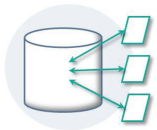
PLATO Services

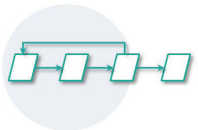
In addition to the standard products and services, PLATO also offers qualified services for the efficient validation of the system:

- Consulting services for the introduction and validation of the software
- Creation of risk analyses for introduction, installation, and updating
- Validation support for specific customizations
- Providing standard documentation relevant to validation (specifications and instructions, for example)
- Generation of documentation (requirement documents, test plans, test reports, and configuration lists, for example)
- Implementation of test systems
- Creation custom SOPs to use XERI™
- Provide validation services such as conducting and documenting tests

PLATO XERI™ Main Points

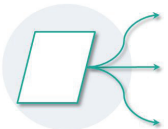


Database-based software



Document lifecycle

Guidelines are automatically considered



The information flow is controlled and transparent

PLATO - *Ideas become Products*

For complex medical devices, a constant stream of product innovations and increasingly shorter development times demand the highest possible quality standards. Meeting these requirements is impossible without professional software support.

The PLATO AG has been providing companies with support for product and process development since 1992. Their solutions for engineering and compliance supply a consistent data concept covering all phases from requirements analysis to production.

In the field of engineering, PLATO solutions provide support for the entire development process, starting with customer requirements and the specification to risk analysis and the actions resulting from the analysis.

In the area of quality management and compliance, PLATO offers workflow-supported solutions based on IBM Lotus Domino for the management of specification documents, for facilitating the entire audit process, and for central action management.

PLATO AG

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PLATO
SOLUTIONS BY SOFTWARE

PLATO XERI™-med

Document control management in the field of medical technology and in the pharmaceutical industry

PLATO XERI™-med

GxP Requirement: Releasing and Reviewing Documents

Documents go through a release and review process

- Release process using defined levels (such as Reviewer, Approved by, Last released by)
- Documentation of the release in the system

Revising and invalidating

- Definable electronic workflows for editing, releasing, publishing, and resubmitting documents
- Electronic signature by the defined person
- Unique relationship between the signature and the document

Timely release and ensuring release

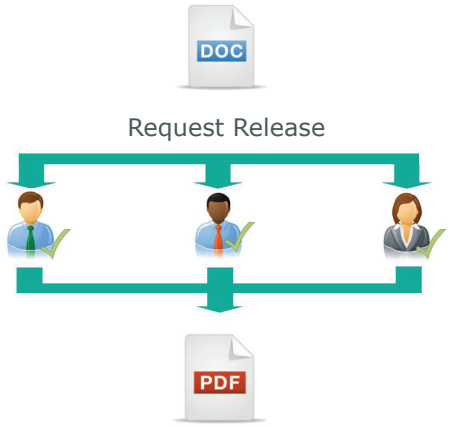
- For every action related to the status and signatures, a definable escalation procedure is executed by the system

Documentation and traceability of the changes

- Changes to documents are documented in an audit trail
- All relevant activities are logged accordingly

Releasing changes to released documents

- Released documents must be versioned content is changed and then correspondingly run through the inspection and approval processes before they are made available to the users of the documents



Overview

PLATO XERI™ provides support for requirements from the GxP environment

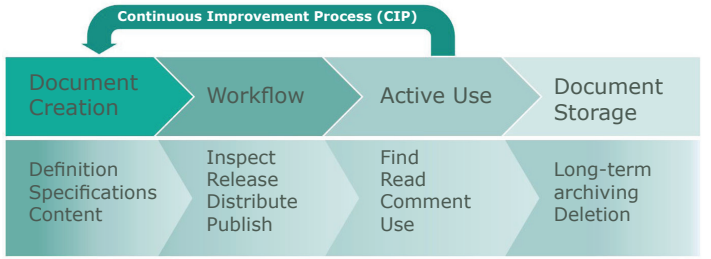
PLATO XERI™ is a document management and work-flow system that aids the creation, inspection, release, distribution, and resubmission processes of guidelines, documented procedures, work instructions, as well as standard operating procedures (SOP).

With XERI™, you can be sure that...

- the correct document,
- in the current version,
- fulfilling the formal conformity requirements (compliance),
- is given to the right document user.

Using PLATO XERI™ supports the following goals:

- Faster, less complicated access to documents
- Easy and validated handling of documents
- Significant reduction in costs through minimization of management work
- Simplification, standardization, and harmonization of the document control system in an organization



GMP requires documents available in electronic form to fulfill the requirements in 21 CFR Part 11 (eRecords, eSig):

- PLATO XERI™ is a closed system
- Electronic signature for all relevant steps of the workflow corresponding to the requirements of 21 CFR Part 11.
- Ability to trace all actions (audit traceability) in the form of an eRecord (Who? What? Why?)
- Electronic password safety based on IBM Domino.

Expert Knowledge

MERCK

The document management system the PLATO AG has significantly lowered the expenses for administration and archiving our quality documentation. Through fast and complete distribution of the numerous guidelines and documented procedures to all necessary company locations, we are able to guarantee our documents are up to date at all times as required by law and certain standards. We see this as an essential contribution to the security and continuous improvement of our quality management system.

Dr. Wolfgang Hehlein, ISO Quality and Environmental Management Systems, Merck KGaA

W.LINK

To manage the QM documentation of a medical products manufacturer according to DIN EN ISO 13485:2003 in a global Matrix corporate group with sixteen individual locations, modification of the XERI software was initiated and implemented together with the PLATO AG in Lübeck. The framework of this implementation also took the process-oriented approach of DIN EN ISO 9001:2000 as well as of DIN EN ISO 13485:2003 into account.

Bärbel Müller, Qualitätsmanagement Waldemar Link GmbH & Co. KG