templates and workflows and ensuring that mandatory information is captured in the desired format. In addition, the solution provides real-time visibility of the project status and the progress inside each document through standard reports and allows users to build customized reports using tools such as Crystal Reports.

QAvalid™ , Clarmon's quality and compliance management suite, provides a simple method to centrally manage and control documents without requiring users to reenter information.

Unique technology embedded in QAvalid™ allows quality professionals to connect and synchronize documents and regulations, drastically reducing the time needed to update documents.

QAvalid™ helps companies improve their efficiency in managing the following processes:

- Computerized System Validation
- Facility Commissioning and Qualification
- Corrective and Preventive Actions
- Equipment Inventory Management
- Change Management
- Audit Management

Clarmon
Compliance Management Solutions

Clarmon Corporation

Clarmon Corporation provides advanced software solutions for quality and compliance management. The majority of Clarmon's customers are Life Science companies that operate inside one of the most highly regulated environments.

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