



THE VALIDATION MANAGER 4.6

PENSA's VALIDATION SOFTWARE SYSTEM

THE *FUTURE* OF VALIDATION IN REGULATED ENVIRONMENTS

For the past ten years PENSA has provided FDA compliance and validation services to worldwide life science firms both large and small. We understand that you are always seeking ways to reduce costs, reduce audit exposure and yet improve your regulatory compliance.

At PENSA our focus is on compliance services and software to meet those objectives. TVM is a productivity solution for FDA validation and compliance management. The application creates efficiencies and benefits that are not possible with manual or template methods.

ABOUT TVM

"The Validation Manager" (TVM) is an industrial strength, knowledge-based solution for regulatory and compliance management and validation of computer software, processes and equipment in the life sciences markets.

Designed by PENSA's consultants with decades of life sciences industry knowledge, TVM is ready to revolutionize your validation activity. Designed with 21 CFR Part 11 compliance and methodologies such as GAMP in mind, TVM is your solution to the painful costs of validation. A requirements driven approach combined with an electronic traceability matrix allows the creation of linked relationships between validation statements making for easy re-validation and change management. The links can be invaluable in clearly providing the documented evidence expeditiously during an audit. Store and manage all documents electronically or publish to a variety of media including MS Word ® and document management systems. TVM is an adaptable compliance tool to save time, cut costs and mitigate risks in your regulated life sciences environment.

*TVM is like having a Validation Manager
in a box !™*

THE TVM METHODOLOGY

A proven validation methodology is built into the TVM system so that all critical compliance steps are performed. In addition, customer specific compliance activities can be added to the methodology making TVM a flexible and adaptable approach to competitive compliance:

Project Management—Provides excellent project management capabilities to manage global validation tasks by system, equipment or by site.

Functional Requirements—Choose appropriate functional requirements from a selectable repository based on risk factors you define.

Add Custom Requirements—Unique objects for your environment are added to the database to maintain a company specific knowledgebase.

Create Electronic Documents—Using the linking feature of TVM's traceability matrix, standard with the product, generate complete validation documentation and publish anywhere.

Compliance Management—Set up secure roles for content authors, reviewers and approvers.

Execute Tests and Capture Results—Test every requirement and capture the results electronically for rapid assessment.

Enforce Compliance Policy Worldwide—TVM enables enforcement of corporate compliance policies across all plants with greater productivity and control for less TCO \$\$ than with manual or template methods.

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TVM's BENEFITS

Collaborate- TVM encourages involvement from a variety of validation backgrounds within the company, ensuring a thorough validation effort. Approvals throughout the process build quality into the content. Multiple users can build documentation *and* approve thereby saving time in the project.

Consistency- By using TVM, the validation methodology becomes consistent across departments and throughout an organization. Enforce a corporate methodology across the world sites.

Traceability Matrix- TVM automatically maintains the linking relationship between requirements, design specifications (SOP's, manuals, training records, etc.), tests, and Regulations, thus ensuring a complete validation effort and to assist with re-validation and Change Control.

Audit tool- Detailed document history is maintained with signatures and a time stamp making a solid audit defense tool. Run report queries on a variety of subjects.

Sharing- Share corporate validation knowledge. Multiple sites can select from a central database to copy content and then add custom objects applicable to each site.

Efficiency- The experience gained by using TVM to validate the initial implementation of a system leads to a faster rollout of the system at subsequent plant sites- a significant time and cost savings.

Reduce Time to Compliance(TTC)- Working with tight budgets and time frames, TVM can reduce TTC for all your systems, processes and equipment by up to 75%- *corresponding to faster time to market.*

***And PENSA is always available
to answer your questions.***

FEATURES

MS Windows ® Style Navigation- Familiar and easy navigation including drag and drop. Spell Check is also built in - more efficient than ever before.

Electronic Approval- Electronic approval of content and documents is 21 CFR Part 11 compliant. The number of approval signatures required is customizable. Failed logon attempts are recorded.

Signed Data- Data entered into fields is digitally signed to prevent tampering.

Test Results Entry- Schedule all or a sub-set of tests for execution. Enter the results of executed tests directly into TVM including a text summary or even a captured image directly from the application being tested.

Route for Approval -Approve documents and objects via email. A TVM license is not required for your colleague.

Embedded Objects -Attach corporate policies and procedures, image files, or hyperlinks as parts of objects.

OPERATIONAL JUSTIFICATIONS

*A new PENSA client expects to save over \$1 M in outside consulting fees by managing the computer systems validation in TVM at all US and international operations.

*A new PENSA client expects to save future head-counts by managing all computer, equipment and process validations in TVM. The payback is expected to be less than one year.

Log on to our website www.GMPs.com to learn more about TVM and other services from PENSA.
Contact PENSA to arrange a demo of TVM.

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