Author-e

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For Pharma

Ensuring the accuracy and consistency of laboratory data such that it complies with regulations like FDA 21 CFR Part 11, GLP & GMP is a challenge for many organisations. When using a paper-based system, development, version control, approval and distribution of SOPs and worksheets are open to errors, and manual data searching/documentation is extremely time consuming. When working in an on-site digital environment, security is a great issue, as healthcare and pharmaceutical databases are increasingly subjected to cyber attacks. Moving to the cloud is a great solution, as this not only places the responsibility of security at the provider, but also allows recovery of files. The cloud also provides the ability to scale up easily, removing the ceiling imposed by on-site storage and supporting data-intense research and development.

The Author-e Pharma solution is an Electronic Lab Notebook & Collaboration Tool for regulated laboratory environments. It serves as a single platform for the management of all quality-related documents and the collection of both structured and unstructured data. As a consequence, the Author-e Pharma solution can be used in both QA/QC and R&D laboratories. For QA/QC laboratories the Author-e Pharma solution migrates all existing documents such as SOPs and worksheets into a controlled electronic environment. Using workflows ensures the correct procedures are used to create, maintain and release procedural documents and worksheets. For R&D laboratories the Author-e Pharma solution offers a collaboration tool that simplifies the collection and sharing of experimental data while securing the intellectual property rights. To comply with regulations related to FDA 21 Part 11 and GLP/GMP, the Author-e Pharma solution includes functions such as audit trail, change control, and e-signature.

Create, review and approve documents: Using workflows and tasks, insights in progress of SOPs and worksheets can be gained through the notification center.

Multi-channel publications: SOPs can be published to multiple formats, such as Word, PDF, e-Pub, HTML and XML. This ensures any organizational requirement regarding publications can be met.

Central layout management: Templates and centralized standardization of fonts, font size, captions, text alignment and spacing ensure that all your documents are consistent with your corporate identity and organizational standards. Forms can be used to standardize data input.

Reusability of content: Sections and documents can be embedded in other documents. This enables modifications to documents to be reflected in all documents that use them, eliminating double maintenance, copy-pasting and confusion about what is the latest version.

Simultaneous writing: Authors can work on the same document at the same time. This prevents locking of documents, thus increasing efficiency.

Version control: All previous versions of documents and files are retained, and can be restored if necessary. This is absolutely necessary to comply with norms and legislation, and allows you to look back at documents that were effective in the past.

User access management: Roles & rights can be defined not only at the document level, but also at the section level. This allows enforcement of refined access policies.

Digital signatures: Workflows can be coupled with digitally signing off tasks. This, combined with version control, ensures traceability of actions, as well as accountability.

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Request a demo: www.authore.com/demo.html

Security & confidentiality

Author is hosted on protected servers supplied by an ISO 27002 and NEN 7510 certified hosting provider in the Netherlands, not subject to the Patriot Act. Full data backups are made weekly, with incremental backups made every day. Your data is kept confidential using encrypted communication with the server, and a non-disclosure agreement. Author-e also provides an on-site solution deployment. Companies and institutions below have acknowledged our solution's compliance with their security requirements. Will your organization be the next?

Author-e users

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