

Meeting the new requirements of ISO 9001:2015 with PLATO XERI™

The documentation in your QM system should perform tasks such as verification of the fulfillment of contractual requirements placed on the QM system, especially for third parties. Furthermore, the procedures should be presented transparently and understandably, and the documentation should make a major contribution to continuously improving processes.

1 Documented Information

In XERI™, you can control and organize your documents easily and efficiently. It is then possible to check, distribute, find, protect, and store information so that the knowledge of your organization is available from one central location. This process is supported by lean workflows for mapping the document lifecycle.

2 Distribution of Responsibilities

Decentralization and flexibilization of QM-related tasks such as e.g. creating documentation, are decisive factors when embedding the QM system into the organization, and correspondingly for the willingness of managers and employees to take responsibility. This is the only way to ensure knowledge and responsibilities are transferred. XERI™ helps you by establishing standards and through its intuitive handling so that everyone can integrate and expand their knowledge.

3 Risk Management

ISO 9001:2015 focuses on the systematic handling of risks. The use of an established tool is beneficial for an efficient risk management. The PLATO e1ns methods toolbox offers every option possible for the systematic identification, analysis, and evaluation of risks and for introducing countermeasures.

YOUR BENEFITS AT A GLANCE

- Low effort required to change and maintain the QM system
- Improved, process-oriented search for information
- Ability to link to the applicable documents (e.g. work instructions, forms)
- Automated distribution to the employees
- All documents are up to date and can be traced via audit trails
- 100% web-based
- Consistent and comprehensive linking of the activities, information, and organizational units present in the process model
- Electronic signature according to FDA 21 CFR Part 11
- Interactive process diagrams
- A wide range of search options such as live searches, tagging, and savable search filters

PLATO XERI™ - Simple & Intuitiv

Creating, releasing, providing, and searching for organizational documents of all kinds are all very easy with XERI™. Live searches, tagging, and savable search filters make it easier for your employees to access the right document. By creating graphic landing pages, companies are able to customize the XERI™ document management software to meet their individual needs.

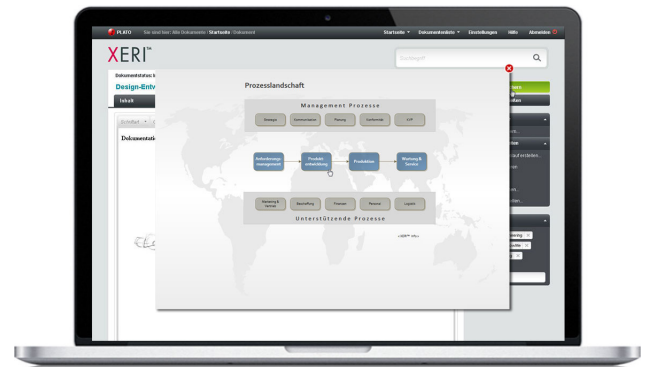


Provide knowledge

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4 Process-oriented

The development, improvement, and documentation of processes are core requirements of ISO 9001:2015. With XERI™, you have the ability to develop your processes quickly and easily on the web by using the process designer and then link them to other processes and documents in XERI™. Again, XERI™ provides you with various workflows, for example the approval process with electronic signature workflow.



Graphical access page

5 Information Security

ISO 9001:2015 is already being referred to as “the digital 9001” because it focuses on electronic forms of documentation instead of on paper manuals. However, organizations must ensure that the standards for electronic information security are followed. Thanks to the latest security standards, multi-level authorization concepts, electronic signatures, and complete traceability, you are always on the safe side with PLATO XERI™.

6 Knowledge Management

One of the most important tasks of an organization is to obtain, expand, transfer, and protect knowledge. This task is also a central component of ISO 9001:2015. XERI™ is an ideal tool for performing this task. All topics relating to knowledge management in an organization such as documented information, communication, integration of external partners, standardization of management systems, and the documentation of processes are organized easily on the web using XERI™ and then made available to the corresponding employees.



Flexible integration capabilities

PLATO XERI™ offers

- A flexible range of applications
- A wide range of functions
- Interfaces and extensions
- An active system
- Quick setup and operation
- Quick, uncomplicated access to documents
- Document handling compliant with standards and legal requirements
- Significant reduction in costs through minimization of management work
- Simplification, standardization, and harmonization of the document control system in an organization