Key Benefits of the FastVal Validation Document Generator™

- **Reduces the time spent on validation projects by up to 70%.**
- **Facilitates Entire Validation Project** – From planning to gathering requirements to writing documentation to testing, FastVal makes validation simple.
- **Improves Document and Protocol Writing** – FastVal generates documents from reusable templates and test steps, allowing validation professionals to produce higher quality documentation more rapidly than with a word processor alone.
- **Complete Project Management Tools** – Manage all aspects of your validation projects, with complete tracking and reports. View the current status of each requirement and document.
- **Matches Your Validation Process** – FastVal seamlessly integrates into your validation process. FastVal uses your existing templates to produce documentation identical to your current documentation.

Generate Any Validation Document

- **Validation Plans and Summary Reports**
- **Requirements and Protocols** – User, Functional and Design specifications. Installation, Operational and Performance Qualifications. User, Factory and Software Acceptance Tests.
- **Trace Matrices** – Requirement tracking built into FastVal. Traceability Matrix is produced automatically and can be customized to meet unique requirements.
- **Risk Assessment** – Assign risk to each requirement and produce automatic risk reports.
- **Data Migration** – Automatically produce documentation for data migration.

Electronic Protocol Execution

- **Screen Capture** – Document validation testing. All screen captures are automatically included in validation tests.
- **Process Control** – Protocol execution tracked with electronic signatures and audit trails.
- **Flexibility** – Execute protocols electronically or on paper.

Validation Project Management Tools

- **Comprehensive** – Track the status of each requirement and each document.
- **Complete** – Reports track all documents and statuses.
- **Change Control** – Track re-validations, program revisions. Retest only requirements which have been changed.

All of your validation projects run from a single program. Validation professionals produce higher quality documentation identical to existing company documentation more rapidly than with a word processor alone. Testing personnel use FastVal to draft, review and execute test protocols. Managers can use FastVal's project management tools to supervise the entire validation process. FastVal is validation made simple.

Validation packages are available.

FastVal™ and Validation Methodology

How do FastVal and our validation methodology allow us to complete projects in 70% of the time as more traditional validation methods without sacrificing quality?

- **Industry Proven Document Templates** – Our validation professionals gather information about your system and its requirements. This information is entered into FastVal and it creates a template. This template forms the backbone of the validation document.
- **Integrated Risk Assessment** – Our validation methodology reviews business functionality and system code. Based on these reviews, we focus validation resources appropriately so high risk portions of the program are exhaustively tested and lower risk portions of the program receive appropriate validation effort.
- **Automatically created Traceability Matrices, Summaries of test cases, Deviations and Test Results** – FastVal automatically creates documents and reports automatically, which traditional validation methods take hours or days to complete.
- **Automatic Generation of Common Test Steps** – FastVal automatically inserts common test steps, such as screen navigation, entering data into fields, printing, etc. These micro test cases are combined to form the backbone of test cases.
- **Tracing Requirements to Individual Test Steps** – FastVal links requirements outlined in the Functional requirements to specific Design requirements. These requirements are then automatically linked to the appropriate steps in the test cases. The Traceability Matrix can be viewed in real-time to know the status of the project and Quality can navigate to the specific test steps to review that system functionality was appropriately tested.
- **Electronic Document Acceptance** – FastVal provides us the technological tools to approved documents electronically. Project managers can check the status of validation documents. Signatories can apply an electronic signature when the document meets with their approval. Electronic document acceptance means no paper documents to walk around, no paper documents to loose and knowing exactly who needs to approve the document.
- **Electronic Protocol Execution** - FastVal allows users to execute their testing protocols. Users can document their testing with screen shots and integrate the screen shots into the final testing documents.
- **Straight Forward Validation Methodology** – Our validation professionals are trained to focus right on the GxP portions of the program which require validation. Screens are tested for correct inputs, processing, outputs and security requirements. Work-flows are identified and tested to ensure they meet business requirements. Systems are tested to ensure compliance with 21 CFR 11.

Simply stated, FastVal facilitates the generation of validation documents creating documents and reports that take traditional validation methods hours or days to complete. We use the saved time to carefully test your system, focusing validation efforts on the highest risk sections of the program. We perform 100% dry-runs of testing protocols to identify and resolve deviations before formal testing begins. We understand that the fundamental goal of validation is to raise the value of your software.
Our validation professionals are skilled in defining system requirements and testing those requirements appropriately and thoroughly without spending unnecessary time on inappropriate testing or unnecessary work. For example, one of our validation professionals:

- Validated a laboratory tracking database with **82 Screens with a total of 748 requirements**, creating a Functional Requirements Specification, Design Specification, Installation/Operational Test Protocol (including 54 Test Cases and 1883 Test Steps), Traceability Matrix and Summary Report in **eight weeks**.
- Validated an equipment tracking database with **20 Screens with a total of 143 requirements**, creating a Functional Requirements Specification, Design Specification, Installation/Operational Test Protocol (including 26 Test Cases and 475 Test Steps), Traceability Matrix and Summary Report in **four weeks**.
- Validated a relational database with **78 Screens with a total of 290 requirements**, creating a Functional Requirements Specification, Design Specification, Installation/Operational Test Protocol (including 48 Test Cases and 1485 Test Steps), Traceability Matrix and Summary Report in **five weeks**.
- Validated a clinical trial database with **16 Screens with a total of 116 requirements**, creating a Functional Requirements Specification, Design Specification, Installation/Operational Test Protocol (including 27 Test Cases and 715 Test Steps), Traceability Matrix and Summary Report in **two weeks**.

In each case, our validation efforts were reviewed by local Quality reviewers and approved as meeting or exceeding their standards.