

## — FLEXIBLE AND STRONG

# **Document Control in the Cloud**

Systematic and effective document control is of crucial importance for the success of a company. With the "Document Center" software from iqs Software GmbH and "XERI" from PLATO GmbH, two recognized and established DMS solutions have been available to the market for many years, both of which ensure document management in accordance with ISO 9001. With the merger of iqs and PLATO to form the new company PeakAvenue GmbH, the two DMS solutions have now also been merged into a new, cloud-native software: "Documents" is the name of the new tool. In "Documents", PeakAvenue aims to combine the strengths of "Document Center" and "XERI".

Whether a small business or a global company: Every day, employees have to deal with many documents that are part of their work and business processes. Documents have to be created, read, checked, released, forwarded and finally archived or deleted. In order to ensure the correct sequence and execution of these work steps and to avoid errors, ISO 9001:2015 has strict requirements for the "control of documented information". Document management systems (DMS) support companies in these processes. Document control is therefore part of a structured quality management system (QMS).

"Documented information" that must be controlled according to ISO 9001 are:

- > Test protocols
- > Checklists
- > Training records
- > Work instructions
- > Process descriptions
- > Quality Management manuals
- > Records, meetings, audits, etc.



#### — STRONG SAFETY BARRIERS MEET FLEXIBLE STEERING

Both the Quality Center module Document Center (DC) from iqs Software GmbH in Bühl and XERI from PLATO GmbH in Lübeck have been two established DMS software solutions for many decades, enabling companies to manage their documents in a user-friendly, secure and flexible manner and in accordance with the requirements of ISO 9001:2015.

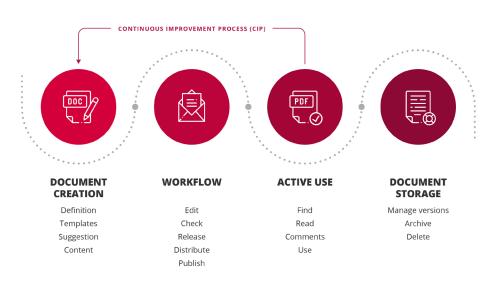
With the merger of iqs and PLATO to form the new company PeakAvenue GmbH, the software is now being brought together as well. "XERI and DC have different strengths - our aim is to combine them in Documents, the new DMS software from PeakAvenue," explains Martina Müller, Product Manager at PeakAvenue. "Perhaps the best way to illustrate it is this: The strength that XERI brings to the table is its guard rails, which prevent the user from violating standards and making mistakes. Document Center, on the other hand, provides good guidance that enables companies to use the DMS software individually and adapt it flexibly to the respective needs and processes of the company."

#### XERI - solid as a rock

So what are the specific success factors of XERI that are reflected in the new software? XERI has specialized in standard documentation, i.e. documents that are alive in the company because they are subject to a constant process of change.

Nico Matthäus, who has developed and supported the software at PLA-TO for many years, therefore sees user acceptance of the software as an important criterion for success. "The management decides on a software, that's one thing. But whether the software is then accepted in the company depends on how intuitive and easy it is to use. With DMS software, you shouldn't have to think or search for a long time to find and use the right document." Clear graphical navigation, for instance, helps XERI users to reach their destination quickly.

In addition to the search function for readers, authors must also be given clear guidelines on how to create the document correctly. "We consider the standardization of processes to be very important: When it comes to creation, distribution or the approval process, it must always be immediately clear which rules apply and what the next step is."



Ultimately, this also leads to a harmonization of document control within the entire company.

Processes and work steps are constantly being improved in production. As a result, the corresponding documentation is updated as well. "The software ensures that the updates always follow the same standard and that the updated documents and templates are quickly made available in the system and that only these, but no older versions, are available," says Matthäus.

The timeliness and correct execution of the documentation is also important for management, as it serves as proof of compliance with the relevant standards to the authorities and during audits. XERI can be configured to cover standards such as ISO-14001, ISO-45001, ISO-50001, ISO-22000 / FSSC 22000 / BRC, ISO-13485, ISO-14971, ISO-27001, TISAX, BAM-GGR0001, EN-9100 or MDR in addition to ISO 9001

"These clear specifications and standards mean that errors, such as the use of incorrect templates or incorrect document creation, are eliminated structurally by the software from the outset," says Matthäus, summarizing the character of XERI.



#### **Document Center - versatile and flexible**

In contrast, the eQMS solution Quality Center's DMS solution Document Center (DC) focuses on flexible usage and application options. "DC enables the customer to link controlled documents, such as work instructions, operating instructions or regulations, to real processes and projects via the eQMS solution. For example, employees are supported in the creation of a project by attaching a corresponding work instruction to a project template," explains Martina Müller. Many customers take advantage of this synergy effect thereby saving resources.

Another special feature of the Document Center is the option to create a company-specific folder structure in addition to the general search function. With the help of this and the graphical interface, you can quickly navigate to a specific topic or area of responsibility. This gives new employees a good overview of the company's organizational structure and work processes.

