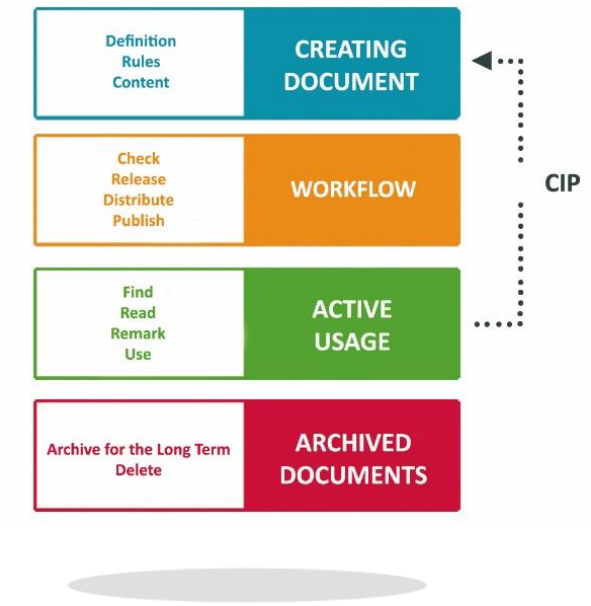
PLATO XERI™

Use in the GxP Environment

PLATO XERI™ is a document management and workflow system for the creation, review, release, distribution and resubmission of guidelines (GL), process instructions (PA), work instructions (WI) and standard operating procedures (SOP).



PLATO XERI™ ensures that...

- the right document,
- in the latest version,
- with fulfilment of the formal conformity requirements (compliance),
- is provided to the right document user.

By using PLATO XERI™ the following goals are supported:

- Fast and easy access to documents
- Simplicity and commitment in dealing with documents
- Considerable cost reduction by minimizing the administrative effort
- Simplification, standardization and harmonization of document management in your organization

GMP Requirements

- PLATO XERI™ is a closed system.
- It supports the electronic signature for all relevant workflow steps according to the requirements of 21 CFR Part 11.
- Traceability of all actions (audit traceability) in the form of an eRecord (Who? What? Why?) in accordance with the requirements of 21 CFR Part 11.

Application Areas of XERI™

- Management systems, business systems, manual management
- Specification documentation, SOP, instructions, flow charts, organization charts, process descriptions
- Form management, reports, protocols, proofs
- Product documentation, requirements specifications, validation documentation, instruction manual
- Marketing and sales documentation, presentations, price lists, corporate design
- Contracts, business agreements, supplier agreements, framework agreements

info@plato.de +49.451.930 986-0 www.plato.de

PLATO XERI™

Use in the GxP Environment

Release and Review of Documents

Documents go through a release and review process

- Release procedure in defined stages (for example, inspector, approver, last approver)
- Documentation of the release in the system

Revision and Repeal

- Definable electronic workflows for editing, approval, publication, resubmission of documents
- Electronic signature by the defined person
- Unique affiliation of the signature to the document
- Archiving of invalid documents with different retention periods possible through different archiving classes

Prompt release and assurance of release

- For each status and signature relevant action a definable escalation procedure is executed by the system.

Documentation and traceability of changes

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

Release of changes to released documents.

- Released documents must be versioned for content changes and then pass through the checking and approval procedure before they are made available to the user of the document

Distribution to defined persons

- Distribution and confirmation to email distribution lists and training participants with electronic signature for confirmation of measures
- Control and traceability of authorized printouts with unique number

LINK

"In order to manage the QM documentation of a medical device manufacturer according to DIN EN ISO 13485:2016 in a worldwide matrix company group with 8 locations, a modification of the software PLATO XERI™ was initiated and implemented together with PLATO AG Lübeck. Within the scope of this implementation, the process-oriented approach of DIN EN ISO 13485:2016 was also taken into account."

Validation Services

In regulated environments the PLATO XERI™ software must be validated according to industry standards or standards required by regulatory authorities. Here and in other cases PLATO can help to reduce the effort for the customer with services and materials (test plans etc.).

In addition to the standard services PLATO offers qualified services for the efficient validation of the system:

- Consulting services for the introduction and validation of the software
- Preparation of risk analyses during introduction, installation and update
- Validation support for customer-specific adaptations
- Provision of standard documentation relevant to validation (e.g. specifications, instructions)
- Creation of documentation (e.g. specification sheet, test plan, test protocols, configuration lists)
- Implementation of test systems
- Creation of customer-specific SOPs for the use of PLATO XERI™
- Performance of validation services, such as test execution and documentation

info@plato.de +49.451.930 986-0 www.plato.de