

Siemens Validation Toolset

taking the complication out of compliance

Risk-based Validation Solutions

Highly regulated processes

In the life sciences industry, high quality and compliance with regulations is a must in all manufacturing areas. The increasing challenges in competition, costs and time pressure are driving Pharmaceutical companies to minimize risk and optimize all process steps.

With FDA's Pharmaceutical cGMPs for the 21st Century initiative it is finally possible to make use of new technologies to drive business challenges such as: quality by design (QbD), faster product development, flexible manufacturing, asset utilization and real time quality assurance.

Process Analytical Technology (PAT), the core of this new regulatory framework, will allow pharmaceutical companies to move away from a rigid validation-based manufacturing paradigm, to a science and engineering-based approach to gain greater process understanding. This change will increase the need for measurement technologies, automation and business integration solutions that can support process design & control and knowledge management. In this context it becomes even more critical to rely on a strong and consistent validation strategy for automation and solutions.

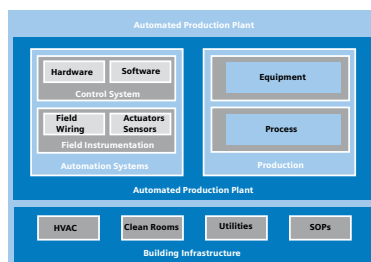
Validation is one of the most critical path items on a project execution plan as well as a significant time and cost component. Therefore, regulatory authorities are recommending that life sciences companies leverage the knowledge of their supplier partners in the development of validation and quality documentation that not only helps to ensure product quality and safety, but also results in cost efficiency. In response to this trend, Siemens has taken its knowledge of the industry and its needs and developed an offering named the Siemens Validation Toolset.

By applying the Siemens Validation Toolset to a regulated project, the validation of a Siemens system can be significantly shortened with respect to time, cost, and risk versus systems that do not offer a validation toolset.

The Validation Toolset is comprised of two main document sets: The Validation Source Book and the GMP-Engineering Manuals.

Validation Source Book

The Validation Source Book defines a complete Life Cycle for the development of a computerized system and addresses each validation phase as it applies to new applications of computerized systems. These phases include project management functions; assisting in defining the appropriate scope and producing the necessary documentation required to support validation. It identifies step-by-step validation activities applicable to a computerized system throughout a life sciences manufacturer's project life-cycle, outlining the issues to be addressed by the client, and examining Siemens role and responsibilities as the "Supplier".



Take the Complication out of Compliance

Answers for Industry.

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The objective of the Validation Source Book is to target three areas of need:

- As a guidance document for the validation of computerized systems in the life sciences industry. Thus the Guideline and its Appendices provide a complete project methodology including document templates together with detailed explanations.
- As a client communication document, the Validation Source Book is intended to demonstrate the validation knowledge and cost effective working methods Siemens provides for regulated life sciences projects. The objective is to facilitate better communication and relationships between the Sales, Projects and Support Services teams. This document shows the life cycle model that may be used in the regulated life sciences industries and the mapping to Siemens' procedures and templates
- As a reference document, providing a uniform understanding of Computerized Systems Validation within the validation program for regulated life sciences applications. And providing a comprehensive reference with respect to the associated concepts, definitions, methodologies, and documentation requirements as they align with Siemens detailed procedures, specifications, protocols, records, and reports.

The validation methodology presented within this documentation set, and endorsed by Siemens, is consistent with that contained in the GAMP 5 Guide "A Risk-based Approach to Compliant GxP Computerized Systems". It applies the scalable Life Cycle approach to support the new FDA Risk-based approach.

The GMP Engineering Manuals

The GMP Engineering Manuals - Are guidelines for system users and configuration engineers to assist them in the integration of Siemens automated systems in a GMP environment with regard to validation and 21 CFR Part 11 compliance. These product specific document sets are based on Siemens system components providing technical details such as functional and detailed design explanations and screenshots that are necessary in the validation specification and testing documentation. Each Siemens GMP Engineering Manual describes what is required of the system, the software, and the procedures for configuring and operating the system in a GMP environment. The relationship between the requirements and implementation is explained based on practical examples.

These manuals are intended for all planners, configuration engineers, and maintenance/service personnel who use control systems in a GMP environment.

The GMP Engineering Manuals are available for the following Siemens system components:

- SIMATIC PCS 7 Process Control System
- SIMATIC WinCC Supervisory Control and Data Acquisition (SCADA) System
- SIMATIC WinCC flexible Software solution for HMI applications
- SIMATIC Step 7 Tools for configuring and programming SIMATIC Controllers
- SIMOTION Motion Control System

In order to find GMP-compliant, high-quality solutions, it is advisable to integrate validation activities at an early stage, preferably right at the start of a project.



The Validation Toolset provides Siemens clients a major head start in their validation efforts versus traditional methods. This document set will help to develop a validation project plan to support you along the way to a qualified system and validated process – both for new plants, and for modifications and extensions to existing plants. Implementing these best practice guidelines helps to streamline validation efforts, reduce risk and ensure project costs and timelines are met.

Documented evidence

With more than 160 years history, Siemens has built a reputation for leading-edge innovation through quality products, services and solutions. Our own certification is the best basis for regulatory compliance. Our internal processes have all received relevant certifications. The Siemens automated systems have been developed according to Siemens' Quality Management System. It surpasses the requirements of ISO 9001 and is in accordance with the GAMP requirements for software development.

Contact us at

pharma.sea@siemens.com

Siemens Energy & Automation, Inc.
Industry Sector
3333 Old Milton Parkway
Alpharetta, GA 30005
1-800-964-4114

info.sea@siemens.com

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