In many modules of the eQMS solution, it is possible to define individual workflows. This also applies to the Document Center. Müller: "If for example, a user sends a document to four different people for approval, they can define in advance that the approval of three of the four people is sufficient for the document to be forwarded in the workflow."

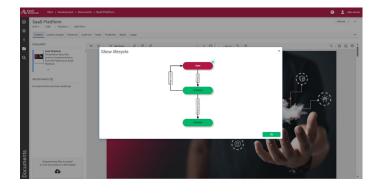
The software provides templates that users can adapt to their individual requirements. "This allows DC to map the respective processes of the company. The software does not force the company to subordinate its processes to the software structure," concludes Müller.

## — PEAKAVENUE DOCUMENTS

## Combines the strengths...

Documents, the new DMS software from PeakAvenue, now combines the strengths of DC and XERI: as with DC, the individual configurability of the software and its linkability with other eQMS modules ensure a high degree of flexibility; at the same time, the creation and use of templates in Documents is subject to a high security standard because - as with XERI - it must be controlled within the DMS software. Key data, for example, is already entered in the document via the template.

The very user-friendly and intuitive graphical navigation has also been adopted and expanded: it now leads not only to documents and folders, but also to entire search queries if required.



## ... and offers new features

When developing Documents, PeakAvenue went beyond simply merging DC and XERI. Customers were asked what additional features the new software should have.

For example: XERI customers categorize their documents into four categories: Scope, Process, Subject Area and Department. Similarly, four different folder structures can now be created in Documents, whereby a document can be located in several folder structures at the same time. This means that different views are possible depending on the respective user. Furthermore, documents can be provided with additional attributes or search terms.

In the new software, the different folder structures are now also assigned to roles. They can be used to predefine employee groups. These have specific authorizations for creating, checking and approving documents. The new software thus strikes a good balance between the free assignability of employees, as is the case with DC, and the strictly personalized assignment as specified by XERI. Certain authorizations can now be extended to all documents within an entire folder.

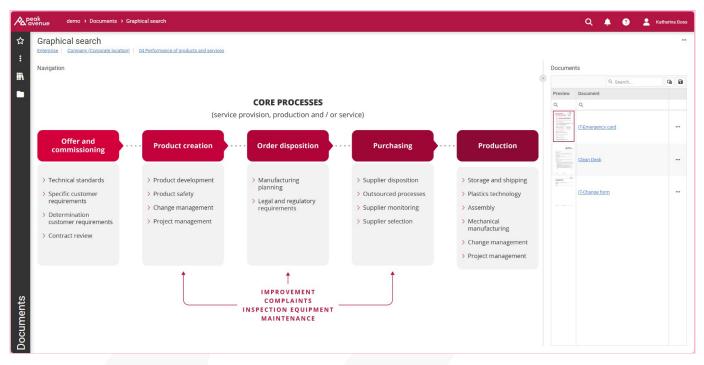
Another interesting topic, especially for the medical and pharmaceutical industries, is electronic signatures. Documents has developed standard-compliant solutions for regulatory requirements, particularly those of the US FDA.



## **Documents - a Cloud Solution**

The new PeakAvenue platform is offered as a cloud solution using the Amazon AWS cloud. The individual modules, such as FMEA, PPAP, APQP, fault tree analysis and complaint management, will be anchored on a platform like Lego bricks and networked in such a way that they communicate optimally with each other. Documents is now the first module to be available on the PeakAvenue platform. Martina Müller explains the advantages offered by a cloud solution: "Employees can open Documents and all PeakAvenue modules in their browser at any time and from anywhere. And they have access to all data." In addition, multiple windows can be opened simultaneously and links can be sent.

It is also possible to integrate the PeakAvenue platform into the company's existing IT landscape, as the PeakAvenue platform has an open architecture with a documented API. This means that other systems can be connected via the Rest API endpoints and communicate optimally with the modules on the platform.



The graphical navigation makes it easier to find documents thanks to clearly arranged topic cards.

#### — OUTLOOK

In contrast to Document Center and XERI, the completely new structure of Documents and the cloud-native platform for the entire system make it necessary for existing customers to migrate their data. "Support for DC and XERI will of course continue. However, a switch to Documents and thus to the PeakAvenue platform should take place sooner or later in order to be able to use the new features and the connection to other modules on the platform," advises Matthäus. PeakAvenue provides customers with individual guidance and support.

Step by step, further PeakAvenue modules are now being anchored on the platform. "We will be able to map the entire product life cycle and integrate all quality and engineering processes," says Müller.

By the way: the new software also includes the integration of AI. It will support users in using the software and can provide rapid support if required.



## — ABOUT PEAKAVENUE

PeakAvenue combines market-leading software solutions from the renowned companies iqs Software GmbH, PLATO GmbH and Isograph Ltd. on a modern platform that covers the entire product life cycle and paves the way directly along the digital thread. This groundbreaking approach sets new standards in engineering and quality assurance - and thus represents a real quantum leap in the product life cycle.

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