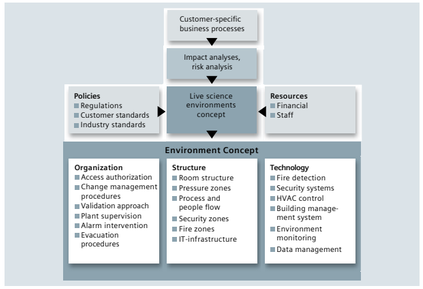

Current validation trends

The validation process as a whole is facing significant changes and new opportunities. The “risk-based approach” specified by the FDA* in the U.S. sets new standards in global regulation activities. It is no longer sufficient simply to validate a system. It is also necessary to answer the question of why a system was validated.

Authorities expect a detailed understanding of products and processes in order to identify critical parameters for patient safety, product quality and data integrity.
ISPE** recommends that suppliers adopt a key role in this process. It is therefore advisable to integrate suppliers as far as possible throughout the entire life cycle of a system, in order to incorporate their
– knowledge
– experience and
– documentation
into the successful validation process.
With EVT, this has never been easier.

* US Food and Drug Administration (FDA)
** International Society of Pharmaceutical Engineering (ISPE)

The solution process

Siemens has been successfully using risk-based methods for the life science industry for many years.

We help industry players to perform detailed analyses of the potential quality impact of the entire building infrastructure.

The result is a project-specific solution concept for optimum validation processes.
This concept is based on a documented impact analysis and a detailed risk analysis which encompasses not only compliance with regulations, but also safety-related and business risks.

Benefits of EVT

- EVT is an in-house tool developed by Siemens to ensure optimum support for our customers in the field of validation.
- EVT is a unique tool that combines the expertise acquired over decades in the life science industry with experience and documentation.
- EVT complies with the latest regulations and is accepted by leading quality experts in the industry.
- EVT speeds up the validation process by:
  – focusing on areas requiring validation
  – reducing the workload involved in coordinating, releasing and managing documents
  – facilitating faster document creation and approval
  – enabling transparent tracking of all project documentation
- EVT reduces project costs by:
  – systematically itemizing all requirements at the start of the project phase
  – reducing the number of changes required and their impact
  – avoiding delays to projects caused by validation documentation

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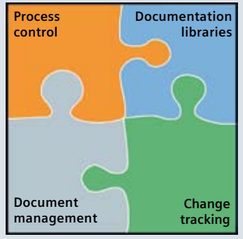
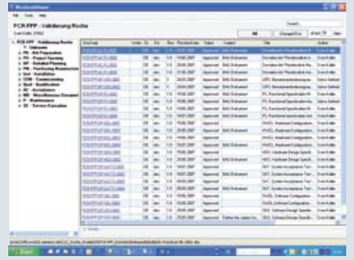
With EVT you reduce validation costs and risks.

Answers for infrastructure. SIEMENS





Electronic Validation Tool EVT: Overview

EVT (Electronic Validation Tool) is a software package that allows you to create comprehensive, project-specific validation documentation based on the latest guidelines and specifications of the pharmaceutical industry.

These components include:

- **Process control,** enabling users to intuitively track and implement the PM@SBT for Pharma project management process.
- Extensive, proven **documentation libraries** simplify the complete project documentation process. The templates provide automatic results in high-quality for the overall project documentation.
- Automated **change tracking** ensures that all document references are updated, even in complex projects.
- The comprehensive functions of the integrated **documentation management** feature help you keep track of all project documentation.

Process control

The PM@Siemens project management process is a tried-and-tested methodology for the implementation of large-scale projects. The process has been specially adapted to the life science industry in line with GAMP recommendations.

EVT provides the user with an efficient overview of the process in hand and assists the project team during every phase of the project life cycle.
The process stages are described in detail and both the inputs and the expected outputs are defined for each stage. This makes it easier to successfully achieve all the project milestones and pass quality gates.

The BT Academy offers specific project management training, which covers the functions and operation of EVT.

Documentation libraries

The extensive documentation libraries reflect the experience acquired by BT in over 1500 projects in the life science industry worldwide.

The documents cover the entire validation process, from the URS and design specifications to the relevant test and training specifications.

The documents meet the highest quality criteria and are accepted by quality experts in the pharmaceutical sector.

Each document contains expert tips for project-specific use.

The documents have been adapted to GAMP5. ISPE requires that pharmaceutical customers integrate their suppliers as far as possible in their projects. As part of this requirement, it should be possible to use the supplier's documents as validation documents without any amendments having to be made. We have already successfully fulfilled this requirement in many pharmaceutical projects with the help of EVT.

Change tracking

Change tracking in a validation project is a challenge. Keeping this information up to date throughout the entire project is time-consuming and demands absolute accuracy.

Thanks to the unique documentation structure and standardized templates, EVT can automatically create and update change tracking data for all project documentation.

The effects of potential changes can be viewed directly in the clearly arranged overview. This ensures that all requirements are covered by the relevant specifications and tests. Any gaps in the change tracking data are flagged for the user's attention.

Change tracking data can be created and synchronized at any point during the project.

Document management

Producing validation documentation is a multidisciplinary task, requiring the skills of authors, reviewers and the people who approve them. These documents are often critical because they need to be approved before a solution can be implemented.

EVT is designed for multidisciplinary document management.
As soon as a document status changes, the relevant team members are informed of what steps they need to take, for example by e-mail.

The project manager can view the status of all project documentation at any time with just one click. The overview also shows the status of the various documents and serves to demonstrate that all documents are in fact available.